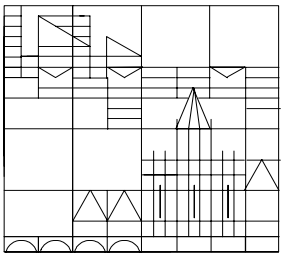

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Conformity Assessment in Germany

Study mandated by the Federal Ministry of Economics and Technology (Research Project No. 57/03)

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Executive Summary

The goal of the present study mandated by the Federal Ministry of Economics in 2004 was to draw up options for designing a future conformity assessment structure in Germany. These options should accommodate the European and international guidelines, satisfy the interest of enterprises in economic and effective conformity assessment and take the concerns of the state into consideration during its application. To this end, it was necessary to illustrate the structure of the current system of conformity assessment in Germany and present the requirements from legal provisions and standards, in particular those of European and international origin (Part One). Against this background, the advisory opinion in the Second Part reaches conclusions and recommendations. They can be summarized as follows:

Summary of the conclusions and recommendations

The starting point for any analysis must be the existence of conformity assessment as a self-supporting system based in the private sector. It can be used for state regulatory objectives to create trust *horizontally* vis-à-vis other private actors or state authorities to facilitate trade in goods and services in the Internal Market or in a *vertical* manner with the purpose of relieving the burden from public authorities. These different aims lead to different functional logics and ultimately to a diversification. A comprehensive regulatory strategy for the use of conformity assessment thus cannot be discerned for the moment – instead, it is a matter of taking action in those areas which urgently require action. Firstly, this includes private sector conformity assessment, whose international integration should be supported by strong and enduring support by the state. Secondly, this includes the incorporation of conformity assessment into the European regulatory strategies based on the New Approach, which demands action at all levels and is imperative for devising a stringent policy. By contrast, the need for action is much lower in the other areas of conformity assessment which do not rely on international recognizibility to the same extent. The need for action is most urgent with regard to the organizational design of accreditation. The study recommends that measures should be taken to establish a national accreditation body in a first step.

Accreditation as a backbone

The instrument of accreditation plays a significant role in the system of conformity assessment. It provides the most important interface with state regulatory interests, and the state is simultaneously required as an authority to reinforce the trust in the accreditation body and thus the conformity assessment bodies as well. Consistent with the European and international specifications and in agreement with the analyzed Member States, we recommend the establishment of a single national accreditation body, if need be in several steps. The establishment of such a national accreditation body, which does not compete with others and has a unique status for the regulatory and non-regulatory sphere, would be permitted by German law.

(1) In the current situation it is indispensable to strengthen accreditation as a mechanism to guarantee the quality and recognizibility of the certificates of conformity and to consolidate the procedures and the organization of accreditation at the national level: Firstly, the system conformity assessment needs an effective mechanism of quality assurance, so that the system can create trust in the certificates from within. To do so, the international conformity assessment system places emphasis on accreditation. Secondly, the horizontal legal acts at the Community level will grant the formal accreditation procedure an important role in the previously inadequate harmonization of the designation procedures. Germany should possess an accreditation system which is integrated into the European structures, is transparent and can thereby gain and maintain the trust of economic operators and public authorities in the other Member States.

(2) Competition at the level of accreditation is not necessary. The German accreditation system as well was not originally based on competition between the accreditation bodies. From a legal perspective, it is permissible to exclude competition from accreditation. This applies both from the perspective of European competition law as well as from the standpoint of German constitutional law. The renunciation of competition bears disadvantages insofar as competition can no longer be used as a means of identifying non-compliance which leads to increases in quality and greater consideration of the concerns of the users of accreditation. This gap will have to be filled with other mechanisms of quality assurance consistent with the European plans, such as an intensification of cooperation in EA, regular

peer reviews among the accreditation bodies and corrective measures in case of non-conformities detected in the review process.

(3) The regulatory sphere and non-regulatory sphere should be consolidated into one accreditation body. In the interest of an export-oriented economy, the state can take on the task of assuring the recognizibility of the certificates of conformity. It fulfils this task by providing an "anchor point" for the systems for assuring quality and recognizibility in the form of an accreditation body for conformity assessment bodies in the non-regulatory sphere. The state administration is particularly well suited to guarantee the functional capability of such an anchor point due to its high capacity for neutrality and the existing monitoring structures. In the countries analyzed in this study these considerations, in particular, have led to the establishment of a uniform accreditation body for the regulatory and non-regulatory sphere. From an economic standpoint the consolidation of accreditation activities in one body generates synergy effects for the conformity assessment bodies, for example because it can help avoid multiple inspections of the same requirements and significantly reduce administrative expenses.

(4) The different economic sectors should be consolidated in one national accreditation body. The other countries studied have had positive experiences with the consolidation of various sectors in one accreditation body, because this ultimately leads to the already mentioned synergy effects. This applies not only with regard to the required administrative expenses, but also with regard to a service offer geared towards the conformity assessment bodies, on the one hand, and the public authorities on the other hand as users of accreditations. Moreover, this service offer would include accreditation in all areas in which there is a demand for it. A national accreditation which has been established on these foundations also can be more easily integrated into the international system of accreditation. This is significant because *effective* mutual control also must be achieved in the international system. The high degree of professional competence, which doubtlessly exists in the sectoralized accreditation bodies of the present German accreditation system, could be integrated into a uniform national accreditation body organized along these lines.

(5) The establishment of a central accreditation body at the federal level is permitted by German law. The Federation has the necessary legislative competence as well as the administrative competence on the basis of Art. 87 para. 3 GG. It would be permissible to establish an independent superior federal agency or a new federal corporation or institution

established under public law *(bundesunmittelbare Körperschaft* or *Anstalt des öffentlichen Rechts)*. It would also be possible to vest a private body with public authority over accreditation tasks (*Beleihung*). This seems to be the more viable option because a large part of the infrastructure is already based in private bodies and – in particular – because private bodies of the current German accreditation system are incorporated into international structures through their membership in the MLA of EA, IAF and ILAC.

Recent developments at the European level

Meanwhile, the review process at the European level has led to the adoption of two horizontal legal acts, a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products and a Decision on a common framework for the marketing of products[1]. As the study had been completed in April 2006, it was only possible to take into consideration the results reached up to then. For the English version, references to the review process have been updated on the basis of the Regulation and the Decision adopted in July 2008. In Germany, efforts are undertaken to restructure the fragmented accreditation system. The obligation in Art. 4 para. 1 of the Regulation to appoint a single national accreditation body should foster this process.

1 Regulation No 765/2008 of 09/07/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ 2008, No. L 218, p. 30, and Decision No 768/2008/EC of the European Parliament and of the Council of 09/07/2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ 2008, No. L 218, p. 82.

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No 761/2001..... of 19/03/2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), OJ 2001, No. L 114, p.1, last amended by Regulation (EC) No 196/2006 of 24/02/2006, OJ 2006, Nr. L 32, p. 4

No 882/2004..... of 29/04/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, OJ 2004, No. L 165, p. 1

No 2092/91 ..... of 24/06/1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs, OJ 1991, No. L 198, p. 1, last amended by Commission Regulation (EC) No 1851/2006 of 14/12/2006, OJ No. L 355, p. 88

No 764/2008..... of 09/07/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ 2008, No. L 218, p. 21

No 765/2008..... of 09/07/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ 2008, No. L 218, p. 30

II. Directives

70/156/EEC..... of 06/02/1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, OJ 1970, No. L 42, p. 1, last amended by Directive 2006/28/EC of 06/03/2006, OJ 2006, No. L 65, p. 27

73/23/EEC..... of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, OJ 1977, No. L 77, p. 29, amended by Directive 93/68/EEC of 22/07/1993, OJ 1993, No. L 220, p. 1; replaced by Directive 2006/95 EC, OJ 2007, No. L 374, p. 10

85/374/EEC..... of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ 1985, No. L 210, p. 29, amended by Directive 99/34/EC of 10/05/1999, OJ 1999, No. L 141, p. 20

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* Valid as of 01/04/2006 (except for Regulations No 765/2008, No 764/2008 and Decision No 768/2008, which have been added for the English version of this study).

III. Documents on the New Approach, the Global Approach and on the principle of mutual recognition

85/C 136/01	Council Resolution of 07/05/1985 on a new approach to technical harmonization and standards, OJ 1985, No. C 136, p. 1
COM/89/209FINAL.	Communication of the Commission to the Council "A global approach to certification and testing quality measures for industrial products" of 15/06/1989, OJ 1989, No. C 267, p. 3
90/ C 10/01	Council Decision of 21/12/1989 on a global approach to conformity assessment, OJ 1990, No. C 10, p. 1
90/683/EEC	Council Decision of 13/12/1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives, OJ 1990, No. L 380, p. 13, repealed by Council Decision of 22/07/1993, OJ 1993, No. L 220, p. 23
Decision 93/465/EEC	Council Decision of 22/07/1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives, OJ 1993, No. L 220, p. 23 ("Modules Decision"); repealed by Decision 768/2008
COM(2003)240 final	Communication from the Commission to the Council and the European Parliament: "Enhancing the Implementation of the New Approach Directives" of 7/5/2003
2003/C 282/02	Council Resolution of 10/11/2003 on the Communication of the European Commission "Enhancing the Implementation of the New Approach Directives", OJ 2003, No. C 282, p. 3
2003/C 265/02	Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition, OJ 2003, No. C 265, p. 2
COM SEC (2001) 1570/1	Commission staff working paper "Implementing policy for external trade in the fields of standards and conformity" of 28/09/2001 [available in the Register of Commission Documents]
Decision No 768/2008/EC	of the European Parliament and of the Council of 09/07/2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ 2008, No. L 218, p. 82

B. National law[1]

I. Gesetze

BauPG ..... Gesetz über das Inverkehrbringen von und den freien Warenverkehr mit Bauprodukten zur Umsetzung der Richtlinie 89/106/EWG des Rates v. 21. Dezember 1988 zur Angleichung der Rechts- und Verwaltungsvorschriften der Mitgliedstaaten über Bauprodukte und anderer Rechtsakte der Europäischen Gemeinschaften (Bauproduktengesetz) v. 10.8.1992 i. d. F. der Bekanntmachung v. 28.4.1998, BGBl. I 812, zul. geänd. durch Art. 8a des Gesetzes vom 6.1.2004, BGBl. I 2

BayBO ..... Bayerische Bauordnung i. d. F. der Bekanntmachung v. 4.8.1997, GVBl 1997, S. 433, zul. geänd. durch § 4 des Gesetzes v. 9.7.2003, GVBl 2003, S. 419

BBodSchG ..... Gesetz zum Schutz vor schädlichen Bodenveränderungen und zur Sanierung von Altlasten (Bundes-Bodenschutzgesetz) v. 17.3.1998, BGBl. I 502, zul. geänd. durch Art. 3 des Gesetzes v. 9.12.2004, BGBl. I 3214

BHO ..... Bundeshaushaltsordnung vom 19. August 1969, BGBl. I 1284, zul. Geänd. durch Artikel 3 des Gesetzes v. 22. 11. 2005, BGBl. I 2809

BImSchG ..... Gesetz zum Schutz vor schädlichen Umwelteinwirkungen durch Luftverunreinigungen, Geräusche, Erschütterungen und ähnliche Vorgänge (Bundes-Immissionsschutzgesetz) v. 15.03.1974 i. d. F. der Bekanntmachung v. 26.9.2002, BGBl. I 3830, zul. geänd. durch Art. 1 des Gesetzes v. 25.6.2005, BGBl. I 1865

BSIG ..... Gesetz über die Errichtung des Bundesamtes für Sicherheit in der Informationstechnik (BSI-Errichtungsgesetz) v. 17.12.1990, BGBl. I 2834, zul. geänd. durch Art. 11 der Verordnung v. 25.11.2003, BGBl. I 2304

ChemG ..... Gesetz zum Schutz vor gefährlichen Stoffen (Chemikaliengesetz) v. 16.9.1980 i. d. F. der Bekanntmachung v. 20.6.2002, BGBl. I 2090, zul. geänd. durch Art. 2 § 3 Abs. 6 des Gesetzes v. 1.9.2005, BGBl. I 2618

DIBtAbkG BW ..... Gesetz (des Landes Baden-Württemberg) zu dem Abkommen über das Deutsche Institut für Bautechnik (DIBt-Abkommen) und über Zuständigkeiten nach dem Bauproduktengesetz v.15.12.1992. GBl. 1992, 761

EichG ..... Gesetz über das Meß- und Eichwesen (Eichgesetz) v. 11.07.1969 i. d. F. der Bekanntmachung v. 23.3.1992, BGBl. I 711, zul. geänd. durch Art. 115 der Verordnung v. 25.11.2003, BGBl. I 2304

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[1] Only German law is listed here. For the legal provisions of other EC Member States and Swiss law please refer to the footnotes in the respective parts of the Appendix.

EMVG ..... Gesetz über elektromagnetische Verträglichkeit von Geräten v. 18.9.1998, BGBl. I 2882, zul. geänd. durch Art. 3 Abs. 5 des Gesetzes v. 7.7.2005, BGBl. I 1970

FStrPrivFinG ..... Gesetz über den Bau und die Finanzierung von Bundesfernstraßen durch Private – Fernstraßenbauprivatfinanzierungsgesetz i.d.F. der Bekanntmachung v. 6. 1.2006, BGBl. I 49

FTEG ..... Gesetz über Funkanlagen und Telekommunikationsendeinrichtungen v. 31.1.2001, BGBl. I 170, zul. geänd. durch Art. 3 Abs. 6 des Gesetzes v. 7.7.2005, BGBl. I 1970

GGBefG ..... Gesetz über die Beförderung gefährlicher Güter (Gefahrgutbeförderungsgesetz) v. 6.8.1975 i. d. F. der Bekanntmachung v. 29.9.1998, BGBl. I 3114, zul. geänd. durch Art. 45 des Gesetzes v. 21.6.2005, BGBl. I 1818

GPSG ..... Gesetz über technische Arbeitsmittel und Verbraucherprodukte (Geräte- und Produktsicherheitsgesetz) v. 6.1.2004, BGBl. I 2 (219), zul. geänd. durch Art. 3 Abs. 33 des Gesetzes v. 7.7.2005, BGBl. I 1970

GSG ..... Gesetz über technische Arbeitsmittel (Gerätesicherheitsgesetz) v. 24.6.1968 i. d. F. der Bekanntmachung v. 11.5.2001, BGBl. I 866; zul. geänd. durch Art. 182 der Verordnung v. 25.11.2003, BGBl. I 304, aufgehoben durch Art. 28 S. 2 des Gesetzes v. 6.1.2004, BGBl. I 2

KrW-/AbfG ..... Gesetz zur Förderung der Kreislaufwirtschaft und Sicherung der umweltverträglichen Beseitigung von Abfällen (Kreislaufwirtschafts- und Abfallgesetz) v. 27.9.1994, BGBl. I 2705, zul. geänd. durch Art. 2 § 3 Abs. 3 des Gesetzes v. 1.9.2005, BGBl. I 2618

LBO BW ..... Landesbauordnung für Baden-Württemberg v. 8.8.1995, GBl. S. 617, zul. geänd. durch Gesetz v. 14.12.2004, GBl. S. 895

LHG BW ..... Gesetz über die Hochschulen und Berufsakademien in Baden-Württemberg (Landeshochschulgesetz – LHG) v. 1. 1. 2005, zul. geänd. geändert durch Artikel 2 des Gesetzes v. 19. Dezember 2005 (GBl. S. 794, 798)

LuftVG ..... Luftverkehrsgesetz i. d.F. der Bekanntmachung v. 27. 3.1999, BGBl. I 550 zuletzt geändert durch Art. 1 G v. 24.5.2006, BGBl. I 223

MPG ..... Gesetz über Medizinprodukte (Medizinproduktegesetz) v. 2.8. 1994 i. d. F. der Bekanntmachung v. 7.8.2002, BGBl. I 3146, geänd. durch Art. 109 der Verordnung v. 25.11.2003, BGBl. I 2304

ProdHaftG ..... Gesetz über die Haftung für fehlerhafte Produkte (Produkthaftungsgesetz) v. 15.12.1989, BGBl. I 2198, zul. geänd. durch Art. 9 Abs. 3 des Gesetzes v. 19.7.2002, BGBl. I 2674

SGB III ..... Sozialgesetzbuch, Drittes Buch – Arbeitsförderung v. 24.3.1997, BGBl. I 594, zul. geänd. durch Art. 2 Nr. 1 des Gesetzes v. 22.12.2005, BGBl. I 3686

StVG ..... Straßenverkehrsgesetz v. 3.5.1909 i. d. F. der Bekanntmachung v. 5.3.2003, BGBl. I 310, 919, zul. geänd. durch Art. 1 des Gesetzes v. 14.8.2005, BGBl. I 2412

UAG ..... Gesetz zur Ausführung der Verordnung (EG) Nr. 761/2001 des Europäischen Parlaments und des Rates vom 19. März 2001 über die freiwillige Beteiligung von Organisationen an einem Gemeinschaftssystem für das Umweltmanagement und die Umweltbetriebsprüfung (EMAS) (Umweltauditgesetz) v. 7.12.1995 i. d. F. der Bekanntmachung v. 4.9.2002, BGBl. I 3490, zul. geänd. durch Art. 8 Abs. 1 des Gesetzes v. 4.12.2004, BGBl. I 3166

II. Verordnungen

AbfKlärV ..... Klärschlammverordnung v. 15.4.1992 (BGBl. I S. 912), zul. geänd. durch § 11 Abs. 2 der Verordnung v. 26.11.2003, BGBl. I 2373

AltholzV ..... Verordnung über Anforderungen an die Verwertung und Beseitigung von Altholz (Altholzverordnung) v. 15.8.2002, BGBl. I 3302

AltölV ..... Altölverordnung v. 27.10.1987 i. d. F. der Bekanntmachung v. 16.4.2002, BGBl. I 1368

AZWV ..... Verordnung über das Verfahren zur Anerkennung von fachkundigen Stellen sowie zur Zulassung von Trägern und Maßnahmen der beruflichen Weiterbildung nach dem Dritten Buch Sozialgesetzbuch (Anerkennungs- und Zulassungsverordnung Weiterbildung) v. 16.6.2004, BGBl. I 1100

BAnerkV ..... Verordnung über die Anforderungen und das Verfahren für die Beleihung und Anerkennung von Konformitätsbewertungsstellen (Beleihungs- und Anerkennungs-Verordnung) v. 7.6.2002, BGBl. I 1792, zul. geänd. durch Art. 3 Abs. 13 des Gesetzes v. 7.7.2005, BGBl. I 1970

BetrSichV ..... Verordnung über Sicherheit und Gesundheitsschutz bei der Bereitstellung von Arbeitsmitteln und deren Benutzung bei der Arbeit, über Sicherheit beim Betrieb überwachungsbedürftiger Anlagen und über die Organisation des betrieblichen Arbeitsschutzes (Betriebssicherheitsverordnung) v. 27.9.2002, BGBl. I 3777, zul. geänd. durch Art. 3 Abs. 42 des Gesetzes v. 7.7.2005, BGBl. I 1970

BioAbfV ..... Verordnung über die Verwertung von Bioabfällen auf landwirtschaftlich, forstwirtschaftlich und gärtnerisch genutzten Böden (Bioabfallverordnung) v. 21.9.1998, BGBl. I 2955, zul. geänd. durch § 11 Abs. 1 der Verordnung v. 26.11.2003, BGBl. I 2373

DepV ..... Verordnung über Deponien und Langzeitlager (Deponieverordnung) v. 24.7.2002, BGBl. I 2807, zul. geänd. durch Art. 2 der Verordnung v. 12.8.2004, BGBl. I 2190

DIBtZustÜV ..... Verordnung (des Landes Baden-Württemberg) zur Übertragung von Zuständigkeiten auf das Deutsche Institut für Bautechnik (DIBT-Übertragungsverordnung) v. 5.6.1999, verkündet als Art. 1 der Verordnung des Wirtschaftsministeriums zur Übertragung von Zuständigkeiten auf das Deutsche Institut für Bautechnik und zur Änderung der PÜZ-Anerkennungsverordnung vom 5. Juni 1999, GBl. S. 262

EMASPrivilegV ..... Verordnung über immissionsschutz- und abfallrechtliche Überwachungserleichterungen für nach der Verordnung (EG) Nr. 761/2001 registrierte Standorte und Organisationen (EMAS-Privilegierungs-Verordnung) v. 24.6.2002, BGBl. I 2247, geänd. durch Art. 6 des Gesetzes v. 21.6.2005, BGBl. I 1666

FeV ..... Verordnung über die Zulassung von Personen zum Straßenverkehr (Fahrerlaubnis-Verordnung) v. 18.8.1998, BGBl. I 2214, zul. geänd. durch Art. 5 der Verordnung v. 22.12.2005, BGBl. I 3716

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GGVSE ..... Verordnung über die innerstaatliche und grenzüberschreitende Beförderung gefährlicher Güter auf der Straße und mit Eisenbahnen (Gefahrgutverordnung Straße und Eisenbahn) v. 11.12.2001 i. d. F. der Bekanntmachung v. 3.1.2005, BGBl. I 36, geänd. durch Art. 3a der Verordnung v. 2.11.2005, BGBl. I 3131

7. GPSGV ..... Siebte Verordnung zum Geräte- und Produktsicherheitsgesetz (Gasverbrauchseinrichtungsverordnung) v. 26.1.1993, BGBl. I 133, zul. geänd. durch Art. 14 des Gesetzes v. 6. 1.2004, BGBl. I 2

8. GPSGV ..... Achte Verordnung zum Geräte- und Produktsicherheitsgesetz (Verordnung über das Inverkehrbringen von persönlichen Schutzausrüstungen) v. 10.6.1992, BGBl. I 1019

9. GPSGV ..... Neunte Verordnung zum Geräte- und Produktsicherheitsgesetz (Maschinenverordnung) v. 12.5.1993, BGBl. I 704, zul. geänd. durch Art. 14 der Verordnung v. 23.12.2004, BGBl. I 3758

12. GPSGV ..... Zwölfte Verordnung zum Geräte- und Produktsicherheitsgesetz (Aufzugsverordnung) v. 17.6.1998, BGBl. I 1393, zul. geänd. durch Art. 19 des Gesetzes v. 6.1.2004, BGBl. I 2

14. GPSGV ..... Vierzehnte Verordnung zum Geräte- und Produktsicherheitsgesetz (Druckgeräteverordnung) v. 27.9.2002, BGBl. I 3777, 3806, geänd. durch Art. 21 des Gesetzes v. 6.1.2004, BGBl. I 2

MedGV ..... Verordnung über die Sicherheit medizinisch-technischer Geräte (Medizingeräteverordnung) v. 14.1.1985, BGBl. I 93, zul. geänd. durch Art. 12 Abs. 56 des Gesetzes v. 14.9.1994, BGBl. I 2325, aufgeh. durch Art. 6 des Gesetzes v. 13.12.2001, BGBl. I 3586

MPV ..... Verordnung über Medizinprodukte (Medizinprodukte-Verordnung) v. 20. 12. 2001, BGBl. I 3854, geänd. durch Art. 1 der Verordnung v. 13.2.2004, BGBl. I 216

SchAV-See ..... Verordnung zur Durchführung der Gemeinschaftsvorschriften über Schiffsausrüstung (Schiffsausrüstungsverordnung-See) v. 20.5.1998, BGBl. I 1168, aufgeh. durch Art. 4 Nr. 3 n. Maßgabe d. Art. 5 Abs. 3 Halbsatz 2 der Verordnung v. 18.9.1998, BGBl. I 3013

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UAGBV ..... Verordnung über die Beleihung der Zulassungsstelle nach dem Umweltauditgesetz (UAG-Beleihungsverordnung) v. 18.12.1995, BGBl. I 2013, geänd. durch Art. 1 der Verordnung v. 13.9.2001, BGBl. I 2427

UAGZVV ..... Verordnung über das Verfahren zur Zulassung von Umweltgutachtern und Umweltgutachterorganisationen sowie zur Erteilung von Fachkenntnisbescheinigungen nach dem Umweltauditgesetz (UAG-Zulassungsverfahrensverordnung) v. 18.12.1995 i. d. F. der Bekanntmachung vom 12. September 2002, BGBl. I 3654

VSU Boden und Altlasten ..... Verordnung über Sachverständige und Untersuchungsstellen für den Bodenschutz und die Altlastenbehandlung in Bayern v. 3.12.2001, GVBl 2001, S. 938, zul. geänd. am 4.8.2003, GVBl. 2003, S. 645

WarnowBeleihVO ..... Verordnung *des Landes Mecklenburg-Vorpommern* zur Beleihung mit dem Recht zur Erhebung von Mautgebühren für die Warnowquerung (WarnowBeleihVO M-V) v. 1. April 2003, GVOBl. M-V 2003, 280

C. Standards cited

DIN EN ISO/IEC 9001:2000 ..... Quality management systems - Requirements (replaces DIN EN ISO 9001:1994-08, DIN EN ISO 9002:1994-08, DIN EN ISO 9003:1994-08)

DIN EN ISO/IEC 17000:2005 ..... Conformity assessment - Vocabulary and general principles

DIN EN ISO/IEC 17011:2005 ..... General requirements for accreditation conformity assessment bodies

DIN EN ISO/IEC 17020:2004 ..... General criteria for the operation of various types of bodies performing inspection

E DIN EN ISO/IEC 17021 ..... Conformity assessment - Requirements for bodies providing auditing and certification of management systems (ISO/IEC 17021.2, draft, status 40.99)

DIN EN ISO/IEC 17024:2003 ..... Conformity assessment – General requirements for bodies operating certification for persons

DIN EN ISO/IEC 17025:2005 ..... General requirements for the competence of testing and calibration laboratories (replaces EN ISO/IEC 17025:2000)

DIN EN ISO/IEC 17040:2005 ..... Conformity assessment – General requirements for peer assessment of conformity assessment bodies

DIN EN ISO/IEC 17050-1:2005 .... Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements

DIN EN ISO/IEC 17050-2:2005 .... Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation

DIN EN 45001 ..... General criteria for the operation of testing laboratories (replaced by DIN EN ISO/IEC 17025:2000)

DIN EN 45002 ..... General criteria for the assessment of testing laboratories (contents adopted by DIN EN 45003)

DIN EN 45003:1995 ..... Calibration and testing laboratory accreditation systems – General requirements for operation and recognition (replaced by ISO/IEC 17011)

DIN EN 45004:1995 ..... General criteria for the operation of various types of bodies performing inspection (replaced by the identical ISO/IEC 17020)

List of Abbreviations

For German law, please refer to of Index of Legal Provisions, Part B, above p. XIX.

ABCB	Association of British Certification Bodies
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé
AkkBV	Akkreditierungs- und Bezeichnungsverordnung (Accreditation and Designation Decree)
AkkG	Akkreditierungsgesetz (Accreditation Law)
AkkGebV	Akkreditierungsgebührenverordnung (Accreditation Fees Decree)
AKKO	Eidgenössische Akkreditierungskommission (Swiss Federal Accreditation Committee)
AkkVV	Akkreditierungsversicherungsverordnung (Accreditation Insurance Decree)
AkkZV	Akkreditierungszeichenverordnung (Accreditation Marks Decree)
AKMP	Akkreditierungsstelle der Länder für Mess- und Prüfstellen zum Vollzug des Gefahrstoffrechts (Accreditation Body of the Laender for Measuring and Inspection Bodies for the Execution of the Dangerous Substances Law)
ASV	Aufzüge-Sicherheitsverordnung (Lifts Safety Decree)
AWB	Algemene Wet Bestuursrecht (Law on General Administrative Law)
BA	Bundesagentur für Arbeit (Federal Labour Agency)
BASt	Bundesanstalt für Straßenwesen (Federal Highway Research Institute)
BauPG	Bauproduktegesetz (Federal Law on Construction Products)
BDI	Bundesverband der Deutschen Industrie e.V. (Federation of German Industries)
BfB	Bundesverband der Freien Berufe
BMTA	British Management and Testing Association
BMWA	Bundesministerium für Wirtschaft und Arbeit (Federal Ministry for Economics and Labour)
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (Federal Ministry for Economic Cooperation and Development)
BNM-FRETAC	Bureau national de métrologie - France Etalonnage Accréditation
BSI	Bundesamt für Sicherheit in der Informationstechnik (Federal Office for Information Security)
CAR	Centrale Accrediterings Raad
CCvD	Centraal College van Deskundigen (Centralised Committee of Experts)
CE	Conformité Européenne
CEOC	International Confederation of Inspection and Certification Organisations
COFRAC	Comité Fançais d´Accréditation
CRO	Common Regulatory Objectives
CvD	College van Deskundigen (Comittee of Experts)
DACH	Deutsche Akkreditierungsstelle Chemie (German Accreditation Body for the Chemical Sector)
DAP	Deutsches Akkreditierungssystem Prüfwesen GmbH

DAR	Deutscher Akkreditierungsrat (German Accreditation Council)
DASET	Deutsche Akkreditierungsstelle Stahlbau und Energietechnik e.V. (German Accreditation Body for Steel Construction and Energy Technology)
DASMIN	Deutsche Akkreditierungsstelle Mineralöl GmbH (German Accreditation Body for Petroleum)
DATech	Deutsche Akkreditierungsstelle Technik (German Accreditation Body for Technology)
DAU	Deutsche Akkreditierungs- und Zulassungsgesellschaft für Umweltgutachter mbH (German Accreditation and Authorization Association)
DGCCRF	Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes
DGKL	Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin (Unified German Association for Clinical Chemistry and Laboratory Medicine)
DGMK	Deutsche Wissenschaftliche Gesellschaft für Erdöl, Erdgas und Kohle e.V. (German Society for Petroleum and Coal – Science and Technology)
DGZfP	Deutsche Gesellschaft für Zerstörungsfreie Prüfung
DIAS	Deutsches Institut für Akkreditierungssysteme (German Institute for Accreditation Systems)
DiBt	Deutsches Institut für Bautechnik
DIHK	Deutscher Industrie- und Handelskammertag (Association of German Chambers of Industry and Commerce)
DIN	Deutsches Institut for Normung (German Institute for Standardization)
DKB	Deutscher Kalibrierdienst
DTI	Department of Trade and Industry
DVS	Deutscher Verband für Schweißen und verwandte Verfahren e.V.
DZV	Direktzahlungsverordnung (Decree on Direct Payments to Agriculture)
EA	European co-operation for Accreditation
EAAB	EA Advisory Board
ECJ	European Court of Justice
ECT	Treaty establishing the European Community
EEA	European Economic Area
EEPCA	European Electrical Products Certification Association
EFAC	European Federation of Associations of Certification Bodies
EFTA	European Free Trade Association
EICTA	European Industry Association on Information Systems, Communication, Technologies and Consumer Electronics
EJPD	Eidgenössisches Justiz- und Polizeidepartement (Swiss Federal Department of Justice and Police)
EK-Med	Erfahrungsaustauschkreis der nach dem Medizinproduktegesetz Benannten Stellen
EMAS	Environmental Management and Audit Scheme
EN	European Standard
EUROLAB	European Federation of National Associations of Measurement, Testing and Analytical Laboratories
EUROMET	European Collaboration in Measurement Standards

EVD	Eidgenössisches Volkswirtschaftsdepartement (Swiss Federal Department of Economic Affairs)
GAZ	Gesellschaft für Akkreditierung und Zertifizierung GmbH
GDCh	Gesellschaft Deutscher Chemiker (German Chemical Society)
GewO	Gewerbeordnung
GG	Grundgesetz (German Basic Law)
GIE	Groupe d´intérêt économique
GLIS	Germanischer Lloyd Industrial Services GmbH
G-Med	Groupement pour l´évaluation des dispositifs médicaux
GNB	Group of Notified Bodies
GS	Geprüfte Sicherheit ("Inspected safety")
HACCP	Hazard Analysis and Critical Control Point
HMG	Heilmittelgesetz (Federal Law on Medicinal Products and Medical Devices)
HSE	Health and Safety Executive
IAF	International Accreditation Forum
ICN	Interdepartementale Commissie voor Normalisatie en Certificatie
ICSMS	Internet-Supported Information and Communication System for the pan-European Market Surveillance of Technical Products (ICSMS)
IEC	International Electrotechnical Commission
IECEE	Worldwide System for Conformity Testing and Certification of Electrical Equipment
ILAC	International Laboratory Accreditation
IQNet	International Certification Network
ISO	International Organization for Standardization
KL-Mess	Koordinierungsstelle der Länder für Messgeräte (Coordination Body of the Länder for Measuring Devices)
KOGB	Koordinierungsgruppe des gesetzlich geregelten Bereichs (Coordination group for the legally regulated areas)
LACORS	Local Authorities Coordinators Regulatory Service
LAI	Bund-Länder-Arbeitsgruppe Immissionsschutz (Working Group for Immission Protection of the Federal Government and the Länder)
LCIE	Laboratoire Central des Industries Electriques
LGA	Landesgewerbeanstalt Bayern
LMET	Landesamt für Mess- und Eichwesen Thüringen (Thuringia State Office for the Measuring and Calibration System)
LNE	Laboratoire National de Métrologie et d´Essais
MepV	Medizinprodukte-Verordnung (Medical Devices Decree)
METAS	Bundesamt für Metrologie (ehemals Bundesamt für Metrologie und Akkreditierung) Federal Office of Metrology (former Federal Office for Metrology and Accreditation)
MHRA	Medicines and Healthcare products Regulatory Agency
MID	Measuring Instruments Directive
MLA	Multilateral Recognition Arrangement
MoU	Memorandum of Understanding
MPG	Medizinproduktegesetz (Medical Devices Law)

MQV	Milchqualitätsverordnung (Decree on Quality Assurance and Quality Control in Dairy Farming)
MRA	Mutual Recognition Arrangement
MSOG	Market Surveillance Operations Group
MSV	Maschinensicherheitsverordnung (Machine Safety Decree)
MULV	Hessisches Ministerium für Umwelt, ländlichen Raum und Verbraucherschutz (Hessian Ministry for Environment, Agrarian Space and Consumer Protection)
NACCB	National Accreditation Council for Certification Bodies
NAMAS	National Measurement Accreditation Service
NCB	National Conformity Assessment Body
NKO	Nederlandse Kalibratie Organisatie
NSS	NKO/STERLAB/STERIN
OHSAS	Occupational Health and Safety Assessment Series
OIB	Österreichisches Institut für Bautechnik (Austrian Institute for Construction Technology)
ON	Österreichisches Normungsinstitut (Austrian Standards Institute)
PÜZ	Prüf-, Überwachungs- und Zertififzierungsstellen (Inspection, Surveillance and Certification Bodies)
QMS	Quality Management System
RAL	Deutsches Institut für Gütesicherung und Kennzeichnung (German Institute for Quality Assurance and Labelling)
RCAB	Recognized Conformity Assessment Body
RISA	Richtlijn Specifiek Accreditatieschema (Directive-specific Accreditation Scheme)
Rn.	Randnummer (Margin Number)
RNE	Réseau national d´essais
RvA	Stichting Raad voor Accreditatie (Dutch Accreditation Council)
SAFed	Safety Assessment Federation
SAL	Staatliche Anerkennungsstelle der Lebensmittelüberwachung (State Recognition Body for Food Surveillance)
SAS	Schweizerische Akkreditierungsstelle SAS (Swiss Accreditation Service SAS)
SCCM	Stichting Coördinatie Certificatie Milieu- en Arbomanagementsystemen
SDoC	Supplier's Declaration of Conformity
SECO	Staatssekretariat für Wirtschaft SECO (State Secretariat for Economic Affairs SECO)
SRA	Strategic Rail Authority
SSVV	Stichting Samenwerken voor Veiligheid
STEG	Bundesgesetz über die Sicherheit von technischen Einrichtungen und Geräten (Law on the Safety of Technical Facilities and Devices)
STEV	Verordnung über die Sicherheit von technischen Einrichtungen und Geräten (Decree on the Safety of Technical Facilities and Devices)
STIPDT	Stichting Persoonscertificatie Deskundig Toezichthouder
STRD	Standards and Technical Regulations Directorate
SWEDAC	Stryrelsen för ackreditering och teknisk kontroll (Swedish Board for Accreditation and Conformity Assessment)
SWETIC	Swedish Association for Testing, Inspection and Certification

TBT Agreement	Agreement on Technical Barriers to Trade
TGA	Trägergemeinschaft für Akkreditierung GmbH (German Association for Accreditation)
THG	Gesetz über Handelshemmnisse (Law on Technical Trade Obstacles)
TSV	Tierseuchenverordnung (Epizootics Decree)
Tz.	Teilziffer (Margin Number)
UGA	Umweltgutachterausschuss (Environmental Verification Committee)
UKAS	United Kingdom Accreditation Service
UNECE	United Nations Economic Commission for Europe
VCA	Veiligheids Checklist Aannemers
VCI	Verband der Chemischen Industrie (German Chemical Industry Association)
VdTÜV	Verband der technischen Überwachungs-Vereine e.V.
VOC	Vereniging Overleg van Certificatie-instellingen
VZertES	Verordnung über Zertifizierungsdienste im Bereich der elektronischen Signatur
WESA	Wetgeving Specifieke Accreditaties
ZDH	Zentralverband des Deutschen Handwerks (The German Confederation of Skilled Crafts)
ZEK	Zentraler Erfahrungsaustauschkreises der Stellen im Aufgabengebiet der ZLS (Central Experience Exchange Committee within the area of activity of ZLS)
ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (Central Authority of the Laender for Health Protection Regarding Medical Products and Medical Devices)
ZLS	Zentralstelle der Länder für Sicherheitstechnik (Central Authority of the Laender for Security Technology)
ZÜS	Zugelassene Überwachungsstelle (Authorized surveillance body)

Introduction

The present study was mandated by the Federal Ministry of Economics in 2004 with the objective of drawing up options for a future conformity assessment structure in Germany[1]. It was motivated by the need to gain an overview of the use of conformity assessment in Germany and of its institutional structures, which appeared to be rather fragmented on the level of accreditation and designation. The wish to improve the transparency and the effectiveness of the national conformity assessment system coincided with the efforts at the European level to enhance the implementation of the New Approach directives. Against this background, this study aimed to develop options which would accommodate the European and international guidelines, satisfy the interest of enterprises in economic and effective conformity assessment and take the concerns of the state into consideration in those areas in which conformity assessment was used in a regulatory context. To this end, it was necessary to illustrate the structure of the current system and present the requirements from legal provisions and standards, in particular those of European and international origin.

Thus, the study outlines the foundations of the phenomenon of conformity assessment (first part, first section) and identifies their European and international context (first part, second section). An essential component of the structural analysis was the study of conformity assessment and accreditation in other European countries (first part, third section). From this the study has gained key insights for the evaluation of the German conformity assessment system, the current state of which will be described in the fourth section. Against this background, the advisory opinion in the second part reaches conclusions and recommendations.

The study is based on the analysis of the applicable legal foundations in European and national law, which takes the state of affairs up to 1 March, 2006 into consideration to the greatest possible extent[2]. Furthermore, official documents and other information from the

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1 The German version of this study has been completed in April 2006. It is available at URL: http://www.bmwi.de/BMWi/Navigation/Service/Veranstaltungen/dokumentationen.html or at http://www.ub.uni-konstanz.de/kops/volltexte/2006/1933/ (13/08/08).

2 Unfortunately, there was no possibility to update information for the English version of this study.

involved actors were analyzed. Particularly fruitful were the talks and interviews with representatives of the responsible ministries, the accreditation bodies and conformity assessment bodies abroad conducted between October and December 2004 and with representatives of the German conformity assessment system conducted in 2005. The former resulted in a short description of the respective conformity assessment and accreditation structures in France, the Netherlands, Austria, Sweden, Switzerland and the United Kingdom which is enclosed in the Appendix. It reflects the state of discussions at the end of the year 2004, i.e. in a rather early phase of the discussion process at the European level. Nevertheless, the description of the legal foundations and the institutional standards should still be valid so that the country reports might still be of interest.

Meanwhile, the review process at the European level has led to the adoption of two horizontal legal acts governing the requirements for accreditation and market surveillance and a common framework for the marketing of products[3]. As the study had been completed in April 2006, it was only possible to take into consideration the results reached up to then. For the English version, references to the horizontal legal provisions in the Second Part of the study have been updated on the basis of the Regulation and the Decision adopted in July 2008. In Germany, efforts are undertaken to restructure the fragmented accreditation system[4]. The obligation in Art. 4 para. 1 of the Regulation to appoint a single national accreditation body should foster this process.

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3 Regulation No 765/2008 of 09/07/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ 2008, No. L 218, p. 30, and Decision No 768/2008/EC of the European Parliament and of the Council of 09/07/2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ 2008, No. L 218, p. 82. For the non-regulated sphere see as well Regulation No 764/2008 of 09/07/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ 2008, No. L 218, p. 21.

4 As a first step, the Federal Ministry of Economics and technology has established an Accreditation Advisory Board (Akkreditierungsbeirat) which provides advice in all aspects concerning accreditation, especially with regard to the external representation of the German accreditation system. For more information see at URL: http://www.bmwi.de/English/Navigation/Ministry/advisory-councils,did=175920.html (10/07/08).

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Konstanz, April 2006/August 2008

Hans Christian Röhl Yvonne Schreiber

Part One: Structural Analysis

First Section: Foundations

A. Foundations of conformity assessment

I. The basic idea of conformity assessment

Section 2.1 DIN EN ISO/IEC 17000:2005 defines conformity assessment as the demonstration that specified requirements relating to a product, process, system, person or body have been fulfilled. This demonstration[1] is provided by a person, organization or body which thereby makes a declaration on the object of conformity assessment. According to the notion of conformity assessment, this declaration shall be *trusted* in legal and economic relations, because the author behind the conformity assessment is trusted as well as his/her examination of the object of conformity assessment on the basis of specified demands in an equally specified procedure. This serves to create trust in the products, services or persons to whom the statement of conformity[2] pertains.

1. Conformity assessment in the private sector

The private sector, in which conformity assessment primary serves to simplify business relations, to facilitate international trade and to promote sales to final customers, places emphasis on this trust. For example, a conformity assessment procedure can demonstrate the compliance with requirements specified by contract to a purchaser of a product in order to make their inspection by the purchaser unnecessary, e.g. before the further processing of a product. To do so, the supplier him/herself may provide a declaration of conformity on the basis of his/her own inspection (supplier's declaration of conformity - SDoC). He/she

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* Please Note: cross references within the footnotes refer to the same Section if not specified otherwise. The same holds for references to footnotes, which are counted from 1 at the beginning of each Section.

1 German: Darlegung, French: démonstration.

2 The term "statement of conformity" is is a generic expression used to include all means of communicating that fulfilment of specified requirements has been demonstrated, for more on the term see DIN EN ISO/IEC 17000:2005, Annex A, A.4.1.

may also have the product inspected by an independent third-party, though. The inspection may pertain to the concrete product thereby. Yet it also may target the construction and manufacturing process of a product and/or the operating procedures in a firm, which are relevant for the quality of the product and the reliability of the supplier. Conformity assessment can take place even without a concrete reference to a product in the form of such an evaluation of management systems in order to optimize operating procedures in view of certain objectives. Such a conformity assessment process helps to reduce the costs or risks within a firm. In particular though, the firm may use the statement of conformity to distinguish itself in the eyes of other potential partners as being efficient, reliable, etc.

Other conformity assessment procedures and the resulting declaration of conformity are more aimed at the final consumer. The declaration or a certificate serve to make a statement on a certain feature of a product, e.g. with regard to its application safety, its innocuousness for one's health or its environmental compatibility. Likewise the product's origin can be certified and serve as a sales argument. What all these forms of conformity assessment have in common is that they are conducted on a voluntary basis – whether this is through a third party or the manufacturer by means of a supplier's declaration –, because the initiator hopes to enjoy the advantages described above.

2. Conformity assessment in the public sector

These voluntary procedures can be distinguished from procedures which are provided for by legal stipulations or are even mandatory. In this so-called "regulatory sphere"[3] the addressees are state agencies, which as a rule must assume on the basis of the conformity declaration that the product complies with the legal requirements. By these means conformity assessment is used to pursue state regulatory objectives, in particular in European product safety law. Additional examples can be found in the areas of environmental protec-

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3 The regulatory sphere includes all conformity assessment programs whose content and procedures are stipulated by law. The participation in the conformity assessment procedure is generally mandatory by law. However, the regulatory sphere in an broader sense also comprises conformity assessment programs in which firms can participate voluntarily, as long as the evaluation criteria and the requirements for the bodies conducting the evaluation are stipulated by legal standards (e.g. EMAS). More on the term below Part I First Section D.I.

tion or work safety[4]. Conformity assessment is used here for several reasons, the most important being the fact that the movement of goods and services can be facilitated by avoiding multiple inspections. This is achieved because the use of conformity assessment allows for approval decisions to be based on technical standards which stipulate regionally or internationally harmonized requirements for products or services and to which the legislator merely refers. Detailed regulations in legal stipulations thus cease to apply. One reason for Member States to maintain their respective national inspection is the lacking trust in state inspection bodies of the other Member States, because their activities can not be monitored. If the Community legislator instead emphasizes conformity assessment following a uniform international procedural and organization standard, individual national inspections should become unnecessary, as the declaration of conformity creates trust in conformity with directives and law beyond national borders.

An additional reason for the use of conformity assessment is that it removes the burden from state enforcement authorities. This is achieved by no longer inspecting products and services by means of state reporting or approval procedures and instead shifting the responsibility to manufacturers, providers and conformity assessment bodies. At the same time, it may be the case that such procedures are perceived by firms as less of a burden.

II. Elements

The definition of conformity assessment in Section 2.1 DIN EN ISO/IEC 17000:2005 “demonstration, that specified requirements relating to a product, process, system, person or body have been fulfilled” stipulates what the standards regard as conformity assessment and thus constitutes the object of conformity assessment from the perspective of the *standards*. It comprises various forms of conformity assessment. They differ with respect to the object of conformity assessment, the type of activity and the author of the demonstration of conformity. The conformity assessment relates to “specified requirements” of different origins.

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4 For more on the forms of use of conformity assessment in the regulatory sphere, see Part I Fourth Section A, in particular A.VI. See also Part Two, A.I.

1. Objects

The object of conformity assessment can be a product which must satisfy specified requirements. This includes technical products, e.g. a machine or other mechanical parts, but also may constitute software such as computer programs[5]. The object of conformity assessment can be a service, such as the transport of goods[6]; but also a technical facility. The latter are examined in particular before initial operation and/or in regular time intervals by means of inspection[7]. Conformity assessment may relate to processes and systems, an example of which is the certification of management systems according to the standard ISO 9001:2000. Furthermore, persons can be scrutinized on the basis of specified requirements. Certification of personnel is frequently used to assess the expertise of persons who are responsible for monitoring the quality of products and processes. An example of this is the certification of persons who work as welders or who conduct certain parts of non-destructive inspections. In the area of management systems, auditors can be certified for example[8]. Finally, conformity assessment bodies themselves can be the object of an assessment on the basis of specified criteria[9]. Put like this, the accreditation of the conformity assessment bodies is a form of conformity assessment[10].

2. Type of activity

According to the type of activity, conformity assessment is divided into the activities testing[11], inspection, certification and accreditation.

According to the definition in Section 4.2 DIN EN ISO/IEC 17000:2005, *testing* means the determination of one or more characteristics of an object and generally refers to materials,

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5 See Section 3.3 DIN EN ISO/IEC 17000:2005.

6 According to the definition of the term in the conformity assessment standards, the term product also comprises services, see Section 3.3 DIN EN ISO/IEC 17000:2005, according to which services constitute one of the different categories of products, see also Note 2 on section 2.1 DIN EN ISO/IEC 17000:2005.

7 See below A.II.2.

8 *Schondey*, DIN-Mitteilungen 10-2005, 32 et seqq., 32.

9 See Section 2.1 DIN EN ISO/IEC 17000:2005.

10 In more detail forthwith under A.II.2 as well as the Second Section, A.I. In order to distinguish between the different levels, an accreditation body is always referred to as such and not as a conformity assessment body, see the Note on Section 2.5 DIN EN ISO/IEC 17000:2005.

11 Including calibration.

products or processes. What is distinctive here is that the result of the test only contains a declaration on the existence of the characteristic.

Certification can pertain to products, processes, systems or persons and contains a (formal) confirmation of the fulfilment of the specified requirements; it is always carried out by an independent third party[12].

The standards conceive *inspection* as the "examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements"[13]. Inspection frequently overlaps with other forms of conformity assessment, in particular testing and product certification[14]. One particularly emphasized feature of inspection is that it frequently relates to the conformity of individual, often complex or critical products and concerns over products and facilities *in use*. Many inspection activities require a professional judgement (on the basis of general requirements). Product certification, in contrast, is frequently used to determine the conformity of products manufactured in a series[15]. Inspection provides information on the state of the object at the time of inspection, while the certification generally aims to assure the continual conformity of the object[16].

Accreditation can also be described as a form of conformity assessment[17]. It essentially distinguishes itself from the other forms of conformity assessment in that the object of assessment is the competence of the conformity assessment body[18] and that accreditation thus assures the quality of the service of conformity assessment at a second, superior level.

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12 Section 5.5 in conjunction with 5.2 DIN EN ISO/IEC 17000:2005.

13 Section 4.3 DIN EN ISO/IEC 17000:2005.

14 However, with regard to product certification only in those cases in which inspection is conducted by an independent third party. (Whereas certification is always conducted by an independent third party, this is not necessarily the case with inspection, for certification see Section 5.5 DIN EN ISO/IEC 17000:2005, for inspection see the description of the three types of inspection bodies in DIN EN ISO/IEC 17020:2004, Section 4.2.1.)

15 More in *Pflumm/Schaub*, DIN-Mitteilungen 10-2005, 26 et seqq., 27.

16 *Pflumm/Schaub*, DIN-Mitteilungen 10-2005, 26 et seqq., table p. 27 above.

17 See the definition of conformity assessment in Section 2.1 DIN EN ISO/IEC 17000:2005, which lists accreditation as a form of conformity assessment in Note 1.

18 Section 5.5 DIN EN ISO/IEC 17000:2005.

3. Conformity assessment by a first, second, third party

Another important aspect is the relation between the person conducting the assessment and the object of conformity assessment. If conformity assessment is carried out by the person who provides the object, i.e. the manufacturer for example, this is a case of "first party conformity assessment"[19]. If conformity shall also be demonstrated towards the purchasers, this generally takes place in the form of a supplier's declaration of conformity[20]. On the one hand, such a supplier's declaration can be required by legally stipulated conformity assessment procedures – an example is the supplier's declaration within the framework of the conformity assessment procedure according to the directives of the New Approach[21]. However, it can also be of importance within the scope of a contract, in particular in the area of investment goods and towards professional purchasers[22].

Conformity assessment can also be conducted by persons or organizations which have a particular interest in the object as users, thus for instance by the purchasers or users of a product or by customers seeking to confirm their trust in the management system of a supplier (conformity assessment by a second party)[23].

Conformity assessment by a third party is performed by a person or body that is independent of the person or organization that provides the object and of user interests in that object[24]. According to the definition in Section 5.5 DIN EN ISO/IEC 17000:2005, certification is always carried out by a third party. The other forms of conformity assessment can be conducted by a first, second or third party.

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19 Section 2.2 DIN EN ISO/IEC 17000:2005.

20 For more on this see, Second Section, B.II.3.

21 For the application possibilities of the supplier's declaration of conformity within the context of avoiding trade obstacles, see also the preparatory report of the TBT Committee for workshop on SDoC organized in March 2005 (*Committee on technical Barriers to Trade*, Workshop on Supplier's Declaration of Conformity – Background Note by the Secretariat); the document is available online at URL: http://www.wto.org/english/tratop_e/tbt_e/tbt_wrkshop_note_21march05_e.doc (4.3.2006).

22 In greater detail *Beer*, DIN-Mitteilungen 10-2005, 43 et seqq., 44.

23 See Section 2.3. DIN EN ISO/IEC 17000:2005.

24 Section 2.4. DIN EN ISO/IEC 17000:2005; the criteria for the independence of the body can be found in the respective international standards and guidelines.

4. Specified requirements

Section 3.1 DIN EN ISO/IEC 17000:2005 conceives specified requirements as needs or expectations stipulated (in writing). These may be stated in normative documents such as regulations or in standards[25] and technical specifications[26]. As standards are very frequently used as specified requirements, conformity assessment is often regarded as a standard-oriented activity[27]. However, this is not mandatory. As the definition shows, conformity assessment can also take place on the basis of legally specified requirements. If the specified requirements are contained in legal provisions, they may refer to technical standards or specifications for the sake of concreteness.

At the level of the requirements placed on the object of conformity assessment, the specified requirements can differ with regard to their degree of concreteness[28], and above all in terms of their point of reference. The specified requirements can contain, for example, concrete features which a certain industrial product must demonstrate (product standards). However, they also may contain rules on the procedures within a firm, by means of which specified requirements are to be fulfilled (process standards)[29]. Besides that, standards can be concerned with testing methods (testing standards)[30]. If the object of the conformity assessment is a conformity assessment body (accreditation), the requirements for the conformity assessment bodies tested during the accreditation are also stipulated in standards[31].

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25 In the following, the term "standard" (German: "Norm", French "norme)" shall only apply to technical standards or procedural standards which are drawn up by the standardization organizations and as such are of a non-binding character, not legal norms though. The term "standard(s)" shall be used in the same meaning as the German term "(technische) Norm". "Standard" is defined as a "document established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context", see EN 45020:1998 (ISO/IEC Guide 2:1996), Section 3.2; more on the technical standard and/or specification in *Marburger*, Regeln der Technik, p. 40 et seqq.

26 A technical specification or description is a document that prescribes technical requirements to be fulfilled by a product, process or service, EN 45020:1998 (ISO/IEC Guide 2:1996), Section 3.4. The technical specification can be a standard or a part of it, but also may exist independently of this, l.c. Note 2.

27 DIN EN ISO/IEC 17000:2005 Annex A Section A.1.1.

28 Requirements stipulated in legal provisions are thus as a rule defined more generally.

29 More on types of standards EN 45020:1998 (ISO/IEC Guide 2:1996), Section 5. Standards can be comprised of elements from different types of standards.

30 For the definition EN 45020:1998 (ISO/IEC Guide 2:1996), Section 5.3.

31 DIN EN ISO/IEC 17020, E DIN EN ISO/IEC 17021, DIN EN ISO/IEC 17024, 17025, ISO Guide 65/DIN EN ISO 45011, DIN EN ISO 45012.

III. Structures and institutions

1. Conformity assessment bodies

The service of conformity assessment is generally offered by so-called conformity assessment bodies (CAB), which operate on the basis of private law[32]. Due to the diversity of the areas of application of conformity assessment both in the regulatory as well as non-regulatory sphere, the organization and focus of the conformity assessment bodies greatly vary: there are numerous specialized conformity assessment bodies which work in a very narrow area and which are partially more active on the national or only regional market – depending on their offer of services. At the other end of the scale we find firms active worldwide, whose offer of services spans across numerous conformity assessment schemes in various specialized areas. This holds, for example, for the conformity assessment bodies of the TÜV-Groups (Technical Inspection Agencies) in Germany or other internationally active firms such as Bureau Veritas, DNV, LRQA or UL. These diversities lead to different economic conditions which are to be taken into account in the design of the conformity assessment system[33].

The conformity assessment bodies have formed associations at the national, European and international level, which are supposed to facilitate the exchange of information as well as the representation of common interests[34].

2. Role of accreditation

Accreditation is according to Section 5.6. DIN EN ISO/IEC 17000 a third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks[35]. Accreditation is supposed to as-

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32 Conformity assessment can also be conducted by state agencies; inspection bodies, in particular, frequently exist within state agencies. What is characteristic, though, is the use of inspection agencies of firms and/or the use of private third parties in the area of certification.

33 This holds for instance for the assessment of the negative impact of (multiple) accreditations, in the regulatory sphere for the obligation to participate in standardization activities, to cooperate with authorities, etc. More on this in the Second Section, B.II.4.b), c).

34 In more detail in the Third Section, D.II.

35 More on the function and organization of accreditation in the Second Section, A.I

sure the quality of the conformity assessment through the inspection and surveillance of the expertise and suitability of the bodies. The results of the conformity assessment should be attributed a greater degree of credibility, which in turn is the basis of the trust that the other participants of the system place in conformity assessment[36].

The evaluation of the conformity assessment bodies is conducted in the international system on the basis of standards which specify the requirements for the conformity assessment bodies[37]. The objective is to ensure that the conformity assessment bodies achieve equal results by means of these harmonized standards. The trust in the equality of the results created this way is supposed to provide the foundations for the mutual recognition of the results of conformity assessment of the bodies partaking in the system[38].

The associations of accreditation bodies at the regional level (e.g. EA) and at the international level (IAF and ILAC) play an important role for the recognition of declarations of conformity. They offer, on the one hand, a forum for the establishment of multilateral agreements on the mutual recognition of conformity assessment results, so-called MLA or MRA. An additional important function is the elaboration of interpretation documents on the standards which contain the requirements for accreditation bodies and guidelines for the accreditation of conformity assessment bodies. The goal of these interpretation documents is to harmonize the application of the standards and thus unify the level of activity of the conformity assessment bodies.

The uniform application of harmonized standards shall ultimately achieve the goal of making products and services marketable on the basis of a one-time conformity assessment and accreditation in the entire associated conformity assessment system (“*one standard - one test - accepted everywhere*”)[39].

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36 See DIN EN ISO/IEC 17011:2004, Introduction.

37 DIN EN ISO/IEC 17020, E DIN EN ISO/IEC 17021, DIN EN ISO/IEC 17024, 17025, ISO Guide 65/DIN EN ISO 45011, DIN EN ISO 45012.

38 More on the mechanisms of the MRA and MLA in the Second Section, A.I.2.b).

39 See DIN EN ISO/IEC 17011:2004, Introduction.

3. Peer assessment

An additional possibility of creating trust in the results of the conformity assessment is the procedure of peer assessment. At the level of conformity assessment, CABs join to become associations with the goal of enabling the mutual recognition of declarations of conformity. These so-called agreement groups commit their members to certain standards and procedural rules, whose compliance is monitored by regular mutual assessment. As members of the association, the conformity assessment bodies are obligated to recognize the declarations of conformity of the other members. The difference to accreditation essentially is that a peer assessment constitutes an appraisal by a body of equal status, not surveillance by a body of secondary status.

Agreement groups are particularly wide-spread in the area of electro-technology; for example, the CB-procedure at IECEE (S*ystem for Conformity Testing and Certification of Electrical Equipment)* can be mentioned here[40]. The mechanism of peer assessment is also applied at the level of the accreditation bodies in order to facilitate the unification of their inspection level[41].

4. Role of standardization

International standardization fulfils several functions for the system of conformity assessment: firstly, it provides harmonized standards in a specific framework which contains material demands on products and services, i.e. standards and guidelines, on the basis of which the objects of conformity assessment can be inspected (standards as a form of specified requirements in line with Section 3.1 DIN EN ISO/IEC 17000)[42]. Secondly, it provides procedural standards which contain rules on how conformity assessment is to be carried out. Among these count the standards containing requirements for conformity as-

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40 In more detail see *Kreß*, DIN-Mitteilungen 10-2005, 41 et seq. See also Second Section, A.II.

41 In greater detail Second Section, A.I.

42 Examples of this are product standards or standards with requirements for management systems such as ISO 9001:2000.

sessment bodies[43] and/or accreditation bodies[44]. Another important function is that they lay down a uniform terminology, e.g. DIN EN ISO/IEC 17000.

The documents supporting the conformity assessment are drawn up by CASCO, the ISO-Committee for Conformity Assessment[45], and published as ISO/IEC-standards and/or guidelines[46]. CASCO consists of representatives of national standardization organizations, representatives of technical committees of the ISO and international organizations[47]. The documents are drawn up in cooperation with the International Electrotechnical Commission IEC[48] and the European Committee for Standardization CEN.

IV. Development

There is hardly any reliable information on the beginnings of conformity assessment and accreditation. This might have to do with the fact that the contemporary institutions have developed out of different forerunners. It can be maintained, though, that conformity assessment in the form of the certification of quality management systems is a long-standing tradition in the Anglo-Saxon countries[49]. The first national standards for quality management systems were developed already in 1958 in the military sector and for the third-party certification of management systems in the electrical industry, for example, in the early 1970s[50]. It is sometimes assumed that these forms of quality assurance developed in reac-

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43 DIN EN ISO/IEC 17020, E DIN EN ISO/IEC 17021, DIN EN ISO/IEC 17024, 17025, ISO Guide 65/DIN EN ISO 45011, DIN EN ISO 45012.

44 DIN EN ISO/IEC 17011.

45 More information on the work of CASCO at URL: http://www.iso.org/iso/en/comms-markets/conformity/iso+conformity-03.html (20.3.2006).

46 The difference between standards and guidelines exists since 1997, in greater detail *Ensthaler et al.*, Akkreditierung (KAN-Bericht 30), p. 43.

47 The Bureau International des Poids et Mesures (BIPM), the International Accreditation Forum (IAF), the International Federation of Standards Users (IFAN), the International Federation of Inspection Agencies (IFIA), the International Certification Network (IQNet), the International Laboratory Accreditation Cooperation (ILAC), the International Personnel Certification Association (IPC), the Organisation Internationale de Metrologie Légale (OIML) and the International Union of Independent Laboratories (UILI) are represented as "liaison members" in CASCO.

48 The International Electrotechnical Commission (IEC) is the leading international standardization organization for the electrical, electronic and related technologies; more information at URL: http://www.iec.ch/index.html (20.3.2006).

49 *Joerges/Falke/Micklitz/Brüggemeyer*, Sicherheit von Konsumgütern, p. 124 et seq.

50 The series of norms ISO 9000 is based, among other things, on the British standard BS 5750, which was created in the 1970s by the British Standards Institute BSI. For the history of certification according to

tion to the increased demand for standardization within the Commonwealth; others see the origins of conformity assessment and accreditation in the military sector (procurement system)[51]. What also seems to be characteristic for the Anglo-Saxon countries is that the inspection system and/or conformity assessment developed as an organization-oriented system with authorized and/or recognized inspection and surveillance *bodies*[52]. In Germany, however, the concept of recognized experts (*anerkannte Sachverständige*) prevailed. According to the classic forms of expert participation, the recognition of experts was based on the professional expertise of the concrete individual, even if the expert, as in the frequently cited example of officially recognized motor vehicle experts, could only conduct his activity as an employee of a technical inspection body[53].

From the German perspective, the surveillance of steam boiler installations is frequently mentioned as a forerunner of conformity assessment in the area of product certification. This took place in Germany by means of "steam boiler surveillance associations" (*Dampfkesselüberwachungsvereine*) approximately since the second half of the 19th century"[54]. The law concerning the operation of steam boilers from 3 May 1872[55] stipulated regular

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the series of standards ISO 9000 see *Ensthaler*, Zertifizierung, Akkreditierung und Normung, p. 65. See also *Wikipedia*, article "ISO 9000" at URL: http://en.wikipedia.org/wiki/ISO_9000 (12.8.2005); BSI at URL, http://www.bsi-global.com/HigherEducation/Quality+Management/History_9000.xalter (12.8.2005); for the development of the quality management systems from the systems for military procurement see *Zollondz*, Qualitätsmanagement, p. 246 et seq. The DTI still promotes the further development of the series of standards ISO 9001:2000 by means of the standardization activities of the BSI, see *DTI* at URL: http://www.dti.gov.uk/strd/certify.html (11.8.2005).

51 *Ensthaler*, Zertifizierung, Akkreditierung und Normung, p. 65, who refers not only to the military sector, but also to the later emerging high standards for nuclear power plants as an impetus for the standardization of quality management systems.

52 The economic efforts to increase production quality in the United Kingdom in the 1980s, which led to an expansion of certified quality assurance systems in the British economy are pointed out in this regard, *Di Fabio*, Produktharmonisierung, p. 25 et seq.

53 For the instrument of recognition of authorized experts in general, see *Scholl*, Private Sachverständige, p. 139 et seq., for motor vehicle experts *ibid*., p. 84 et seq.

54 The first steam boiler surveillance association in Germany was founded in 1866 in Mannheim, and was likely modelled after an English association, the Manchester Steam Users Association for the Prevention of Steam Boiler Explosions and for the Attainment of Economy in the Application of Steam. The main focus of the first established associations was on the years 1870 to 1880; *Wiesenack*, Technische Überwachungsvereine, p. 4, 18.

55 Gesetz betreffend den Betrieb der Dampfkessel (Law concerning the operation of steam boilers) from 3 May 1872, GS p. 515, quoted in *Wiesenack*, Technische Überwachungsvereine, p. 16.

inspections of the boilers. The associated regulation[56] arranged for "steam boilers whose proprietors were members of associations which carry out regular and thorough surveillance of the boilers" can be exempted from the official revision (surveillance). The associations whose membership allowed for this privilege were announced in the Official Journal[57]. Two features of the use of "conformity assessment" in the regulatory sphere already become evident here: inspectors organized by private law are used and official control is limited for the sake of "self-control"[58].

Accreditation appears to have primarily developed for laboratories[59]. The first accreditation systems are said to have emerged in Australia, initially with the objective of a better utilization of the inspection system for quality assurance. In the 1970's a concentration on the area of calibration laboratories could be observed. Since the 1980's the accreditation of laboratories has established itself as a general instrument to demonstrate their competence by an independent third party. In this regard, there is an apparent correlation to the GATT-Agreement, which viewed accreditation as a mechanism to promote the mutual recognition of test results[60]. The accreditation of certification bodies is associated with the certification of management systems, which developed in particular in North America and the United Kingdom and then spread elsewhere[61]. When the New Approach originated, eight accreditation networks for testing laboratories had already been developed or were already estab-

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56 Regulativ, die periodische Untersuchung der Dampfkessel betreffend (Regulation, concerning the period inspection of steam boilers), from 24 June 1872 (MBI. i.V. p.183), quoted in *Wiesenack*, Technische Überwachungsvereine, p. 16.

57 *Wiesenack*, Technische Überwachungsvereine, p.16.

58 The stenographic transcript of the consultations on the quoted law states on this that the minister regards "the greatest possible" limitation of the official controls to the benefit of self-control not only as unobjectionable, rather in fact as very desirable. The introduction to the law of 3 May 1872 states: "There was not the slightest doubt about the great advantage of the protection associations over official surveillance… Every knowledgeable boiler proprietor will from now on be inclined to choose the best over the lesser good – while he did not have this choice according to all previous provisions, but instead still had to accept the official revision along with the cooperative revision. In the future the official revision should only be a penalty for those who do not wish to join the association, and a refuge for those who are able to do so" quoted in *Wiesenack*, Technische Überwachungsvereine, p. 16, 17.

59 See on the following the short outline of the development of accreditation in a position paper of Eurolab Nr. 2/2000 "What conformity assessment operators expect from accreditation", May 2000, available online at URL: http://141.63.4.16/docs/pos/el_01-01_00_381.pdf (20.3.2006).

60 The TBT-Agreement was established during the 1994 Uruguay Round as a result of the revision of the so-called *Standards-Code*, which had already been passed in 1979 during the Tokyo round and favours the recognition of test results, more on this in the Second Section, C.I.

61 The origin of third-body certification in the United States in the 1970s is mentioned in *Di Fabio*, Produktharmonisierung, p. 25.

lished in the EC[62]. As for the accreditation of certification and surveillance bodies, three individual state accreditation systems existed (in the Netherlands, in the United Kingdom and in Portugal)[63]. In Europe, in the 1990's, the accreditation of laboratories and other conformity assessment bodies was consolidated in uniform accreditation bodies, which offer accreditation for the different forms of conformity assessment[64].

B. Functions of conformity assessment

I. The significance of conformity assessment for the private sector

Conformity assessment aims to create trust in products, services or persons by testing their conformity with specified demands in an equally specified procedure. With this objective, the system of conformity assessment has primarily established itself in the private sector. It predominantly serves to simplify business relations, facilitate international trade or promote sales to end customers, for example by demonstrating to the purchaser of a product the compliance with requirements specified by contract.

The particular mechanism of conformity assessment is trust: the internationalized and dislocated economy based on division of labour enables advances in innovation and productivity, which are imperative for maintaining competitiveness and achieving economic growth. However, the competence, experience, and information required for judging the skills and services of the respective business partners are generally lacking – especially in view of the increasingly complex products and services. The lacking information must be replaced by trust in the cooperation partner and/or in a certain system of trust creation.

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62 These were incidentally not operated by authorities, Communication of the Commission on a Global Concept, COM (89) 209 final from 15.6.1989, Official Journal EC 1989, No. C 267, p. 19.

63 Communication of the Commission on a Global Concept, COM (89) 209 final from 15.6.1989, Official Journal EC 1989, No. C 267, p. 19. Accreditation bodies dealing with laboratories, metrology, and calibration can also be found among the forerunners of UKAS, RvA and COFRAC, see Third Section, C.II.

64 The accreditation bodies in France, the Netherlands and the United Kingdom, which are organized by private law, were created by the merging of several accreditation bodies, which always included an accreditation body for laboratories. More in the Third Section, C.II. The EA emerged in 1997 as a result of the merging of the European Accrediation of Laboratories (EAL) and European Accreditation of Laboratories (EAC), Draft 2005-5 "The development of the European infrastructure for accreditation" from 16.6.2005, p. 1, the document is available at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/certif_2005_05.pdf (15.3.2006).

Conformity assessment creates trust in different ways:

- In the case of conformity assessment by a first party[65], the manufacturer assumes trust for him/herself and thus for the conformity assessment carried out by him/her (supplier's declaration).
- The manufacturer can also have the product tested by an independent third party though. In such cases this body assumes trust for itself.

The trust creation process is reinforced by the fact that procedures and structures are oriented towards harmonized standards and their inspection during a recognition procedure, typically by means of accreditation.

II. Application of conformity assessment in contexts governed by public law

Taking its use in the private sector as an example, national and supranational legislators have also made use of the institution of conformity assessment; accordingly, the implementation of conformity assessment procedures is now provided for or even mandatory in an array of legal provisions. However, these regulations do not consistently follow the same functional idea. The most significant reason at the moment is still the substitution of official national authorization procedures by applying trustworthy and thus recognizable international conformity assessments to facilitate the international movement of trade and services. However, it can increasingly be observed that national legislators fall back on conformity assessment to relieve the burden from state enforcement authorities, by placing the inspection of products and services in the area of responsibility of manufacturers, providers and conformity assessment bodies.

1. Trust in public law relations: horizontal recognition

The introduction of conformity assessment by the state, which was primarily initiated by European law and served to enable and/or facilitate the international movement of trade and services, is based on the notion of trust. In the classic nation state this notion of trust is

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65 See above A.II.3.

not an issue, because the possibility of complete information and complete control of results is assumed here on the basis of the idea of state sovereignty. Due to the increasing phenomenon of cooperation in international and in particular in European contexts, this conceptional basis no longer is sustainable though. The activities of foreign bodies are no longer reached by the information and decision-making mechanisms of the nation state. If the activities of such foreign bodies shall be accepted domestically to avoid multiple inspections, trust-creating mechanisms are required which allow for the acceptance of foreign decisions.

This particularly holds in the EC, where one cannot automatically assume that states have trust in the decisions of administrative authorities of other Member States. Instead, such trust must first be created through concrete mechanisms: in national contexts the continual practice and conduct leads to greater familiarity with certain structures, their expertise and their resources[66]. Such experience has yet to be accumulated at the European level. Thus, assessments made by a national administrative body are not trusted in European contexts simply because the national body is integrated in the respective national administrative organization. In some circumstances, the organizational affiliation with the administration even substantiates the suspicion of an inclination to favour national interests[67]. In contrast, the use of conformity assessment, for example within the framework of the New Approach, leads to the *recognizibility* of the individual assessments due to inspections based on harmonized provisions and the transparent specification of procedures and structures in the respective standards. In this respect, the term “horizontal” application of conformity assessment is used, because it aims to achieve the recognizibility of the testing results beyond borders in other Member States.

In concrete terms, this takes place through the mechanism of mutual recognition of testing and inspection reports, test results and certificates (statements of conformity). The most important examples are conformity assessment procedures in the framework of the New

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66 Typically the appeal to “time-tested facilities with a long security technology tradition”, e.g. in *Becker*, Festschrift für Wlotzke, p. 445 (460). On the limits of the capacity to export German notions of safety in the machinery branch, see ECJ 28.1.1986, Case 188/84, Collection 1986, 419 (paras. 15-22 - Holzbearbeitungsmaschinen).

67 See *Majone*, Mutual Trust, p. 19.

Approach, which serve as harmonization measures to achieve the free movement of goods within the European Union[68]. The TBT-Agreement and the recommendations of the UN-ECE (United Nations Economic Commission for Europe) arrange for conformity assessment procedures as a mechanism to simplify market access regulations[69]. What is characteristic of conformity assessment in this context is the orientation of the institutional and procedural arrangements towards the *recognition* of the declarations of conformity.

2. Use of conformity assessment in other state contexts

Nowadays, the use of conformity assessment by the state spans beyond these horizontal efforts at creating trust:

- Firstly, EU law demands the introduction of certain conformity assessment procedures in national law in order to guarantee a certain uniform quality of the enforcement infrastructure or in order to first create such a structure at all. The results of such conformity assessments – for example in case of EMAS – do not primarily target recognizibility in other Member States, rather the vertical assurance of a comparable level of enforcement.
- The analysis of legal provisions in Germany and in the other examined countries will show that the use of conformity assessment or – to be more precise – the transfer of testing and assessment tasks to conformity assessment bodies frequently also serves the purpose of relieving the burden from public authorities[70]. At the same time, this allows for the incorporation of the special expertise of the conformity assessment bodies which they have accumulated within the scope of their testing activities in the regulatory and non-regulatory sphere, through specialization and – not least – their proximity to the market and the manufacturer. Here the use of conformity assessment is not to the same extent driven by the need to reach horizontal recognition. As in numerous other cases of the use of private entities the state could equally draw on its own procedural

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68 In more detail below in the Second Section, B. See *Röhl* in: Schmidt-Aßmann/Schöndorf-Haubold, Der Europäische Verwaltungsverbund, p. 154 et seqq.

69 See Art. 5 to 9 of the TBT-Agreement (see the Second Section, C.I.2), UNECE Recommendation "L" - An International Model for Technical Harmonisation Based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards (Trade/2P.6/2002/7), 2002, see No. 2, No. 26 (see the Second Section, C.II.2).

70 See Fourth Section, A.VI, Part Two, A.I.(3).

and structural provisions and would not have to refer to the international standards and the structures which have evolved through them. By using conformity assessment, the state merely is falling back on available regimes of norms and existing structures. If private entities are used in this manner when enforcing police law, they are continually bound to the responsible authorities through recognition procedures, in order to assure their expertise and their independence. In this context, legal regulations frequently resort to an accreditation, which is more or less closely oriented towards or is based on harmonized accreditation rules from the non-regulatory sphere[71]. This can also be the case when no regulations on the (international) recognition of the declarations of conformity exist in the concerned area.

C. Restriction to a functional and standard-oriented concept of conformity assessment

The definition of conformity assessment given in Section 2.1 DIN EN ISO/IEC 17000:2005, "demonstration that specified requirements related to a product, a process, system, person, or body have been fulfilled", would comprise besides the processes listed up to now an array of additional inspections, confirmations, certificates, etc. in both the non-regulatory and regulatory sphere, which are conducted on the basis of different criteria, in different procedures and with very different objectives. However, it would be neither appropriate nor continuative to deal with the totality of such forms of incorporating experts into state decision-making processes and/or the use of private experts in legal relations between private bodies within the framework of this analysis. A majority of these forms does not draw on conformity assessment as a self-sustaining system, nor do they reclaim the predicate "conformity assessment" by referring to the relevant standards. The just mentioned definition of conformity assessment thus does not suffice to restrict the object of analysis; only an internal system meaning can be attributed to it.

The object of the analysis must instead be identified independently on the basis of the *functions* of the conformity assessment and the *reference to standards*. As just described, the particular *functions* of conformity assessment are to facilitate the international movement

71 More on this in the Second Section, B.III.1, Third Section, B.

of goods by enabling the recognition of declarations of conformity as well as the positioning of private third parties in the (European) enforcement of police law disburdens authorities and at the same time makes the expertise of the private third parties useful (see under I.). These functions of conformity assessment are supported by the reference to harmonized standards, because they generally include the requirements for the inspected product and because - above all - the activity of the conformity assessment itself is constituted by the relevant standards, which in turn facilitates the recognition of the declaration of conformity. The *reference to harmonized standards* thus constitutes the second criterion for the restriction of the forms of conformity assessment addressed here (II.). One particular consequence of this commitment to a functional and standard-based concept of conformity assessment is that certain forms of the use of private experts, as known from classical police law, are not part of this analysis (III.). The same holds for the marks of quality, which nevertheless should be briefly presented in the following (IV.).

I. Starting point: functions of conformity assessment

As already seen, conformity assessment serves to simplify business relations in the private sector; in an international context it serves above all to facilitate trade. In the regulatory sphere as well conformity assessment is used to promote the free movement of goods through recognizable declarations of conformity. In order to limit the concept of "conformity assessment", our analysis shall first concentrate on this characteristic: the orientation towards the recognizibility of the produced declarations of conformity. Accordingly, above all those conformity assessment systems which pursue this objective shall be examined.

Many areas in which private bodies intervene into the enforcement of standards, serve not so much the objective of creating trust at the national or international level, rather the objective of removing the burden from the authorities and productive cooperation. They shall be examined[72] to the extent that they offer insights on the structure of conformity assessment procedures in the regulatory sphere. The additional criterion of reference to standards must prove to apply here.

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72 As long as they *call for* harmonized accreditation standards, more on this below.

II. Significance of the reference to standards

In their quality as technical standards, the standards of the series ISO/IEC 17000 and EN 45000[73] are not binding. They are not attached normative valence until reference is made to them, for instance by the reference to the relevant standards in contractual agreements and legal provisions or by the intentional use of the terms "conformity assessment" or "accreditation" in this sense. This study treats as conformity assessment only those forms of incorporating private experts which explicitly appeal to the standards of the series ISO/IEC 17000 and/or EN 45000 or make it clear by other means that conformity assessment is to be conducted in accordance with these standards[74].

This specification of the object of analysis is substantiated by the relevance of the reference to standards for the recognition of the declarations of conformity, which was identified as the decisive function of the conformity assessment:

The recognizibility of declarations of conformity can be established when the objects of the conformity assessment are inspected on the basis of *harmonized* requirements. In this manner, the harmonized requirements during the conformity assessment provide the basis for the recognition of inspection reports, certificates, etc. The specified standards are frequently international or at least regionally harmonized standards; hence, conformity assessment is often understood as an activity relating to standards[75]. The specification of the requirements in standards or technical specifications is not mandatory; specified requirements can result, for example, from legal provisions, which, however, may contain a significantly less detailed inspection program. However, the appeal to uniform material criteria substantially contributes to the establishment of recognizible declarations of conformity. Therefore, those conformity assessment programs which operate on the basis of standardized requirements play a special role.

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73 To the extent that these are still used and have not been replaced by standards of the series ISO/IEC 17000 et seqq.

74 A summary of the forms of conformity assessment not covered by the analysis can be found below C.III.3.

75 DIN EN ISO/IEC 17000:2005 Annex A Section A.1.1.

The activity of conformity assessment itself is constituted above all by the pertinent standards, which provide the procedures and structures of conformity assessment. In the international system of conformity assessment the recognition of declarations of conformity essentially depends on whether the conformity assessment bodies operate according to uniform procedures – this is achieved by means of harmonized procedural standards, which are bindingly imposed on the conformity assessment bodies in accreditation procedures or other assessment procedures[76]. If private third parties are incorporated into the enforcement of police law, the expertise of the bodies is typically inspected by means of recognition procedures and on the basis of requirements which are equally stipulated by standards (accreditation). The analysis shall thus shed light on such procedures in which conformity assessment bodies operate on the basis of harmonized inspection criteria and harmonized standards, i.e. according to the relevant standards of the series ISO/IEC 17000.

III. Objects of this study

1. Conformity assessment and the involvement of experts under public law

In public law there exists an immeasurable array of cases in which private experts are involved in the inspection of legal requirements in one way or another[77]. As a result of the limitation to a functional and standard-related concept of conformity assessment, numerous forms of this classical type of expert involvement are not among the objects of analysis, although they also could be included under the broad definition in Section 2.1. DIN EN ISO/IEC 17000. However, since they demonstrate no reference to procedures or structures of conformity assessment at all, they shall not be dealt within this analysis.

For example, the inspection engineer for construction statics, the head district chimney sweeper, or the officially designated land surveyor can be mentioned as classic forms of expert involvement. Often private persons are required to demonstrate compliance with

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76 Requirements for conformity assessment bodies for the accreditation procedures are contained in DIN EN ISO/IEC 17020, E DIN EN ISO/IEC 17021, DIN EN ISO/IEC 17024, 17025, ISO Guide 65/DIN EN ISO 45011, DIN EN ISO 45012.

77 See the comprehensive compilation on the participation of experts in public law in *Scholl*, Private Sachverständige, p. 45 et seqq.; see also the examples in *Seidel*, Privater Sachverstand, p. 195 et seqq.; on various *types* of experts (89) 209 ibid. p. 167 et seqq.

legal provisions and are therefore forced to mandate private assessors to obtain a certificate demanded by law[78]. The legal foundations regularly standardize requirements for these assessors which are supposed to ensure their professional expertise and independence. These requirements resemble the demands which are stipulated in legally mandated conformity assessment procedures with regard to the expertise and independence of conformity assessment bodies[79]. These forms of expert participation primarily serve the purpose of integrating the particular expertise of the professional expert into the official procedures and making administrative activities simpler and at the same time more effective[80]. To this extent, conformity assessment and expert participation overlap in their functions. Uniform inspection criteria and the qualification and independence of the experts also play a role in the case of the classic form of expert participation, and experts are generally subject to an official recognition procedure. However, since the administrative procedures are mostly tailored to the national sphere and the recognition of inspection reports and certifications by other authorities is not necessary, the harmonization of the inspection criteria and the requirements for the inspectors are usually less significant. The addressee of the inspection report and/or the certificate is generally the (national) agency which is responsible for the enforcement of the legal provisions. Therefore the references to technical standards and the specification of criteria for inspectors are less geared towards guaranteeing a uniform inspection which takes place at the same level and achieves recognizable results, than guaranteeing a level of inspection which is regarded as necessary and sufficient for the respective area.

Unlike most models of expert participation in the national context, the forms of use of conformity assessment in the regulatory sphere are explicitly geared to enable the recognition of declarations of conformity. This very recognition of the results has the decisive advan-

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78 The assessments and/or test reports sometimes form the basis of the subsequent official decision, e.g. on the authorization of a product or the operation of a facility. Other times, though, the inspection is also completely delegated to the private expert, see *Scholl*, Private Sachverständige, p. 11 et seqq., p. 279 et seqq., (286 et seq.) for examples of the participation of private assessors in preventive administrative procedures and on the use of so-called verifiers and the waiver of approval procedures.

79 See e.g. the requirements in § 4 (experts) and § 11 (inspection bodies) of *VSU Boden und Altlasten* (Ordinance on experts and inspection bodies for soil conservation and the treatment of contaminated sites in Bavaria) for examinations according to the Federal Soil Conservation Law (BBodSchG), more in this in the Fourth Section, A.II.2.

80 See *Scholl*, Private Sachverständige, p. 109 et seqq. (for all forms of expert participation).

tage which enables the use of conformity assessment to facilitate market access in Europe. When observing conformity assessment as a regulatory instrument, one should primarily take such forms of use of private third parties into account which aim for recognizible declarations of conformity. However, an examination of selected legal foundations also shows that – primarily motivated by European guidelines – "bodies" instead of individual experts are used[81] and that the instrument of accreditation serves to examine the expertise and adequacy of the bodies. As a result, some of the most recent legal foundations more or less explicitly provide for the use of accreditation or at least the use of accreditation standards for the inspection of the expertise of the bodies[82]. These regulations should indeed be taken into consideration due to their reference to standards, regardless whether they are simultaneously geared towards the production of recognizible declarations of conformity.

2. Marks of quality

The marks of quality (*Gütezeichen*) are also in terminological proximity to conformity assessment. Marks of quality are used to designate products and services which are produced or offered according to specified quality criteria[83]. The objective of the marks of quality is to designate and increase the quality of goods or services and provide consumers neutral,

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81 For example according to § 9 para. 2 clause 2, § 18 BBodSchG (Federal Soil Conservation Law): inspection bodies (Untersuchungsstellen) next to authorized experts; see also the statements substantiating the draft of a law to amend the appliance safety law (Gerätesicherheitsgesetz) and the chemicals law (Chemikaliengesetz) from 2.6.2000, BT Drs. 14/3491 p. 1 et seqq., which states in this regard that the individual-related technical inspection system does not comply with the structures of a organization-related inspection system stipulated by European community law. By creating inspection bodies (*zugelassene Überwachungsstellen*) the technical inspection system is supposed to be harmonized with the European structures "in the interest of the long-term assurance of the competitiveness of the national system of technical surveillance in a European service market" (p. 10); more on this in the Fourth Section, A.IV.2.

82 See e.g. for inspection bodies (*zugelassene Überwachungsstellen*) within the framework of the monitoring of appliances according to the GPSG § 17 para. 5 GPSG, which provides for an "accreditation" as a requirement for designation (without reference to harmonized standards), see the Fourth Section, A. IV.2; in the driving licence system § 72 FeV (reference to DIN EN 45013 in the Ordinance text), see the Fourth Section, A.V.1; for the certification of carriers and measures for the professional further development the "Anerkennungs- und Zulassungsverordnung Weiterbildung – AZWV (Recognition and Authorization Ordinance for further education): reference to DIN EN 45012 in the justification of the Ordinance, see the Fourth Section, A.V.2; further examples in the Fourth Section, A.

83 Definition according to RAL, Grundsätze für Gütezeichen, 16th edition May 2003, Item 1.2 "Ausweise der Gütesicherung". The document is available online at URL: http://www.ral.de/gz/de/guetezeichen/index.html?content5.shtml (25.8.2005).

reliable information for their selections on the market[84]. According to German law, marks of quality cannot be created for individual products, rather only for types of goods and service categories. Many product marks of quality concern the construction sector, others the agriculture and nutrition sector and others the service sector[85].

The marks of quality system in Germany is essentially regulated by the "Principles for Marks of Quality" of the RAL (German Institute for Quality Assurance and Labelling)[86]. The requirements for the marks of quality are defined by RAL together with producers and suppliers, businesses and consumers, inspection institutions and authorities during a recognition procedure[87]. The marks of quality are published in the German Federal Gazette (*Bundesanzeiger*) and registered as collective marks; they must be accessible to everyone. The bearers of the marks are the quality assurance associations, which create an ordinance (*Zeichensatzung*) for the respective symbol. On the basis of their articles of association, they grant the right to bear the mark of quality to users, who voluntarily pledge to comply with the quality conditions. The quality monitoring extends to the compliance with the quality conditions and the correct use of the marks of quality. This occurs through the self-monitoring of the users of the mark, but also by means of monitoring by third-parties such as inspection bodies, institutes, or sworn experts. The quality assurance associations must add clauses to their ordinances which ensure that they continually conduct monitoring measures and demonstrate this to the RAL[88]; furthermore, they must arrange for certain penalties in the case of violations[89]. Similar regulations exist in Austria, for example[90].

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84 RAL, Grundsätze für Gütezeichen (Fn. 83), Item 1. The designation "Gütezeichen" has been used since 1932 in goods traffic, RAL, Grundsätze für Gütezeichen, (Fn. 83), Einführung, p. 4.

85 Currently over 160 marks of quality exist; list of the RAL-marks of quality at URL: http://www.ral.de under *Gütezeichen/Gütezeichen-Liste* (25.8.2005).

86 Deutsches Institut für Gütesicherung und Kennzeichnung e.V. – RAL; see RAL, Grundsätze für Gütezeichen (Fn. 83). The principles have existed since 1973 and have been modified several times since then.

87 See RAL, Grundsätze für Gütezeichen (Fn. 83), Item 1.2 "The quality requirements can be associational quality requirements or the result of limited cooperation between the bearer of the mark of quality and the levels of the economy interested in the concerned good or service or the extensive cooperation of a non-profit corporation (e.g. DIN). The concerned expert and market groups (as a rule the associations of the supplying economy and the consumers/users affected by the quality assurance as well as associations from the inspection system, concerned state bodies and where necessary other professional institutions) are involved in drawing up the quality requirements)" More on the recognition procedure RAL, Grundsätze für Gütezeichen (Fn. 83), Item 3.

88 RAL, Grundsätze für Gütezeichen (Fn. 83), Item 2.7.1.

89 RAL, Grundsätze für Gütezeichen (Fn. 83), Item 2.7.2. RAL is authorized to conduct re-examinations of its own, l.c., Item 2.7.1.

When the authorization to bear the mark of quality is granted, it demonstrates that specified requirements with regard to a product or service have been fulfilled[91]. However, the main purpose of the mark of quality is to make the products distinguishable to the user or consumer on the basis of the special above-average quality. The mutual recognition of marks and/or the facilitation of the movement of goods, however, are not the intention of the harmonized requirements. Since they are not geared towards mutual recognition and there is no reference to European or internationally harmonized standards, the marks of quality shall thus not be considered in the following.

3. Summary

Accordingly, the objects of this analysis are procedures to inspect:

- products, including services and persons
- mandated by private parties (voluntarily or because a conformity assessment procedure is required by law)
- on the basis of harmonized criteria, which are regularly stipulated in standards,
- by private bodies which operate on the basis of harmonized procedural rules stipulated in the corresponding standards,
- for which the relevant inspection criteria and procedural rules explicitly refer to the relevant standards of conformity assessment or at least otherwise make a reference to this by the intentional use of the terms “conformity assessment” or “accreditation” along these lines.

The study primarily deals with those conformity assessment systems which are aimed at the mutual recognition of the produced declarations of conformity (testing and inspection reports, test results, certificates, etc.). Additional forms of use, in particular accreditation in

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90 Unlike in Germany, a state permit is required in Austria to bear a mark of quality. The legal basis for this is the Ordinance on marks of quality from 1942 (Verordnung über Güte-, Prüf-, Gewähr- und ähnliche Zeichen from 9 April 1942, StF: dRGBL I, 273/1942, last amended BGBl. I No. 191/1999). The permit can be issued to individual manufacturers, or – as is generally the case – issued for association marks; in this case the association then must offer a guarantee for compliance, § 2 para. 1 Gütezeichenverordnung.

91 See the definition in Section 2.1. DIN EN ISO/IEC 17000:2005-03.

the regulatory sphere, will be considered to the extent that they provide stimuli for structuring conformity assessment procedures in the regulatory sphere in general.

Besides the already addressed classical incorporation of experts and the marks of quality, the following phenomena are not part of the object of analysis due to the lacking reference to harmonized inspection or procedural standards:

- The accreditation of study courses at institutions of higher educations[92].
- The official determination of compliance with legal provisions, as regularly takes place by means of administrative bodies, such as during the enforcement of public law provisions (e.g. the determination of compliance with emissions limits).
- Attestations of accountants, assessments of private experts within the framework of contractual relationships etc.

The following forms of accreditation, among others, are not included in the definition of conformity assessment in Section 2.1. DIN EN ISO/IEC 17000:2005-03:

- The accreditation of diplomats.
- The accreditation of journalists, athletes at the Olympic Games etc.

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92 The accreditation of study courses is a procedure to assure the quality of newly introduced Bachelor and Master study courses at German institutions of higher education. The requirement for the accreditation of study courses generally results from the State University Laws (Landeshochschulgesetze), e.g. § 78 para. 3 Landeshochschulgesetz Baden-Württemberg. The accreditation should serve to assure the quality of university degrees. Study courses in Germany are accredited by independent accreditation agencies which compete with one another. These are in turn accredited by an accreditation council. The term accreditation is thus used at both levels of quality assurance. The accreditation council is embedded in a foundation for the accreditation of study courses in Germany *(Stiftung zur Akkreditierung von Studiengängen in Deutschland)*, which is established by law. The accreditation by the accreditation council authorizes the agencies for a limited period of time to accredit study courses by awarding the foundation's official seal. The "accreditation" of study courses thus constitutes a quality assurance procedure for newly introduced study courses, which can be conceived in the broadest sense as conformity assessment. The structure is similar to conformity assessment to the extent that the expertise of the agencies is inspected and monitored by the accreditation council. The systems are thus also comparable to those described here to the extent that they should contribute to the equal status of the diplomas and facilitate the mutual recognition of university degrees. The national accreditation systems also work together at a regional (e.g. Germany, Austria, Switzerland) and European level for this purpose. More at URL: http://www.akkreditierungsrat.de/ (20.3.2006).

D. Usage of important terms and concepts

I. Regulatory and non-regulatory sphere

In the debate on conformity assessment, the regulatory sphere is distinguished from the non-regulatory sphere[93]. The basis of the distinction is the question whether a conformity assessment procedures is stipulated by law and/or whether the participation in it is bindingly prescribed by legal provisions[94]. If one applies a broad concept of the regulatory sphere, it would include all conformity assessment regulations whose content and procedures are provided for by law, regardless whether the participation in the conformity assessment procedure is bindingly prescribed by law. These also entail, for example, conformity assessment regulations such as the provisions on the GS-mark and EMAS, because in theses cases as well the criteria of evaluation and the requirements for the bodies conducting the assessment are stipulated by legal provisions[95] (regulatory sphere in broad terms). According to a wide-spread more narrow understanding, the regulatory sphere only includes those matters, for which it is also legally binding and mandatory to conduct a conformity assessment procedure (regulatory sphere in the narrow sense)[96]. As long as not

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93 However, this primarily holds for the debate in Germany and is likely caused, in particular, by the traditional separation of private accreditation bodies and state accreditation and recognition bodies. In other countries there is much less of a differentiation between the regulatory and non-regulatory sphere; accreditation, above all, is regarded more as a uniform institution. More on this in the Third Section, A, B.

94 Assuming this differentation, see also DAR, Handbuch, Section 3, definitions under "Gesetzlich nicht geregelter Bereich"; the handbook is available online at URL: http://www.dar.bam.de/qm2.html (13.2.2005). Art. 3 Regulation (EC) No 765/2008 now speaks of compuslory and non-compulsory conformity assessment.

95 Generally by reference to technical standards.

96 An even different view in *Ensthaler*, who – with regard to accreditation – aims to examine the distinction between regulatory and non-regulatory sphere from a specific "internal market perspective" and assigns areas to the non-regulatory sphere of accreditation which are not regulated by directives based on the New Approach and for which national provisions do not require an "assessment by state agencies alone" i.e. by state accreditation bodies; *Ensthaler/Strübbe*, Leitfaden (Modul 2 Part 1), Section 1.3.3. This limitation of the concept introduces questions as to how the accreditation body is organized (as a state agency which exerts sovereign legal authority), into the distinction between regulatory and non-regulatory. This is understandable against the background of the current German accreditation system, but not mandatory. From the standpoint of other European countries, it is indeed conceivable and virtually the normal case that legal regulations stipulate as mandatory the accreditation by an accreditation body organized by private law and acting on the basis of private law, e.g. as a central component of an official designation procedure (examples in the Third Section, B, C.). Characteristic of accreditations in the regulatory sphere is also not that they are carried out by state agencies alone, rather that they are provided for or prescribed by legal provisions. (The contrary of course holds for the recognition or designation of bodies, which always takes place by means of state agencies; but this again cannot be equated with accreditation, see just Section 7.2 DIN EN ISO/IEC 17000:2005) The distinction between the regu-

otherwise specified, the definition of the regulatory sphere in the broader sense shall be used here. Conversely, all areas in which the content of the conformity assessment procedure and the requirements for the bodies are not stipulated by legal provisions belong to the non-regulatory sphere[97].

If the legal provision which regulates the conformity assessment reverts to European secondary law (e.g. the national implementation law of a European directive), the "*harmonized* regulatory sphere" is concerned, because the conformity assessment procedures are applied here on the basis of harmonized European law[98]. If the demand for a conformity assessment procedure is based on autonomous national law, the regulated *non-harmonized* sphere is concerned. As a result, the regulatory harmonized sphere can be identified in uniform fashion for all of Europe: it is restricted by the Europe-wide regulations in the form of directives and regulations. The regulatory non-harmonized sphere, on the other hand, must be regarded from a national perspective, because each state can call for conformity assessment procedures in its own legal provisions and thus determine the regulatory sphere[99], as long as the matter is not extracted from national regulation by means of supranational law.

II. Conformity assessment and accreditation

The distinction between conformity assessment, on the one hand, and accreditation, on the other hand, serves the purpose of terminological clarity. According to the definition in Section 2.1 DIN EN ISO/IEC 2005, conformity assessment also comprises accreditation, and subsequently accreditation bodies could also be designated as conformity assessment bodies. The object of accreditation is, however, always a conformity assessment body[100]. In order to achieve consistent usage of the term, DIN EN ISO/IEC 17000:2005 limits the

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latory and non-regulatory sphere should thus not be equated with the distinction between the – German – state and non-state accreditation bodies.

97 See as well DAR, Handbuch (Fn. 94), Section 3, definition under "Gesetzlich nicht geregelter Bereich".

98 The extent, to which this has been harmonized at the international level, shall not be addressed for the purposes of this study.

99 The problems associated with this distinction are evident: what is "regulated" in one state, is not necessary regulated in another state – this applies to the European level, but especially beyond the European sphere. In practice, however, this distinction has a less far-reaching meaning than one might assume. This holds in particular for those states which unlike Germany have achieved a strong consolidation of both areas at the organizational-institutional level or never regarded these as separate.

100 Section 5.6 DIN EN ISO/IEC 17000:2005.

definition of the conformity assessment bodies to the effect that accreditation bodies are not conformity assessment bodies[101]. This also has the advantage that a generic term exists for the remaining bodies, regardless of the form of conformity assessment conducted. Thus the term *conformity assessment body* designates a body which conducts testing[102], inspections or certifications[103]. *Accreditation bodies* are always referred to as such. For reasons of comprehensibility and simplicity, the term *conformity assessment* shall also be used only for the mentioned activities, *excluding accreditation*, thus in deviation from the definition in Section 2.5 DIN EN ISO/IEC 17000:2005. If accreditation is also referred to, "conformity assessment and accreditation" is used.

101 Note on Section 2.5 DIN EN ISO/IEC 17000:2005.

102 Including calibration.

103 This terminological limitation applies unconditionally to the international framework of conformity assessment and conformity assessment in Germany, as long as not noted otherwise. The analysis of conformity assessment systems of other countries has revealed that – like in Germany – the relevant legal provisions and papers do not always or do not yet follow the definitions of the term recently determined at the international level. For example, it is sometimes noticeable that the term "certification" is used as a generic term for the different forms of conformity assessment and also designates activities like testing and inspection; the same holds then for the use of the term "certification body". These national peculiarities are maintained to the extent that this is necessary in order to correctly describe the concerned matters. Clarifications are added as often as possible.

Second Section: The European and International Context of Conformity Assessment and Accreditation

As an international system, conformity assessment enables the recognition of conformity certificates and can thus contribute to facilitating international trade and commerce. From an economic standpoint, this is the basis of conformity assessment to the extent that it is aimed at creating trust horizontally[1]. For this function of conformity assessment the mechanisms facilitating the mutual recognition of declarations are of particular significance and will thus be presented first. Drawing on the example of the regulations based on the New Approach, the Second Section will describe how conformity assessment in the regulatory sphere can be used to promote the free movement of goods. These regulations make conformity assessment a particularly useful regulatory instrument.

A. Mechanisms to facilitate the recognition of statements of conformity

First the mechanisms will be presented which allow for the recognition of results of the conformity assessment as equal in the international system of conformity assessment. In the first instance, the instrument of accreditation of conformity assessment bodies shall be presented, which serves to ensure the quality of conformity assessment. However, the accreditation also provides the institutional framework in which agreements on the mutual recognition can be established. Besides accreditation, the evaluation of bodies by so-called agreement groups can also facilitate mutual recognition. How such agreement groups operate shall be explained on the basis of an example from the electric branch.

I. Accreditation

1. Functions of accreditation and consequences for its form of use

According to Section 5.6. DIN EN ISO/IEC 17000, accreditation is a third-party attestation related to a conformity assessment body conveying formal demonstration of its compe-

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1 For the functions of conformity assessment see above First Section B, below Fourth Section A.VI, on its use from a horizontal and vertical perspective (in the regulatory sphere) Part Two, A.I.

tence to carry out specific conformity assessment tasks. Thus, accreditation is supposed to bear proof of the quality of conformity assessment by the regular inspection of the competence and adequacy of the bodies on the basis of harmonized requirements[2]. The aim is to increase the trust which the affected persons place in the results of conformity assessment. In the regulatory sphere these are primarily state authorities, who for example rely on declarations of conformity when products are put on the market. In the non-regulatory sphere, firms trust in the conformity of products with standards[3]. Besides assuring the quality of conformity assessment, accreditation in the international system serves an additional purpose: it is supposed to facilitate cross-border trade and commerce by creating foundations for the declarations of conformity by accredited conformity assessment bodies to be recognized internationally to the greatest possible extent. The accreditation bodies and their regional and local organizations are supposed to create a forum in which agreements on the mutual recognition of the results of conformity assessment can be established. The objective is to attain recognition on the basis of a single conformity assessment and single accreditation[4]: *certified once – accepted everywhere*. For example, the IAF (International Accreditation Forum) describes its role as follows[5]:

> "The primary purpose of IAF is two-fold. Firstly, to ensure that its accreditation body members only accredit bodies that are competent to do the work they undertake and are not subject to conflicts of interest. The second purpose of the IAF is to establish mutual recognition arrangements, known as Multilateral Recognition Arrangements (MLA), between its accreditation body members which reduces risk to business and its customers by ensuring that an accredited certificate may be relied upon anywhere in the world. The MLA contributes to the freedom of world trade by eliminating technical barriers to trade. IAF works to find the most effective way of achieving a single system that will allow companies with an accredited conformity assessment certificate in one part of the world, to have that certificate recognised else where in the world. The objective of the MLA is that it will cover all accreditation bodies in all countries in the world, thus eliminating the need for suppliers of products or services to be certified in each country where they sell their products or services. Certified once – accepted everywhere."

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2 The requirements for conformity assessment bodies are specified in standards, upon which accreditation bodies base their evaluation; the relevant standards are currently DIN EN ISO/IEC 17020 (Inspection bodies), E DIN EN ISO/IEC 17021 (Certification bodies for management systems, Standard still in preparatory phase; currently still applicable ISO Guides 62 and 66, DIN EN 45012), DIN EN ISO/IEC 17024 (Certification bodies for persons), DIN EN ISO/IEC 17025 (Inspection and calibration laboratories), ISO Guide 65/DIN EN ISO 45011 (Certification bodies for products).

3 See DIN EN ISO/IEC 17011:2004, Introduction. See also First Section, B.I.

4 DIN EN ISO/IEC 17011:2004, Introduction.

5 See for example the description of the role of IAF under URL: http://www.iaf.nu (20.10.2005), Section "About IAF – Role of IAF".

Another important task is drawing up interpretation documents on the standards which specify requirements for accreditation bodies as well as guidelines for the accreditation of conformity assessment bodies. The objective of these interpretation documents is to harmonize the application of the standards by the accreditation bodies and thus achieve uniformity in the level of activity of the conformity assessment bodies[6].

These functions have consequences for the structure of accreditation: in order to create trust, the accreditation body must be impartial and objective[7]. Accreditation bodies basically strive to offer an externally inspected guarantee for impartiality and orientation towards the public good by means of organization, by (self-)commitment to certain organizational forms and procedural rules,[8] and through self- and external control and transparency mechanisms[9].

In order to enforce the requirements for the conformity assessment bodies, the accreditation body must have sufficient authority, which is assured by corresponding implementation mechanisms. The international standards thus describe accreditation as a task of "authorized", "authoritative" bodies, whose authority generally is derived from sovereign bodies[10]. A closer examination of the accreditation systems in other countries will show that accreditation bodies, as a rule, are more or less closely associated with the state[11]. The state functions as a point of reference, which gives credibility to accreditation and thus conformity assessment altogether. The extent to which the accreditation body must be associated with the state in order to fulfil its function on the one hand, and how much distance from the state is required in order to maintain its independence vis-à-vis the state as a

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6 IAF under http://www.iaf.nu/ (26.2.2006) under About IAF/4. IAF Programmes. Such specific accreditation rules and guidelines for the interpretation of the standards are also assessed critically from the standpoint of the conformity assessment bodies. If the status of interpretation documents has not been specified, uncertainties with regard to the requirements to be fulfilled may result from explanatory and supplementary documents, see the reference in the position paper from eurolab No. 2/2000 "What conformity assessment operators expect from accreditation", March 2000, under 2. (top of p. 5); the document is available online at URL: http://141.63.4.16/docs/pos/el_01-01_00_381.pdf (20.3.2006).

7 DIN EN ISO/IEC 17011:2005-02, Introduction, Section 4.3.

8 Laid down in DIN EN ISO/IEC 17011:2004 „General requirements for accreditation bodies accrediting conformity assessment bodies".

9 *Röhl*, Akkreditierung und Zertifizierung, p. 71.

10 DIN EN ISO/IEC 17011:2005-02, Introduction, Section 3.2. The English version of the standard is as follows: "The authority of an accreditation body is generally derived from government".

11 More in Third Section, C.III.2.

"client" on the other hand is one of the questions which must be taken into account when establishing accreditation bodies.

An additional question is to what extent a profit and/or competition orientation of accreditation bodies is compatible with the functions of accreditation. Since this question – at least in the international debate – also bears references to certain mechanisms of cooperation between the accreditation bodies, it shall be postponed; more on this under Item 3 in this section.

2. Organization of accreditation at the national, regional and international level

The following section provides an overview of the organization of the accreditation bodies at the national, regional and international level. At the same time, it shall outline how the agreements on the recognition of certificates of conformity function at the international and regional level.

a) The model of a single national accreditation body

An examination of the organization of accreditation worldwide reveals that the model "one accreditation body per country" is the rule from a European and international standpoint[12]. Exceptions are, for example, the USA and Canada, which allow for multiple accreditation bodies[13]. In several countries, multiple accreditation bodies operate in different areas[14]. Whether they are structured as state authorities or agencies or on the basis of private law and linked to the governments by means of agreements, the accreditation bodies are, as a rule, associated with the state in a certain manner. They fulfil the function of a national accreditation body, which represents the accreditation system of the respective country internationally[15].

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12 See also the overview in *Wloka et al.,* Anerkennung und Akkreditierung (Module 3), Sections 3.3.6, 3.3.7.

13 These countries have also advocated competition between accreditation bodies, *Wloka,* DIN Mitteilungen 10-2005, 23 et seqq., 24.

14 For example Italy or Australia, *Wloka et al.,* Anerkennung und Akkreditierung (Module 3), Section 3.3.6.

15 More on this in the Third Section, C.I, C.III.2, C.IV. In the international debate the question has been raised now and then whether every country actually requires its own accreditation body. If the volume of

b) International level: IAF and ILAC

At the international level there are two associations of accreditation bodies, IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation). IAF comprises accreditation bodies which accredit conformity assessment bodies for management systems, products, services, personnel, etc.[16]. ILAC is a platform for cooperation between accreditation bodies which conduct accreditations of laboratories and inspection bodies, including calibration[17].

IAF and ILAC maintain agreements on the mutual recognition of conformity assessment (MLA or MRA), in which the members commit themselves to regard the accreditations issued by the other co-signatories as equal to theirs[18]. Furthermore, they pledge to recognize the declarations of conformity of those conformity assessment bodies which are accredited by the participating accreditation bodies as equivalent or take measures to ensure that these are recognized as equal by their users[19]. Accreditation bodies are free to join IAF as long as they express their willingness to strive for accession to the IAF-MLA to achieve mutual recognition. A prerequisite for accession to the MLA is, among other things, compliance with harmonized demands placed on accreditation bodies[20]. Accreditation bodies who have signed the ILAC Mutual Recognition Arrangement (ILAC MRA) are free to

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conformity assessment services is low in a national economy, this does not seem to be sensible from an economic perspective. However, in any case, the organization of accreditation at the international level currently builds on this model.

16 Essentially, this may concern the accreditation of certification bodies; the distinction between the IAF and ILAC can be made more easily on the basis of the area of activity of the ILAC, which comprises the accreditation of laboratories and inspection bodies; the areas of activity particularly overlap with regard to inspection bodies. IAF and ILAC strive for increased cooperation, see the "ILAC-IAF Agreement for closer cooperation" from 17 September 2005, available online at http://www.ilac.org/ in the category "International Partnerships" (26.10.2005).

17 ILAC under URL: http://www.ilac.org (20.10.2005).

18 On how the ILAC Arrangement works see *ILAC* at URL: http://www.ilac.org (20.10.2005) under "How does the arrangement work?"; on the IAF MLA IAF under http://www.iaf.nu/ (26.2.2006) under "About IAF/11. IAF Multilateral Recognition Arrangement (MLA)". A sample of the ILAC Recognition Arrangements (ILAC-P5:2004) is available online at URL: http://www.ilac.org/downloads/Ilac-p5-2004.pdf (24.2.2006). The IAF Multilateral Recognition Arrangement (MLA) is available online at URL: http://www.iaf.nu/ (24.2.2006), under Publications/ 3. Multilateral Recognition Arrangement Documents (ML Series).

19 Detailed regulations in the ILAC Recognition Arrangement under Item 4; with comparable results the IAF Multilateral Recognition Arrangement (Fn. 18), Section 4.

20 In its documents the IAF partially still refers to the ISO Guide 61, which was replaced by ISO/IEC 17011:2004; this standard will also be decisive for the IAF in the future. See *Wloka*, DIN Mitteilungen 10/2005, 23 et seq., 25 above.

become full members of the ILAC. This entails, among other things, the obligation to comply with the standard ISO/IEC 17011 with regard to the requirements for accreditation bodies as well as to assure that the accreditation bodies comply with the requirements of ISO/IEC 17025, combined with the corresponding interpretational guidelines of the ILAC[21]. A decision is made on accession to the MLA during a peer evaluation-procedure[22]. As a rule, the evaluation of the accreditation bodies is repeated every four years.

During the establishment of the MLA/MRA, IAF and ILAC fall back on regional cooperation between accreditation bodies such as the European Cooperation for Accreditation (EA), die Interamerican Accreditation Cooperation (IAAC), the Pacific Accreditation Cooperation (PAC) or the Southern African Development Community in Accreditation (SADCA)[23]. They recognize regional groups of accreditation bodies, if they have demonstrated their competence in maintaining regional MLA's during a peer evaluation-procedure[24]. The evaluation and surveillance of the IAF or ILAC members can then be delegated to the regional groups[25]. Besides this, the admission of individual accreditation bodies by means of peer evaluation procedures remains a possibility[26].

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21 ILAC, ILAC Mutual Recognition Arrangement (Fn. 18) under "How does the arrangement work?".

22 More on the IAF-MLA IAF, Policies and Procedures for a Multilateral Recognition Arrangement on the Level of Accreditation Bodies and on the Level of Regional Groups, Issue 4 (IAF ML 4:2005), available online at URL: http://www.iaf.nu/ (26.2.2006) under Publications/3. Multilateral Recognition Arrangement Documents (ML Series); for the accession procedure to the MRA/MLA see also Fn. 23.

23 Besides individual accreditation bodies, regional associations of accreditation bodies are also free to become members of IAF. The IAF granted EA and PAC the status of "special recognition" with the consequence that membership in EA-MLA or PAC-MLA is regarded as sufficient to also fulfil the requirements of the IAF MLA. Accreditation bodies, which have signed the EA- or PAC-MLA are automatically admitted to the IAF MLA, IAF under URL: http://www.iaf.nu (26.2.2006) under "About IAF/12. MLA Signatories". In this regard, ILAC also recognizes regional cooperation groups, which maintain their own MLA; for the recognition procedure for these regional groups such as EA ILAC-P2:2003, for the evaluation procedure for individual accreditation bodies by regional groups for the purposes of the ILAC MRA see ILAC P1:2003; the documents are available online at URL: http://www.ilac.org/ (26.2.2006) under "Publications/ Procedural Series (P series)".

24 See above Fn. 23 as well as the joint document IAF/ILAC-A1:2005 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements for Evaluation of a Regional Group, available online at http://www.iaf.nu/ (26.2.2006) under "Publications/6. IAF-ILAC Joint Publication (A Series)".

25 IAF/ILAC-A1:2005 (Fn. 24), Preamble.

26 The corresponding procedure is described in "IAF/ILAC-A2:2005 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements for Evaluation of a Single Accreditation Body"; the document is available online at http://www.iaf.nu/ (26.2.2006) under Publications/6. IAF-ILAC Joint Publication (A Series).

c) Associations at the regional level applied to the example of EA

At the European level the accreditation bodies have joined to form the European Cooperation for Accreditation - EA. EA emerged in 1997 as a result of the merger between EAC und EAL[27] and obtained the legal status of an association based on private law in accordance with Dutch law in 2000[28]. The membership is only open to nationally recognized accreditation bodies, which must prove – among other things – that they comply with the demands of the relevant European standards and the related interpretational documents of EA[29]. In particular, the members may only carry out their activities as *non profit distributing* and accreditation must be the last level of the assessment of technical competence, independence, and integrity[30].

According to the *Articles of Association* it is the task of EA to harmonize accreditation and provide for its consistency as a service for commerce and industry and in accord with their needs and economic conditions. EA is supposed to support the establishment of agreements on mutual recognition at the international level while promoting trust in the European infrastructure and the competence in conformity assessment[31]. An additional task of EA is the creation of a MLA at the European level[32]. EA maintains a MLA for different scopes of accreditation[33]. The procedure for the admission of accreditation bodies is based

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27 European Accreditation of Laboratories (EAL), European Accreditation of Certification (EAC).

28 Draft CERTIF 2005-5 "The development of the European infrastructure for accreditation" from 16.6.2005, p. 1, the document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/certif_2005_05.pdf (15.3.2006). The "Articles of Association" of EA (version from 3.5.2004) are available in an English translation at URL: http://www.european-accreditation.org/Content/EA/pdf/articlesofAssociationEN.pdf (6.3.2005).

29 Art. 4 No. 1 Articles of Association (Fn. 28); EA-2/01 – S1 Criteria for Membership, 1.1; the document is available online at URL: http://www.european-accreditation.org under Publications/General/Procedural and Policy Documents Series 2 (4.3.2006). According to Art. 4 No. 6 of the Articles of Association, the general assembly of EA may terminate the membership of an accreditation body under certain conditions.

30 EA-2/01 – S1 Criteria for Membership (Fn. 29), 1.2, 1.4.

31 Art. 2 Articles of Association (Fn. 28).

32 Art. 2 Articles of Association (Fn. 28).

33 Overview at URL: http://www.european-accreditation.org/content/mla/what.htm (4.3.2006). The current signatories of the MLA from the German accreditation system are DACH, DAP, DATech, DKD and TGA as members of the DAR, but not the recognition and accreditation bodies of the regulatory sphere, EA-01/08 EA Multi and Bilateral Agreement Signatories; respectively upon specification of the areas of accreditation. The document is available online at URL: http://www.european-accreditation.org under Publications/General/Publicity and Information Documents Series 1 (4.3.2006).

on the joint document of ILAC and IAF on the admission of individual bodies to a MLA[34]. To create mutual trust, EA conducts regular peer evaluations[35]. The accreditation bodies participating in the MLA are obligated to provide assessors for doing so[36].

EA has an Advisory Board (EAAB) which consists of representatives of conformity assessment bodies, industry and trade, national authorities, the European Commission and standardization organizations[37]. The EAAB is supposed to form a link between EA and the European Commission, EFTA, the national authorities of the Member States as well as trade and industry. The Board is supposed to ensure that EA promotes open and transparent conformity assessment, in particular when the conformity assessment procedures serve purposes of EU law. Furthermore, it is to make sure that the accreditation is carried out in accordance with international accreditation practices and that quality-driven competition takes place between the conformity assessment bodies[38].

3. Competition between accreditation bodies?

Whether operating for a profit and in competition with other accreditation bodies is compatible with the task of accreditation bodies is disputed in the international debate. The core issue is whether competition contributes to the quality of accreditation or, in contrast, is disadvantageous for the trust-creating function of accreditation.

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34 See above b); EA-2/02 (rev. 2) – EA Policy and Procedures for the Multilateral Agreement, 1.1.; the document is available online at URL: http://www.european-accreditation.org under Publications/General/Procedural and Policy Documents Series 2 (4.3.2006).

35 On additional trust-creating measures EA-1/06 EA Multilateral Agreement, p. 3 Introduction; the document is available online at URL: http://www.european-accreditation.org under Publications/General/Publicity and Information Documents Series 1 (4.3.2006).

36 EA-1/06 EA Multilateral Agreement (Fn. 35); p. 4 under 4 (VII).

37 List of the members (last updated 9.3.2006) under URL: http://www.european-accreditation.org/Content/EA/docs/lst-eaab-rev12.pdf (20.3.2006). On the composition of the Board see EAAB Terms of Reference, 2. The document is available online at URL: http://www.european-accreditation.org under What is EA?/EA's structure and organisation/Terms of reference (4.3.2006).

38 EAAB Terms of Reference (Fn. 37), 1.2. For the future significance of the incorporation of the accreditation bodies into EA after a revision of the New Approach see Part Two, C.II.3.

a) Arguments

One argument against competition among the accreditation bodies is essentially that it leads to higher costs with lower quality, but not to a greater credibility of the results of accreditation. It purportedly undermines the independence of the accreditation bodies from their clients, which is essential for creating trust. A multitude of accreditation bodies is allegedly disadvantageous for transparency, which constitutes a core functional prerequisite of the entire system. Accordingly, when there is competition, an institution is required to control these bodies to prevent a decrease in quality. Thus, an additional level purportedly must be introduced above the accreditation bodies. This only makes sense when it creates additional benefits, which is not the case though.

The advocates of competition point out the advantages which competition can have with regard to specialized expertise, competition and customer friendliness. They expect an increase in the quality of accreditation, e.g. also by means of the specialization of accreditation bodies which this allows for. However, this calls for mechanisms which prevent competition at the expense of quality. To assure quality though, it is not imperative to create an additional control level above accreditation; this can also be guaranteed among the accreditation bodies by means of mechanisms such as peer assessments. The example of the USA demonstrates that conformity assessment as an economic sector can sustain numerous accreditation bodies. In less economically attractive areas of accreditation, a state offer can ensure that accreditation is also provided as a form of quality assurance. Different national accreditation bodies could be incorporated into the international system of quality assurance when organizations such as IAF and ILAC are based on regional groups, as is currently already the case with EA and PAC. These regional groups are responsible for compliance with demands in their areas. By these means, numerous accreditation bodies could also be integrated at the national level, if necessary through the introduction of additional regional or national levels.

Others shed doubt on the last mentioned argument by contending that this leads to an even greater “mediatisation” of control than previously. In the existing system, it is already apparent that the coordination of the mutual assessment is associated with great expenditures and that the harmonization of activities is more difficult to reach, the greater the number of members in the system. This effect is purportedly further increased due to further delegation of control.

At the European level this question has gained in significance, in particular due to the current situation in the German accreditation system, which allows for competition between accreditation bodies from a legal standpoint. One cited argument against competition between accreditation bodies at the national level is that accreditation as such is not economically lucrative; as a rule, accreditation bodies are able to cover their own operating costs at best. The national market is purportedly too small to sustain several accreditation bodies – this also holds for national economies of a comparable size to that of Germany and with a similar number of conformity assessment bodies. Moreover, an accreditation offer must be guaranteed in economically less attractive or new areas – this is said to be ensured more effectively by a *national* accreditation body. Observers additionally point out the current organisation at the international level, which is based on the principle "one body per country", organizes peer evaluation procedures on these foundations. This would be complicated if competition were introduced.

b) Currently prevailing opinion at the European and international level

At the international level an agreement could not be reached when drawing up the "requirements for accreditation bodies"[39] so that the question about the permissibility of competition from the standpoint of standardization remains unanswered; the introduction to ISO/IEC 17011 maintains that accreditation bodies "normally operate in a non-profit distributing manner"[40]. Moreover, membership in EA is only open to accreditation bodies which do not deliver surplus to their owners, whether private or public[41]. In Europe one must assume a trend towards the exclusion of competition: most Member States of the European Union lean towards excluding competition and would like to organize quality assurance in a network-like structure, with EA, the EA-MLA, mandatory interpretational documents and processes of peer evaluation at its core. Accordingly, the proposals for revising the New Approach envision the organization of accreditation free of commercial competition[42].

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39 ISO/IEC 17011:2004.

40 For DIN EN ISO/IEC 17011 see *Wloka*, DIN Mitteilungen 10/2005, 23 et seq., 24.

41 EA-2/01 – S1 Criteria for Membership (Fn. 29), 1.2.

42 CERTIF 2005-16 rev. 2 "Elements for a horizontal legislative approach to technical harmonisation" from 23.2.2006, Item 6.1.a), p. 17, the document is available online at URL:

c) Rules on cross-border accreditation

Closely related to competition issues is the position of the accreditation bodies on matters of so-called cross border accreditation. As a rule, accreditation bodies operate from a national base[43] and offer accreditation for conformity assessment bodies in their country of residence. The regulations on cross-border accreditation concern the question whether accreditation bodies should be allowed to accredit conformity assessment bodies which are based in another country, thus whether accreditation bodies may geographically expand their activities. From the standpoint of the international associations of accreditation bodies, cross-border activities run counter to the concept of the MLA, whose aim is to achieve the greatest possible degree of international recognition of certificates of conformity on the basis of *one* accreditation. However, they recognize the need of the market for cross-border accreditations for certain precisely defined situations, e.g. if a conformity assessment scheme cannot be offered by a national accreditation body[44].

Besides the problem that not all accreditation bodies offer accreditation for all conformity assessment programs demanded by the market, the conformity assessment bodies also express a need for accreditation by a foreign or several accreditation bodies. An important reason is that the respective national market has yet to fully accept the principle of mutual recognition which supports the MLA, thus still insists on the accreditation from a "national" accreditation body. That might have to do with the existing doubts with regard to the harmonization of the accreditation level up to now, in particular due to the multitude of bodies admitted to the international associations and the MLA. When accreditation in the regulatory sphere is concerned, conformity assessment bodies simultaneously point out that state agencies are more easily convinced of the competence of the respective confor-

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http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_16_rev_2.pdf (15.3.2006). For the exclusion of competition now Art. 6 Regulation (EC) No 765/2008; see as well Part Two C.II.3.b. (i).

43 As a rule as the "national" accreditation body, see above A.I.2.a).

44 As an introduction to Section 3 of the ISO/IEC-Guides 61 for the accreditation of certification bodies for management systems, the IAF drew up guidelines on cross-border accreditation; the situations in which these are supposed to be permissible are listed in Section 1F; see IAF Guidance on Cross Frontier Accreditation, Issue 1, Version 3 (IAF GD 3:2003 last updated 1.12.2003), available online at http://www.iaf.nu/ (26.2.2006) under Publications/4. IAF Guidance Documents (GD Series); the DAR offers a translation in the document DAR-3-EM-20, available online at http://www.dar.bam.de/pdf/dar_3_em_20.pdf (26.2.2006). For cross-border accreditation see now Art. 6 para. 3, Art. 7 Regulation (EC) No 765/2008.

mity assessment body by the national accreditation body familiar to them, even when the directives are based on the principle of a Europe-wide service market of Notified Bodies. Accordingly, international certification bodies often have several parallel accreditations.

4. Criticism of accreditation and summary

If one examines the mechanisms to assure the quality of conformity assessment across the different areas, accreditation with its national, regional, and international organizations turns out to be the most firmly established model[45]. Accreditation is based on the harmonization of the requirements placed on the accreditation bodies themselves, the peer evaluation processes during accreditation, the harmonized requirements placed on conformity assessment bodies as well as the elaboration of guidelines for their application. The organization of the accreditation bodies among one another is oriented towards the creation of a "network"[46] in which the bodies mutually monitor each other.

The acceptance of the MLA on the market as well as among governments and authorities essentially depends on the extent to which these elements are jointly capable of actually providing for a comparable level of conformity assessment. Criticism is sometimes expressed in this regard. For example, the current mechanisms of peer evaluation are viewed as inadequate for guaranteeing sufficiently dense control over the accreditation bodies. The delegation of the evaluation and surveillance to regional associations of accreditation bodies can ease the procedure; at the same time it also delegates the exerted control, which can also mean a loss in effectiveness. In view of the peer evaluation procedures among the accreditation bodies, the qualification and instruction of the assessors as well as the composition of the evaluation teams have become the focus of attention. Sometimes the argument is put forward against the activities of the accreditation bodies that they are excessively oriented towards purely formal criteria without sufficiently taking their impact on the quality of conformity assessment into account; the actual professional competence of the body is purportedly only insufficiently grasped by the evaluation procedures. Another mentioned difficulty is that market participants and agencies/governments are still not adequately fa-

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45 For peer evaluation procedures see below II.

46 See e.g. the IAF-Guidelines on cross frontier accreditation (Fn. 44), 1 B.

miliar with the procedures and organization of the accreditation. This is problematic for two reasons: Firstly, accreditation relies on transparency and comprehensibility to generate trust in products, services, etc. Secondly, its success also depends on whether it is demanded by the clients of the conformity assessment bodies, thus whether it has additional benefits for the conformity assessment bodies on the market[47]. Currently an attempt is being made to enhance the transparency and effectiveness of the system[48].

II. Peer assessment in agreement groups

Peer assessment is an alternative to accreditation. As just described, this mechanism is used among the accreditation bodies in order to achieve a harmonization of their inspection level. Peer evaluation is also used by conformity assessment bodies, though, in order to facilitate the mutual recognition of product inspection reports or – in a further step – product certificates in so-called agreement groups. For peer assessments, as are common in such agreement groups and among accreditation bodies, ISO/IEC 17040 was provided as a standard which governs core elements of the evaluation procedure[49].

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47 Up to now, there are still few significant data on the cost-benefit relationship of accreditation; see however *Schüttpelz*, Auswirkungen der Akkreditierung, in particular p. 165 et seq.; building on this *Ensthaler/Strübbe*, Analyse (Module 2 Part 2), p. 76 et seq. On the expectations of conformity assessment bodies for accreditation see also the position paper from eurolab Nr. 2/2000 "What conformity assessment operators expect from accreditation", May 2000, available online at URL: http://141.63.4.16/docs/pos/el_01-01_00_381.pdf (20.3.2006). Eurolab mandated a survey in 2001 among laboratories on client satisfaction with European accreditation bodies. The survey results from Germany have been compiled by Eurolab-Germany in a technical report; EUROLAB Deutschland, Technischer Bericht 2003, available online at URL: http://www.eurolab-d.bam.de/dokumente/Technischer%20Bericht.PDF (20.3.2006). The evaluation of the Europe-wide survey is published as EUROLAB Technical Report 2/2002 (available from eurolab aisbl).

48 See at the international level the formulation of demands placed on accreditation bodies in DIN EN ISO/IEC 17011:2004, the regulation of peer evaluation processes in DIN EN ISO/IEC 17040 or at the European level the considerations on the further development of the European accreditation policy with a potentially greater incorporation of EA and the Member States into the monitoring of the national accreditation bodies, CERTIF 2005-16 rev. 2 (Fn. 42), C 6, p. 16 et seq. For recent developments see Part Two C.II.3.b).

49 More on the need for this standard and its potential benefits in *Kreß*, DIN-Mitteilungen 10-2005, 41 et seq.

Agreement groups of conformity assessment bodies are particularly wide-spread in the area of electrical engineering. Of particular practical significance is the CB-procedure[50] at the IECEE (Worldwide System for Conformity Testing and Certification of Electrical Equipment – IECEE)[51], on the basis of which an explanation will be given how recognition in agreement groups functions[52]:

The CB-procedure allows for the mutual recognition of *inspection reports* for electrical equipment between the national conformity assessment bodies. The basic principle of the CB-procedure is that a manufacturer in Country A, who would like to gain access to the market of Country B, can facilitate the acquisition of national symbols, marks or authorizations when conformity assessment bodies in Country B recognize an inspection report issued in Country A[53]. The program does not require the applicable national standards or legal provisions in Country B to completely match the standards of the IEC[54]. The manufacturer may obtain an inspection report from an inspection body participating in a CB-procedure in Country A. He/she may submit the inspection report with the inspection cer-

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50 The CB-FCS procedure for recognizing conformity *certificates* which goes beyond the CB-procedure shall not be considered here; for more on this see IECEE at URL: http://www.iecee.org/cb_fcs/Default.htm (26.2.2006).

51 The IEC (International Electrotechnical Commission) is the leading international standardization organization for the areas electrical, electronic and related technologies. On the basis of the standards it sets, it organizes various multilateral programs for conformity assessment; more at IEC under http://www.iec.ch/conformity/ (26.2./2006) with a short overview and references to the Internet presence of the various programs.

52 For more agreements on the mutual recognition of conformity assessment results and/or the simplified issue of joint symbols in the area of electrical engineering, see the procedures supervised by Cenelec such as CCA, HAR, ENEC or EMCRAFT, more at URL: http://www.cenelec.org/Cenelec/Conformity+Assessment/MRAs/About+MRAs/About+MRAs.htm (10.3.2003).

53 See IECEE "About the CB-Scheme" at URL: http://www.iecee.org/cbscheme/cbfunct.pdf (26.2.2006). For more details on the procedural rules see "Basic Rules" at URL: http://www.iecee.org/cbscheme/pdf/IECEE01.pdf (26.2.2006) as well as the "Rules of Procedure", available online at URL: http://www.iecee.org/cbscheme/pdf/IECEE02.pdf (26.2.2006).

54 A certain degree of harmonization has to have taken place though. Special national requirements, which are not covered by the IEC standards, are inspected in a supplementary procedure. Along with that an index of the special national requirements is maintained within the framework of the program (in the *CB Bulletin*). The index is drawn up by help of the national conformity assessment bodies (called NCBs), who are committed to display deviations to the IEC standards in the conformity assessment schemes used in their country and to feed this information into the joint system. The publication of the differences to the respective national requirements is supposed to facilitate recognition and promote harmonization (the objective is "*one test, one certification, one mark*").

tificate to an inspection body in Country B who is involved in the CB-procedure[55]. It then issues the inspection body its own inspection mark on the basis of the inspection report of the body in Country A. The members of the program are obligated by a multilateral agreement to recognize the inspection reports of the other participants. A prerequisite for this is trust in the quality of the inspection conducted. To guarantee this, *peer assessments* are carried out for the bodies during the acceptance procedure[56].

On the whole, the experiences with the CB-procedure in practice are evaluated positively. Whether the systems established for electrical and electronic technologies can be transferred to other product areas is uncertain though. There are some indications that the success of the IECEE-CB-procedure can also be traced back to the fact that it is used in a closely linked professional community, in which technical harmonization is highly advanced. There are also indications that the system of peer assessment, which must manage without a superior level of oversight, reaches its limits when the number of participants becomes so large that the group of participants becomes unmanageable for the participating bodies.

There may be “interfaces” between peer evaluation and accreditation. For example, during the evaluation of a body in the CB-procedure, an existing accreditation can be taken into consideration[57]. Sometimes the suggestion is put forward to further develop these interfaces, e.g. one proposal is to use the results of a peer assessment in an agreement group during formal accreditation.

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55 If there are special national requirements in Country B which are not inspected by the body in Country A, these are additionally inspected by body B.

56 On the procedure IECEE, Rules of Procedure (Fn. 53), 5.1.2 through 5.1.7.

57 IECEE, Rules of Procedure (Fn. 53), 5.1.1.c. and 5.2.1.d, 5.3.1.c.

B. New Approach and Global Approach as a model for the use of conformity assessment for the pursuance of state regulatory objectives

The European Community uses standardization and conformity assessment in the directives based on the New Approach to dismantle technical trade obstacles within the Community and to realize the free movement of goods laid down in Article 28 EC, and to promote foreign trade within the framework of agreements with third countries. The basic principles of the regulatory concept implemented here shall first be described. The Commission Communication "Enhancing the implementation of the New Approach Directives"[58] served to introduce a comprehensive revision of the New Approach and the Global Approach, which is supposed to result in a horizontal legal act in the near future[59]. The proposals drawn up during this debate shall only be indicated here: The remarks in this section focus on the current design of the directives based on the New Approach and the procedures and structures developed on these grounds[60]. The analysis of the guidelines for the future design of conformity assessment, accreditation and designation at the national level, as they result from the preparatory work on a horizontal legal act, will be reserved to the conclusions in Part Two.

I. Harmonization approaches before the introduction of the New Approach

Since the middle of the 1980s the European Community has been drawing on the harmonization concept of the so-called "New Approach" and the "Global Approach" to reduce trade obstacles within the Community and to realize the free movement of goods laid down in Art. 28 EC. The starting point of this harmonization approach is the "Council Resolution

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58 COM (2003) 240 final from 7.5.2003.

59 For the preparatory works for the Commission proposal see CERTIF 2005-16 rev.2 (Fn. 42). This study was completed in 2006. Meanwhile, the revision of the New Approach led to the issue of the Regulation No 765/2008 of 09/07/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, and Decision No 768/2008/EC of the European Parliament and of the Council of 09/07/2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC. For more details on the content of the horizontal legal acts see Part Two, in Particular under C.II.3.

60 The same holds for the following remarks in the Third and Fourth Sections on the use of conformity assessment abroad and on the structure of conformity assessment in Germany, which also reflect the current situation.

of 7 May 1985 on a new approach to technical harmonization and standards"[61]. The resolution constituted the (preliminary) termination of various efforts by the European Community to harmonize product safety law[62].

First, it had become apparent that the provisions of primarily legislation alone could only insufficiently contribute to the dismantling of technical barriers to trade[63]. Art. 28 EC remains ineffective, as long as reasons of public interest in terms of Art. 30 EC or vital interests in terms of the Cassis legislation substantiate a regulation by the individual Member State[64]. For these reasons, each Member State could determine the level of protection for product safety itself and create the administrative structure for its enforcement[65]. The primary law basis of Art. 28 EC merely obligates the Member States to regard foreign standards and administrative structures as equivalent when such equivalency actually exists[66]. However, in practice proof of this equivalency can hardly be demonstrated[67]. The information procedure introduced by the Directive 83/189/EEC (today Directive 98/34/EC – TRIS) can provide a contribution to avoiding trade obstacles[68], however only to a limited extent due to the limited effects of Art. 28 EC with regard to the justification of national regulations. The Community searched for a solution to the harmonization problem at the level of secondary law and opted for a strategy of harmonizing product standards by means of

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61 Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, Official Journal EC 1985 No. C 136, p. 1.

62 More details on the development in *Merten*, Private Entscheidungsträger, p. 24 et seq., see also *Di Fabio*, Produktharmonisierung, p. 1 et seq.

63 *Röhl*, in: Schmidt-Aßmann/Schöndorf-Haubold (eds.), Der Europäische Verwaltungsverbund, p. 153 et seq., p. 154 et seq., detailed overview in *Merten*, Private Entscheidungsträger, p. 25 et seq.

64 See ECJ from 28.1.1986, Case 188/84, Rec. 1986, 419 (paras. 15-22) – wood processing machines.

65 *Götz*, in: Götz/ Selmer/Wolfrum (eds.), Lib. Am. Jaenicke, 1998, p. 763 (766).

66 ECJ from 17.12.1980, Case 272/80, Rec. 1980, 3277 (para. 13-15) – Frans-Nederlandse maatschappij voor biologische produkten; from 28.1.1986; Case 188/84, Rec. 1986, 419 (paras. 15-17) – wood processing machines. For the practical use of the principle of mutual recognition on the basis of Art. 28, 30 EC, see the "Commission interpretative Communication on faciliting the access of products to the markets of the Member States, the practical application of mutual recognition" (2003/C 265/02), EC Official Journal C 265 from 4.11.2003, p. 2; see now also Regulation (EC) No 764/2008 of the European Parliament and of the Council laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC.

67 *Merten*, Private Entscheidungsträger, p. 28.

68 Accordingly the Member States are obligated to notify the Commission and the other Member States of every draft of a technical provision with regard to products before they are passed as national laws. This procedure is supposed to enable the monitoring of the national provisions and promote transparency. Further information on the TRIS (Technical Regulations Information System) under URL: http://europa.eu.int/comm/enterprise/tris/about/index_de.htm (20.3.2003).

community law[69]. Initially, though, it primarily pursued the approach of detailed harmonization, thus the specification of all product requirements in detail in corresponding sector-specific directives[70]. However, it quickly became evident that the boundaries of effectiveness of legislation had been reached due to the overregulation of content[71]. Moreover, the legislative procedures and bodies of the EC were unsuitable for this type of technical legislation for various reasons[72]. The tedious and time-consuming legislative procedures were unable to keep pace with technical developments[73].

Another solution approach was already pursued in the low voltage directive[74], which was passed in 1973 and contained an assumption of conformity with the "good engineering practice in safety matters" in favour of those products which satisfied the safety demands of harmonized standards[75]. The resolution on the New Approach[76] from 1985 drew on this technique of referring to technical standards.

II. Basic principles of the New Approach and the Global Approach

The basic principles of the New Approach and the Global Approach shall be presented in the following. After a short overview of the three regulatory areas – legislation, market access, and market surveillance – the activities of the conformity assessment bodies shall be addressed on the basis of the modules for conformity assessment. This will be followed by a few remarks on the role of the manufacturer or marketer. The segment concludes with

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69 Another approach would have been to lay down the obligation to recognize the national legal provisions equivalent in secondary law; for the doubts expressed in this regard see *Merten*, Private Entscheidungsträger, p. 29 et seq. On the different instruments – here in reference to foreign trade policy – see also the working paper of the Commission "Commission staff working paper implementing policy for external trade in the fields of standards and conformity assessment: a tool box of instruments", COM SEK (2001) 1570/1, p. 15.

70 An example of this is the area of type approvals for motor vehicles, see *Röhl*, Akkreditierung und Zertifizierung, p. 21 et seq., 41 et seq. On the concept of detailed harmonization, see also *Merten*, Private Entscheidungsträger, p. 30 et seq.

71 *Röhl*, Akkreditierung und Zertifizierung, p. 41 et seq.

72 *Röhl*, Akkreditierung und Zertifizierung, p. 41 et seq.; *Merten*, Private Entscheidungsträger, p. 30 et seq.

73 *Merten*, Private Entscheidungsträger, p. 32 with further references.

74 Directive 73/23/EEC (Low voltage directive).

75 More in *Merten*, Private Entscheidungsträger, p. 32 with further references.

76 EC Official Journal 1985 No. C 136, p. 1.

a closer look at the role of the Notified bodies, which are the core administrative entities within the framework of the New Approach.

1. Legislation, market access, and market surveillance

The resolution on the New Approach stipulates guidelines for technical harmonization and standardization, which fall back on four basic principles and then, in an additional step, provide a scheme for their implementation in the directives to be passed[77]. It solves the harmonization problem by means of a differentiation into three separate regulatory areas[78]: *legislation* specifies the requirements for products in abstract terms, *market access* regulates the admission to the European market for the individual product and *market surveillance* reacts to dangers emanating from products which are already on the market.

As for legislation, not all product safety requirements are laid down in legal acts. The directives restrict themselves to specifying "Essential Requirements"[79]. The products must satisfy these in order to be put on the market. Detailed requirements are contained in harmonized technical standards which are drawn up by the European standardization organizations by means of special procedures. Unlike the Essential Requirements of the directives, these standards are not binding, although a product is assumed to conform to a directive when it meets the harmonized standards[80]. The manufacturer may opt to not manufacture according to these standards, but bears the burden of proof that his/her products conform to the requirements of the directive[81].

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77 Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, EC Official Journal 1985 No. C 136, p. 1, Annex II "Guidelines for a New Approach to technical harmonization and standards".

78 Applied to the example of the machine directive in *Scheel*, Privater Sachverstand, p. 55 et seq., in detail on the regulatory approach of the New Approach in *Merten*, Private Entscheidungsträger, p. 37 et seq.

79 E.g. Art. 3 Directive 1999/5/EC (Radio equipment and telecommunications terminal equipment); Art. 3 in conjunction with Annex I of Directive 93/42/EEC Medical devices).

80 Qualified as being in violation of the EC Treaty e.g. by *Breulmann*, Normung und Rechtsangleichung, p. 175 et seq.; *Rönck*, Technische Normen, p. 170 et seq.; *Schulte*, in: Rengeling (ed.), EUDUR, § 17 Rn. 104-120; for a critical view see also *Klindt*, EuZW 1998, 426. In contrast, a convincing review is given by *Di Fabio*, Produktharmonisierung, p. 6 et seq.; in particular *v. Danwitz*, in: Rengeling (ed.), Umweltnormung, 1998, p. 187 (205 et seq.); see also *Marburger*, in: Festschrift für Feldhaus, p. 387 et seq., 395.

81 For the resulting "de facto obligation" see *Merten*, Private Entscheidungsträger, p. 44 et seq., 46.

The regime of market access was also restructured. For all products the rule applies that they can only be put on the market when their conformity with the requirements of the directives has been certified and this conformity has been confirmed by the affixing of the CE-marking[82]. Once the CE-marking is applied, the respective product falls under the free movement clause, i.e. it is marketable in the entire EC and additional authorization procedures or systematic controls by one Member State are not permissible[83]. This also holds for indirect restrictions[84]. In a large share of the cases the manufacturer him or herself may certify such conformity with the directives and affix the CE-marking. For potentially more dangerous products, he/she must involve a "Notified Body" for this purpose which assesses the conformity of the product with the requirements of the respective directive[85].

The Member State administrations do not come in contact with the products until the third phase of the market access regime, *market surveillance*[86]. The authorities of the Member States monitor the market for the emergence of products which do not comply with the requirements of the directives or are not correctly labelled with the CE-marking. Accordingly, they take the necessary measures which may even include banning the product. However, the measures taken by the Member States are subject to a Community control procedure, the so-called safeguard clause procedure: according to this, a product ban issued by one Member State during market surveillance must be reported to the Commission. It only is effective when it is confirmed by the Commission after a Community control procedure (Art. 95 para. 10 EC) with the participation of all Member States and as a rule the manufacturer as well[87]. Before this conformation the Member States may only take preliminary measures[88].

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82 E.g. Art. 11, 17 Directive 93/42/EEC (Medical devices), in accordance with § 6 para. 1 Medical Devices Law; *Di Fabio*, Produktharmonisierung, p. 59 et seq.

83 See Art. 4 para. 1 Directive 93/42/EEC (Medical devices).

84 ECJ from 25.3.1999, Case C-112/97, Rec. 1999, I-1821 (paras. 43-45) – COM/Italy.

85 In greater detail in B.II.4.a).

86 E.g. Art. 8 para. 1 Directive 93/42/EEC (Medical devices); § 25 et seq. Medical Devices Law; §§ 8 et seq. GPSG.

87 In this case the other Member States are obligated to take the necessary measures. Council resolution on the New Approach (Fn. 61), Annex II B VII 3, p. 7. If the lack of a technical standard is ascertained during the procedure, its presumptive effect can be revoked when the Commission and the Member States remove the standard from the published list. If the product risk is based on errors by the Notified Body, the Member State must examine its recognition.

88 However, the safeguard clause procedure used in practice for most directives has proven to be hardly suitable. On its role in the future see CERTIF 2005-16 rev. 2 (Fn. 42), A.4 b), p. 6; C 8.4, p. 25 et seq.;

2. Harmonization of the conformity assessment procedures: Global Approach and Modules Decision

a) Legal foundations

In 1989 the New Approach was supplemented with the "Global Approach" or the "Global Concept", which strove for the harmonization of the conformity assessment procedures provided for in the New Approach. Initially the Commission presented a "Global Approach to Certification and Testing"[89], in which it stressed the need to harmonize the conformity assessment procedures and set uniform requirements for the Notified bodies[90]. The Council drew on this in its "Council Decision on a Global Approach for Conformity Assessment"[91] and encouraged the creation of a uniform system of procedural steps for the different phases of conformity assessment. This was implemented in 1990 in the so-called "Modules Decision"[92], which provided eight different modules for conformity assessment, towards which the directives were supposed to be oriented. In 1993 the Council harmonized the rules on affixing and using the CE-marking[93]. The modules had to be adjusted to the changes resulting from this, so that the Modules Decision from 1990 was replaced by the Council Decision 93/465/EEC (hereafter the Modules Decision)[94].

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for proposed changes in the safeguard clause procedures see now Art. R31 et seqq. Decision No 768/2008/EC.

89 A Global Approach to Certification and Testing, COM (89) 209 final from 15.6.1989, EC Official Journal 1989, Nr. C 267, p. 3.

90 COM (89) 209 final from 15.6.1989, EC Official Journal 1989, No. C 267, p. 3 et seq., in particular p. 4, 16, 18 et seq.

91 Council Decision of 21.12.1989 on a Global Approach to Conformity Assessment, EC Official Journal 1990, No. C 10, p. 1.

92 Council Decision of 13 December 1990 concerning the modules for various phases of conformity assessment used in the technical harmonization directives, 90/683/EEC, EC Official Journal 1990, Nr. L 380, p. 13.

93 Council Decision of 22.7.1993 concerning the modules for various phases of conformity assessment used in the technical harmonization directives and the rules for affixing and the use of the CE conformity marking (93/465/EEC), EC Official Journal 1993, Nr. L 220, p. 23.

94 Council Decision of 22.7.1993 concerning the modules for various phases of conformity assessment used in the technical harmonization directives and the rules for affixing and the use of the CE conformity marking (93/465/EEC), EC Official Journal 1993, Nr. L 220, p. 23. As the Modules Decision only harmonized the procedures for directives to be passed in the future, an amendment directive was required for the adjustment of the directives passed until then, which the Council jointly passed with the Modules Decision, Directive 93/68/EEC of the Council from 22 July 1993 on the modification [of various] directives, Official Journal No. L 220, p. 1.

b) Overview of the modules

The Modules Decision from 1993 contains the eight basic modules of the resolution from 1990 as well as different variations of these modules[95]. Generally a product is subject to conformity assessment both in the product design phase as well as the production phase[96]. The modules accordingly refer to the product design phase, the product manufacturing phase, or both and can be combined with one another so that entire conformity assessment procedures can be brought together. Only the main features of the eight basic modules shall be outlined in the following[97]. A graphic overview of the modules with the respective tasks of the manufacturers and Notified Bodies is provided by the table on the Draft Certif 2005-14[98].

Module A (internal control of production) provides for internal design and production control by the manufacturer and does not require the intervention of a Notified Body[99]. The CE-marking is affixed by the manufacturer on the basis of a supplier's declaration. Module B (EC-type examination) is applied in the production design phase and must be supplemented by a module which provides for an inspection in the production phase (Modules C, D, E and F). The type examination is carried out by a Notified Body at the request of the manufacturer. The type examination in the manufacturing stage can be supplemented by Module C (conformity to type of construction), after the manufacturer him or herself has certified the conformity of the product with the type of construction[100]. The use of a Noti-

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95 On the additional elements of the options in comparison to the basic modules see *European Commission*, Guide ('blue'), Table 5/3, p. 36.

96 Council Decision 93/465/EEC, Annex A I. c).

97 For more information on the modules see also *Röhl*, Akkreditierung und Zertifizierung, p. 8 et seq., in detail in *Merten*, Private Entscheidungsträger, p. 62 et seq.

98 Available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_14_table.pdf (2.3.2005). The table is in CERTIF 2005-16 rev. 2 (Fn. 42), printed in Annex 2 as Table 1, see also remarks there on the modules after a possible revision (Tables 2 and 3). With regard to the revision of the New Approach an adaptation of the conformity assessment procedures is currently being debated. For the results see now Decision No 768/2008/EC, Annex II (table OJ L 218, p. 126).

99 However, this is different in option Aa, see e.g. the tables on Draft CERTIF 2005-14 (Fn. 97), see also *Röhl*, Akkreditierung und Zertifizierung, p. 9 et seq.

100 More in *Merten*, Private Entscheidungsträger, p. 65 et seq., also on possible supplementary inspections of individual aspects or random inspections by a Notified Body.

fied Body is not mandatory for this[101]. Module D (production quality assurance) is also only used in the manufacturing stage. A Notified Body is called on here to conduct an initial inspection of the quality assurance system established by the manufacturer for production, final inspection, and testing of the product and to continually inspect the system. Module E (product quality assurance) is designed in a similar manner. The Notified Body also conducts an initial inspection and continual testing of the quality management system of the manufacturer; unlike in Module C the quality management system relates to the product, not to its manufacturing process[102]. Ultimately, Module B can be replaced by Module F (inspection of the products). In contrast to Module C, a Notified Body certifies conformity with the type of construction here. Additional modules are Module G (unit verification), which pertains to the production and manufacturing phase and according to which every product is examined by a Notified Body, which then issues a conformity certificate. According to Module H (full quality assurance) the manufacturer maintains an approved quality assurance system, which covers the design, the production, the final inspection and the testing of the product itself. The Notified Body carries out an initial test and continual surveillance of the quality management system.

From these modules, the Community legislator selects for the directives those which it wishes to specify for the conformity assessment procedures in the scope of the directive. The selection of the more or less elaborate modules must be oriented, in particular, towards the type of product and the type and significance of its production as well as the potential endangerment of the protection goals like safety, health, etc., and respect the principle of proportionality[103]. Normally the selection between several conformity assessment procedures is left up to the manufacturer[104].

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101 The directives may stipulate Notified Bodies to inspect special aspects of the product or conduct random inspections, Table on CERTIF 14 (see above Fn. 97).

102 This distinction draws on a division into different quality assurance procedures, as was specified while the modules in the standards of the series of standards ISO 9000 (status quo 1987) were drawn up, see Draft CERTIF 2005-1 rev.1 “The quality assurance modules after the introduction of ISO 9001:2000” from 6.6.2005, Item 2 p. 1 and under c; available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_1_rev_1.pdf (15.3.2006).

103 *European Commission*, Guide (‘blue’), 5.1, p. 34.

104 *European Commission*, Guide (‘blue’), 5.1, p. 34.

3. Guarantee by the manufacturer to comply with the legal requirements

The overview of the modules reveals that Notified Bodies come into operation in the majority of the modules[105]. A closer examination shows, however, that the New Approach also places great emphasis on the responsibilities of the manufacturer:

First, one must bear in mind that Module A (internal control of production) in the scope of numerous directives suffices for less dangerous or simply designed products[106]. This pertains to a large part of the marketed products. In this case the Community places trust in the manufacturer alone, who declares the conformity of the product with the requirements. Whether a conformity assessment procedure with the involvement of Notified Bodies is stipulated is determined by the Community legislator upon the passing of the sector-specific directive, under particular consideration of the risk potential of the products, but also the principle of proportionality[107]. Due to the significant expenditure of time and finances associated with the use of Notified Bodies, industries frequently prefer Module A[108].

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105 On the basis of the modules according to the Modules Decision for Module B, D, E, F, G and H, as well as in options Aa and the alternatives within B, see e.g. the overview in Table I on CERTIF 2005-16 rev. 2 (Fn. 42).

106 This holds for example for electric operating resources in the low-voltage area, in accordance with § 3 para. 1 of the 1st GPSGV (Equipment and Product Safety Law Ordinance) in conjunction with Annex IV of the directive 73/23/EEC (low-voltage directive); the marketing of toys, when the manufacturer respects harmonized norms, § 3 para. 1 of the 2nd GPSGV (Equipment and Product Safety Law Ordinance); simple models of personal protective equipment according to § 3 of the 8th GPSGV (Equipment and Product Safety Law Ordinance) in conjunction with Art. 8 para. 3. Directive 89/686/EEC; Medical devices with low risk potential, § 6 para. 4 MPV (Medical devices ordinance) in conjunction with Annex VII Directive 93/42 EEC (Medical devices).

107 As for the criteria, the Modules Decision states that the following items are to be considered when specifying the selection possibilities for the manufacturer: suitability of the modules for the type of product, type of dangers, economic infrastructure of the sector (e.g. existence or non-existence of neutral bodies), type and scope of production etc. The considered factors must be explicitly mentioned in these directives. Efforts are made to avoid prescribing modules which entail too large burdens in relation to the pursued objectives. Council Decision 93/465/EEC Annex A e), g).
For the deliberations on the use of the SDoC in the regulatory sphere from an international perspective, see the preparatory report of the TBT Committee on the workshop on SDoC organized in March 2005 (*Committee on technical Barriers to Trade*, Workshop on Supplier's Declaration of Conformity – Background Note by the Secretariat), in particular under II. The document is available online at URL: http://www.wto.org/english/tratop_e/tbt_e/tbt_wrkshop_note_21march05_e.doc (4.3.2006).

108 See for example the assessment by EICTA, "European Industry Association on Information Systems, Communication, Technologies and Consumer Electronics (EICTA) view on Market Surveillance as related to the New Approach Directives" in: UNECE, Market Surveillance in the ECE Region, New York and Geneva 2004, Part 2 Chapter 7 Section 2 (p. 45). The report is available online at URL: http://www.unece.org/trade/ctied/wp6/documents/trd_301_guide8.pdf (3.3.2006).

Furthermore, it should be pointed out that all directives based on the New Approach require the manufacturer or his/her authorized agent established in the Community to submit an EC conformity declaration, when the product is put on the market[109]. This also applies when a Notified Body is used. This declaration also contains the name and address of the involved Notified Body[110]. Those addressed by the conformity declaration are, above all, state authorities, and in some cases also the consumers or users of the product[111]. For the market surveillance authorities, the EC conformity declaration is an important point of reference. During the revision of the New Approach, the proposal has been put forward to continually add a mandatory notice to the declaration of conformity that the declaration has been submitted under the sole responsibility of the manufacturer[112]. It is evident here that according to the understanding of the Community legislator, the manufacturer remains continually responsible for the conformity of the product with the legal requirements, even if he/she draws on an inspection report or a certificate from a Notified Body when submitting the declaration of conformity. This corresponds with the product liability law, which has been partially harmonized in Europe by Directive 85/374/EEC[113]. To a certain extent, the manufacturer or marketer is accordingly liable regardless of negligence or fault[114].

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109 *European Commission*, Guide ('blue'), 5.4, p. 38.

110 The exact content of the declaration of conformity is specified by the respective directive. The EC declaration of conformity must be kept for at least ten years, as long as not prescribed otherwise by the EC directive. Draft CERTIF 2005-2 "EC Declaration of Conformity" from 21.3.2005 contains an overview of the contents required by the directives (Table for comparison with the requirements of standard ISO/IEC 17050-1). The document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/sogs_n506_draft_certif_2005_2_version2.pdf (3.2.2006).

111 Draft CERTIF 2005-2 (Fn. 110), Item 3, p. 2.

112 Draft CERTIF 2005-2 (Fn. 110), Item 2, p. 1 et seq. A proposal has also been made to harmonize the content of the declaration of conformity in the area of application of the directives based on the New Approach and thus to orientate it towards ISO/IEC 17050. For the contents of the EC declaration of conformity see now Art. R10 Decision No 768/2008/EC. For the significance of the declaration of conformity and the supporting standard ISO/IEC 17050 Parts 1 and 2 see *Beer*, DIN-Mitteilungen 10-2005, 43 et seq.

113 *European Commission*, Guide ('blue'), 3.7, p. 27. In 1985 the principle of objective liability or liability regardless of negligence or fault was introduced in Directive 85/374/EEC on liability for defective products. According to this principle, the manufacturer of a defective movable item is obligated to compensate for bodily damage and damage to the *private* property of persons [however, not for commercially used items, see Art. 9 lit b) of the directive], regardless whether the manufacturer acted in negligence or not, see Art. 1, 7 Directive 85/374/EEC. See also COM (89) 209 final from 15.6.1989, EC Official Journal 1989, No. C 267, p. 12.

114 See § 1 ProdHaftG, for remarks on this MünchKomm-*Wagner*, ProdhaftG, Einleitung, Rn. 14, 15 et seq. The classification of the liability according to the product liability law and the ProdHaftG as liability regardless of negligence or fault is disputed though, see *Wagner*, l. c.

4. On the role of Notified Bodies

For high-risk products the directives based on the New Approach provide for the use of Notified Bodies. In view of the protection goals of product safety law, the effectiveness of a market access regime is best demonstrated on those products which may encroach upon the health of many of their users and consumers or cause significant damage. Therefore, it appears justified when the regulations of the New Approach pay particular attention to the activities of the Notified Bodies and to assuring their competence. Thus, in the following, the tasks of the Notified Bodies during the conformity assessment procedure as well as their obligations for information exchange with authorities and other Notified Bodies shall be examined in detail. The section concludes with a brief outlook on the question of the legal classification of their activities between private and public law.

a) Tasks in the conformity assessment procedure

The tasks of the conformity assessment bodies are specified by the respective modules. They act upon the basis of a private law treaty with the manufacturer[115]; the manufacturer may freely select the Notified Body[116]. If the result of the assessment is positive, the Notified Bodies issue a statement of conformity, e.g. in the form of an EC type examination certificate (Module B) or another certificate of conformity on the basis of the conducted tests. As for the modules which draw on quality assurance systems, the surveillance of the quality assurance system is one of the tasks after its initial inspection. As a rule, the validity of the issued confirmations is limited; usually the maximum duration of validity is specified by the directives and their implementation laws[117]. The directives based on the New Approach and/or their implementation provisions partially already specify that the

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115 As a rule, conformity assessment bodies are private entities. The designation and notification of state inspection bodies etc. is not excluded, see *Röhl*, Akkreditierung und Zertifizierung, p. 68 et seq.; on this practice in medical devices law see *Merten*, Private Entscheidungsträger, p. 122 et seq. On the classification of the activity as being based on private law in other legal systems see the Third Section, D.III.

116 E.g. § 11 para. 9 Directive 93/42/EEC (Medical devices), § 8 para. 2 of the medical devices law; *European Commission*, Guide ('blue'), Item 6.4, p. 45.

117 E.g. § 11 para. 11 Directive 93/42 EC (Medical devices), § 17 para. 1 MPG in conjunction with § 3 para. 5 MPV.

conformity assessment bodies may consider and accept statements of conformity from other bodies[118].

If the evaluations reveal that the requirements of the directives are not (no longer) fulfilled, the Notified Bodies must limit, suspend or revoke the issued confirmations if the non-conformities are not corrected through adequate measures[119]. The bodies are supposed to take the principle of proportionality into account here[120].

b) Passing on information to authorities

The Notified Bodies are additionally obligated to pass on information to state agencies. This includes data on the suspension or the revocation of confirmations and – as a rule on request – their issue or refusal[121]. These can be of particular significance for market surveillance[122].

The information obligations of the Notified Bodies can also facilitate their surveillance by their Designating Authorities. Thus, in some countries the authorities which are responsible for designation or the accreditation carried out within this context require the Notified Bodies to present an activity report every year[123]. The report gives the responsible authorities an overview of the activities of the body and can thus serve as a point of reference for potential further measures.

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118 E.g. Art. 11 para. 7 Directive 93/42/EEC (Medical devices), Art. 8 para. 5 Directive 99/385 EC (Active implantable medical devices), see 3 para. 4 of the medical devices law. See also *European Commission*, Guide ('blue'), 6.5, p. 46. On the possible future design of this regulation, see CERTIF 2005-16 rev. 2 (Fn. 42), Item 5.4, p. 15.

119 E.g. § 18 para. 1 MPG.

120 Explicitly in Art. 16 para. 6 Directive 93/42/EEC (Medical devices); Art. 16 para. 6 Directive 98/79/EC (In-vitro diagnostic medical devices); § 18 para. 1 MPG; the principle of proportionality is also mentioned in CERTIF 2005-16 rev. 2 (Fn. 42), Item 5.4, p. 15.

121 E.g. Annex IV Part 1 Module B1 No. 7 Directive 1999/36/EC (transportable pressure equipment) on the EC type examination certificate; Annex V A No. 7, B No. 7 Directive 95/16/EEC (Lifts directive) with regard to the EC type inspection, already in the provision on the Notified Bodies Art. 16 para. 5 Directive 1 Directive 93/42/EEC (Medical devices), generally now CERTIF 2005-16 rev. 2 (Fn. 42), Item 5.4, p. 15.; see now Art. R28 para. 2 Decision No 768/2008/EC.

122 On potential future obligations on behalf of the Notifies Bodies in this regard see CERTIF 2005-16 rev. 2 (Fn. 42), C.5.3, p. 14.

123 This holds for example for the Netherlands, France or Austria; see for the Netherlands in particular Appendix, Second Section, B.III.4 (b), for France Appendix, First Section, B.III. On potential future expansions of such obligations see CERTIF 2005-16 rev. 2 (Fn. 42), Item 5.4, p. 15.

c) Exchange of information and cooperation among Notified Bodies

The Modules Decision already specified that the Commission together with the Member States should provide for close cooperation among the Notified Bodies to improve the uniform technical application of the modules[124]. This cooperation is regarded as indispensable, when a guarantee is required that the Notified Bodies are operating consistently and at the same level[125]. To this end, Groups of Notified Bodies (GNB) were created for the exchange of experience in the scope of some directives[126]. The objective is the uniform application of the technical requirements for the products, the promotion of the transparency of activities and trust of the executive authorities in the results of the conformity assessment, as well as to assure the participation of the authorities in the "management" of conformity assessment and to guarantee coherent standardization activities at the European level[127]. Currently 17 GNBs exist, to which Notified Bodies, the Commission, the Member States, the standardization organizations and business representatives belong[128]. The groups convene once or twice annually, but primarily use Internet-supported systems to exchange information so that it is not required to be present in person[129].

A review of the work of the GNB during the revision of the New Approach has shown that the participation in the groups varies from sector to sector, but leaves much to be desired in several groups. The participation obligation is indeed problematic for small bodies, in particular, due to the high expenditure involved. An additional factor is that the conformity assessment bodies compete with one another and are thus only interested in cooperating to a limited extent; they are likely to be rather reserved towards too closely meshed guidelines

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124 Council Decision 93/465/EEC, Annex I A h. A framework for this cooperation was outlined by the paper CERTIF 94/6 rev6 from 1998; available online as Annex B to Draft CERTIF 2005-8 "Creating a network of notified bodies" from 24.8.2005 at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_8.pdf (4.3.2006). See also *European Commission*, Guide ('blue'), 6.6, p. 47 et seq.

125 Draft CERTIF 2005-8 (Fn. 124), Item II p. 1.

126 For medical devices law see *Höppner*, in: Anhalt/Dieners (eds.), Handbuch des Medizinproduktsrechts, § 14 Rn. 6 et seq.; *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinproduktsrechts, § 12 Rn. 52.

127 Draft CERTIF 2005-8 (Fn. 124), Item II p. 1 et seq.

128 In greater detail in Draft CERTIF 2005-8 (Fn. 124), Item III p. 2; see also the overview in Annex A of the document, which lists, among other things, the total number of previous sessions and the number of participants per session.

129 In greater detail in Draft CERTIF 2005-8 (Fn. 124), Item III p. 2. Sometimes committees exist for cooperation at the national level, which then send representatives to the GNB, e.g. for the lifts directive.

for their activities. In view of the participation of the area-specific authorities of the Member States in the GNB, it is necessary for the concerned authorities to be represented sufficiently and regularly. Currently, uncertainty also prevails with regard to the extent to which the guidance documents and recommendations for use drawn up by the GNBs are to be binding[130].

In addition to this cooperation in the Groups of Notified Bodies, the bodies are required to give other bodies which are active in the scope of the same directives, information on issued and revoked confirmations, modifications, restrictions, etc. on request[131]. With regard to these provisions the practical implementation is also problematic.

d) On the categorization of their activities

As a rule Notified Bodies are private entities[132]. They operate on the basis of a private law contract with the manufacturer and the manufacturer may freely select the Notified Body[133]. Although the activities of the conformity assessment bodies are thus based in a private law environment, various provisions show that the bodies are simultaneously incorporated into the enforcement of product safety law. This arouses doubts on the categorization of their activities as being purely based on private law.

(i) Relationship to the manufacturer

This becomes apparent in the relationship with the manufacturer: the conformity assessment bodies must have the possibility to suspend, restrict, or revoke the inspection report if the evaluation reveals that the requirements of the directives are not conformed with. For several regulatory areas, the implementation provisions for the directives explicitly provide

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130 Draft CERTIF 2005-8 (Fn. 124), Item III p. 3. See the open wording in *European Commission*, Guide ('blue'), 6.6, p. 47 et seq. and see now Art. R17 para. 11 Decision No 768/2008/EC: "apply as general guidance".

131 E.g. Art. 16 para. 5 Directive 93/42/EEC (Medical devices), *European Commission*, Guide ('blue'), 6.3, p. 44.

132 The designation and notification of state inspection bodies etc. is not excluded, see *Röhl*, Akkreditierung und Zertifizierung, p. 68 et seq.; on this practice in medical devices law see *Merten*, Private Entscheidungsträger, p. 122 et seq.

133 For a categorization of the legal relationships as being based on private law in other countries, see the Third Section, D.III.

for this authority to unilaterally revoke the certificate[134], sometimes this is implicitly required. The manufacturers must grant the conformity assessment bodies access to their rooms and production facilities to conduct the inquiry and assessment and they are obligated to make the relevant documents available. As a rule, the contracts of the conformity assessment bodies contain clauses which guarantee these obligations of the manufacturer[135]. Additional provisions can be found which require the conformity assessment bodies to substantiate negative decisions to the manufacturer[136]. The conformity assessment bodies are obligated to operate on a neutral basis without discriminating[137] and to respect the principle of proportionality[138]. These provisions show that the body is attributed unilateral powers vis-à-vis the manufacturer. To compensate for this unilateral authority, obligations to state reasons or, for example, the obligation to respect the principle of proportionality are imposed on the body by means of legal provisions. Such obligations are characteristic of the sovereign enforcement of administrative law by state authorities.

(ii) Legal consequences of the conformity assessment procedure

The consequences of the conformity assessment procedure also show that the conformity assessment bodies are granted unilateral powers, which cannot be simply understood as a reflection of private self-regulation[139]. Thus, the bodies which must be obligatorily involved in the conformity assessment procedure ultimately and bindingly decide on the

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134 See § 18 para. 1 MPG.

135 See e.g. the "Prüf- und Zertifzierungsordnung (PZO) und Allgemeine Geschäftsbedingungen der TÜV Rheinland Product Safety GmbH (TRPS)" (Inspection and Certification Ordinance and General Terms and Conditions of the Technical Inspection Agency), Section 4.5; the document is available online at URL: http://www.de.tuv.com/de/produkte_und_leistungen/produktsicherheit_und_qualitaet/pruef_und_zertifizierungsordnung.html (3.3.2006); see also *Edelhäuser* in: Anhalt/Dieners (eds.), Handbuch des Medizinproduktsrechts, § 5 Rn. 52.

136 E.g. for the rejection of the construction type certificate Annex V A No. 5 Directive 95/16/EEC (directive relating to lifts).

137 For certification bodies this is based on the standards, which contain requirements for the bodies, e.g. ISO/IEC Guide 65:1996 (Product certification bodies), Section 4.1; DIN EN ISO/IEC 17024:2003 (Personnel certification), Section 4.1.1.

138 Explicitly in Art. 16 para. 6 Directive 93/42/EEC (Medical devices); § 18 para. 1 Medical Devices Law; the principle of proportionality is also mentioned in CERTIF 2005-16 rev. 2 (Fn. 42), Item 5.4, p. 15; see now Art. R27 para. 2 Decision No 768/2008/EC.

139 In greater detail in *Röhl*, in: Schmidt-Aßmann/Schöndorf-Haubold (eds.), Der Europäische Verwaltungsverbund, 153 et seq., 164 et seq.

market access of the products[140]. Due to EC law, Member States may not inspect products systematically during market surveillance[141]. This is only permissible in special cases of suspicion. The market surveillance agencies of the Member States can then indeed divert from the assessment of conformity with the directive and ban the sale of the product, but only temporarily until the conclusion of a safeguard clause procedure[142].

(iii) Conclusion

The classification of the conformity assessment bodies into the classical system of German administrative law bears difficulties, because, until now, this only permits the involvement of private parties in the sovereign enforcement of public law in certain, narrowly defined forms[143]. From a purely national perspective, there are some arguments in favour of qualifying the Notified Bodies as entities vested with public authority ("Beliehene"[144])[145]. In consideration of the cross-European activities of the Notified Bodies and the cross-European regulatory impact of their certificates, the legal regime which governs the relationship with the manufacturer may not be based on national public law, though, as would be the case with "Beleihung"[146]. With regard to a "Beleihung," the legal relationship between the manufacturer and Notified Body would be oriented towards German public law,

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140 See *Röhl*, Akkreditierung und Zertifizierung, p. 24 et seq.; see also *Voßkuhle*, in: Hoffmann-Riem/Schmidt-Aßmann (eds.), Verwaltungsverfahren und Verwaltungsverfahrensgesetz, p. 277 et seq., 313; on the crucial significance of certification see also *Merten*, Private Entscheidungsträger, p. 214.

141 For example, § 8 para. 2 No. 2 GPSG accordingly only provides for a random inspection; the broad wording of § 26 para. 2 MPG "on an appropriate scale" is not unproblematic.

142 See above B.II.1.

143 For the comparable discussion in the Netherlands, see Third Section, D.III.1, in greater detail in the Appendix, Second Section, B.II.

144 In German administrative law, the term "Beleihung" signifies the act of vesting a private entity with public authority; the entity is called "Beliehener".

145 Consequently along these lines *Scheel*, DVBl. 1999, 442 (446 et seq.); *idem*, Privater Sachverstand, p. 97 et seq., for the GPSG; *Kadelbach*, Allgemeines Verwaltungsrecht, p. 329 et seq. See also BVerwG, NVwZ-RR 1991, 330 et seq. (on the inspection of a mining test route by a notified testing body – however not according to the Global Approach). Similar for Dutch law in *G. Evers*, Tilburg Foreign Law Review 2003, 342 et seq. (355). In the area of construction products law *Koch/Molodowsky/Famers* assume a "Beleihung" of the certification bodies for the certification according to § 26 of the BayBO, *Koch/Molodowsky/Famers*, BayBO, § 26 para. 4.1 with additional references on contrary views as well.

146 See *Röhl*, Akkreditierung und Zertifizierung, p. 24 et seq.; *Merten*, Private Entscheidungsträger, p. 160 (157 et seq.); in terms of the result, see also *Kage*, Medizinproduktegesetz, p. 192. Contrary to *Kadelbach*, Allgemeines Verwaltungsrecht, p. 331, one would also have to assume the same for the relationship between the environmental verifier according to the Eco-Audit/EMAS-Regulation and the inspected firm, because the environmental verifier can also operate across Europe, Art. 4 para. 5 Regulation 761/2001 (EMAS).

and the Notified Bodies would practically be incorporated into the regime of public law enforcement. In view of the principle of state immunity, this would lead to difficulties when considering that the bodies operate across Europe and in this regard also have e.g. the right to enter the business facilities of their clients abroad[147]. There would also be problems with respect to the legal protection against the actions of the Notified Bodies[148].

The literature has yet to reveal a clear picture: the procedures of conformity assessment in product safety law are partially categorized as "regulated self-regulation[149]. This is not likely to do justice to the special nature of this constellation: the conformity assessment procedures are conducted by third parties on the basis of compulsory law, and primarily by private entities. Their legal status and structure result from EC legal provisions rather than from self-organization. One should also bear in mind that the Community/State legislator does not renounce setting material requirements for the products, so the program of standards governed by public law is still maintained[150]. Only the control of the products before being marketed is transferred to private third parties. They are monitored via the procedure of designation and the state aims at orientating their activities towards the public interest. So the state only partially refrains from monitoring and surveillance measures[151]. By setting legally binding requirements for the products, establishing conformity assessment procedures through directives resp. implementation laws and the incorporation of the Notified Bodies by means of designation and surveillance, the share of regulation or "steering" is clearly greater than that of "self-regulation" in the entire system.

It is sometimes assumed that the conformity assessment bodies assume tasks which lie exclusively in the area of responsibility of the manufacturer[152]. For medical devices law, which offers at least some more information on the rights and obligations of the bodies,

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147 In greater detail *Röhl*, Akkreditierung und Zertifizierung, p. 26 et seq.

148 In greater detail *Röhl*, Akkreditierung und Zertifizierung, p. 27.

149 „*Gesteuerte Selbstregulierung*" according to *Schmidt-Preuß*, VVDStRL 56 (1997), p. 160 et seq., 173 (there Fn. 38); see also *Di Fabio*, Produktharmonisierung, p. 64; *Seidel*, Privater Sachverstand, p. 269 et seq.; *Weber*, Europäische Einwirkungen, p. 201 et seq.

150 According to *Scholl*, Private Sachverständige, p. 287.

151 *Scholl*, l. c.

152 *Hofmann*, Rechtsschutz und Haftung, p. 42 et seq., in particular Fn. 108; *Schmidt-Aßmann*, Ordnungsidee, Kapitel 3 Rn. 57. For a similar view see also *Peine*, § 9 Rn. 21; following *Schmidt-Preuß*, VVDStRL 56 (1997), p. 160 et seq., 167 (there Fn. 18) as well as p. 173 (there Fn. 38).

some observers hold that in the legislator's view the medical devices law is executed by private entities in the administration of private tasks, whose fulfilment is in the interest of the public[153]. The categorization of the activities of the Notified Bodies as sovereign is rejected with the reference that it is not a public approval procedure, rather a mere certification of conformity with the directive which authorizes the manufacturer to affix the CE marking which lies within his/her area of responsibility[154].

In this concept, however, the unilateral decision-making powers of the bodies, which were presented at the beginning, are difficult to classify. In particular due to the unilateral competences of the bodies and the foundation of their activities on European law, there are many arguments for qualifying the activities of the bodies as public and describing the Notified Bodies as core components of a new, European administrative structure which assumes European administrative tasks[155]. From this standpoint, it appears consequent for the legal foundations to bind the bodies to the principle of proportionality and stipulate hearing obligations and obligations to state reasons for decisions[156].

The question of the legal categorization of the activities of the Notified Bodies cannot be answered conclusively here, as this would go beyond the scope of the present study. However, for the purposes of this study one should bear in mind that the Notified Bodies are the core of the administrative structures for the enforcement of European product safety law. It is imperative to link the bodies to the state in order to guarantee that their activities are

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153 For this result, see *Merten*, Private Entscheidungsträger, p. 168 et seq.; see also *Merten*, DVBl. 2004, 1211 et seq.

154 According to *Schorn*, Medizinprodukterecht, § 3 MPG Rn. 74 et seqq. (Rn. 75), with a reference to the consultations on the draft of the medical devices law, during the course of which references to a status of the bodies governed by public law were deliberately removed from the draft. For an additional view in opposition to the categorization as sovereign see *Deutsch* in: Deutsch/Lippert/Ratzel, Medizinproduktegesetz, § 15 Rn. 3. For a similar result in constructive devices law (opening civil law proceedings for legal disputes over the issue of a certificate) see *Sauter* (ed.), § 24 LBO Rn. 8 with further references; an opposing view in *Koch/Molodowsky/Famers*, who categorize the certification procedure as being based on public law and qualify the certification bodies according to § 26 BayBO as "Beliehene", *Koch/Molodowsky/Famers*, BayBO, § 26 para. 4.1 with additional references on contrary views as well.

155 In detail in *Röhl*, Akkreditierung und Zertifizierung, p. 24 et seq., p. 23 et seq.; apparently tending towards the same view *Kage*, p. 189 et seq., 197; also *Voßkuhle*, in: Hoffmann-Riem/Schmidt-Aßmann (eds.), Verwaltungsverfahren und Verwaltungsverfahrensgesetz, p. 277 et seq., 313 et seq.

156 An obligation to state a reason for rejecting a construction type certificate is included e.g. in Annex V A No. 5 Directive 95/16/EEC (Lifts); on the principle of proportionality explicitly Art. 16 para. 6 Directive 93/42/EEC (Medical devices); § 18 para. 1 MPG; the principle of proportionality is also mentioned in CERTIF 2005-16 rev. 2 (Fn. 42), Item 5.4, p. 15; see now Art. R27 para. 2 Decision No 768/2008/EC.

oriented towards the protective goals of safety, health, etc. or – stated more generally –the common good. If their activities are qualified as sovereign, this is already required for reasons of democratic legitimacy[157]. Yet even if the Notified Bodies are categorized as acting purely on the basis of private law, due to their central role for the execution of product safety law it is indispensable to assure the sufficient qualification of the bodies and to monitor the proper execution of tasks[158]. The procedures of accreditation and designation serving this purpose will be addressed more thoroughly in the following.

III. Procedures and structures to assure the competence of the Notified Bodies

The procedures of accreditation and designation are significant for the functioning of the conformity assessment system for several reasons: first, they play a decisive role in assuring the competence and independence of the Notified Bodies and thus for the safety of the products. The procedures are supposed to make sure that the competition between the bodies does not lead to a decline in the quality of the services they offer. Furthermore, differences in the designation procedures of the Member States can lead to competitive disadvantages for the bodies on the European service market. For this reason, a certain degree of synchronization of the procedures is necessary as well. Ultimately the designation procedures are to be structured to the extent that they demonstrate the competence of the European conformity assessment system in relation to third-countries as well[159].

Despite the great significance of the harmonization of the procedures, the resolutions on the New Approach and the Global Approach were given hardly any binding specifications for this. Among other things, this led to differences in the designation practices of the various Member States. The same holds for the cooperation between the national accreditation bodies in EA, which is also only scarcely backed by legislation.

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157 In greater detail *Röhl*, in: Schmidt-Aßmann/Schöndorf-Haubold (eds.), Der Europäische Verwaltungsverbund, p. 153 et seq., 170 et seq., see also *Sydow*, Verwaltungskooperation, p. 249 et seq.

158 For more details on the focus of the so-called *Verifikateure* on the execution of police law in the public interest, see *Scholl*, Private Sachverständige, p. 279 et seq., in particular p. 315 et seq.

159 See COM (2003) 240 final from 7.5.2003, 2.2.3, p. 10.

1. Differences in the designation procedures of the Member States

As already illustrated, the Notified Bodies form the administrative core in the execution of product safety law. The designation of the bodies is the task of the Member States, and it is often emphasized that each Member State bears the responsibility to ensure that the bodies notified by it conduct their activities according to the law[160]. The directives based on the New Approach standardize Essential Requirements for the bodies which the Member States must inspect while designating the bodies[161].

The procedures and organization of the designation as well as the continual inspection of the bodies are hardly stipulated by the directive, though. This results from a deliberate political decision to focus on the principle of mutual recognition and thus to leave the designation of the bodies up to the individual countries to the greatest possible extent, i.e. even with regard to organization and procedures[162]. Subsequently, differences in the designation procedures of the Member States have emerged, in particular with regard to the relevance of the requirements for conformity assessment bodies laid down in the harmonised standards and their relationship to the Essential Requirements stipulated by the directives.

a) Role of accreditation during designation and surveillance

The Decision of the Council on a Global Approach maintained as a guideline that for the designation process the requirements laid down in the series of standards EN 45000 should be used and that in all Member States as well as in the Community itself the establishment of accreditation systems should be promoted[163]. According to the Modules Decision, an

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160 See e.g. COM (2003) 240 final from 7.5.2003, 2.2.5, p. 11 (on surveillance), *Ensthaler et al.*, Akkreditierung (KAN-Bericht 30), p. 78.

161 E.g. Annex XI Directive 93/42/EC (Medical devices), Annex IV Directive 97/23/EG (Pressure equipment), Annex VII Directive 95/16/EC (Lifts). The directives list similar criteria of competence as material requirements for designation, which indeed differ upon detailed analysis, sometimes without any particular concern in the matter being recognizible; *Ensthaler et al.*, Akkreditierung (KAN-Bericht 30); p. 15, 56 et seq., 66, 110 et seq; COM (2003) 240 final from 7.5.2003, 2.2.3, p. 10.

162 COM (2003) 240 final from 7.5.2003, 2.2.3, p. 9, with reference to the subsidiarity principle.

163 Council Decision of 21.12.1989 on a Global Approach to Conformity Assessment, EC Official Journal 1990, No. C 10, p. 1. See also the Communication of the Commission on a Global Approach, COM (89) 209 final from 15.6.1989, EC Official Journal 1989, No. C 267, p. 19. At that point in time (1989) eight accreditation networks for inspection laboratories had already accordingly been developed or established,

accreditation according to the series EN 45000 should support the assumption that the requirements of the directives for the Notified Body have been complied with[164]. Hence, the directives based on the New Approach contain an assumption provision, on the basis of which the compliance with the Essential Requirements laid down in the annexes is presumed, when they meet the "relevant" harmonized standards[165]. However, the use of accreditation for designation was not mandatory for the Member States[166].

The result of this restraint was that there was initially no systematic exchange of information about the respective national procedures of the bodies' designation and surveillance and that differences emerged in the procedures[167]. By principle, most countries indeed fall back on accreditation by a national accreditation body for designation. However, even when accreditation is used, differences can result in the way that the accreditiation procedures are incorporated[168]. The analysis of the designation procedures of the individual countries during this study has confirmed that without detailed knowledge of the relevant legal foundations and – above all – the *practices* of the Designating Authorities it is difficult to correctly describe the function of accreditation for the designation decision[169].

The same holds for the continual surveillance of the Notified Bodies. The "Blue Guide" specifies surveillance as an obligation of the Member States[170], but mandatory requirements for this are missing. The directives do indeed stipulate that the Member States must revoke the designation when the requirements for it are no longer met[171]. However, the informational basis for such a decision must first be created. The Designating Authorities may react to complaints or examine the competence of the involved Notified Body when

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and for certification and inspection bodies three individual national accreditation systems existed in the Netherlands, the United Kingdom, and in Portugal.

164 Council Decision 93/465/EEC, Annex I A m).

165 E.g. Art. 16 para. 2 clause 2 Directive 93/42/EEC (Medical devices); Art. 12 para. 2 clause 2 Directive 97/23/EC (Pressure equipment), Art. 9 para. 2 clause 2 Directive 95/16/EC (Lifts). The standards are normally not further specified.

166 See e.g. *European Commission*, Guide ('blue'), 6.1, p. 40.

167 COM (2003) 240 final from 7.5.2003, 2.2.4, p. 10 et seq.

168 See COM (2003) 240 final from 7.5.2003, 2.2.4, p. 11.

169 In greater detail in Third Section, B.I, II.

170 *European Commission*, Guide ('blue'), 6.1, p. 42.

171 E.g. Art. 12 para. 3 Directive 97/23/EC (Pressure equipment), similar in Art. 16 para. 3 Directive 93/42/EEC (Medical devices).

products appear which prove not to be in conformity with laws despite the inspection by a Notified Body. Yet until now mechanisms are lacking which allow them to observe the continual activities of the Notified Bodies independently of such events. If notifications are based on an accreditation procedure, at least, the accredited bodies come under regular surveillance according to the accreditation standards[172]. Thus, the consistent use of accreditation is one approach to guarantee for regular surveillance; in case of a harmonized application of the accreditation standards in this regard sufficient surveillance can also be demonstated vis-à-vis the other Member States by this means[173]. A supplementary option is the expansion of the information obligations of the Notified Bodies towards the Designating Authorities, e.g. in the form of activity reports required in some Member States[174].

Altogether the Member States tend to have little concrete information on the designation systems of the other Member States[175]. This has created a lack of transparency which undermines the trust which is a basic requirement for the mutual recognition and acceptance of the issued certifications[176]. The alignment of the *level* of the designation procedures in the individual Member States, which constitutes the core point of reference for mutual trust in the Notified Bodies, is still insufficient though[177].

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172 On re-assessment and surveillance see DIN EN ISO/IEC 17011:2005, Section 7.11, in particular 7.11.3.

173 On the surveillance of the bodies in other Member States, see Third Section B.III.

174 See above B.II.4.b), see now also CERTIF 2005-16 rev. 2 (Fn. 42), Item 5.4 , p. 15.

175 COM (2003) 240 final from 7.5.2003, 2.2.3, p. 9. The Commission held consultations in 2000 within the framework of the Senior Official Group for Standardization (SOGS) on designation and notification procedures in the Member States, which were sluggish at the beginning, though, and also were only able to offer a rough overview of the procedures. The results confirm the differences in the designation procedures, but at the same time the need for information as well, which would allow for a comparison of the procedures and thus an assessment of their equivalence. Germany presented a description of the system, which is published as SOGS-Document N 377 DE from 20.10.2000. SOGS N 377 DE as well as system descriptions from other Member States during the consultation are published as Appendix 1 and 4 on Module 3 of the study on "Auswirkungen einer Neuordnung des deutschen Anerkennungs- und Akkreditierungswesens", see *Wloka et al.*, Anerkennung und Akkreditierung (Module 3), also available online at URL: http://www.dar.bam.de/news.html (20.3.2006).

176 This is the finding of the Commission based, among other things, on the consultations held in the Member States in 2002, COM (2003) 240 final from from 7.5.2003, 2.2.3, p. 9 et seq.; on the consultations 1.1, p. 4.

177 With regard to this finding, see also *Ensthaler et al.*, Akkreditierung (KAN-Bericht 30), p. 74 et seq., who propose a harmonization of the designation criteria on the basis of "Common Elements", l. c., p. 110 et seq.

b) Relationship between accreditation rules and harmonized standards

One difficulty in using accreditation during the designation procedures is determining the relationship between the requirements specified in the directives and the criteria of the series of standards EN 45000 et seqq. and EN ISO/IEC 17000 et seqq.[178]. The standards of the series EN 45000 et seqq. resp. ISO/IEC 17000 et seqq. stipulate as *general* standards the requirements for the bodies independent of the branch and product category for which the accreditation is to apply. However, accreditations are always issued for a certain area of applicability (*scope*) and are thus never restricted to the mere fulfilment of the general standards of the series EN 45000 et seqq. resp. ISO/IEC 17000 et seqq. Accreditation on the basis of these standards always implies that the general criteria are supplemented and further specified during the assessment for the particular technical area in which the conformity assessment body applies for an accreditation[179].

The Netherlands, for example, have reacted to this difficulty by developing a system of directive and law-specific accreditation standards (*Risa* and *Wesa*). The agreement between the RvA and several ministries from June 2005 assumes that for the regulatory sphere special accreditation rules are specified in the individual areas which take the special demands of the regulatory sphere into account – however these are to be based to the greatest possible extent on the internationally harmonized accreditation standards to guarantee the closest possible link between the two areas[180]. In the United Kingdom, the DTI and other ministries in cooperation with UKAS have developed *Guidelines*, which UKAS uses as a basis when evaluating the bodies which are to be notified. The directive-specific *Guidelines* which concretize the Essential Requirements of the directives are based to a great extent on the standards of the series EN 45000 and ISO 17000[181].

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178 The question as to the extent to which the standards cover all requirements in terms of technical competence and all organizational requirements, e.g. in terms of liability insurance or sub-contracting, shall not be addressed here; for the so-called "Delta" assumed here see Draft CERTIF 2005-6 "Accreditation in support of designation of notified bodies" from 17.6.2005 under 2.2. (b), p. 5 et seq. "Coverage", which does not see a need for further requirements (but does indeed see a need for more precise guidelines on the use of the standards). The document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/certif_2005_06.pdf (15.3.2005).

179 Based on the summary on this problem in Draft CERTIF 2005-6 (Fn. 178), 1.2, p. 2 et seq. See also *European Commission*, Guide ('blue'), 6.1, p. 41 et seqq.

180 More on this in Third Section, B.I; B.III; Appendix, Second Section B.III.3.

181 More in Third Section, B.I; B.II; Appendix, Sixth Section, B.II.2.

However, the conformity assessment bodies also view such special accreditation rules and guidelines for interpreting the standards critically. When the status of interpretation documents is not specified, explanatory and supplementary documents can also lead to uncertainties with regard to the requirements to be fulfilled[182].

2. The current role of EA

As an association of accreditation bodies at the European level, EA serves to promote the transparency and consistency of accreditation on the whole, regardless whether the accreditation bodies are active in the regulatory or non-regulatory sphere[183]. Yet precisely in the scope of the directives based on the New Approach, the Community and the predominant majority of Member States also fall back on EA to create trust in the Notified Bodies. Countries which regularly draw on the accreditation by national accreditation bodies for the designation require them to participate in EA[184]. The national accreditation bodies of the Member States are full members of EA[185] and they participate in the peer evaluation-procedures of EA, which serve to create an equivalent level of accreditation. Corresponding to this function, EA has until now been linked with the national authorities and the Commission by means of the EA Advisory Board (EAAB)[186]. The Board is to guarantee that the interested groups have sufficient influence on the accreditation policy of EA and

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182 See in this regard the reference in the position paper from eurolab No. 2/2000 "What conformity assessment operators expect from accreditation", March 2000, under 2. (p. 5 above,), it primarily addresses guidelines from IAF and EA, but also national documents; the document is available online at URL: http://141.63.4.16/docs/pos/el_01-01_00_381.pdf (20.3.2006).

183 See e.g. the description of the role of EA in EAAB Terms of Reference, 0 (Background). The document is available online at URL: http://www.european-accreditation.org under What is EA ?/EA's structure and organisation/Terms of reference (4.3.2006).

184 The accreditation bodies, which are organized on the basis of private law, are required by the agreement with the government to regularly participate in EA, see Art. 5 of the MoU by UKAS, Art. 4 of the framework agreement with COFRAC and Art. 5 of the agreement between the Dutch government and the RvA [see also Art. 11 para. 1 b) of the agreement]. For the mentioned agreements, see Third Section, C.III.2.b).

185 The current signatories to the MLA from the German accreditation system are DACH, DAP, DATech, DKD and TGA as members of the DAR, but not the recognition and accreditation bodies of the regulatory sphere, see EA-01/08 EA Multi and Bilateral Agreement Signatories; with an indication of the respective areas of accreditation. The document is available online at URL: http://www.european-accreditation.org under Publications/General/Publicity and Information Documents Series 1 (4.3.2006).

186 For information on the composition of the board, which includes representatives of conformity assessment bodies, trade and industry, national authorities and the Commission as well as the standardization organization see above A.I.2.c).

make sure that EA promotes open and transparent conformity assessment during its activities, in particular to the extent that EU law is applied in doing so[187].

Altogether though, the relationship between EA and the Commission resp. the authorities of the Member States is not very close: the significance of EA is reflected neither in the legal foundations at the European level, nor is the participation in EA specifically provided for the accreditation systems of the Member States[188]. From the perspective of the accreditation bodies themselves, it is not legally mandatory[189], even though it is in practical terms imperative for the recognizibility of the accreditation and the statements of conformity. From the perspective of the Member States as well, the role of EA, in particular that of the EA-MLA, in creating trust in the Notified Bodies is not concretely defined by European law.

EA relies on its authority to enforce its demands vis-à-vis the accreditation bodies. It currently draws this authority from the contractual (self-)obligation of the accreditation bodies. To safeguard the effectiveness of the mechanisms to enforce the demands, it is recommandable to put EA's authority vis-à-vis the national accreditation bodies on solid legal footing[190]. If the role of accreditation during the designation procedure is enhanced in the future, it is advisable to make the participation of the national accreditation bodies in EA legally mandatory and also set the legal status of EA vis-à-vis the Commission and the Member States in law.

3. Special organizational forms in individual sectors (medical devices)

Examining the implementational guidelines for the directives based on the New Approach across various branches, it appears that structures have developed at the Community level in individual branches, which focus more on close cooperation between the Designating

187 See EAAB Terms of Reference (Fn. 183), 0.2, 1.2; 3.1.

188 See also CERTIF 2005-16 rev. 2 (Fn. 42), B.3 d), p. 5.

189 Apart from provisions of applicable national law.

190 For the considerations with regard to revising the New Approach see the discussion paper Draft CERTIF 2005-5 (Fn. 28) "The development of the European infrastructure for accreditation"; as well as CERTIF 2005-16 rev.2 (Fn. 42), C.6.4, Annex 5. For the relationship between the national accreditation bodies and EA after the revision of the New Approach see Part Two, C.IV.5.

Authorities than on cooperation between the accreditation bodies. This holds, in particular, for the area of medical devices[191]. The analysis of the designation procedures in the examined countries has confirmed that the accreditation by national accreditation bodies plays a minor role here than in the other areas[192]. As regards the harmonization of the requirements during the designation procedure and the harmonization of conformity assessment, substantial results were attained[193], e.g. concerning the organization of the exchange of experiences and the creation of common rules and procedures for the selection and surveillance of Notified Bodies[194].

However, it has also become evident that the insufficient participation by the national recogniation/accreditation bodies resp. the Designating Authorities in MLAs may be problematic when the international mechanisms for the recognition of certifications fall back on accreditation[195]. Whether it is worthwhile to opt for cooperation between the authorities in the respective branch (instead of using accreditation and the cooperation of accreditation bodies) must first be decided at the European level.

IV. The role of market surveillance within the framework of the New Approach

The authorities of the Member States monitor the market for the emergence of products which do not conform with the requirements of the directives, which do not correctly display the CE-marking or for which the required documentation does not exist. If the au-

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191 On the structures in the medical devices branch see *Soltau* in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12, in particular Rn. 51 et seq.

192 Unlike in other branches, the responsible authorities in the medical devices branch in France and the United Kingdom do not refer to the accreditation from the national accreditation body, but instead conduct the evaluation of the bodies on their own, more in Appendix, First Section, B.I.1; Appendix, Sixth Section, B.II.1.

193 More in *Soltau* in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12, in particular Rn. 51 et seq.; on the exchange of experience between the Notified Bodies and the meaning of the recommendations drawn up in this context see *Höppner* in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 14. See also the extensive guidelines on the implementation of the provisions at URL http://europa.eu.int/comm/enterprise/medical_devices/meddev/ (4.3.2006).

194 See for instance the paper "Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices", MEDDEV 2.10-2 Rev. 1 (April 2001), available online at URL: http://europa.eu.int/comm/enterprise/medical_devices/meddev/2_10_2date04_2001.pdf (6.3.2006).

195 For example, during the conclusion of the MRA with Australia it became apparent that the responsible German designation body (a state authority) indeed was a Member of the DAR, but not a signatory of the relevant MLA; a separate evaluation of the accreditation body was necessary. See the reference to this in *Wloka et al.*, Anerkennung und Akkreditierung (Module 3), Section 2.3.

thorities determine nonconformities, they are obligated to take the necessary measures[196]. Market surveillance by national authorities thus constitutes an essential supplement to the conformity assessment system in the phase after the market entry of the products and/or directly after they are put on the market, which is crucial for the functioning of the market access regime[197]. At the same time, market surveillance is to ensure that all citizens profit from a high level of protection in the internal market. Furthermore, effective market surveillance is in the interest of economic actors as well, because it reveals unfair practices and can hence contribute to equal competitive conditions for firms in the internal market[198].

The task of market surveillance is explicitly attributed to the Member States: they also remain responsible for safety in their area of authority when conformity assessment is used[199]. At the same time, market surveillance is the only point of reference for the activities of the Member States at the product level: the authorities of the Member States encounter the products in the area of market surveillance and there only. However, the market surveillance obligation may not have the effect that the Member States conduct systematic pre- or post market tests. This would run contrary to the principle of the directives based on the New Approach according to which the authorities as a rule must assume that the products are in conformity with the directives. Generally, only random tests are permitted[200]. This shows the crucial significance of the supplier's declarations and the ac-

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196 This obligation is generally derived from Art. 10 ECT, and for the directives based on the New Approach from the "safeguard clauses" of the directives, according to which the Member States take all necessary measures so that the products can only be put on the market and in operation when they fulfil the requirements of the directive and/or do not endanger one's safety and health, see e.g. Art. 2 Directive 93/42/EEC (Medical devices), Art. 2 Directive 97/23/EC (transcribed here with "market surveillance"); see Draft CERTIF 2005-7, Annex, 2; the document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_7.pdf (20.3.2006). See also *European Commission*, Guide ('blue'), 8.1. (p. 53).

197 See the Resolution of the Council from 7 May 1985 on a New Approach to Technical Harmonization and Standardization, EC Official Journal 1985 Nr. C 136, p. 1, Annex II, at the beginning; for the meaning of market surveillance for the functioning of the system, see also COM (2003) 240 final from 7.5.2003,2.5.1, p.17 et seq.; see also CERTIF 2005-16 rev. 2 (Fn. 42), B.4 (p. 6).

198 On the objectives of market surveillance *European Commission*, Guide ('blue'), 8.1. (p. 53), COM (2003) 240 final from 7.5.2003, 2.5.1, p.17.

199 Resolution of the Council from 7 May 1985 on a New Approach to Technical Harmonization and Standardization, EC Official Journal 1985 Nr. C 136, p. 1, Annex II, at the beginning; see also above Fn. 196.

200 Resolution of the Council from 7 May 1985 on a New Approach to Technical Harmonization and Standardization, EC Official Journal 1985 Nr. C 136, p. 1, Annex II, B II.2, see No. 1 of the substantiation. This would contradict the free movement clause of the directives, according to which the Member States

tivities of the Notified Bodies, which make the ultimate and binding decision on market access[201]. With view to their obligation to guarantee a sufficient level of protection, the Member States must find a middle way between respecting the free movement clauses of the directives and ensuring effective market surveillance[202].

If the Member States take measures which limit or prohibit the marketing of a product, they are subject to a Community control procedure, the so-called safeguard clause procedure: according to this a product ban declared by a Member State in the framework of market surveillance must be reported to the Commission. It is only effective, when it is confirmed by the Commission according to a "Community control procedure" (Art. 95 para. 10 EC) with the participation of all Member States and as a rule the manufacturer as well[203]. Until the confirmation is issued, the Member States may only take preliminary measures. If the limiting measure is confirmed, the other Member States are required to take the according measures[204]. If it is determined during the procedure that a technical standard is not sufficient, it may be revoked. If the product risk is based on errors made by the Notified Body, a Member State must re-evaluate its recognition[205]. However in practice, the safeguard clause procedure as used in most directives has turned out to be rather unsuitable, on the one hand due to the long duration of the procedure, and on the other hand due to the fact that the Commission must accordingly deal with extremely difficult technical matters, for which it does not have the necessary expert knowledge; according to the conceptual design of the directives based on the New Approach, it is instead the specialized authorities who have these special skills and knowledge[206].

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do not prevent the marketing of products, which bear a CE-marking and have undergone the required conformity assessment procedures, see e.g. Art. 4 para. 1 Directive 93/42/EEC (Medical devices). For the ban on systematic tests see *Di Fabio*, Produktharmonisierung, p. 65, *Merten*, Private Entscheidungsträger, p. 74, 89.

201 See above B.II.4.d).

202 On the various strategies of market surveillance see COM (2003) 240 final from 7.5.2003, 2.5.4, p. 21 et seq.; differences in the level of surveillance can also be observed, Draft CERTIF 2005-7 (Fn. 196), Annex, 3.

203 In this case the other Member States are required to take the necessary measures. Council resolution on the New Approach (Fn. 61), Annex II B VII 3, p. 7.

204 Council Resolution on the New Approach (Fn. 61), Annex II B VII 3.

205 *European Commission*, Guide ('blue'), 8.3.3. (p. 61).

206 For a more thorough overview of the problems associated with the safeguard clause procedure, see COM (2003) 240 final from 7.5.2003,2.5.4, p. 21 et seq. On its future role CERTIF 2005-16 rev. 2 (Fn. 42), A.4 b), p. 6; C 8.4, p. 25 et seq. and now Art. R31 et seqq. Decision No 768/2008/EC.

The absence of a preventive monitoring instrument in the phase of market entry and the trans-European marketability of the products pose great challenges to the authorities of the Member States, though: this pertains to the creation of information on the products on the market and the formation and preservation of the specialized knowledge required for monitoring. Along with that, resource-related problems emerge for example when establishing inspection capacity and – above all – due to the necessity of coordination of market surveillance at the national and European level[207].

V. EU bilateral agreements on mutual recognition

The European Community uses standardization and conformity assessment not only to facilitate the free movement of goods on the common market, but also within the framework of bilateral agreements with third-countries to promote foreign trade. Currently MRA (Mutual Recognition Agreements) exist with Australia, Canada, Japan, New Zealand, Switzerland, the USA and Israel[208]. We will present how such agreements function and their advantages and disadvantages in the following[209].

1. Mode of operation of the MRA

A classic MRA authorizes the contract parties to subject products to a conformity assessment procedure before their export into the other contracting state in accordance with the legal provisions of the later import state. By consenting to the MRA every importing party

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207 For more on the challenges and initial solution approaches see Part Two, D. To promote cooperation between administrative authorities at the Community level, groups were created for individual directive areas, in which representatives of the market surveillance authorities participated (Administrative Co-Operation – AdCo-Groups). Such groups exist, for example, for directives 73/23/EEC (Electrical equipment designed for use within certain voltage limits), 89/336/EEC (Electromagnetic compatibility), 98/37/EC (machines), 89/686/EEC (Personal protective equipment)), 94/25/EC (Sport boats), 95/16/EC (Lifts), 99/5/EC (Radio equipment and telecommunications terminal equipment) as well as 88/378/EEC (Toys), COM (2003) 240 final, under 2.5.3, p. 20, Draft CERTIF 2005-7 (Fn. 196), Annex 1, 7.2. a) ii. During the revision of the New Approach the proposal has been made to further define the status and aims of these groups as well as their legal foundations and to provide them with a more solid basis for their activities, COM (2003) 240 final , under 2.5.3, p. 20; see also CERTIF 2005-16 rev. 2, 8.3.1 (p. 22).

208 The MRA with Israel has yet to enter the phase of execution; the MRAs with Canada, the USA and Japan are only practiced in two areas; more on the respective MRAs under URL: http://europa.eu.int/comm/enterprise/international/index_en.htm (25.10.2005).

209 See also the country report on Switzerland, Appendix, Fifth Section, B.II, which describes how the Switzerland-EC MRA functions. On the MRAs in greater detail see *Ensthaler et a.l*, Akkreditierung (KAN-Bericht 30), p. 82 et seq.

agrees to acknowledge the results of this conformity assessment so that products can be exported and put on the market of the other contracting party without additional procedures[210]. Conformity assessment procedures are thus conducted according to the law of the respective other contracting party[211]. Therefore, the MRA as a rule does not require the harmonization of the technical provisions of all parties or the recognition of their equivalence[212]. If the provisions are not uniform, the product must be inspected according to the provisions of both contracting parties to be marketable in both countries. The advantage of the MRA is that this inspection can be conducted by one and the same conformity assessment body.

If the provisions are harmonized, the MRA may be taken a step further: an agreement can be made that the products should also be marketable in the importing state on the basis of the provisions on conformity assessment of the exporting state. In such cases the product must only be inspected once. This level has been reached for certain product groups in the Switzerland-EC MRA[213], but altogether this can be viewed as a rare exception; MRA can be used precisely in such situations in which a harmonization of the provisions appears to be unachievable or too complicated[214].

As a rule, MRA consist of a framework agreement, which contains the requirement for mutual recognition. Among other things, the framework agreement regulates the procedure for designating the conformity assessment bodies, whose reports, certificates, etc. must be recognized. In order to determine the professional competence of the bodies, the MRA

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210 For the instruments used by the MRAs see the working paper of the Commission "Commission staff working paper implementing policy for external trade in the fields of standards and conformity assessment: a tool box of instruments", COM SEK (2001) 1570 (de), p. 15; see also the communication of the Commission on a Global Approach, COM (89) 209 final from 15.6.1989, EC Official Journal 1989, No. C 267, p. 26 et seq.

211 *European Commission,* Guide ('blue'), p.71.

212 COM SEK (2001) 1570 (de), p. 15. On the difference between the instruments of harmonization, recognition of the equivalence of the legal provisions and MRA COM SEK (2001) 1570 (de), p. 12 et seq.

213 The agreement on the mutual recognition of conformity assessments between Switzerland and the EC enables market access for products by means of the recognition of declarations of conformity and testing results and/or certificates of conformity. The scope of the agreement comprises the majority of the product areas governed in the EU by the directives based on the New Approach. The Switzerland-EC MRA provides two different levels of mutual recognition, depending on whether the material requirements for the products have been harmonized – e.g. in the medical devices branch – or whether different requirements still exist. More on the Switzerland-EC MRA see Appendix, Fifth Section, B.II.

214 See COM SEK (2001) 1570 (de), p. 18.

primarily refer to accreditation on the basis of the relevant international documents; in this regard, it is deemed important that the accreditation bodies participate in agreements on mutual recognition (MLA) or are otherwise involved in programs for comparison or the exchange of experiences[215]. Means other than accreditation are permitted to certify competence; however, the conformity assessment body must also demonstrate its adequacy by means of comparison with other bodies[216].

The framework agreement is supplemented with sector-specific annexes, which specify the area of applicability of the agreement, e.g. for telecommunications equipment, medical devices, and the like. In the case of the classical MRA, the sector-specific annexes contain a list of the respective legal provisions of the contract parties, which are the basis of the recognizable conformity assessment, as well as a list of the notified conformity assessment bodies, information on the Designating Authorities and, where applicable, further regulations on the procedures for the designation of bodies and additional specifications, for example transitional regulations[217].

2. Difficulties of the MRA

One advantage of bilateral MRA is that the concept of mutual recognition of the results of conformity assessment can be expanded to third-countries and that international commerce can be promoted therewith. However, even if the harmonization of the legal provisions is not necessary, the EU views it as a de facto requirement that the contracting parties operate at a comparable level of technical development and that they have compatible procedures for the authorization of products, a compatible concept of conformity assessment as well as a corresponding infrastructure[218]. Successful MRA are demanding. Along with that, it is not only difficult to negotiate the MRA, but also to create a sufficient basis of trust for its actual implementation, which allows for a transition into the execution phase. For example,

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215 See e.g. the Australia-EC MRA, EC Official Journal L 229 from 17.8.1998, Annex Procedures for the designation and monitoring of conformity assessment bodies, B 6 a; the text of the agreement is available online at URL: http://europa.eu.int/comm/enterprise/international/aus_en.htm (26.10.2005).

216 According to the Australia-EC MRA (Fn. 215), Annex "Procedures for the designation and monitoring of the conformity assessment bodies", B 6 b.

217 See for example the listing in the Australia-EC MRA (Fn. 215), Art. 3 Section 2.

218 See COM SEK (2001) 1570 (de), p. 16, see also p. 17 et seq.; *European Commission*, Guide ('blue'), p. 71 et seq.

the MRA with Israel has yet to enter the execution phase, and the MRA with Canada, the USA and Japan for instance operate in two areas only[219].

C. Standardization and conformity assessment in the international context

The principles of the New Approach presented in Section B serve to promote the free movement of goods within the Community. At the international level as well, standardization and conformity assessment play a significant role in avoiding and dismantling technical trade barriers. Above all, the guidelines of the Agreement on Technical Barriers to Trade within WTO should be taken into account here, as the regulations of the New Approach and national conformity assessment systems must meet their demands.

Standardization and conformity assessment are the subject of consultations of various organizations at the international level, e.g. OECD or UNECE. UNECE has passed a recommendation on standardization and conformity assessment, which contains suggestions for the practical implementation of the guidelines of the TBT agreement and is thereby inspired by the New Approach. These activities can only be indicated here.

I. Guidelines of the agreement on technical trade obstacles

The TBT Agreement within the WTO framework[220] views standardization and conformity assessment from the perspective of avoiding and/or dismantling unnecessary trade obstacles. In the following, only those guidelines and statements in the provisions of the TBT Agreement shall be singled out which are directly relevant for the design of conformity assessment procedures. However, first the aims and the essential regulatory content of the TBT Agreement shall be briefly presented.

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219 The MRA with Australia, New Zealand, and Switzerland are in the phase of execution for the most part. Current information on the different MRA is available at URL: http://europa.eu.int/comm/enterprise/international/index_en.htm (25.10.2005).

220 Agreement on Technical Barriers to Trade (TBT) from 15 April 1994, published, among other places, in EC Official Journal L 336 from 23.12.1994, p. 86 et seq.

1. Aims and essential regulatory content of the TBT Agreement

The TBT Agreement came about during the Uruguay Round through the revision of the so-called *Standards Code*, which had been passed in 1979 during the Tokyo Round and already dealt with standardization and conformity assessment[221]. The TBT Agreement was incorporated into Annex 1 A of the GATT 1994 as a multilateral agreement on the trade of goods and is binding for all WTO Member States[222]. The scope of the TBT Agreement only comprises goods[223].

In the preamble the agreement emphasizes the contribution which international standards and conformity assessment can make towards facilitating trade, but it also refers to the danger that technical regulation, standardization and conformity assessment procedures can lead to the creation of trade obstacles. The agreement attempts to counter this. Starting with the basic freedom of the Member States to autonomously determine the level of protection to be achieved[224], the TBT agreement contains regulations in Art. 2 to 4 on technical provisions[225] and standards, which deal with their development, approval and application[226]. Art. 2.1 of the TBT Agreement standardizes a ban on discrimination (most favoured nation clause and the principle of national treatment)[227]. According to Art. 2.2 of the TBT Agreement, technical provisions with the intention of creating unnecessary trade barriers may not be approved. They must pursue a justified objective and may not be de-

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221 So-called Tokyo Standards Code or TBT 1979, the name of the agreement was "Agreement on Technical Barriers to Trade" (Document Number LT/TR/A/5); the document is available online from the WTO at URL: http://www.wto.org/english/docs_e/legal_e/tokyo_tbt_e.pdf (27.2.2006). See *Jessen/Gehring* in: Hilf/Oeter (eds.), WTO-Recht, § 20 Rn. 8 et seq.; *Wiemer*, Produktsicherheit, p. 46 et seq.

222 *Jessen/Gehring* in: Hilf/Oeter (eds.), WTO-Recht, § 20 Rn. 13; *Wiemer*, Produktsicherheit, p. 45.

223 Services are not included, see Art. 1.3 of the TBT Agreement; see also *Jessen/Gehring* in: Hilf/Oeter (eds.), WTO-Recht, § 20 Rn. 16. By contrast the definition of "product" in Section 3.3 DIN EN ISO/IEC 17000:2005, according to which services form one of the categories of products. On the concept of goods in the TBT, see *Wiemer*, Produktsicherheit, p. 45, 185, 190 et seq.

224 See the preamble of the TBT Agreement.

225 In the terminology of the agreement this pertains to legally binding provisions, see Annex I No. 1 of the TBT Agreement, see also *Jessen/Gehring* in: Hilf/Oeter (eds.), WTO-Recht, § 20 Rn. 18.

226 Art. 2 pertains to the development, approval and application of technical provisions by bodies of the central government, Art. 3 contains supplementary regulations for local governments/administrations or non-state bodies; according to Art. 3 the Member States are obligated to take necessary measures which guarantee compliance with the obligations at these levels as well.

227 More in *Wiemer*, Produktsicherheit, p. 196 et seq.

signed to restrict trade any more than necessary[228]. Art. 2.4 of the TBT Agreement stipulates that the Member States are to use international standards as the foundation for technical provisions, as long as they exist and are suitable.

Articles 5 to 9 of the TBT Agreement contain the specifications on the conformity assessment procedures, and the following articles concern the notification procedure for technical provisions, standards and conformity assessment procedures as well as the institutional framework and the settlement of disputes. Appendix 3 of the agreement contains a code of behaviour for the development, approval, and application of standards by the standardization organizations.

2. Guidelines and statements with regard to the structure of conformity assessment

Art. 5.1 of the TBT Agreement stipulates a ban on discrimination for conformity assessment, which is further elaborated on in paragraph 2[229]. Art. 5.1.2 of the TBT Agreement contains a parallel provision on Art. 2.2, according to which conformity assessment procedures may not be applied with the intention or effect of creating unnecessary trade obstacles. They may not be more strict than necessary in order to allow the importing Member State adequate trust in the conformity of the goods with the applicable technical provisions and standards, but the potential dangers of the product are to be taken into account.

According to Art. 5.4 of the TBT Agreement the Member States must ensure that existing directives and recommendations of international standardization organizations are made the basis of the conformity assessment activities during procedures which call for proof of compliance. According to Art. 5.5, the conformity assessment procedures should be harmonized to the greatest possible extent.

One must emphasize Art. 6 of the TBT Agreement, which calls on the Member States to facilitate the recognition of the results of the conformity assessment procedures of other Member States to the greatest possible extent, as long as they are convinced that these pro-

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228 More in *Wiemer*, Produktsicherheit, p. 221 et seq.

229 For example, with regard to the sequence of processing applications (Art. 5.2.1), the processing period (Art. 5.2.2), fees (Art. 5.2.5) etc.

cedures "offer an assurance of conformity with applicable technical regulations or standards equivalent to their own procedures." (Art. 6.1)[230]. To create this trust with regard to the technical expertise of the bodies, the provision refers to accreditation on the basis of the relevant directives or recommendations of international standardization organizations as a possibility of verification (Art. 6.1.1). Moreover, the Member States are required to demonstrate willingness to enter into negotiations for the conclusion of aggreements on mutual recognition (Art. 6.3) and to allow for the participation of conformity assessment bodies located in other Member States in their conformity assessment procedures. Art. 9 concerns the establishment and participation in regional and international conformity assessment systems.

II. Activities at the international level

At the international level various organisations including the OECD and the UNECE deal with standardization and conformity assessment for the sake of dismantling trade obstacles[231]. The activities of these organizations cannot be presented and evaluated in detail here. However, the reviews and standpoints by business participants, government representatives, etc. contained in the respective publications may offer valuable insights for dealing more thoroughly with the impact of conformity assessment on trade, in particular. Thus, selected publications shall be referred to here:

1. OECD

In the past the OECD has repeatedly offered workshops on standardization and conformity assessment as well as their integration into national regulatory strategies[232]. An example of this is the workshop on the topic "Standards and Conformity Assessment in Trade: Minimising Barriers and Maximising Benefits" in November 2005 in Berlin, which was hosted by BMZ (Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung) and

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230 For this aspect e.g. the Commission Communication on a Global Approach, COM (89) 209 final from 15.6.1989, EC Official Journal 1989, Nr. C 267, p. 26 et seq.

231 The UNECE has 55 Member States, including the countries of Western, Central and Eastern Europe, North America, as well as Central Asia; a list of members is available online at URL: http://www.unece.org/oes/member_countries/member_countries.htm (27.2.2006).

232 On the activities of the OECD, see also *Ensthaler et al.*, Akkreditierung (KAN-Bericht 30), p. 40.

the former BMWA (Bundesministerium für Wirtschaft und Arbeit)[233]. The workshop which primarily served to facilitate the exchange of experience dealt with standardization and conformity assessment as well as their implications for world trade on the basis of examples from several sectors[234].

In a study from the year 2000 an attempt was made to determine the extent to which business enterprises are burdened by expenses, which result by complying with technical requirements and verifying this, in particular due to different technical standards and conformity assessment procedures[235]. Looking at three different product groups (terminal telecommunication equipment, dairy products, and automobile components) and on the basis of interviews with business participants, the study examines trade between the United Kingdom, Japan, and Germany. One result of the study was that the benefit of MLA for the recognition of the results of conformity assessment procedures is evaluated very differently in various sectors, depending on the density of the regulations existing in the sector[236]. It was additionally stressed that the time invested in conformity assessment can substantially contribute to indirect costs, in particular when the products have a short marketing time span, as in the telecommunications branch[237]. Emphasis was also put on the great significance of product requirements, which are not stipulated as legally binding, but are placed on the products by the market[238].

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233 A summary of the consultations and speakers' contributions is available at http://www.oecd.org/dataoecd/19/27/36223999.pdf (10.3.2006). The BMWA has developped into the BMWT (Bundesministerium für Wirtschaft und Technologie).

234 The OECD has made a summary of the consultations and speeches available at URL: http://www.oecd.org/dataoecd/19/27/36223999.pdf (10.3.2006).

235 The study "An Assessment of the Costs for International Trade in Meeting Regulatory Requirements" (TD/TC/WP(99)8/FINAL) is available online at URL: http://www.oecd.org/dataoecd/33/14/1955269.pdf (10.3.2006).

236 OECD, Assessment of Costs (Fn. 235), p. 103.

237 OECD, Assessment of Costs (Fn. 235), p. 103.

238 OECD, Assessment of Costs (Fn. 235), p. 103. For further results, see the summary l. c., p. 102 et seq.

2. The "Recommendation L" of the UNECE

a) Background

Along with other organizations, the UNECE has also dealt with the practical integration of standardization and conformity assessment into technical regulation policies. The work group[239] responsible for technical harmonization and standardization presented a recommendation on standardization policy in October 2002, which contains a proposal for an international model of technical harmonization of technical regulations and the free movement of compliant products[240]. The New Approach and the Global Approach Model likely provided inspiration for essential elements of the proposal.

The recommendation of the UNECE first states that a structural framework has already been created by the provisions of the TBT Agreement, which is to ensure that technical regulation and standardization do not create any unnecessary trade obstacles. The proposed model is to supplement the TBT Agreement by offering solutions for the practical implementation of technical harmonization[241]. In this regard, the recommendation stipulates a series of voluntary principles and procedures for application to certain branches. According to the work group, it is also based on various preliminary activities of other organizations such as the WTO, the OECD, the APEC or ASEM[242].

b) Core elements of the proposal

The recommendation contains the proposal on a "model" for the harmonization of technical regulations and the free movement of compliant products"[243]. The core element of the

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239 Working Party on Technical Harmonization and Standardization Policies, WP 6. Homepage of the WP 6 at URL: http://www.unece.org/trade/ctied/wp6/index_wp6.htm (27.2.2006).

240 UNECE Recommendation "L", An International Model for Technical Harmonization Based on Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards (TRADE/2P.6/2002/7), the document is available online at URL: http://www.unece.org/trade/ctied/wp6/documents/wp6_02/wp6-02-07e.pdf (27.2.2006). The proposal was prepared by an ad-hoc work group of specialists for standardization and regulatory techniques (so-called START-Team), see No. 1 of the document.

241 UNECE Recommendation "L" (Fn. 240), No. 7.

242 UNECE Recommendation "L" (Fn. 240), No. 12.

243 Proposal for a Model for the Harmonization of Technical Regulations and Free Circulation of Compliant Products, UNECE Recommendation "L" (Fn. 240), No. 15 et seq.

model is an agreement on "*Common Regulatory Objectives – CRO*, which interested states may conclude. The agreement must contain a mechanism which enables market access in the participating states for the products which fall under the scope of the agreement and conform to the CRO. With regard to setting product requirements, the recommendation recommends limiting these to "relevant" aspects and structuring them proportionally in terms of the danger stemming from the product[244]. The participating states are supposed to grant market access without additional requests[245].

While developing the CRO, one must inspect whether international standards exist which can be drawn on. If this is the case, the CRO should refer to the standards and specify their use in greater detail[246]. A proposal has been made to add a list of standards to the CRO and adherence to these – in part or in their entirety – is to be equivalent to conformity with the CRO. The CRO may contain a rule of assumption in favour of the fulfilment of these standards[247]. The CRO are also supposed to make regulations on the proof of conformity, preferably using the supplier's declaration (SDoC). More stringent conformity assessment procedures may come under consideration when health and safety issues are of particular relevance. When conformity assessment by a third party is regarded to be necessary, *Recognized Conformity Assessment Bodies – RCABs* are to be utilized. The CRO must contain requirements for the technical expertise of the bodies[248]. The Member States are responsible for market surveillance on their territory and have the right to take non-compliant products off the market. To do so, a safeguard clause procedure (modelled after the directives based on the New Approach) has been proposed[249].

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244 UNECE Recommendation "L" (Fn. 240), Annex B under "Product requirements"; these are similar to the "Essential Requirements" in the directives based on the New Approach.
245 UNECE Recommendation "L" (Fn. 240), No. 15-18.
246 UNECE Recommendation "L" (Fn. 240), No. 24 et seq.
247 UNECE Recommendation "L" (Fn. 240), Annex B under "Reference to standards clause".
248 UNECE Recommendation "L" (Fn. 240), No. 26 et seq., Annex B under "Compliance clause".
249 UNECE Recommendation "L" (Fn. 240), No. 29.

Third Section: Conformity Assessment and Accreditation in other European Countries

The following section summarizes the results from the analysis of conformity assessment policy in France, the Netherlands, Austria, Sweden, Switzerland and the United Kingdom. In the following we shall single out certain issues and present them comparatively[1].

The remarks are based on a comprehensive evaluation of the respectively applicable legal foundations, which to the greatest extent possible take the state of affairs on 1 March 2006 into account, as well as official papers and other information from the involved actors. The conversations and interviews conducted between October and December 2004 with representatives of the responsible ministries, accreditation bodies and conformity assessment bodies were particularly fruitful. The assessments given in the text reflect the state of the discussion at this point in time. The activities to further develop the New Approach were still significantly less advanced at this point in time and were thus only to a limited extent subject of the conducted talks.

The cross-comparison addresses questions which are particularly interesting for the comparison with the German conformity assessment system described in the Fourth Section. Hence, it does not schematically reflect the situation in all analyzed countries, rather concentrates on respective solution approaches which appear to be worthy of emphasis in comparison to the German situation. The focus of the analysis is placed on the regulatory sphere. As the directives based on the New Approach constitute the main area of application of conformity assessment in all countries, their implementation shall be analyzed in particular. The section thus begins with an overview of state interests in the use of conformity assessment, followed by an overview of the procedures of accreditation and designation and/or recognition. The greatest differences in comparison to Germany can be seen in the organization and structure of accreditation, which will be illustrated afterwards. The section ends with several observations on the role of the conformity assessment bodies.

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1 The following is thus an overview which frequently must refrain from a presentation of the context of the described regulations and numerous details. More on conformity assessment and accreditation in the respective countries analyzed can be found in the Appendix.

A. State interests during the use of conformity assessment in the regulatory sphere

The object of analysis in the six countries was, among other things, the question to what extent and in which areas conformity assessment is used in the regulatory sphere and for what purposes. One should first bear in mind that the emphasis is placed on the regulatory harmonized sphere in all countries, in particular during the implementation of the directives based on the New Approach. However, differences can be identified with regard to the incorporation of conformity assessment into the respective regulatory strategy. This was discussed in particular detail in the case of the Netherlands. In the case of the United Kingdom as well one can observe that a conformity assessment policy exists which regards conformity assessment as an element of a regulatory strategy which is supposed to remove the burden from the state and enterprises. Since the assessment of the function and significance of conformity assessment can be detected particularly well in the regulatory approaches of the Netherlands and United Kingdom and because these countries have a – well-documented – *policy* of conformity assessment, the approaches followed there shall be briefly presented[2].

I. Netherlands: conformity assessment as a regulatory instrument

In the Netherlands, conformity assessment procedures in the regulatory sphere have already been in use since the late 1970s. A study mandated by the Ministry of Economic Affairs revealed that at the time of analysis eighty different regulations existed alone in the regulatory sphere which fall back on the instrument of conformity assessment in a different manner[3]. It is noteworthy that the Dutch government has been dealing systematically with various aspects of standardization and conformity assessment since the beginning of the 1990s[4]. The motive for these considerations was, on the one hand, the use of conformity assessment at the European level through the directives based on the New Approach. On

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2 For the approaches of the other countries please refer to the beginning of each Section in the Appendix.

3 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 10.

4 As far as can be seen, the first summarizing document in this context is a report by the Ministry of Economic Affairs from 1995 entitled “Normen, certificaten en open grenzen”, NCOG-Nota. The report was continued by the report “Internationaal is de norm” – IN-Nota; this report is available online at URL: http://192.87.114.76/nl/act/specials/kenb/internationaal.pdf (22.7.2005).

the other hand, conformity assessment was considered to be a potential regulatory instrument during a debate on deregulation as well.

In the Netherlands conformity assessment in conjunction with the free movement of goods is viewed as an important element of economic growth. Thus it is in the interest of the state to promote the certification infrastructure as a whole. This primarily holds with respect to the regulatory sphere, in which the use of conformity assessment additionally has the effect of removing the burden from the state, but also for the non-regulatory sphere. An additional advantage in the regulatory sphere is seen in the fact that the expertise existing among market participants can be used through the instrument of conformity assessment. At the same time firms are relieved of administrative obligations. In this regard conformity assessment systems in the non-regulatory sphere could in turn be of significance for the state, when conformity assessment indirectly promotes objectives which are in the interest of the state, e.g. in terms of environment or health protection[5].

In a cabinet position from November 2003 the government drew up guidelines for dealing with conformity assessment in the future[6]. These are supposed to provide a basic structure, according to which future regulations are to be aligned[7]. A clear division of responsibilities between ministries, the accreditation body and conformity assessment bodies should lead to greater consistency in conformity assessment. The cabinet position accordingly describes three basic options for the use of conformity assessment[8]:

1. Self-regulatory option

The *Zelfreguleringsvariant* (self-regulatory option) comprises forms of conformity assessment regulations which do not originate in the regulatory sphere and primarily pursue private objectives. The conformity assessment does not serve to verify legally required

5 See *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 57.

6 Cabinet position from 14 November 2003, printed in: Kamerstukken Tweede Kamer, vergaderjahr 2003/2004, 29 304, No. 1.

7 A harmonization of the diverse options is to be reached in the medium-term this way. A systematic revision of the existing regulations is not planned. The regulations are to be adjusted to the greatest extent possible when revisions are required.

8 Cabinet position 2003 (Fn. 6), p. 12, 19 et seqq.

demands and is not associated with any legal consequences; participation in the certification programs is voluntary. However, such programs can also serve objectives which are important from the view of the state, e.g. security or health protection[9]. Therefore, the advancement of the certification infrastructure comes under consideration in this area, in particular in order to increase transparency in this service sector and thereby increase the contribution of the certification regulation to the realization of public objectives. In order to promote the trust of the market in certification, an accreditation of the certification body by the Accreditation Council (RvA)[10] is regarded as desirable. This option is supposed to be used when the state trusts in the self-regulatory forces of the market or wishes to take deregulatory measures[11]. The certification schemes for organically grown products are an example of this[12].

2. Option to support surveillance measures

According to the *Toezichtsondersteuningsvariant* (option to support surveillance measures) the participation in the certification program is also voluntary. The certificate functions as evidence that a company has, e.g., paid particular attention to complying with legal guidelines. During approval, monitoring or surveillance measures, the state may call on the presentation of this certificate[13]. According to this option, no recognition or designation of the conformity assessment bodies is supposed to take place through state bodies. However, the certificate is only supposed to be treated as evidence if it was issued by a body which in

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9 These certification regulations are to be distinguished from those which do not even indirectly serve any public concerns, such as a majority of the certifications according to ISO 9001:2000; Cabinet position 2003 (Fn. 6), p. 20.

10 Raad voor Accreditatie; more on the Dutch accreditation body in Appendix, Second Section, D.

11 Cabinet position 2003 (Fn. 6), p. 12, 20.

12 For example the certification of organically grown products by Skal. More on this in *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 56 et seqq. Skal certifies agrarian products on the basis of different certification schemes; among other things according to the EC-Organic foodstuffs regulation (Council Regulation No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs), besides this on the basis of a certified scheme for organically grown products and a certification scheme from the voluntary sphere, which is regulated by Dutch law, see Skal at http://www.skal.nl/ (24.7.2005) under “Accreditation”. Whether the cabinet position calls for the state to promote certification schemes to the extent that a legal framework is created for voluntary schemes remains to be seen. However, a difference to the *Toezichtsondersteuningsvariant* (see 2. for this) also exists in the case of legally stipulated certification schemes, because according to the *Zelfreguleringsvariant* the transparency created by the certification primarily serves the consumer and the state does not attach any legal consequences to the existence of the certificate.

13 Cabinet position 2003 (Fn. 6), p. 20.

turn was accredited by the Dutch accreditation body RvA[14]. One specified motive for the use of this option is that the certification provisions contribute to making the market participants more aware of the demands on their product and enabling more effective state surveillance[15]. The certification according to ISO 14001 and EMAS in the environmental sphere is mentioned as an example of this[16].

3. Authorization option

The *Toelatingsvariant* (authorization option) comprises regulations for which the certification is required as proof of legally stipulated demands[17]. The certificate can be an obligatory requirement to begin a certain activity or to substantiate an assumption that the legal requirements have been fulfilled. A distinction is made between two sub-options, the *onvoorwaardelike* (approximate meaning "unconditional") and the *voorwaardelijke* (approximate meaning "conditional")[18]. According to the "unconditional" option, state bodies only examine by means of surveillance measures whether the certificate exists[19]. The properties or abilities which are regarded as proven by the certificate are no longer tested[20]. As for the "conditional" option, the certificate provides a (disprovable) assumption that the legal requirements have been fulfilled. Here, the monitoring/surveillance (*nalevingstoezicht*) can be aimed at establishing whether the requirements which are inspected during the certificate have in fact been fulfilled. This option is used, in particular, during the implementation of the directives based on the New Approach in product safety law. According to both sub-options, the certificate bodies are designated by the responsible minister on the basis of legally stipulated requirements[21]. To increase the state's trust in the

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14 Cabinet position 2003 (Fn. 6), p. 20.
15 Cabinet position 2003 (Fn. 6), p. 20.
16 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 91.
17 Cabinet position 2003 (Fn. 6), p. 12, 21.
18 The options differ according to the focus of potential surveillance measures, more on this in an instant.
19 According § 2 Art. 7.32 para. 2 of the Arbeidsomstandighedenbesluit (work conditions resolution), for example, the crane operator must always carry the certificate.
20 Similar to a driving licence, it is thus only inspected whether a valid proof of ability exists, not whether its holder actually (still) has the certified abilities.
21 Cabinet position 2003 (Fn. 6), p. 21.

results of the certificate activities, the state must watch over or monitor the quality of the activities of the certification bodies[22].

These three options already demonstrate different forms of use of conformity assessment in the regulatory sphere: on the one hand, the promotion of certain regulatory objectives by means of (voluntary) conformity assessment procedures, on the other hand removing the burden from the state in the execution of tasks, e.g. during (facility) surveillance or by refraining from preventive state controls, for instance when regulating market access for products[23].

II. United Kingdom: economic policy standpoint and co-regulation

In the United Kingdom emphasis is placed on the economic policy significance of conformity assessment and its incorporation into the regulatory strategy of co-regulation[24]. Conformity assessment is seen as an element to create trust among customers in products and services, to increase the competitiveness of the economy, and to facilitate trade, both at the national and international level. It creates the necessary link to standardization, which is also strongly viewed from an economic policy perspective and promoted accordingly[25]. This way, conformity assessment becomes an indispensable component of the national infrastructure in the areas of economy, technology, and standardization[26]. Similar to standardization, conformity assessment is also a suitable component of a regulatory strategy which refrains from strict guidelines to the greatest possible extent and focuses on the ele-

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22 Cabinet position 2003 (Fn. 6), p. 22. For example, Art. 7b of the Warenwet (Goods law) stipulates that the responsible minister monitors whether the bodies conduct their activities purposefully and in accordance with the law. According to Art. 7d of the Warenwet the minister can give general instructions to the body.

23 For the different functions of conformity assessment from the German perspective, see First Part, Fourth Section, A.VI, more general Part Two, A.I.

24 For the basic principles of conformity assessment policy in the United Kingdom see the paper published by the Department of Trade and Industry (DTI), "Conformity Assessment Policy in the United Kingdom", May 2005, URN 05/1241, available online at URL: http://www.dti.gov.uk/strd/capp0505.pdf (26.7.2005).

25 DTI, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 4. A reference is made there to the National Strategic Standardisation Framework (NSSF), which is supplemented by the conformity assessment policy. For a summary of the NSSF see the strategy paper at URL: http://www.nssf.info/resources/documents/NSSF_Strategy.pdf (11.8.2005) as well as in general at URL: http://www.nssf.info (11.8.2005).

26 See DTI, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 1, 4.

ment of co-regulation. It is thus emphasized that the conformity assessment in the regulatory sphere does not place an additional burden on the firms, but instead should promote economic activity[27]. To this extent, the New Approach with its elements of the reference to standards and self- and third-party certification fits well into the national regulatory strategy[28].

Conformity assessment is primarily used in the areas covered by the directives based on the New Approach, but it also comes under consideration for the national, non-harmonized sphere. It is emphasized that one should resort to the infrastructure developed in the non-regulatory sphere to the greatest extent possible during the use of conformity assessment to support state regulation[29]. By principle, the conformity assessment bodies should be able to offer their activities in competition with one another and on a free market[30]. The positioning of conformity assessment in the private sector and contracts as a basis of the legal relationships – e.g. between the conformity assessment bodies and their clients or between the accreditation agency and the conformity assessment bodies – are regarded as strong points of the system, which should be maintained.

B. Designation and accreditation in the regulatory sphere

During the examination of the guidelines of the directives based on the New Approach it was already pointed out that the directives only stipulate Essential Requirements, which the Member States must inspect during the designation of the bodies. The procedures and the organization of the designation procedures and continual inspection of the bodies were

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27 See for example the emphasis on the economic advantages of conformity assessment and the simultaneous warning about potential obstacles to trade and innovations in: DTI, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 1, 2, 4.

28 Before the introduction of the directives based on the New Approach in the product safety law there apparently was no comprehensive system of caveats to licence or other obligatory security inspections. The English law on consumer goods safety traditionally focused on voluntarily following Safety Regulations, which was only safeguarded by penal sanctions. A clause, according to which only safe products could be put on the market, existed since 1974 for work health and safety in the Health and Safety at Work Act 1974, while for consumer protection it was introduced with the Consumer Protection Act 1987. For consumer goods safety it has been shown that consumer protection policy approaches were always closely linked with deregulatory approaches, through which unnecessary burdens and expenses for the British economy were to be avoided. See *Joerges/Falke/Micklitz/Brüggemeyer*, Sicherheit von Konsumgütern, p. 106 et seqq., in particular p. 115, 115 et seqq.

29 DTI, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 2.

30 DTI, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 2.

left up to the Member States to a great extent. As a result, differences in the designation procedures of the Member States have emerged, in particular with regard to the use of accreditation[31]. In the following an attempt is made to offer a descriptive summary of the role of accreditation for the procedures of recognition and designation of bodies. It was also pointed out that the specification of the relationship between the requirements laid down in the harmonized standards and the criteria to be inspected during a designation or accreditation frequently poses difficulties[32]. The solutions for dealing with this shall also be presented in an overview. The basis of the analysis is a selection of the respective currently applicable legal foundations for the designation or recognition of the bodies[33].

I. Function of accreditation in the designation procedure

The designation or recognition of bodies is incumbent upon a state agency in all countries, which as a rule is the responsible ministry or an agency subordinate to it[34].

The extent to which the agencies rely on the accreditation or take it into account varies:

- In Switzerland accreditation as a procedure to evaluate the competence and adequacy of the bodies plays a decisive role, both in the domestic sphere as well as for the purpose of international agreements. According to Art. 18 of the Law on Technical Trade Obstacles (Gesetz über technische Handelshemmnisse - THG), accreditation is indeed not the only means to demonstrate competence – according to Art. 18 para. 1 letter c) of the THG other procedures may also come under consideration. However, according to the Dispatch on the THG this shall only concern certain areas in which accreditation is not

31 See above Second Section, B.III.1.

32 See above Second Section, B.III.1.b).

33 Once again this is a summarizing overview, which cannot comprehensively address the context of the regulations; a more thorough presentation can be found in the Appendix.

34 One exception with regard to the responsibility of area-specific ministries or agencies is Sweden, because here the national accreditation body as a state agency is also responsible for the designation and notification of the bodies to the EU and conducts an inspection (*bedömning*) of the competence of the bodies in this framework. The participation of the area-specific authorities is ensured by the fact that they are able to participate in the assessment procedure, more in the Appendix, Fourth Section, B.II.

possible or appears to be disproportionate from an international comparison[35]. The regulation in the Accreditation and Designation Decree (Akkreditierungs- und Bezeichnungsverordnung - AkkBV)[36] and the area-specific laws frequently distinguishes itself by the fact that the accreditation by the state accreditation body is not followed by an additional decision by an area-specific agency on the recognition[37]. By these means the assessment of the competence and adequacy of the bodies is concentrated within the Swiss accreditation body SAS. The consideration of potential special requirements of the regulatory sphere is ensured by the incorporation of the area-specific agencies into the accreditation procedure[38]. In practice, the designation of the bodies in the framework of MRA with third countries is also generally based on an accreditation by the SAS.

- In Austria the accreditation law (Akkreditierungsgesetz - AkkG) in conjunction with the area-specific laws stipulates the requirements for conformity assessment bodies within the framework of official procedures to assess the competence of testing, inspection, and certification bodies. The means by which the accreditation by the accreditation body of the Federal Ministry for Economy Affairs is incorporated varies. The regulations on the designation or recognition of conformity assessment bodies in the area-specific laws generally refer to the accreditation according to the Austrian accreditation law, subject to more specific regulations in the area-specific laws[39]. In summary, it can be stated that the legal provisions require an accreditation of the bodies (e.g. laws governing trade and industry, medical devices law) or at least an inspection comparable to the accreditation according to

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35 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995, 95.013, p. 521 et seqq., p. 607.

36 In the Switzerland-EC MRA the term “designation” (Bezeichnung) is used for the recognition of bodies for activities in the scope of this agreement, see Appendix, Fifth Section, A.III.

37 For instance the ordinance on the safety of technical facilities and equipment (Verordnung über die Sicherheit von technischen Einrichtungen und Geräten - STEV) only stipulates that the involved conformity assessment bodies must be accredited (or authorized by other means); a recognition procedure which draws on this accreditation is not provided for, Art. 6 para.. 1 STEV. The same regulatory mechanism can be found, for example, in Art. 11 para. 1 of the medical devices ordinance (Medizinprodukteverordnung - MepV).

38 Art. 11 AkkBV.

39 § 71 para. 5 clause 1 GewO, for example, states that bodies approved by the Federal Ministry for Economic Affairs and accredited according to the accreditation law are to be authorized for inspection, whether the machines, devices, equipment, etc. fulfil the requirement stipulated by the ordinance. According to § 36 para. 2 of the MPG a prerequisite for designation in the medical devices sector is that the body has been accredited by the Federal Ministry for Economic Affairs for the corresponding areas of activities according to the accreditation laws.

the AkkG (e.g. regulations of the boiler law)[40]. At the same time, the provisions frequently contain their own regulations on the requirements for conformity assessment bodies. In such cases it is not always easily recognizable whether these requirements exceed those of the accreditation law or the relevant European directive.

- In France the accreditation by the national accreditation body COFRAC is not always a legally binding prerequisite for designation and notification. In practice, though, this is done very frequently. Whether an accreditation is requested is decided by the responsible ministry or the relevant area-specific law[41]. One would welcome a European regulation which would require the accreditation as a prerequisite for notification. Currently the approaches of the different ministries vary, sometimes even within the same ministry[42]. Sometimes the relevant legal foundations do not refer to the accreditation at all, other times they contain a rule of assumption in favour of accreditation – sometimes with explicit mention of COFRAC. As for medical devices, the agency responsible for the designation, Afssaps, does not fall back on the accreditation, rather carries out the inspection of the bodies on its own[43].

- In the United Kingdom the DTI and the majority of the other ministries mandate UKAS to conduct the evaluation of the competence and independence of the bodies[44]. The DTI and other ministries in cooperation with UKAS have developed *guidelines* for the regulatory sphere, upon which UKAS bases its assessment of the bodies to be notified[45]. A separate accreditation by UKAS according the series of standards EN 45000 is explicitly recommended, but is not a binding requirement for recognition and notification[46]. After the inspection of the body, UKAS offers a recommendation on the basis of which the respon-

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40 For more see the Appendix, Third Section, B.I.2.

41 With this, France sees itself in accordance with the legal situation in Europe, as the directives based on the New Approach also do not – yet – prescribe the accreditation as compulsive.

42 For a more detailed overview of selected legal situations, see Appendix, First Section, B.I.

43 Art. R5211-54 Code de la Santé Publique, more in the Appendix, First Section, B.I.1.

44 DTI, Assessment of Applicants for Appointment as Notified Bodies; Monitoring of Notified Bodies; and Surveillance/Assessment of Manufacturers by Notified Bodies: Some Principles, December 1998, p. 1; available online at URL: http://www.dti.gov.uk/strd/nbprin.pdf (27.7.2005); quoted in the following, DTI, Assessment of Notified Bodies; for a comparison of the other ministries see the overview in: UKAS, Assessment of approved and notified bodies (P 16), Edition 9, May 2004, Annex (p. 3 et seq.) available online at URL: http://www.ukas.com/Library/downloads/publications/P16.pdf (27.7.2005).

45 For the meaning of the guidelines see below II.

46 DTI, Assessment of Notified Bodies (Fn. 44), p. 1, 2.

sible ministry decides on the designation and notification. However, not all ministries resort to UKAS for the assessment of the competence and independence of the bodies. The Department of Health, Medicines and Healthcare, which is responsible for medical devices, has transferred this task to a subordinate agency, the Medicines and Healthcare products Regulatory Agency (MHRA)[47].

- The Dutch government maintains an agreement with the Dutch accreditation body, RvA, which stipulates the mutual rights and obligations[48]. The agreement specifies that in the future every recognition or designation is to be preceded by accreditation or an assessment by the RvA[49]. The agreement conceives *accreditation* as an inspection by the RvA based on European or international norms, and an *assessment* as an inspection by the RvA on the basis of the criteria stipulated by the responsible minister[50]. The inspection report of the RvA should play a significant role in the decision of the responsible minister on the recognition of the body[51]. However, it is not compulsory for the ministry during the designation or recognition[52]. The guidelines for dealing with conformity assessment in the future which are laid down in the cabinet position from 2003 also contain statements on the use of accreditation according to the respective option[53]. According to the self-regulation option accreditation is regarded as desirable. As for the option to support surveillance measures, the certificate shall only be attributed a legally advantageous indicative effect if

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47 MHRA is a state agency; it has the status of an Executive Agency of the Department of Health. MHRA is also responsible for the designation and notification of the bodies; see Appendix, Sixth Section, B. II. 1, in particular Fn. 16.

48 Ministerie van Economische Zaken, Raad voor Accreditatie, Overeenkomst Staat – Raad voor Accreditatie, available online at URL: http://www.rva.nl/pdfdoc/30062005.pdf (3.7.2005); quoted in the following as “Overeenkomst”. For more information on the agreement see below C.III.2.b) and Appendix, Second Section, D.III.

49 Overeenkomst (Fn. 48), Toelichting under “Europese context”, p. 12. In the areas of application of conformity assessment analyzed in the study by the University of Tilburg this was until now for the most part, but not exclusively the case, *Eijlander/Evers/van Gestel*, Certificatie en accreditatie p. 19 et seq., 59 et seqq., in particular 63 et seqq.; more on this in the Appendix, Second Section, A.II.1.

50 More on this distinction in Appendix, Second Section, B.III.3.

51 Overeenkomst (Fn. 48), Section 2 para. 5 clause 3, Toelichting under “Bestuurlijke status van de RvA” (p. 13).

52 This provision is likely due to the fact that a classification of the activities of the RvA as sovereign is avoided in these cases and the decision for recognition constitutes the definitive legal act in the relationship between the state and the body to be recognized. See Overeenkomst (Fn. 48), Toelichting under "Bestuurlijke status van de RvA" (p. 13). Otherwise the RvA would also have to be classified as an administrative organ when the argument that the conformity assessment bodies conduct a public activity is taken as a basis.

53 For the options above A.I.

it has been issued by a body which is itself accredited by the Dutch accreditation body RvA[54]. With regard to the authorization option, which applies in particular to the designation of bodies within the framework of the directives based on the New Approach, the accreditation or assessment by the RvA is also provided for and already takes place today[55].

- In Sweden the assessment of the competence of conformity assessment bodies is always conducted by the Swedish national accreditation body SWEDAC[56]. This applies regardless whether the competence assessment is carried out for the purpose of notification of a body to the EU or whether an accreditation in the regulatory non-harmonized sphere is concerned. There is no need to structure the accreditation by the national accreditation body as a prerequisite for a state designation. In order to be designated, bodies require no previous accreditation by SWEDAC by means of a special procedure[57]. If an accreditation already exists, it is assumed that the body fulfils the respective requirements[58]. If no accreditation exists, SWEDAC conducts an assessment of the competence and adequacy of the body which corresponds with the inspection during the accreditation procedure[59]. As activities exclusively in the regulatory harmonized sphere are often not worthwhile for the bodies from an economic standpoint and the requirements often correspond with each other anyway, Notified Bodies often have one or several accreditations from SWEDAC as well.

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54 Cabinet position 2003 (Fn. 6), p. 20, see Appendix, Second Section, B.I.2.

55 For the assessment criteria, see below II as well as the Appendix, Second Section, B.III, in particular 3.b) (i), for the directive- and law-specific accreditation criteria.

56 SWEDAC is a state agency which is associated with the Ministry for Foreign Affairs. More on SWEDAC in the Appendix, Fourth Section, C. By way of exception, the responsibility for the designation lies with the government when a state agency applies for the designation. In this case SWEDAC also carries out the competence assessment, while the government makes the decision on the designation, though, § 5 para. 2 Förordning (2005:894) om teknisk kontroll.

57 See the justification for the bill for the Lag (1992:1119) om teknisk kontroll, Prop. 1991/92:170, p. 55; *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives, Section "Background and legal base", online at URL: http://www.swedac.se/sdd/swinternet.nsf/webAttDoc/ADMR-64ZHF3/$File/Notified%20bodies.pdf (28.4.2005), Section "Assessment procedure" at the end.

58 § 4 para. 2 clause 2 Lag (1992:1119) om teknisk kontroll.

59 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 57), Section "Assessment procedure" at the end.

II. Relationship between the harmonized norms and the criteria for recognition and designation

One difficulty in the use of accreditation during the designation procedure consists in the specification of the relationship between the requirements specified in the directives and the general criteria of the series of standards EN 45000 et seqq. or EN ISO/IEC 17000 et seqq.[60]. Accreditation on the basis of these standards always implies that the general criteria are supplemented in order to be further specified for the technical area for which the conformity assessment body applies for accreditation[61].

Some countries have reacted to this difficulty by drawing up directive- and law-specific accreditation standards for the regulatory sphere. This holds, for example, for the *Risa* and *Wesa*, which have been used up to now in the Netherlands. In this case special accreditation programs were developed for several areas within the framework of an agreement between the responsible ministry and the RvA, which were tailored to the criteria of the directives (Risa) or the national laws (Wesa). The agreement between the RvA and the government (see above I.) also stipulates that the assessment of bodies in the regulatory sphere by the RvA must be conducted according to criteria defined by law (or statutory instrument). The criteria are to be defined by the responsible minister and can take particular requirements of the regulatory sphere into account. They should be based to the greatest possible extent on internationally harmonized accreditation standards[62]. The Risa and Wesa are revised for this and are given a new denomination.

In the United Kingdom the DTI and other ministries in cooperation with UKAS have developed *Guidelines*, which UKAS takes as a basis when assessing the bodies to be notified. To fulfil the Essential Requirements of the directives, the *Guidelines* refer to the *relevant* requirements of the standards, thus not to the standard or standards as a whole. They con-

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60 See above Second Section B.III.1.

61 According to the summary on this problem in Draft CERTIF 2005-6 “Accreditation in support of designation of notified bodies” from 6/17/2005, under 1.2, p. 2 f; the document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/certif_2005_06.pdf (15.3.2005). See also *European Commission*, Guide (‚blue’), 6.1, p. 41 et seq.

62 *Overeenkomst* (Fn. 48), Section 1 lit. c., *Toelichting* under *Afstemming activiteiten* (p. 12). More in the Appendix, Second Section, B.III.3.

cretize the minimum criteria of the directives for designation and put the conformity assessment activities in relation to the relevant EN45000/ISO17000 standards, to the Essential Requirements for health and safety (in the directives) and to product standards, to the extent that they exist. The *Guidelines* make it clear that the accreditation is not mandatory, but do use the standards of the series EN45000/ISO17000 as a basis for assessment. UKAS is supposed to carry out its assessment on the basis of the requirements of the *Guidelines.* It is supposed to draw up an evaluation of the body applying for designation with regard to its compliance with the requirements of the *Guidelines* and also submit a recommendation on the competence of the applicant to the responsible authority, in particular with respect to the special obligations in the conformity assessment procedure and the requested work area[63].

For the accreditation rules used by SWEDAC, please refer to the Appendix, Fourth Section B.IV; for the accreditation requirements of the Swiss Accreditation body SAS, see the Appendix, Fifth Section, B.IV; for France Appendix, First Section, B.II.1 and Austria, Appendix, Third Section, B II. 2.

III. Surveillance of the Notified Bodies

Generally, the continual surveillance of the Notified Bodies is based, above all, on the regular inspection of the bodies carried out by the national accreditation body during the accreditation process. In some cases and in some countries, the area-specific laws and/or designation decisions of the bodies can subject the bodies to further obligations with regard to surveillance[64]. These include, for example, admittance of the Designating Authorities to the offices of the bodies, monitoring rights when carrying out witness audits or the obligation to annually present an activity report, which provides the responsible authorities an overview of the activities of the body and can also serve as a point of reference for potential further measures[65].

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63 More in the Appendix, Sixth Section, B.II.2.

64 For example for France see the Appendix, First Section, B.III, for the United Kingdom the Appendix, Sixth Section, B. II. 3.

65 This holds, for instance, for the Netherlands, France, or Austria; for the Netherlands in particular, see the Appendix, Second Section B.III.4 (b), for France Appendix, First Section, B. III. For potential future ex-

C. Organization and incorporation of the accreditation body

The greatest differences in comparison to Germany can be found in the organization and incorporation of the accreditation body. The analyzed countries have a national accreditation body, which provides a comprehensive accreditation offer in the regulatory and non-regulatory sphere and in the various sectors. The accreditation bodies are either based in state agencies or organized on the basis of private law; in the latter case they are associated with the state or individual ministries by means of agreements. They have a unique status at the national level and are integrated into the international structure of accreditation via EA as well as IAF and ILAC.

I. A national accreditation body

First of all, it can be ascertained that all analyzed countries have opted for the establishment of only one national accreditation body, which offers accreditation for the regulatory and non-regulatory sphere[66]. The organizational separation of the accreditation systems, as has evolved in Germany[67], is unusual from a foreign perspective, and the reasons for this appear to be difficult to fathom. One of the mentioned advantages of a uniform and/or single accreditation body active in both areas is that this particularly promotes transparency as an important function condition of the system as a whole[68]. Furthermore, it allegedly ensures for both areas that the accreditation rules can be kept in line with modern technology and that it promotes a uniform interpretation of the requirements[69]. Finally, economic reasons are mentioned, in particular that accreditation can also be offered in those areas in which the demand is not that great, making accreditation cost-effective.

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tension of such obligations see CERTIF 2005-16 rev. 2 "Elements for a horizontal legislative approach to technical harmonisation", 6.1.a) from 23.2.2006, Item 5.4 p.15; the document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_16_rev_2.pdf (15.3.2006). See as well Part Two C.IV.5.

66 For the role of the state in accreditation, see below C.III.1. For more on the tasks of the accreditation body, see for France Appendix, First Section, C; for the Netherlands Appendix, Second Section, D; Austria Appendix, Third Section, C; Sweden, Appendix, Fourth Section, C; for Switzerland, Appendix, Fifth Section, C and for the United Kingdom Appendix, Sixth Section, C.

67 See Fourth Section, B.I.

68 See Appendix, Second Section, D.I.4 a) – Netherlands, see also Appendix, Sixth Section, C.I.3 – United Kingdom (on the "recognizibility" of the accreditation when used internationally).

69 See Appendix, Second Section, D.I.4 a) – Netherlands; Sixth Section, C.I.3 – United Kingdom.

II. Organization of the accreditation body

As for the organization of the accreditation body and its association with the state, two basic models can be differentiated. In Austria, Switzerland, and Sweden, accreditation is structured as a public activity of a state agency. The Austrian accreditation body is based directly in the ministry[70]. The Swiss accreditation body SAS is also organized as a part of an agency. Up to now, it was incorporated as a department of the Federal Office for Metrology and Accreditation (metas). Since April 2006 it is directly subordinate to the State Secretary for Economic Affairs (seco)[71]. SWEDAC is an independent, but state agency, which is associated with the Ministry for Foreign Affairs[72]. In the remaining states the accreditation bodies are organized on the basis of private law, for example in the form of a registered association - *association déclarée* (COFRAC), a non-profit-distributing company, limited by guarantee (UKAS) or a foundation (RvA). Accordingly, the legal relationship between the accreditation body and the conformity assessment bodies is governed by public law in the case of the Austrian BMWA, the SAS and possibly SWEDAC as well, whereas in the case of COFRAC, UKAS and RvA it is governed by private law.

The accreditation bodies governed by private law were created by the merger of several accreditation bodies, which were previously active in various areas of accreditation. France, for example, first had accreditation systems for testing laboratories in the Réseau national d'essais (RNE) and for calibration laboratories in the Bureau national de métrologie (BNM-FRETAC)[73]; these were merged with the establishment of COFRAC. The RvA developed in 1995 from a merger between the *Raad voor Certificatie* and the foundation

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70 See the statements on the government bill for accreditation law, quoted according to *Österreichisches Normungsinstitut (ON)*, Akkreditierungsgesetz, p. 15.

71 The type of incorporation into *metas* led to concerns with regard to the impartiality of the accreditation body and the corresponding requirements of the ISO/IEC Standards 17011t. On 1.4.2006 the SAS was transferred as a unit from the *metas* to *SECO*. The former Federal Office for Metrology and Accreditation was renamed into Federal Office for Metrology (METAS); see the Decree on the Modification of the Accreditation and Designation Decree (Verordnung zur Änderung der Akkreditierungs- und Bezeichnungsverordnung - AkkBV) from 10.3.2006, AS 2006, 1089, Section I, Art. 5 para.. 1; Section III No. 1. See also the Appendix, Fifth Section, C.I.

72 SWEDAC, SWEDAC's Duties, URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html. One particularity is that SWEDAC in its role as the accreditation body is also responsible for the designation of bodies to the EU.

73 *Couret/Igalens/Penan*, Certification, p. 19.

NKO/STERLAB/STERIN (NSS)[74]. The merge of the bodies was encouraged and promoted by the ministry for economic affairs[75]. In the United Kingdom the government itself initially maintained an accreditation system with an accreditation body for inspection and calibration laboratories and an accreditation body for certification bodies[76]. In 1995 a decision was made to establish a uniform accreditation body, which is not based within state agencies, but still maintains close relations with the government.

III. Responsibility of the state for accreditation

Two types of questions arise with regard to the responsibility of the state for accreditation: on the one hand, it must be decided whether and to what extent the state should promote accreditation or even offer it itself by means of a state agency. On the other hand it must be clarified to what extent the accreditation must be associated with the state in order to guarantee the state sufficient influence on the accreditation. This holds in particular when the state falls back on the accreditation for the recognition and/or designation in the regulatory sphere.

1. Role of the state in accreditation

When examining the functions of accreditation it was already pointed out that the accreditation must be conducted in an impartial and objective manner in order to create trust in the quality of the accredited conformity assessment[77]. Impartiality and objectivity are characteristics which are generally attributed to state organizations[78]. The state can thus serve as a

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74 The NSS in turn originated as a result of the merger between the Dutch Organization for Calibration (Nederlandse Kalibratie Organisatie – NKO) and STERLAB/STERIN, an accreditation body for laboratories and inspection bodies; *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 59.

75 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 59.

76 DTI, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 4 et seq. The accreditation of inspection and calibration laboratories was carried out by the National Measurement Accreditation Service (NAMAS), a department of the National Physical Laboratory, which itself was subordinate to the DTI. The National Accreditation Council for Certification Bodies (NACCB), which formally constituted a committee of the BSI, was responsible for the accreditation of certification bodies. An accreditation body for inspection bodies did not exist. UKAS originated from NAMAS and NACCB at the initiative of the DTI.

77 See above Second Section, A.I.1.

78 The fact that the accreditation body must have sufficient authority to enforce the demands placed on the conformity assessment bodies also is related to this. The international norms therefore describe accredita-

point of reference for the accreditation and contribute to creating credibility for the entire system of conformity assessment, by offering accreditation by a state agency or at least by providing state controls[79]. The credibility of the results of conformity assessment is consistently regarded as being of public interest. This applies not only to the regulatory sphere, but also to the non-regulatory sphere, because conformity assessment can promote objectives which are in the interest of the public as well[80]. Subsequently accreditation – in the regulatory and non-regulatory sphere – is regarded as being of public interest, which has the consequence that the state is jointly responsibility for its functioning[81]. In the Netherlands, an additional argument is put forward that the state bears particular responsibility for the accreditation when it – as is the case in the Netherlands – falls back on the use of conformity assessment on a large scale and leaves responsibility up to the market by means of a far-reaching deregulation. It must be assured here that such a system which focuses on deregulation does indeed function[82].

Thus if the authorized accreditation is offered directly by state accreditation bodies, they may add particular credibility and authority to it. This also supports accreditation in the non-regulatory sphere, which is why, for example, the accreditation by SWEDAC is conceived as an *offer* which allows the bodies in the regulatory as well as non-regulatory sphere to demonstrate their competence and adequacy[83]. From the perspective of the other Member States, it appears to be a matter of course to use the authority as well as the professional competence of the national accreditation body in both areas.

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tion as a task of "authorized bodies", whose authority is generally drawn from governmental bodies, DIN EN ISO/IEC 17011:2005-02, Introduction, Section 3.2. The English version of the standard is entitled: "The authority of an accreditation body is generally derived from government".

79 The Dispatch on the Swiss THG stated along these lines that the independence and credibility of the accreditation bodies played a decisive role, which is why they constitute as a rule a state or state-controlled institution; Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995, 95.013, p. 521 et seqq., 607.

80 See, for example, for the self-regulation option in the Netherlands above A.I.

81 E.g. for the Netherlands Appendix, Second Section, D.I.1, D.I.4.b); for the United Kingdom Appendix, Sixth Section, C.I.1.

82 For the context behind the assessment, see the Appendix, Second Section, D.I.4.b).

83 See Appendix, Fourth Section, C II.

2. Association of the accreditation body with the state

a) Relevance of the association with the state

The question as to the extent to which the accreditation body must be associated with the state and how this is to be arranged can be addressed from different perspectives. In functional terms, such an association is required for the credibility and authority which it shall create, as already described. If legal regulations use the accreditation for competence assessment and for monitoring the conformity assessment bodies, the quality of the accreditation must be guaranteed. Additionally, the responsible authorities must have sufficient understanding of and influence over the accreditation procedures. An association between the accreditation body and the state can also be necessary to assure its incorporation into the international system, e.g. by obligating the accreditation body to participate in MLA and peer reviews. This guarantees the recognizibility of the certificates and simultaneously contributes to quality assurance.

Conversely, one should also bear in mind that the demanded independence and objectivity of the accreditation body could be an obstacle to a closer incorporation in state structures of supervision and instruction. It must be assured, in particular, that no conflicts of interest result, when for example subordinate bodies are simultaneously responsible for state conformity assessment bodies which are applying for accreditation[84]. Furthermore, the international standards for accreditation bodies require the participation of *all* interested parties, which means that the other participating parties (conformity assessment bodies, industry, etc.) must have sufficient opportunities to enforce their positions[85].

b) Arrangements in the analyzed countries

In Austria, Switzerland, and Sweden, accreditation is a public activity conducted by a state agency. The Austrian accreditation body is based directly in the Ministry for Economic

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84 See also the EA guidelines for the use of EN 45010 (IAF Guidance on Application of ISO/IEC Guide 61 - Issue 3), EA-3/08, available online at URL: http://www.european-accreditation.org/n1/doc/EA-3-08.pdf (10.3.2006)

85 ISO/IEC 17011:2004, Section 4.3.1, 4.3.2. For an interpretation of such a requirement, see the EA Guidelines on the use of the EN 45010 (Fn.84), Section G.2.1.8.

Affairs, while SAS is under the control of the State Secretary for Economic Affairs (seco), and SWEDAC is subordinate to the Ministry for Foreign Affairs as an independent, but state agency[86]. Aside from manners concerning the sufficient independence from the state, which is less problematic in practice, the forms of association with the state are more relevant for accreditation bodies organized by private law. In the United Kingdom, France and the Netherlands, the national accreditation body is associated with the state by means of an agreement, whose primary content will be presented in the following[87]:

- In December 2003 France concluded a framework agreement with COFRAC for the regulatory sphere[88]. The participating ministries recognize COFRAC as the national accreditation body and authorize it to promote the French accreditation system and make European and international institutions familiar with it. For these purposes, COFRAC is supposed to take part in multilateral agreements within the framework of EA, ILAC and IAF[89]. The framework agreement arranges for COFRAC to consult the concerned departments of the ministry with regard to the general orientation of its activities and offers the possibility of supplementing existing agreements with separate contracts with individual ministries. These contracts may specify, in particular, the procedures for the observance of the accreditation for recognitions and designation in the regulatory sphere or define certain accreditation programs which the concerned ministry deems necessary[90]. The state may monitor compliance with the agreement by means of inspections and audits[91].

- The Dutch government has maintained an agreement with the RvA since 1994, which was revised and renewed for June 2005[92]. In the agreement, the government grants

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86 See above C.II.

87 More on the status of the accreditation body in France in the Appendix, First Section, C, in particular C.I.3, in the Netherlands Appendix, Second Section, D and in the United Kingdom, Sixth Section, C.

88 The contract partners of COFRAC are four ministries : Le Ministre de l'Economie, des Finances et de l'Industrie, le Ministre de l'Equipement, des Transports, du Logement, du Tourisme et de la Mer, la Ministre de l'Ecologie et du Développement durable, le Ministre de l'Agriculture, de l'Alimentation, de la Pêche et des Affaires rurales, see the header of the framework agreement. The framework agreement is online at URL: http://www.industrie.gouv.fr/portail/pratique/index_normalisation.html (22.3.2005).

89 Art. 3 para. 1, Art. 4 of the framework agreement (Fn. 88).

90 Art. 6 of the framework agreement (Fn. 88).

91 Art. 3 para. 2 of the framework agreement (Fn. 88).

92 Ministerie van Economische Zaken, Raad voor Accreditatie, Overeenkomst Staat – Raad voor Accreditatie (Fn. 48).

the RvA the status of a "national accreditation body"[93]. The new agreement shall promote communication between the accreditation body and state authorities, in particular, and create more transparency with regard to accreditation. This is to be reached, by means of a clear description of activities by the responsible ministries, parameters to measure the quality of the services of the RvA and reporting obligations[94]. If necessary, the agreement is to be supplemented by additional agreements with individual ministries[95].

- UKAS operates on the basis of a Memorandum of Understanding[96] with the Secretary of State for Trade and Industry, which enumerates the areas of activity for which UKAS is recognized as the national accreditation body[97]. The MoU states that UKAS represents the United Kingdom in the associations of accreditation bodies and that it shall promote the international recognizibility of the accreditation system of the United Kingdom[98]. Art. 11 commits UKAS to integrity and impartiality, Art. 10 to the application of the international standards etc. and in particular the regular participation in a third-party assessment.

IV. Unique status of the accreditation body

As is also the case with the majority of countries internationally, the states examined in this study have opted against competition at the level of accreditation[99]. However, the national accreditation bodies have a *de facto* monopoly on accreditation, both in the regulatory as well as non-regulatory sphere. In the countries which have a state accreditation body, their unique status in the regulatory sphere results from the establishment of just one accredita-

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93 Overeenkomst (Fn. 48), Section 2 para. 2, Toelichting under Europese Kontext (p. 11); see also Cabinet Position 2003 (Fn. 6), p. 24 (No. 28).

94 Overeenkomst (Fn. 48), Overwegende under h, see the reporting and publication obligations in Section 6 of the agreement, performance indicators in Section 7, the regulation on evaluation in Section 8, on the designation of contact persons in Section 9 as well as Toelichting under Aanleiding voor deze nieuwe overeenkomst (p. 10), and under kwaliteitsimpuls (p. 13); see also Cabinet Position 2003 (Fn.6), p. 4 (No. 8).

95 Overeenkomst (Fn. 48), Overwegende under j; see also Cabinet Position 2003 (Fn. 6), p. 4 (No. 11).

96 The text of the Memorandum is available at URL: http://www.ukas.com/Library/downloads/About_UKAS/MOU.pdf (10.3.2005).

97 Memorandum of Understanding (Fn. 96), Art. 1 in conjunction with Annex 1.

98 Memorandum of Understanding (Fn. 96), Art. 5, 9 – as also the adoption of the corresponding accreditation practice as an internationally accepted modell, see Art. 9, clause 2.

99 On the reasons Second Section, A.I.3.

tion body. The accreditation body offers "accreditation from one source" for the regulatory and non-regulatory sphere in order to make accreditation as attractive as possible for the conformity assessment bodies. In the countries whose accreditation bodies are organized according to private law, the agreements between the state and accreditation body form the basis of their unique status in the regulatory sphere[100]. In formal terms, the legal regulations do not grant them a monopoly status. Assessments of the legal situation assume in part that it would be impossible to prevent other accreditation bodies from becoming active. However, the accreditation bodies are currently not subject to any competition[101]. The governments attempt to support this system by enabling the national accreditation bodies to offer a broad range of services and, where compatible with their task, accommodate the needs of the conformity assessment bodies and industry, so that the offer of the national accreditation bodies themselves and, above all, the recognizibility of the certificates and inspection reports are sufficiently persuasive arguments for accreditation.

V. Participation in the accreditation infrastructure at the European and international level

Ultimately, one should mention that the national accreditation bodies of the examined countries are all members of the associations of accreditation bodies at the European level and signatories of the MLA. This holds not only for the accreditation bodies based on private law, for which this – among other things – is explicitly stipulated in the agreements with the responsible ministries, but also for SWEDAC and the official accreditation bodies in Austria and Switzerland, which is entirely self-evident from the perspective from abroad. All accreditation bodies regularly participate in the peer assessments of EA. One frequently mentioned advantage of one national accreditation body is that it considerably

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100 The framework agreement grants COFRAC a unique status to the extent that COFRAC is recognized as the "national accreditation body", more in Appendix, First Section, C.I.3. In the agreement from 15 June 2005 the government allocates the RvA the status of a "national accreditation" body, more in Appendix, Second Section, D.I.3. In the Memorandum of Understanding, the Secretary of State for Trade and Industry recognizes UKAS as the only national accreditation body for the evaluation and accreditation of conformity assessment bodies, more in Appendix, Sixth Section, C.I.3.

101 In some cases other accreditation bodies are active, but due to the narrow scope of their activities they may be disregarded.

facilitates the representation of the respective national accreditation system at the European and international level.

D. The role of the conformity assessment bodies

Finally, several aspects shall be singled out which concern the activities of the conformity assessment bodies.

I. Number of bodies

In this regard it would first be interesting to determine the overall significance of conformity assessment as a service in the analyzed countries. However there is a lack of sufficient data on the number of bodies active in the inspection and conformity assessment system. The number of *bodies notified* within the scope of the directives based on the New Approach and within the framework of MRA with third countries is specified in the database of the Commission, NandoIS. It lists 223 Notified Bodies for the United Kingdom, 112 for Germany, 85 for France, 47 for Sweden, 28 for the Netherlands, 19 for Austria, and 16 for Switzerland[102]. Thus, it is not generally true, as often claimed, that Germany has notified the most bodies, but for the areas of application of individual directives this is indeed the case[103]. To a certain extent the number of *accredited* bodies, which can generally be found in the annual reports of the accreditation bodies, also allows an overview of the scope of conformity assessment activities[104]. The RvA maintains approximately 538 bodies, the recognition body of the Austrian Federal Ministry for Economic Affairs approximately 160 inspection and surveillance bodies and 42 certification bodies, SWEDAC approximately 466 laboratories, 58 certification bodies and numerous inspection bodies, and the SAS a total of approx. 650 bodies[105].

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102 Query in the database NandoIS from 15.3.2006, by country, referring to all directives based on the New Approach, URL: http://europa.eu.int/comm/enterprise/nando-is/home/.

103 This holds, for example, for the area of application of the directives on medical devices, see Appendix, First Section, Fn. 28.

104 The following indications are approximate values, which do not always take differences in counting methods in account (e.g. total number of accreditations conducted or currently maintained accreditations).

105 For the figures on France, see the annual report of CORFAC for the year 2004, p. 8, available online at URL: http://www.cofrac.fr/fr/documentation/Rapports/Rapport_2004.pdf (15.3.2004); no figures exist

II. Cooperation and exchange of information between the bodies

The analysis of the conformity assessment systems in the studied countries shows that the degree of organization of the conformity assessment bodies tends to be low at the national level. There are indeed sometimes associations of conformity assessment bodies in the countries[106], which in part also fulfil functions in certain committees and serve as contacts for the responsible ministries or the accreditation body. However, it cannot be claimed that the conformity assessment system altogether is organized in associations or unions, which would enable the bundled representation of the interests of all bodies[107]. This might also have to do with the different areas of activity of the bodies, their different profiles and the resulting, frequently very different interests[108]. To a limited extent, the existing associations of conformity assessment bodies also serve to facilitate the exchange of experience. Groups who exchange experiences in order to contribute to the uniform application of the harmonized standards and/or the requirements of the directives and who draw up guidelines etc., are generally guided by the state and not the personal initiative of the conformity assessment bodies. The difficulties associated with the cooperation of Notified Bodies in the *Groups of Notified Bodies* have already been pointed out[109].

At the international and European level the conformity assessment bodies have created associations, which are supposed to facilitate the exchange of information as well as the representation of common interests. At the European level, one must mention CEOC, a federation of independent private, but also semi-state and state organizations dealing with technical inspection, surveillance, the certification of products and quality assurance sys-

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for UKAS. The figures indicated for the countries comprise bodies in the regulatory and non-regulatory sphere. For information on when the figures were compiled and the division into different sectors, see Appendix, Second Section, D.I.2 (RvA), Third Section, C.I. (Austrian Federal Ministry of Economic Affairs), Fourth Section, C. (SWEDAC) and Fifth Section, C.I. (SAS). Peculiarities of national provisions, e.g. which lead to the high number of over 1800 inspection bodies in Sweden, are also to be taken into consideration in the number of accreditations.

106 In the Netherlands VOC (Appendix, Second Section, D.), in Austria austrolab (Appendix, Third Section, D.II:), in Sweden SWETIC (Appendix, Fourth Section, D.II.), in the United Kingdom ABCB, SAFED, (Appendix, Sixth Section, D.II, see here for EFAC as well), on Switzerland Appendix, Fifth Section, D.II.; for Germany the VAZ e.V. (http://www.vaz-ev.de) and the VUP must be mentioned (http://www.vup.de/).

107 The mentioned associations often represent a more or less large share of the conformity assessment bodies active in the respective country.

108 See above First Section, A.III.1.

109 See above Second Section, B.II.4.c).

tems. Most members of CEOC are Notified Bodies within the framework of the directives based on the New Approach. Among the objectives of the CEOC are thus the representation of common interests towards the institutions of the EU and EFTA and consulting them on conformity assessment issues[110]. In the chemical sector Eurachem is active at the European level[111] and Euromet in the area of metrology[112]. As for the laboratory sector, one must mention the organization Eurolab, whose active members represent the laboratory sector in their respective countries[113]. EEPCA is active in the electric branch[114]. Like CEOC, Euromet, Eurachem and Eurolab, EEPCA is a member of the EA Advisory Boards[115]. The four last mentioned organizations have concluded a Memorandum of Understanding with EA[116]. EFAC must also be mentioned[117]. Moreover, conformity assessment bodies have also jointly created an international network, IQNet[118]. The partners of IQNet offer conformity assessment services worldwide. IQNet is an Associate Member of the IAF.

III. Classification of the activities of Notified Bodies between private and public law

In all examined countries the legal relationships between the Notified Bodies and their clients are based on a private law contract which stipulates the mutual rights and obligations. In cases in which the use of Notified Bodies is mandatory by law, the question arises whether the conformity assessment bodies are fulfilling a public activity in the regulatory

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110 Among the tasks and objectives of CEOC are also to promote security through independent conformity assessment, the exchange of information on the occurrence of damage between the bodies, the participation in the standardization work, more under URL: http://www.ceoc.com (20.3.2006) under "About CEOC".

111 More at http://www.eurachem.ul.pt/ (20.3.2006).

112 More at http://www.euromet.org/ (20.3.2006).

113 As a rule a national association exists in the Member States of the EU and EFTA, in Germany Eurolab-Deutschland, whose office is maintained at the Bundesanstalt für Materialforschung und -prüfung BAM (Federal Institute for Material Research and Testing); see URL: http://www.eurolab-d.bam.de/geschaeftsstelle.html. More on Eurolab at http://141.63.4.16/index.html as well as http://141.63.4.16/docs/EL_01-01_03_257_eurolab_strategy.PDF (20.3.2006).

114 European Electrical Products Certification Association, more at URL: http://www.eepca.org (20.3.2006).

115 Second Section, A.I.2.c), B.III.2.

116 The text of the agreement is available at URL: http://www.european-accreditation.org/Content/EA/docs/FinalMoU_4EandCEOC.pdf (20.3.2006).

117 More at http://www.efac.demon.co.uk/ (20.3.2006) as well as Appendix, Sixth Section, D.II.

118 International Certification Network, more on IQNet at URL: http://www.iqnet-certification.com/ (20.3.2006).

sphere[119]. This question is also of practical interest because the classification as public activities has consequences for the legal relationship between the conformity assessment bodies and the state (in particular with regard to the democratic legitimacy of the bodies and their surveillance), but also for the legal relationship with their clients. Like in Germany, there is an extensive debate in the Netherlands on the dogmatic classification of the activities of the conformity assessment bodies and the legal consequences; in the other analyzed countries this is not discussed as intensely[120]:

1. The Netherlands

In the Netherlands, the broad use of conformity assessment procedures raised questions with regard to cases in which conformity assessment bodies can be classified as *bestuursorganen* (administrative bodies)[121]. Whether a conformity assessment body can be categorized as a *bestuursorgan* essentially depends on whether it exercises public power. In Dutch law, the categorization of a non-state institution as an administrative organ can result from Art. 1: 1 para. 1 no. 1 b Algemene Wet Bestuursrecht (AWB). According to this, bodies who are vested with public authority (*openbaar gezag*) can also be conceived as administrative bodies[122]. This is the case when they are authorized by public law to determine the rights and obligations of other legal subjects. As a rule, this is assumed when they are authorized to issue public legal acts[123].

If one assumes that a conformity assessment body exercises public power, it constitutes a *zelfstandig bestuursorgan* (independent administrative body), but only with regard to the special task assigned by the ministry[124]. If a body is classified as a *zelfstandig bestuursor-*

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119 For a classification of the activities of designated bodies according to the directives based on the New Approach, see above Second Section, B.II.4.d).

120 This holds in particular for the legal situation in France and Austria, which will thus not be addressed in the following, as well as for the United Kingdom. In any case, though, the positioning of the conformity assessment in the private sector and contracts as a basis of the legal relationships are regarded as a strong point of the system, which should be maintained.

121 More in Appendix, Second Section, B. II.

122 "Openbaar gezag" also means "public agency", or "authority".

123 Cabinet position 2003 (Fn. 6), p. 16.

124 *Zelfstandige bestuursorganen* are characterized by the fact that they are vested with public authority, but are not hierarchically subordinate to a minister. For the concept see *Van Wijk/Konijnenbelt/Van Male*, Hoofdstukken van Bestuursrecht, p. 85; in greater detail *Zijlstra*, Zelfstandige Bestuursorganen, p. 75 et seqq. see also the bill on a framework law on z*elfstandige bestuursorganen* in the version from 2.5.2002,

gan, there are ramifications for the legal relationship between the body and state as well as for its rights and obligations towards its clients. With regard to the legal relationship with the state it is crucial that the body assumes a public activity, without being incorporated into the hierarchical structure of the administration in the classical sense. This raises the question how the exercise of the public activity can be sufficiently legitimated[125]. As a result of the categorization as a *zelfstandig bestuursorgan* it is particularly significant in relation to clients that the conformity assessment body is subject to the obligations of administrative law. This has consequences for the structure of the activities of the bodies, for example with regard to the treatment of the applications or possibilities for complaints and legal action of the clients.

Whether the conformity assessment bodies exercise public power in the course of a legally stipulated conformity assessment procedure and are thus to be categorized as administrative bodies is difficult to assess because the areas of activity of the conformity assessment bodies in the regulatory sphere in the Netherlands are very diverse[126]. In the course of the aspired restructuring of conformity assessment it is thus supposed to be explicitly clarified whether the used conformity assessment bodies should receive the status of an administrative body. For the use of conformity assessment according to the authorization option – thus during the implementation of the directives based on the New Approach, for example – this is likely to be the case.

2. Sweden

In Sweden the horizontal legal foundations on accreditation emphasize that the conformity assessment should not be of sovereign nature. This issue was debated during the implementation of the directives based on the New Approach. The justification for the bill for the *Lag om teknisk kontroll* makes it clear that Notified Bodies do not carry out administra-

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Eerste Kamer der Staten-Generaal, Regels betreffende zelfstandige bestuursorganen (Kaderwet zelfstandige bestuursorganen), Vergaderjaar 2001–2002 No. 276 (27426).

125 Additionally, it is particularly necessary for a relationship of accountability to be established through which the activities of the body can be sufficiently controlled. This relationship of accountability is generally created in the public administration by means of instruction and control rights of higher administrative levels. As for conformity assessment bodies, effective mechanisms must also be implemented to allow for the control of their activities.

126 For the lines of argument, see Second Section, B.II.1.

tive tasks, and in particular do not make decisions on behalf of the Swedish government or the EU[127]. The motive for this categorization was, above all, the consideration that the conformity assessment body solely determines the conformity of a product with certain requirements. This was qualified as a purely technical assessment, in contrast to a public decision on the legal permissibility of marketing a good. From the Swedish standpoint this categorization was also significant for the creation of the system of open competition among private conformity assessment bodies.

3. Switzerland

In Switzerland Art. 35 clause 1 of the AkkBV stipulates that an accreditation by the Federation does not imply a transfer of public authority. The dispatch on the Law on Technical Trade Obstacles states on this that the accreditation should instead constitute a "certification of ability" which "grants [the bodies] the right to be active on the free market as the state-qualified providers of services"[128]. The activities of the bodies are thus market-based – in contrast to a system of state-organized inspections[129].

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127 Prop. 1991/92:170, Bilaga 11, p. 60.

128 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995, 95.013, p. 74.

129 The regulation is to be seen in relation with the specification in clause 2 of the provision, according to which the bodies remain responsible for their activities, in particular for the inspection results they arrive at and the conformity certificates they issue. This is motivated above all by liability law.

Fourth Section: Conformity Assessment and Accreditation in Germany

The following section addresses the use of conformity assessment and accreditation in accordance with the currently applicable provisions of German law. We first identify the forms of use of conformity assessment in the regulatory sphere with the aim of gaining an overview of the functions which conformity assessment in the regulatory sphere fulfils or can fulfil. In addition, certain issues and legal areas shall be selected on the basis of which the different ways of incorporating conformity assessment bodies into the execution of administrative law can be illustrated particularly well. A comprehensive presentation of all legal provisions which draw on conformity assessment in one way or another is not intended and would hardly be possible. The examination of the forms of use of conformity assessment in the regulatory sphere is followed by a presentation of the structures of accreditation in Germany in their current form. The section refrains from presenting conformity assessment systems which are exclusively used in the non-regulatory sphere, because on the one hand, there is a vast array of such conformity systems and on the other hand, there are hardly any motivations for the state to become active in this area[1].

A. Use of conformity assessment procedures in the regulatory sphere

There are several possible points of reference to describe the various forms of conformity assessment in the regulatory sphere, for example the question whether it is governed by harmonized European legal provisions or national law, whether the regulations primarily serve to implement the free movement of goods or are aimed more at simplifying state surveillance and enforcement tasks[2]. However, many legal regulations which draw on conformity assessment systems or at least elements of them cannot be clearly classified according to these distinctive features. Therefore, the following remarks are oriented towards various selected issue areas or legal areas, in order to gain an overview of potential forms of use of conformity assessment in the regulatory sphere.

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1 See below Part Two, A.II.1, B.I., B.III.

2 For this differentiation see above First Section, B.II.

We shall present conformity assessment procedures for product safety law according to the model of the directives based on the New Approach, as well as conformity assessment regulations in the so-called regulated environmental area including EMAS. Regulations aiming for consumer and labour protection as well as selected individual regulations from additional areas shall follow. In a summarizing section, typical forms of conformity assessment will be elaborated upon these foundations. To the greatest possible extent, we will focus on how bodies are accredited and recognized, because there is a particular need for action in this area, as will be shown.

I. Implementation of the directives based on the New Approach in the core area of product safety law

The directives in product safety law based on the New Approach are distinguishable by the fact that Essential Requirements are stipulated for both the products to be inspected as well as the inspecting bodies. A presumption of conformity with the directives exists for products and/or bodies which comply with requirements laid down in harmonized norms. Accreditation on the basis of harmonized standards is supposed to promote and facilitate the free movement of goods by contributing to the equivalence of the issued conformity certificates through the assessment and surveillance of the Notified Bodies, so that their certificates will in turn be recognized in all of Europe. For the implementation of the directives, German legislators have designed the procedure for the notification of bodies as an official procedure which in part draws on accreditation standards. However, it is frequently unclear to what extent the notification procedure falls back on harmonized standards and what role accreditation according to these standards plays in a (two-step) accreditation and notification procedure[3].

[3] It is particularly unclear whether the term accreditation always pertains to an accreditation procedure based on the relevant standards or whether it refers to a recognition procedure in which the use of these standards is not necessarily obligatory. Subsequently, the relationship between accreditation and notification and/or recognition is frequently not clearly defined.

This shall be outlined in the following on the basis of the most important provisions for the implementation of the directives based on the New Approach[4]. We have chosen the large area of regulations on machines, equipment and other devices within the scope of the Equipment and Product Safety Law as well as the regulations on medical devices – the latter on the one hand because conformity assessment in this area is of great economic interest, and on the other hand due to the special structures developed at the European level for the medical devices sector[5]. Finally, we will briefly address two additional areas, including the regulations on construction products, because they particularly show the interlinkages between the responsibilities of the Federal and State governments during the issue and enforcement of the provisions to place goods on the market.

1. Equipment and product safety law

Under the auspices of the Equipment and Product Safety Law (Geräte- und Produktsicherheitsgesetz - GPSG)[6], the requirements of a large number of New Approach directives have been implemented into German law by means of special ordinances[7]. While incorporating the conformity assessment procedures provided for in the directives, the GPSG stipulates the requirements for placing goods on the market[8]. Hence, the GPSG is an integral part of a uniform EC-wide authorization system for a broad array of products which facilitates the marketing of products for the entire European market on the basis of the features characteristic of the New Approach and the Global Approach: The limitation of legal

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4 Due to their similar regulatory structure and for reasons of space, we will not address all areas of the New Approach directives.

5 See above Second Section, B.III.3.

6 Law on Technical Work Equipment and Consumer Products (Gesetz über technische Arbeitsmittel und Verbraucherprodukte – Geräte- und Produktsicherheitsgesetz – GPSG) from 6.1.2004. The GPSG merges the old Equipment Safety Law (Gerätesicherheitsgesetz - GSG) and the Product Safety Law (Produktsicherheitsgesetz - ProdSG), without providing for fundamental changes in the concerned area; see *Klindt*, NJW 2004, 465 et seq.

7 E.g. Directive 73/23/EEC (Low-voltage); Directive 88/378/EEC (Safety of toys); Directive 87/404/EEC (Simple pressure vessels); Directive 90/396/EEC (Appliances burning gaseous fuels); Directive 89/686/EEC (Personal protective equipment); Directive 98/37/EC (Machines); Directive 94/25/EC (Recreational craft); Directive 94/9/EC (Equipment and protective systems intended for use in potentially explosive atmospheres); Directive 95/16/EC (Lifts).

8 The use of authorized surveillance bodies in accordance with §§ 14 et seq. GPSG concerning the surveillance of technical installations as well as the regulations on issuing the GS-mark shall not be considered here, because these regulations, which better attributed to the category of (pre-emptive) work health and safety measures, do not serve to facilitate the free movement of goods to the same extent. For the GS-mark and the authorized surveillance bodies, see below A.IV.

regulations to Essential Requirements, their specification in (non-binding) standards, to the benefit of which a presumption of conformity applies, and the inspection of compliance with these requirements through conformity assessment procedures which are based on a supplier's declaration, but additionally call for the consultation of Notified Bodies for hazardous products, the bodies beeing in turn recognized on the basis of harmonized requirements[9].

a) Requirements for the products

With regard to introducing products on the market, a distinction must be made in the GPSG between the sphere harmonized by European directives and the non-harmonized sphere[10]. As for the harmonized sphere, § 4 Para. 1 Clause 1 GPSG stipulates that a product can only be put on the market, when it complies with the requirements of the ordinance based on § 3 para. 1 GPSG. However, the ordinances refer to the Essential Requirements of the respective directive and state that a product may only be introduced to the market when it complies with these[11]. This will be presumed if the manufacturer has manufactured the product according to a harmonized product standard[12]. The application of the harmonized standard remains voluntary so that the manufacturer may basically select another technical solution, as long as the conformity with the requirements of the directive has been assured. However, the manufacturer must demonstrate this.

b) Conformity assessment procedures

According to the ordinances, an additional prerequisite for introducing goods to the market is that the manufacturer and/or marketer submits a *declaration*, with which he or she confirms that the Essential Requirements have been complied with and that the procedures of

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9 On the innovative power of this system see *Röhl*, in: Schmidt-Aßmann/Schöndorf-Haubold, Der Europäische Verwaltungsverbund, p. 154 et seq., 160 et seq.

10 See § 4 para. 1 and para. 2 GPSG; *Wilrich*, GPSG, § 4 Rn. 7, 8 et seq. The following remarks concentrate on the harmonized sphere because the majority of products fall under harmonized European requirements.

11 See e.g. § 2 of the 9th GPSGV (Machine Ordinance), § 2 para. 1, 2 of the 14th GPSGV (Pressure Equipment Ordinance), § 3 para. 1, 2 of the 12th GPSGV (Lifts Ordinance).

12 § 4 para. 1 clause 2 GPSG, see the definition of the harmonized standard for the area of applicability of the GPSG in § 2 para. 16 GPSG.

conformity assessment provided for in the respective directive have been complied with[13]. With this, the correct execution of one of the available conformity assessment procedures is a requirement for market access. For the majority of the products that fall under the GPSG and the relevant ordinances, in particular for most machines[14], an internal control of production including technical documentation by the manufacturer according to module A suffices[15]. The participation of authorized bodies is mandatory for hazardous products, e.g. for more dangerous machines[16]. Generally, a type examination is required. In certain cases a document inspection procedure may suffice when harmonized standards exist and are adhered to[17]. As a rule, the type examination is supplemented by an inspection in the stage of production, e.g. according to module D (production quality assurance) or module E (product quality assurance)[18].

c) Recognition of the "authorized bodies"

According to § 11 para. 1 GPSG, the potentially consulted "authorized bodies" *(zugelassene Stellen)* are recognized by the Central Authority of the Laender for Security Technology (*Zentralstelle der Länder für Sicherheitstechnik* - ZLS)[19]. According to § 11 para. 1 clause 2 GPSG an accreditation on the basis of harmonized standards can be taken into

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13 See e.g. § 3 para. 1 No. 1, 2 of the 9th GPSGV (Machine Ordinance), § 4 para. 1 No. 1 a, b of the 14th GPSGV (Pressure Equipment Ordinance), § 4 para. 1 No. 1 a, b of the 12th GPSGV (Lifts Ordinance).

14 § 3 para. 1 No. 2 of the 9th GPSGV in conjunction with Art. 8 para. 2 lit. a) Directive 98/37/EC (Machines).

15 Electrical operational equipment in the low-voltage segment according to § 3 para. 1 of the 1st GPSGV in conjunction with Annex IV of the directive 73/23/EEC (Low-voltage directive); toys if the manufacturer adheres to the harmonized standards, § 3 para. 1 of the 2nd GPSGV; simple models of personal protective equipment § 3 of 8th GPSGV in conjunction with Art. 8 para. 3 Directive 89/686/EEC.

16 Art. 8 para. 2 lit. b), c) Directive 98/37/EC (Machines) in conjunction with Annex IV of the Directive 98/37/EC. The same applies to e.g. simple pressure vessels, § 3 para. 3 of 6th GPSGV; appliances burning gaseous fuels, Art. 8 para. 1 Directive 90/396/EEC and § 3 para. 1 of the 7th GPSGV; security construction parts for lifts, Art. 8 para. 2 Directive 95/16/EC, and (as a rule) personal protective equipment, § 6 of the 8th GPSGV.

17 E.g. Art. 8 para. 2 lit. c Directive 98/37/EC (Machines) or for simple pressure equipment, § 3 para. 3 clause 2 of the 6th GPSGV.

18 For the modules see above Second Section, B.II.2.b).

19 The responsibility of the ZLS is based on § 11 para. 1 GPSG; see *Abkommen über die Zentralstelle der Länder für Sicherheitstechnik und über die Akkreditierungsstelle der Länder für Meß- und Prüfstellen zum Vollzug des Gefahrstoffrechts* (ZLS/AKMP) from 16/17 December 1993 (published in Baden-Württemberg Law Journal 1994, 533 et seq., and other places), changed by the Agreement from 3 December 1998 and the Agreement from 16 December 2003, Art. 2 para. 2. The agreement is available under URL: http://www.zls-muenchen.de/de/doku_pdf/abkommen-zls.pdf (14.2.2006). More on the ZLS below under B.II.2.a)(i).

consideration here[20]. The justification of the GPSG stated in this regard that the term accreditation procedure ("Akkreditierungsverfahren") had been replaced by the term recognition procedure ("Anerkennungsverfahren"), because the former was very closely linked with the series of standards EN 45000, not only in the general use of the term, but particularly in the European context. However, in the regulatory sphere additional requirements were to be complied with along with the requirements based on the relevant harmonized standards[21]. This was taken into consideration with the "two-step approach" of accreditation and recognition. An accreditation on the basis of the standards would generally be an integral part of a recognition procedure, though[22]. The justification of the GPSG argues that synergetic effects could be reached as the harmonized accreditation standards for the assessment of conformity assessment bodies were used elsewhere both in regulatory and in the non-regulatory sphere[23]. According to the ZLS the respective standards of the series DIN EN 45000 et seqq. and ISO/IEC 17000 et seqq. are applied in the application procedure for Notified Bodies within the scope of the European directives[24].

The recognition of statements of conformity issued by Notified Bodies of other Member States within the framework of the GPSG is assured by the fact that the GPSG and the related ordinances always call for the use of "authorized bodies." According to the definition in § 2 para. 15 GPSG, these also include bodies which were notified by other Member States of the European Community or the EEA.

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20 According to the the justification on § 11 para. 1 GPSG, this pertains to the harmonized standards of the series EN 45000, BR-DRS 631/03 of 5.9.2003, Section 4.1 (on § 11 GPSG). This may also be an accreditation issued by another accreditation body. The ordinance addressed in § 11 para. 1 GPSG in accordance with § 3 para. 3 GPSG has – as far as can be seen – not been issued. As regards the transition period, § 21 para. 1 GPSG refers to § 9 para. 2 GSG, which itself contains no reference to harmonized requirements for conformity assessment bodies. However, an assumption of conformity with the harmonized requirements can be found in the relevant directives, e.g. in Art. 9 para. 2 clause 2 Directive 98/37/EC (Machines).

21 These are not further specified.

22 BR-DRS 631/03 from 5.9.2003, Section 4.1 (on § 11 GPSG).

23 Provided that the standards indeed further specify the requirements of the ordinances. As a rule, it is at the discretion of the authority whether an accreditation is actually considered, BR-DRS 631/03 from 5.9.2003, Section 4.1 (on § 11 GPSG).

24 ZLS under URL: http://www.zls-muenchen.de/ (14.2.2006) under "application procedure".

2. Medical devices law

For medical devices, the systematic market access regime which entails conformity assessment and covers all devices is a new phenomenon: According to the earlier legal situation, only implantable and several especially listed medical devices were subject to the requirement of an official authorization[25]. All other medical devices did not require authorization, but the manufacturer could subject them to a voluntary inspection for the GS-mark[26]. Now a conformity assessment procedure is mandatory before marketing any medical devices[27], § 6 para. 1 Medical Devices Law (Medizinproduktegesetz – MPG)[28]. For this purpose, medical devices have been divided into certain classes[29] on the basis of which Art. 11 of the directive stipulates which of the conformity assessment procedures of the Annexes II to IV are applicable[30]. Unlike the products that fall under the GPSG, the consultation of a certification body is frequently required in the area of applicability of the MPG, while the supplier's declaration according to Module A only suffices for products of class I. An assumption of conformity with the requirements of the MPG to the benefit of products which comply with harmonized standards is included in § 8 MPG.

The bodies active within this framework are notified to the EC-Commission in accordance with § 15 para. 1 MPG after an "accreditation procedure" has been conducted. The MPG formally distinguishes between the notification of the bodies and the accreditation, which is a prerequisite for notification according to § 15 para. 1 clause 2 MPG[31]. Accreditation

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25 § 5 of the earlier MedGV (Ordinance on the Safety of Medical-technical equipment – Medical Devices Ordinance – from 14.1.1985). Once again here, the main focus of the inspection is placed on the assessment by a (private) inspection body, § 5 para. 2 of the Ordinance.

26 See A.IV.1 for more information on the GS-mark.

27 See the directives on Active implantable medical devices (Directive 90/385/EEC) and Medical devices (Directive 93/42/EEC). The system of the directive on In-vitro diagnostics (Directive 98/79/EC) is similar to that of the other two directives.

28 Medical Devices Law (Medizinproduktegesetz - MPG), version from 7.8.2002. See *Schlund*, ArztR 1995, 235 et seq.; *Meyer-Lüerßen/Will*, PharmaRecht 1995, 34 et seq.; *Deutsch/Spickhoff*, Medizinrecht, Rn. 1196 et seq., 1213 et seq.

29 §§ 4 to 6 of the Ordinance on Medical Devices (Verordnung über Medizinprodukte - MPV) in conjunction with the annexes of the respective directive.

30 For the conformity assessment procedures in medical devices law see *Edelhäuser* in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 5 Rn. 22 et seq.

31 The extent to which the designation takes on a meaning of its own here remains unclear. It appears sensible to conceive the notification according to § 15 para. 1 MPG as an independent administrative act following the accreditation, whose own regulatory content entails a kind of "issue of authorization" to become active as a Notified Body, while the accreditation initially only includes the specification of the

and notification are conducted by the "responsible authority" in accordance with § 15 MPG. The Länder have transferred this task to common authorities created by treaty: The Central Authority of the Laender for Security Technology *(Zentralstelle der Länder für Sicherheitstechnik* - ZLS*)* in Munich is responsible for the active implantable medical devices that fall under the medical devices law[32] and the Central Authority of the Laender for Health Protection Regarding Medicinal Products and Medical Devices *(Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten - ZLG*) in Bonn for all other medical devices[33].

The accreditation by the ZLG or the ZLS is designed by the MPG as an administrative act[34]. From the perspective of the MPG the accreditation is an official procedure to determine the competence and suitability of the conformity assessment bodies, based on material requirements which result from the respective annexes of the directive[35]. With regard to the requirements to the conformity assessment bodies, the MPG itself contains no explicit reference to the standards of the series EN 45000 and ISO/IEC 17000. However, the directives which shall be implemented by the MPG contain a presumption of conformity in favour of the bodies which satisfy harmonized criteria[36]. Due to this, according to accreditation rules applied by the ZLG and ZLS the compliance with the requirements from the harmonized standards is a prerequisite for accreditation[37]. However, for the area of activity

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competence and suitability of the body; see *Merten*, Private Entscheidungsträger, p. 186. An independent inspection program for the decision of designation which exeeds the requirements inspected during the accreditation cannot be found in the MPG.

32 The responsibility of the ZLS is based on § 1 para. 2 of the agreement on the *Zentralstelle der Länder für Sicherheitstechnik* (Fn. 19); more on the ZLS below under B.II.2.a)(i).

33 The responsibility of the ZLG results from the agreement on the *Abkommen über die Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten*, GV. NRW 1994 p. 972, modified by the Agreement from 9.2.1999 (GV. NRW p. 54), available online at URL: http://www.zlg.de under *Wir über uns/Staatsvertrag* (16.2.2006). More in *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 33. More on the ZLG under B.II.2.a)(ii).

34 See § 15 para. 1 clause 3, 4 MPG.

35 See the version of the § 15 para. 1 MPG; see also *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 14, 15.

36 Art. 16 para. 2 Directive 93/42/EEC (Medical Devices), Art. 11 para. 2 clause 2 Directive 90/385/EEC (Active implantable medical devices), Art. 15 para. 2 clause 2 Directive 98/79/EC (In-vitro diagnostics).

37 See the General Accreditation Rules of the ZLG, which mention compliance with the harmonized standards as a prerequisite for accreditation: ZLG, Allgemeine Akkreditierungsregeln (200_AR01_031031), 1.2, available online at URL: http://www.zlg.de/download/MP/200_AR01_AllgAkkRegeln.pdf (16.2.2006). More on the requirements for accreditation *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 14 et seq.; *Merten*, Private Entscheidungsträger, p. 188 et seq. The ZLS

of the ZLG one may observe that the requirements of the harmonized standards are supplemented with further requirements based on recommendations as e.g. MEDDEV[38] papers as a prerequisite for accreditation. Additionally, they are further specified and supplemented by special accreditation rules developed by the Accreditation Board of the ZLG[39]. The General Accreditation Rules of the ZLG list as cumulative prerequisites for accreditation the requirements of the relevant EC directives, the MPG and the ordinances issued on this, as well as the criteria resulting from MEDDEV Paper 2.10/2, as well as the requirements from the harmonized standards[40] and further specified requirements defined by the ZLG[41]. To conclude we can say that in the area of medical devices law the relationship between the criteria resulting from the different levels of law is relatively unclear. This particularly affects the legal relevance of harmonized standards and thus the basis of the presumption of conformity.

3. Other areas

a) Electro-magnetic compatibility; radio equipment and telecommunications terminal equipment

Besides the areas that fall under the GPSG and the MPG, the New Approach and the Global Approach have been implemented in numerous other product segments[42]. Additional important segments are, for example, the areas of applicability of the directives on electro-magnetic compatibility[43] as well as radio equipment and telecommunications ter-

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uses the series of standards EN 45000 and ISO/IEC 17000 for its responsibilities within the framework of the MPG; the statements on the GPSG (above A.I.1.c) apply accordingly.

38 See Second Section, B.III.3.

39 See *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 15 et seq.

40 According to the currently valid version of the document the bodies must fill the "general criteria for operating inspection laboratories according to DIN EN 45 001 and DIN EN ISO/IEC 17025 (under consideration of DIN EN 45 002 and DIN EN 45003) or the general criteria for certification bodies according to DIN EN 45 011, DIN EN 45 012 and/or DIN EN 45 013 (under consideration of DIN EN 45 010)".

41 ZLG, Allgemeine Akkreditierungsregeln (Fn. 37), Item 1.

42 See the schematic overview of the KOGB "Akkreditierungs-, Anerkennungs-, Benennungs- und Notifizierungsverfahren im gesetzlich geregelten Bereich in Deutschland unter dem Blickwinkel der Richtlinien nach dem neuen oder globalen Konzept – Schematische Darstellung" (no complete listing) (KOGB – 07-06, updated 30.11.2005), available at URL: http://www.bundesnetzagentur.de/media/archive/4370.pdf (19.2.2006).

43 2004/108/EC (replaces Directive 89/336/EEC), implemented in the Law on Electro-Magnetic Compatibility (Gesetz über elektromagnetische Verträglichkeit - EMVG) and the related Ordinance on the re-

minal equipment[44], in which the recognition of the conformity assessment bodies is incumbent upon the Federal Network Agency (*Bundesnetzagentur*)[45]. The Notified Bodies active in the area of electro-magnetic compatibility[46] have the peculiarity that they are *Beliehene* according to § 7 para. 4 clause 2 EMVG, § 5 BAnerkV[47].

b) Construction products

The construction sector has a special status to the extent that the product authorization procedures indeed also draw on the basic principles of the New Approach and the Global Approach, but distinguish themselves from these in certain ways: According to the CPD[48] the Member States must ensure that only products which are fit for the intended use are put on the market[49]. The construction products directive stipulates Essential Requirements for this in Annex I. However, these are not related to the construction products, rather the *buildings* erected with them[50]. To further specify the Essential Requirements, European technical specifications must be drawn up. This can be done by developing harmonized standards or through the recognition of national standards. For certain exceptional cases, so-called European technical authorizations are mandatory[51]. The compliance of the construction products with the technical specifications must be secured in all cases by conformity assessment procedures which result in the CE-marking[52]. Additionally, the construction products directive also allows for the use of products which comply with national provisions, as long as this is not ruled out in the respective technical specifications; the EC au-

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quirements and the procedure for the *Beleihung* and recognition of conformity assessment bodies from 7.6.2002 (BAnerkV 2002). See *Röhl*, Akkreditierung und Zertifizierung, p. 17 et seq. The previously existing regulation, the BAnerkV of 1999, is no longer effective according to Art. 3 of the BAnerkV 2002.

44 Directive 1999/5/EC, implemented by the Law on Radio Equipment and Telecommunications Terminal Equipment (Gesetz über Funkanlagen und Telekommunikationsendeinrichtungen - FTEG).

45 § 7 para. 4 EMVG, §§ 3 para. 2, 4 para. 2 BAnerkV 2002.

46 In contrast to the other bodies designated as “responsible bodies” (zuständige Stellen).

47 See *Röhl*, Akkreditierung und Zertifizierung, p. 64 et seq. For the concept of „Beleihung“ see above Second Section B.II.4.d)(iii), there Fn. 144.

48 Directive 89/106/EEC - CPD.

49 *Sauter* (ed.), § 17 LBO Rn. 2.

50 *Sauter* (ed.), § 17 LBO Rn. 2; *Röhl*, Akkreditierung und Zertifizierung, p. 20 et seq.

51 For construction products which are not as security-relevant a certificate from a recognized inspection body also suffices, for the whole procedure see *Sauter* (ed.), § 17 LBO Rn. 3.

52 *Sauter* (ed.), § 17 LBO Rn. 3.

thorization thus does not constitute the only possibility of market access[53]. In these cases the manufacturer has the right to select between two procedures: proof on the basis of harmonized standards based on the Construction Products Law (Bauproduktengesetz - BauPG), which results in the CE-marking, or the so-called national path. The latter follows a procedure governed by the Federal States' construction codes[54], according to which the products are marked with an "Ü"-mark[55].

The construction products directive thus contains both regulations on *placing goods on the market* as well as the on the *use* of construction products. The former were implemented at the Federal Level by the BauPG while the construction codes of the Länder cover rules for use. However, the applicability of the BauPG essentially depends on whether harmonized standards, European technical authorizations or authorization guidelines have been drawn up and published for the construction products[56]. If this is not the case, the regulations of the BauPG are void and the provisions of the Federal States' construction codes are definitive[57]. As the harmonization of the procedure of the CPD had been progressing rather tediously, a long transition phase was expected. Therefore, the Länder decided to adjust the compliance procedure in their construction codes to that of the directive so that the procedure of proof for construction products in the states' construction codes and the federal Construction Products Law (BauPG) now coincide to a large extent[58].

The execution of the conformity assessment procedures is incumbent on inspection, surveillance, and certification bodies (Prüf-, Überwachungs- und Zertifizierungsstellen - PÜZ)[59]. The authorities of the Federal States are responsible for the recognition of the PÜZ, while executing both the BauPG and the Federal States' construction codes. However, they have partially transferred their responsibilities to the German Institute for Con-

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53 *Sauter* (ed.), § 17 LBO Rn. 3; *Röhl*, Akkreditierung und Zertifizierung, p. 21.

54 Näher *Sauter* (ed.), § 17 LBO Rn. 14.

55 See e.g. § 17 para. 1 No. 1 LBO BW (national sphere) and § 17 para. 1 No. 2 LBO BW (European sphere); see the schematic overview of the different proof procedures in *Sauter* (ed.), § 17 LBO Abb. 1; see also Rn. 20.

56 See § 3 para. 1 BauPG, in greater detail in *Sauter* (ed.), § 17 LBO Rn. 12.

57 *Sauter* (ed.), § 17 LBO Rn. 12.

58 In greater detail in *Sauter* (ed.), § 17 LBO Rn. 10 et seq.

59 For the respective tasks in accordance with the Laender construction codes, see *Sauter* (ed.), § 25 LBO Rn. 8.

struction Technology (*Deutsches Institut für Bautechnik* - DIBt)[60]. The execution of the recognition procedures by the DIBt according to uniform standards and through simplified and clear procedures is supposed to accelerate the recognition procedures[61]. The Länder among each other recognize the recognitions from the PÜZ[62].

II. The so-called regulated environmental area

In environmental law there are numerous procedures which prescribe inspections by testing bodies which possess a designation, notification or another type of recognition. This holds for example for certain tests based on waste laws, soil protection laws, immission protection laws or water laws, which are to be conducted by inspection laboratories or measuring bodies[63]. These inspections are conducted in part by mandate of the responsible authority. Sometimes the person affected by the standard is required to obtain proof of compliance with the legal requirements from such inspection bodies. With this, obligations are transferred to private inspection bodies and/or those affected by the law and thus the burden is removed from state executive authorities.

In order to guarantee uniform federal quality requirements for conducting these inspections and to facilitate the recognition of the proof of competence for testing bodies between the Länder, the Länder partially draw on accreditations by accreditation bodies from the non-

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60 The possibility of delegation of tasks is offered by Art. 2 para. 5 of the Agreement on the German Institute for Construction Technology (Abkommen über das Deutsche Institut für Bautechnik - DIBt-Abkommen), published as Appendix on the *Gesetz über das Deutsche Institut für Bautechnik* from 22 April 1993 (Gesetz- und Verordnungsblatt für Berlin p. 195), Art. 2 para. 5, para. 3; last amended by No. 1 DIBt Amendment Agreement from 14.10.2004, published on 23.5.2005 (Sachsen-Anhalt, GVBl. p. 265). An authorization for delegating the authority is contained, for example in the case of the State of Baden-Württemberg Art. 2 para. 1 of the *Gesetz zu dem Abkommen über das Deutsche Institut für Bautechnik (DIBt-Abkommen) und über Zuständigkeiten nach dem Bauproduktengesetz* from 15 December 1992 (GBl. 1992, 761); use was made of this in the *DIBt-Übertragungsverordnung* from 5.6.1999, GBl. p. 262.

61 *Sauter* (ed.), § 25 LBO Rn. 6.

62 For instance, this is based on § 25 para. 2 LBO BW, § 27 para. 2 BayBO. For the recognition of the results from bodies recognized abroad, which takes place in a special procedure, see e.g. § 25 para. 2 clause 2 and para. 3 LBO BW, see *Sauter* (ed.), § 25 LBO Rn. 12 et seq.

63 § 18 BBodSchG, § 26 BImSchG, from the waste-related segment § 6 para. 6 AltholzV (matured forest), § 5 para. 2 AltölV (used oil), § 3 para. 8 and § 4 para. 9 BioAbfV (bio-waste) and § 9 para. 2 BioabfV (soil), § 11 para. 3 DepV (emissions) and Annex 4 of the DepV (waste) as well as § 3 para. 5 and 6 AbfKlärV (sewage sludge) and § 3 para. 2 AbfKlärV (soil).

regulatory sphere to demonstrate the competence of the bodies[64]. This shall be further explained in the following on the basis of the regulations on waste management as well as two additional examples (§ 26 BImSchG and § 18 BBodSchG)[65].

1. Recognition of the proof of competence for testing bodies: the example of waste law

In order to guarantee uniform quality requirements for conducting inspections, the Länder have concluded an "Administrative Agreement of the States on the Proof of Competence and Notification of Inspection Laboratories and Measuring Bodies in the Legally Regulated Environmental Area"[66]. The agreement is applied to the extent that waste law, soil protection law, chemical law, immissions law or water law stipulates that certain testing and surveillance tasks are to be carried out or may be carried out by notified inspection laboratories or measuring bodies[67]. The agreement is supposed to create a uniform framework for the different areas in order to determine the professional expertise of the laboratories. To this end, the Länder on the one hand develop area-specific modules, e.g. for waste or sewage, in which they define requirements for the bodies. Furthermore, they offer the bodies the possibility to fall back on an accreditation by an "evaluated" accreditation body to prove the fulfilment of the requirements. The states have concluded an agreement with three accreditation bodies from the non-regulatory sphere for this purpose[68]. This system ultimately enables the recognition of the proof of conformity between the Länder during the notification of the inspection bodies.

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64 For the division of accreditation bodies in bodies for the regulatory and non-regulatory sphere, see below, Fourth Section, B.I, B.II .

65 Comparable regulations exist for the area of sewage testing, for which an area-specific module was also elaborated; information on this at URL: http://www.lubw.baden-wuerttemberg.de/servlet/is/3588/ (16.2.2006). There is a similar form of cooperation between states and accreditation bodies with regard to drinking water surveillance; see DAP-News No. 4/2005, available online at URL: http://www.dap.de/95doc/dapnews42005.pdf (16.2.2006).

66 "Verwaltungsvereinbarung der Länder über den Kompetenznachweis und die Notifizierung von Prüflaboratorien und Messstellen im gesetzlich geregelten Umweltbereich" (Administrative Agreement of the States on the Proof of Competence and Notification of Measuring Bodies in the Legally Regulated Environmental Area) from 29.11.1999, effective as of 16.1.2001, published in the Federal Gazette (*Bundesanzeiger*) No. 220 from 2002, p. 25450; also available online at URL: http://www.lubw.baden-wuerttemberg.de/ under Qualitätsmanagement/Laboranerkennungen/Aktuelle Informationen (16.2.2006)).

67 With the restriction of possible special regulations, § 1 para. 2 of the administrative agreement (Fn. 66).

68 For the agreement see below b).

a) Requirements for the bodies and procedures for demonstrating competence

According to the ordinances issued on the basis of the recycling management and waste law (Kreislaufwirtschafts- und Abfallgesetzes - KrW-/AbfG), testing bodies must be recognized by the responsible state authority in order to conduct certain inspections[69]. For example, the State of Baden-Württemberg has further specified the requirements for the testing bodies dealing with waste management in an administrative provision[70]. With regard to the expertise-related requirements, it refers to the "waste-specific module" (Fachmodul Abfall)[71] which was developed by the Länder working group for waste. This module stipulates in detail the obligations of the testing bodies with regard to personal, operational, and equipment-technical requirements as well as quality management[72]. The basis for this is § 4 of the Administrative Agreement of the States[73], according to which the inspection laboratories and measuring bodies must comply with the requirements based on DIN EN 450001 and the requirements defined by the Länder in area-specific individual modules.

The waste-specific module additionally regulates procedures for demonstrating competence and the "notification"[74] by the respective Federal State. A notification body of the respective State is responsible for the notification. Upon request by the laboratory, it may take into account an accreditation in accordance with DIN EN ISO/IEC 17025 by an

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69 § 6 para. 6 AltholzV (matured forest), § 5 para. 2 AltölV (used oil), § 3 para. 8 and § 4 para. 9 BioAbfV (bio-waste) and § 9 para. 2 BioabfV (soil), § 11 para. 3 DepV (emissions) and Annex 4 of the DepV (waste) as well as § 3 para. 5 and 6 AbfKlärV (sewage sludge) and § 3 para. 2 AbfKlärV (soil).

70 Administrative provision of the Ministry for the Environment and Transport on Testing Bodies For Waste Management (Verwaltungsvorschrift des Ministeriums für Umwelt und Verkehr über Untersuchungsstellen in der Abfallwirtschaft) from 18 May 2004 – Az. 25-8980.11/3, available online at URL: http://www.lubw.baden-wuerttemberg.de/ under Qualitätsmanagement/Laboranerkennungen/Abfall (16.6.2006).

71 Section 2.4. of the Administrative provision (Fn.70). The waste-specific module was drawn up on the basis of § 4 of the Administrative Agreement of the Laender (Fn. 66). The module is available online at URL: http://www.lubw.baden-wuerttemberg.de/ under Qualitätsmanagement/ aboranerkennungen/Abfall (16.2.2006).

72 Waste-specific module (Fn. 71), Section 1.

73 See Fn. 66.

74 Notification is according to § 2 of the Administrative Agreement of the Laender (Fn. 66) the "administrative act of the respective responsible state agency to recognize, authorize, designate or notify the inspection laboratories and measuring bodies according to the respectively applicable legal provisions". Accreditation is defined as the "formal recognition of the competency of an inspection laboratory or a measuring body by means of an evaluated accreditation system to conduct certain tests or types of tests. It is based on DIN EN 45 000 et seq.".

"evaluated" accreditation body, provided that this is valid and covers the area of testing applied for[75]. If the body does not have such an accreditation, it is free to obtain one; additionally, there is also the possibility of having the proof of competence tested directly by a responsible body designated by the state[76]. The area-specific modules provide for regular and repeated audits for the sake of quality assurance[77].

b) Agreement with accreditation bodies from the non-regulatory sphere

In order to ensure that the states and the accreditation bodies use uniform requirements for demonstrating competence, the states have concluded an administrative agreement[78] with three accreditation bodies of the non-regulatory sphere (DAP, DACH and DASMIN[79]). It defines the requirements based on DIN EN 450001 and/or 17025 in the respectively applicable versions and the requirements contained in the individual area-specific modules as the standard for the inspection[80]. Double inspections are avoided as the existing accreditations are taken into consideration during the notification; conversely the results of the competence assessment carried out during a notification procedure can be built on during an accreditation[81]. The agreement additionally stipulates that the participating accreditation bodies create a common group of assessors for the purpose of professional cooperation and that the Länder authorities and the accreditation bodies mutually inform each other about

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75 Waste-specific module (Fn. 71), Section 3.2.1.

76 See also the corresponding regulation in § 4 para. 3 of the of the Administrative Agreement of the Laender (Fn. 66).

77 Waste-specific module (Fn. 71), Section 3.4.

78 *Vereinbarung der Länder mit beteiligten Akkreditierungsstellen zur Zusammenarbeit bei der Akkreditierung und Notifizierung von Prüflaboratorien und Messstellen im gesetzlich geregelten Umweltbereich*, concluded by the 55th Conference of Environment Ministers on 25/26 October 2000 in Berlin (Last updated: 26.10.2000), published in the Federal Gazette/Bundesanzeiger No. 220 from 2002, p. 25450; also available online at URL: http://www.lubw.baden-wuerttemberg.de/ under Qualitätsmanagement/Laboranerkennungen/Aktuelle Informationen (16.2.2006).

79 The DASMIN has transmitted its accreditation activities to the DACH on 1.1.2006, see DASMIN at URL: http://www.dasmin.de/ (13.2.2006).

80 § 3 of the Agreement of the States with Participating Accreditation Bodies (Fn. 78). As a rule, only the accreditations of these accreditation bodies are recognized, see e.g. the Merkblatt der LUBW zur Bestimmung von Untersuchungsstellen in der Abfallwirtschaft in Baden-Württemberg (Stand 23.1.2006) under 3; the information bulletin is available online at URL: http://www.lubw.baden-wuerttemberg.de/ under Qualitätsmanagement/Laboranerkennungen/Abfall (16.2.2006).

81 §§ 4, 5 of the Agreement of the States with Participating Accreditation Bodies (Fn. 78).

notifications, accreditations, and the results of external assessments of competence[82]. A coordination committee which consists of an equal number of representatives of the Länder and the involved accreditation bodies oversees the execution of the agreement.

c) Recognition of the proof of competence

The Administrative Agreement of the States on the Proof of Competence and Notification of Measuring Bodies in the Legally Regulated Environmental Sphere stipulates that the determinations of competence for a notification are mutually recognized among the states[83]. In this system, too, the professional expertise of the notifying authority is of particular significance, not only because according to the administrative agreement proofs of competence which have been established during a notification procedure may be recognized (see above b). Accordingly, the area-specific modules specify requirements for the responsible notification bodies (i.e. state authorities) of the states, which pertain to their knowledge of the legal rules and professional expertise[84]. As a rule, the Federal State in which the body has its headquarters is responsible for the initial notification. Inspection bodies from other European countries may apply for a notification in the Federal State in which they would like to operate[85].

d) Summary

To demonstrate the expertise of inspection bodies during the sovereign notification decision in the so-called regulatory sphere, the states fall back on an accreditation which can be carried out by accreditation bodies of the non-regulatory sphere. This model thereby uses the already existing accreditation structures and thus manages without a competence assessment by the official authorities – in this regard it distinguishes itself from the structure

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82 § 7, 6 of the Agreement of the States with Participating Accreditation Bodies (Fn. 78). The agreed group of assessors is still being set up, see DAP News No. 3/2005, available online at URL: http://www.dap.de/95doc/dapnews32005.pdf (16.2.2006).

83 § 6 para. 1 of the *Verwaltungsvereinbarung der Länder über den Kompetenznachweis und die Notifizierung von Prüflaboratorien und Messstellen im gesetzlich geregelten Umweltbereich* (Fn. 66); See also the waste-specific module (Fn. 71), Section 4.

84 Waste-specific module (Fn. 71), Section 2.

85 Waste-specific module (Fn. 71), Section 2.

of recognition and accreditation within the scope of the GPSG and MPG[86]. The basis for the accreditation is the standard ISO/IEC 17025, which contains general requirements with regard to the expertise of testing laboratories. These are further defined and supplemented by area-specific modules drawn up by the states for certain sectors (waste, water). The accreditation bodies use this as a basis for accreditation, which is substantiated by a contractual agreement with the states. The inspection body indeed still needs a notification for every federal state in which it would like to become active[87]; the proof of competence upon which the notification is based is recognized, though. Even if difficulties still arise when these regulations are enforced in practice[88], the model shows than an accreditation on the basis of ISO/IEC 17000 et seq. – further specified by clearly defined and transparent area-specific requirements in the regulatory sphere – can be the basis for a sovereign notification decision, without arousing fears of a deterioration of quality.

2. Additional examples: § 26 BImSchG, § 18 BBodSchG

An additional example of the consideration of accreditation during sovereign recognition and notification procedures can be found in immission protection law:

According to § 26 of the Federal Immission Protection Law (Bundesimmissionsschutzgesetz - BImSchG) the responsible authority according to federal law can demand an operator of technical installations to conduct measurements and other tests of emissions or immissions in the vicinity of his/her facilities by a body notified by the responsible state authority (measurements for special reasons). The Working Group for Immission Protection of the Federal Government and the Länder (Bund-Länder-Arbeitsgruppe Immissionsschutz - LAI*)* has drawn up a guideline for notification according to § 26 BImSchG, the so-called "notification guideline" (Bekanntgabe-Richtlinie)[89]. Accordingly the concerned

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86 See above A.I.1, 2.

87 In contrast to the Notified Bodies based on the New Approach, which may operate in all Member States on the basis of the designation and notification and whose statements of conformity are recognized within all European countries.

88 See DAP News No. 3/2005, available online at URL: http://www.dap.de/95doc/dapnews32005.pdf (16.2.2006).

89 Richtlinie für die Bekanntgabe von sachverständigen Stellen im Bereich des Immissionsschutzes in der Fassung des LAI-Beschlusses (Directive on the Stipulation of Expert Bodies in the Area of Immission Protection in the version of the LAI decision) from the 106th meeting from 9/30 to 2.10.2003 in

bodies must prove their expertise before the notification; this pertains to the requirements for the staff, expertise of measuring and testing procedures, technical equipment, practical experience, knowledge of the facilities and knowledge of area-specific immission protection regulations[90]. To demonstrate competence, the Bekanntgabe-Richtlinie refers to the "fulfilment of the material requirements based on the currently applicable DIN EN ISO/IEC 17025 standards and the demands specified in the *Bekanntgabe-Richtlinie*"[91]. It additionally provides for the inspection of these requirements to be conducted either during the stipulation procedure by the responsible state authorities or during an accreditation procedure by accreditation systems that the notifying state cooperates[92]. If an accreditation is used as proof of expertise for the notification, the applicant is supposed to contact the responsible state body beforehand in order to prove additional requirements[93].

The provisions on inspections in accordance with § 18 of the Federal Soil Protection Law (Bundesbodenschutzgesetz - BBodSchG) are comparable with § 26 BImSchG. The Federal Soil Protection Law partially requires inspections to be conducted by authorized inspection bodies[94]. The detailed regulations on the requirements for authorized inspection bodies with regard to their expertise and reliability are incumbent on the Länder[95]. Examples for the consideration of accreditations can also be found here: Bavaria has regulated the concerned requirements in the Ordinance on Experts and Inspection Bodies for Soil Protection and Residue Treatment in Bavaria (*VSU Boden und Altlasten*). It stipulates that for the competence assessment of inspection bodies an accreditation can be recognized upon application, as long as the accreditation is valid, complete and applicable to the requested area of inspection[96].

Hamburg (*Bekanntgabe-Richtlinie*), available online at URL: http://www.lai-immissionsschutz.de/veroeff/Bekanntgabe-RL%20_10_2003_.pdf (16.2.2006).

90 Section 3 of the *Bekanntgabe-Richtlinie* (Fn. 89).

91 Section 3 of the *Bekanntgabe-Richtlinie* (Fn. 89).

92 Section 3 of the *Bekanntgabe-Richtlinie* (Fn. 89).

93 Section 3 of the *Bekanntgabe-Richtlinie* (Fn. 89); this pertains to independence, reliability, primary occupation, secondary provisions on the *Bekanntgabe*.

94 § 9 para. 2 clause 2 BBodSchG. An obligation to mandate experts or inspection bodies only exists when the authorities stipulate this. In this case as well, the inspection bodies are generally mandated by the persons affected by the law, *Scholl,* Private Sachverständige, p. 70, there Fn. 157.

95 § 18 BBodSchG.

96 § 15 para. 4 VSU *Boden und Altlasten*. More on this in the procedural ordinance for inspecting and announcing experts and inspection bodies according to § 18 BBodSchG from 12.6.2002 (adapted on

III. Environmental verifiers (EMAS)

Another example of the use of conformity assessment bodies in the regulatory sphere is the certification of environmental management systems according to the community system Eco- Management and Audit Scheme (EMAS). The aim of EMAS is to improve the environmental performance of organizations. By creating incentives to participate in this system, the state can indirectly pursue the goal of environmental protection and at the same time remove the burden from the executive authorities to a certain extent by allowing for simplifications in official surveillance procedures[97]. The participation in this system is voluntary for the firms. However, the conformity assessment procedure is defined itself by legal provisions[98] and the participation in EMAS is associated with certain simplifications during official surveillance, which have positive effects for the firm[99].

1. Purpose and mode of operation

EMAS aims to improve the environmental performance of "organisations"[100], usually firms, who, among other things, create an environmental management system and subject it to an objective evaluation by environmental verifiers in regular intervals[101]. The firms are expected to voluntarily participate in EMAS, because it is supposed to help reduce expenses and bears other advantages with regard to the image of the firm in public. Above all however, the participants might also be privileged with regard to "regulatory control"[102], i.e. they enjoy privileges during the state surveillance of operating facilities and equipment. Germany has made use of this possibility in the EMAS Privilege Ordinance (EMAS-

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10.11.2005), available online at URL: http://www.bayern.de/lfw/service/download/sv/verfo_boden.pdf (20.3.06).

97 For the goals of EMAS see e.g. *Klöpfer*, Umweltrecht, § 5 Rn. 445 et seq., on the development of environmental protection audits in the USA *ibid*, Rn. 444, *Ensthaler*, Zertifizierung, Akkreditierung und Normung, p. 80.

98 Regulation (EC) No 761/2001 of the European parliament and of the council of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS-Regulation); implemented in the Environmental Audit Law (Umweltauditgesetz - UAG).

99 Due to this legal reference to the EMAS participation, the system shall be regarded as part of the regulatory sphere in a broader sense (above First Section, D.I).

100 The definition of the concept of organisation in Art. 2 lit. s) Regulation (EC) No. 761/2001 comprises "a company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administrations"..

101 Art. 1 para. 2 lit. a), b) Regulation (EC) No. 761/2001.

102 Regulation (EC) No. 761/2001, Recital 9.

Privilegierungsverordnung)[103]. For example, some otherwise applicable reporting and notification obligations no longer apply, the company may refrain from mandating a safety inspector, or inspection and measuring intervals can be extended[104].

Every organization that wishes to participate in this system must define an environmental concept, which includes the objectives and principles of action of the organization with regard to the environment. It must carry out an environmental review of its activities, products, and services[105], introduce an environmental management system, conduct a regular environmental auditing and draw up an environmental statement. The latter must be validated by an environmental verifier[106]. The declaration of validity is passed on to the responsible authority of the Member State and made accessible to the public. Inspected organizations are entered into an EMAS registry[107].

2. Tasks and authorization of the environmental verifiers

According to the EMAS-Regulation, the task of the environmental verifier is to test the compliance to the Regulation with regard to the environmental review, the environmental

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103 Verordnung über immissionsschutz- und abfallrechtliche Überwachungserleichterungen für nach der Verordnung (EG) Nr. 761/2001 registrierte Standorte und Organisationen – EMASPrivilegV (Ordinance on immission protection and waste law surveillance simplifications for locations and organizations registered according to the Regulation (EC) No. 761/2001) from 24.6.2002.

104 For example, § 2 EMASPrivilegV provides for simplifications of reporting and notification obligations of the business organization in accordance with § 52 a BImSchG and § 53 KrW-/AbfG. According to § 3 para. 1 EMASPrivilegV, the company can refrain from mandating a safety inspector in further defined cases, according to para. 2 reporting obligations of the firm are cancelled. § 4 EMASPrivilegV provides for simplifications in determining emissions in accordance with § 28 para. 1 No. 2 BImSchG (extension of the time period until the inspection to three years and approval for the inspection to be conducted by own personnel); additional simplifications are contained in § 5 EMASPrivilegV (for repeated measurements and functional inspections), § 6 EMASPrivilegV (security-technical inspections in accordance with § 29a BImSchG), § 7 EMASPrivilegV (emission reports) and § 8 EMASPrivilegV (extension of measuring intervals in certain cases). More on such "diagonal links" to police law (Ordnungsrecht) in *Scholl*, Private Sachverständige, p. 307 et seq.

105 Those organizations which already have a certified and recognized environmental management system are exempted, for more details see below.

106 According to Annex V Item 5.5.1. Regulation (EC) No. 761/2001, the verifier becomes involved on the basis of a written agreement with the organization; it determines the areas to be assessed and requires the organization to cooperate with the environmental verifier.

107 Art. 6 Regulation (EC) No. 761/2001, Art. 32 et seq. UAG. A prerequisite for this among other things is that an authorized environmental verifier or an authorized organization of environmental verifiers is responsible for the declaration of the validity of the environmental declaration, Art. 33 para. 1 No. 1 UAG. In Germany the registration of inspected organizations is carried out by the Chambers of Industry and Commerce and Chambers of Crafts, § 35 UAG; a common German registry exists.

management system, the environmental auditing and their results as well as to inspect the environmental statement and declare it as valid[108].

The Member States must create a system for the authorization of independent environmental verifiers or organizations of environmental verifiers and the surveillance of their activities[109]. The requirements for the authorization and surveillance of the environmental verifiers are governed by Annex V of the EMAS-Regulation. Concerning the requirements for the assessors, the Regulation does not refer to harmonized standards, rather draws up a catalogue of criteria. In Germany the authorization of environmental verifiers is governed by the Environmental Audit Law (Umweltauditgesetz - UAG)[110]. The task of authorizing and monitoring the environmental verifiers has been transferred to the German Accreditation and Authorization Association *(DAU – Deutsche Akkreditierungs- und Zulassungsgesellschaft für Umweltgutachter mbH)*, which for this purpose has been vested with public authority[111].

The verifiers authorized in one Member State may operate in all other Member States according to Art. 4 para. 5 of the EMAS-Regulation; they must report the commencement of activities in another Member State and are thus subject to the surveillance of the authorization system of this state. According to Art. 5 para. 8 EMAS-Regulation the authorization

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108 Art. 3 para. 2 lit. d), Annex V Section 5.4 Regulation (EC) No. 761/2001. More on the tasks of the verifiers in "Leitlinie des Umweltgutachterausschusses zu den Aufgaben des Umweltgutachters nach der Verordnung (EC) No. 761/2001 (EMAS II)", 4th Edition 2001, under URL: http://www.umweltgutachterausschuss.de/downloads/Aufgabenleitlinie_Aufl4.pdf (6.12.2006). The authorized environmental verifiers may also operate within the framework of other German laws, depending on their area of authorization; an overview is provided by the DAU under URL: http://www.dau-bonn-gmbh.de/dauList.htm?cid=203 (6.12.2006). See also the Section on professional waste disposal firms in waste law: A crosslink to EMAS exists here to the extent that an assumption of conformity applies during the recognization of technical surveillance organizations if the organizations or experts are authorized as environmental verifiers.

109 Art. 4 Regulation (EC) No. 761/2001.

110 §§ 4 et seqq. UAG (authorization) and §§ 15 et seqq. UAG (surveillance).

111 UAG-Beleihungsverordnung (UAGBV). The authorization procedure is stipulated in greater detail in the UAG authorization procedure ordinance (UAGZVV). In view of the tasks of the environmental verifiers, the environmental verifier committee (UGA) is above all responsible for developing interpretational guidelines on §§ 4 to 18 UAG, § 21 para. 1 No. 1 UAG; see e.g. the UGA-Aufsichtsrichtlinie from 22.2.2004, which further specifies the use of monitoring instruments by the DAU. For the DAU see under B.II.2.b)(ii).

bodies of the Member States form a forum which draws up guidelines for the exercise of the activity as well as a procedure for peer review among the assessors[112].

3. The problem of sufficient incentives for participation

In the case of EMAS it appears that systems of conformity assessment oriented towards voluntary participation must provide the firms sufficient incentives to participate in order to reach the pursued regulatory objective, in this case an improvement of environmental performance. The promotional use of the EMAS logo can be an economic advantage. Further economic benefits might be, for example, determining cost-savings potential, advantages with regard to insurance premiums, or the granting of credits, lower liability risks, etc.[113]. This may be supplemented by the above-mentioned privileges during official surveillance in accordance with environmental law[114].

From the standpoint of businesses, this often does not seem to be sufficient though. In Germany the participation in the system is indeed by far the highest in comparison with other Member States, but it has been stagnating for some time now and across Europe it leaves much to be desired[115]. EMAS is subject to competition from ISO 14001, which was indeed increasingly integrated into EMAS[116] with the EMAS II-Regulation[117], but is still

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112 See *Klöpfer*, Umweltrecht, § 5 Rn. 474. No information exists on the practical activities of the forum.

113 *Scholl*, Private Sachverständige, p. 308, in particular Fn. 855; *Klöpfer*, Umweltrecht, § 5 Rn. 448.

114 See above A.III.1.

115 For the number of registered organizations per country see the EU register under URL: http://europa.eu.int/comm/environment/emas/about/participate/sites_en.htm (16.2.2006). For the debate on the future of EMAS see the UGA statement at URL: http://www.umweltgutachterausschuss.de/downloads/ZukunftEMAS_Stellungnahme.pdf (6.12.2006); *Langerfeldt*, NVwZ 2002, 1156 et seq., 1164; *Knopp*, NVwZ 2001, 1098 et seq., 1099; with regard to Germany *Schäfer*, p. 113 et seq.

116 The demands of EMAS go beyond those of ISO 14000. For example, an environmental audit generally must be carried out before an EMAS registration and the firms must submit an environmental declaration, which is validated. Concerning the requirements for the environmental management system, art. 3 para. 2a) sub-paragraph 1 Regulation (EC) No. 761/2001 refers to Annex I, which reflects Section 4 of EN/ISO 14001:1996 (Annex I was revised by Regulation (EC) No. 196/2006 of the Commission of 3.2.2006, Official Journal L 32 from 4.2.2006, p. 4, and adapted to ISO 14001:2004). ISO 14001 is thus a component of EMAS. A further simplification is made by Art. 3 para. 2a) Sub-paragraph 2 in conjunction with Art. 9 Regulation (EC) No. 761/2001, according to which organizations with a certified environmental management system do not have to carry out a formal environmental management system if they have established a recognized environmental management system in accordance with Art. 9 of the Regulation; the recognition in accordance with Art. 9 requires the recognition of the authorization requirements. For more on the differences between ISO 14000 and EMAS see *European Commission* at

preferred by many businesses as the simpler system[118]. There are frequent complaints that the legal privileges of participating in EMAS are not sufficient to encourage firms to participate[119].

IV. Consumer protection and work safety

Besides the regulations on placing products on the market, the GPSG also contains provisions on the issue of the GS-mark, a voluntary safety mark. During the introduction of the GS-mark considerations about consumer protection prevailed, but the GS-mark also gained significance with regard to preventive work safety. In this area as well, private inspection bodies recognized by the state are mandated to issue the inspection mark. The surveillance of facilities in accordance with the GPSG is also supported by "authorized surveillance bodies". The revision of the regulations on the surveillance of operational facilities illustrates that the inspection system has now evolved into an international or in any case European service market. The proven quality of conformity assessment services not only has a functional meaning for products to access the market and to facilitate the movement of goods. Conformity assessment is also in itself an interesting segment of the service market from an economic standpoint on which the traditionally strong German inspection system competes with inspection bodies from other countries.

1. GS-mark

The GS-mark is a voluntary safety mark the use of which is governed the GPSG. "GS" means "geprüfte Sicherheit" ("inspected safety")[120]. The GS-mark declares that the safety

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URL: http://europa.eu.int/comm/environment/emas/tools/faq_en.htm (4.12.2005) under the FAQ on EMAS and ISO 14001.

117 Regulation (EC) No. 761/2001.

118 See *Scholl*, Private Sachverständige, p. 308, in particular Fn. 855.

119 For a sceptical view with regard to the benefits of EMAS for deregulation, see e.g. *Siemens AG*, Leitsätze zu Standardisierung, Normung, Technischer Regelsetzung und Konformitätsbewertung (TN0170), Item 3.3.3. (p. 21); the document is available online at URL: http://w4.siemens.de/ct/de/corporate/sr/principles.pdf (16.2.2006). On the development of EMAS and ISO 14000, see the response of the German Federal Government to the Small Petition (Kleine Anfrage) of the Members of the Bundestag Birgit Homburger, Angelika Brunkhorst, Michael Kauch, additional representatives and the FDP parliamentary party "10 Jahre Öko-Audit-System der EU (EMAS)" – BT-Drs. 15/5777 from 15.6.2005.

and health of the user are not endangered in cases of intended use as well as in the case of predictable improper use of the product[121]. CE-marking does not generally rule out the use of the GS-mark[122].

The requirements for affixing the GS-mark are stipulated in § 7 GPSG. It is issued upon application by authorized GS-inspection bodies[123]. An initial prerequisite for awarding the GS-mark is that a type examination test has been conducted for the product which demonstrates the agreement of the construction type with the product requirements according to § 4 para. 1 to 3 GPSG and, where applicable, other applicable legal provisions[124]. Furthermore, the GS-issuing body must inspect whether the product has been manufactured in accordance with the inspected construction type[125]. The issue of the GS-mark is linked with production surveillance by the GS-inspection body[126]. According to § 7 para. 2 clause 2 GPSG the GS-inspection bodies must revoke the issued mark when the requirements are

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120 Art. 7 para. 1 GPSG.

121 ZLG under URL: http://www.zls-muenchen.de/ (6.12.05) under "Zuständigkeitsbereiche/GS-Zeichen". The GS-mark is a safety mark, not a quality mark, in contrast to the common perception among consumers, *Wilrich*, GPSG, § 7 Rn. 1.

122 The GS-mark may be borne next to this, as long as this is not prohibited by law and as long as the information it provides is not already provided by the CE mark; the obligatory production control for the GS-mark plays a key role here. See § 7 para. 1 clause 1 GPSG, Exclusion e.g. in § 4 para. 4 of the 7th GPSGV (appliances burning gaseous fuels) and § 5 para. 4 of the 8th GPSGV (personal protective equipment). See *Wilrich*, GPSG, § 7 Rn. 3, § 6 Rn. 27, § 6 Rn. 27.

123 § 7 para. 1 clause 2 GPSG. The manufacturer may freely select the GS-inspection body.

124 § 7 para. 1 clause 2 No. 2 GPSG. The construction type inspection is also carried out by the GS-inspection body. However, the body that inspects the construction type and the body that inspects the conformity with the construction type do not need to be identical, see the justification for the Draft of the Second Law to Amend the Equipment Safety Law, BT-Drs. 12/2693, p. 3 et seq., p. 23 (on § 3 para. 4 GSG, the previous regulation on § 7 GPSG). Thus the wording of para. 1 clause 2 No. 1 "wenn der GS-Stelle … ein Nachweis … vorliegt" ("if the GS-inspection body has proof").

125 § 7 para. 1 clause 2 No. 2 GPSG.

126 § 7 para. 1 clause 2 GPSG. According to § 7 para. 3 clause 2 GPSG, the manufacturer must tolerate the control measures. The Central Experience Exchange Committee (Zentraler Erfahrungsaustauschkreis zugelassener Stellen, ZEK) according to the GPSG has defined minimal requirements for the issue of a GS-mark. Accordingly, the surveillance of production is to be carried out by product inspections (item inspections or statistical controls) or quality assurance measures for the product or production, based on the corresponding modules of the Modules Decision. See the Board Decision of the Main Group for the Exchange of Experiences of Authorized Bodies on the minimal requirements for the issue of a GS according to § 7 para. 1 Number 1 and 2 Equipment and Product Safety Law (GPSG), ZEK-GB-2004-02 – summary of the old board decisions 16/94, 1/98 and 1/99 including the ZEK-GB-2004-01 from 21.9.2004, BArbBl. No. 1/2005, p. 55, available online at URL: http://www.zls-muenchen.de/de/left/erfahrungsaustausch/doku_pdf/38_2-04_gb2004-02.pdf (6.12.2006), in particular under C.

no longer met; it must inform other GS-issuing and responsible authorities of the revocation[127].

The notification of the GS-inspection bodies and their surveillance take place through a recognition procedure, which is carried out by the Central Authority of the Laender for Security Technology (Zentralstelle der Länder für Sicherheitstechnik, ZLS)[128]. The provisions for GS-inspection bodies do not contain a reference to harmonized standards, but in practice the ZLS draws on the accreditation standards as well when recognizing GS-inspection bodies. According to § 11 para. 3 GSPG bodies abroad can meanwhile also be notified as GS-inspection bodies under certain conditions.

The provisions on the GS-mark had been added to the Equipment Safety Law (*Gerätesicherheitsgesetz – GSG*) in 1979[129]. The aim of introducing the GS-mark was to create a uniform safety mark, in order to increase the safety awareness of the consumers by restricting this to one seal. The accident prevention report of the Federal Government from 1973 states in this regard that the marks of inspection bodies used up to then failed to provide consumers a clear overview and that the multitude of seals confuse consumers[130]. A uniform security seal was considered to be imperative from the standpoint of consumer protection. At the beginning, the introduction of the GS-mark was difficult, most likely

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127 § 7 para. 2 clause 3 GPSG, the ZEK provides a registration for this, available online at URL: http://www.zls-muenchen.de/de/left/erfahrungsaustausch/doku_pdf/06_1-05_meldung-entzug-gs-zeichen.doc (6.12.2006). See *Wilrich*, GPSG, § 7 Rn. 13 for the purpose of the newly introduced provision.

128 Art. 2 para. 2 first hyphen of the Agreement on the Central Authority of the States for Security Technology and on the Accreditation Body of the Laender for Measuring and Inspection Bodies for the Implementation of Dangerous Substances Law [Abkommen über die Zentralstelle der Länder für Sicherheitstechnik (ZLS) und über die Akkreditierungsstelle der Länder für Meß- und Prüfstellen (AKMP) zum Vollzug des Gefahrstoffrechts] from 16-17 December 1993, amended by the Agreement of 3 December 1998 and the Agreement of 16 December 2003, consolidated version available online at URL: http://www.zls-muenchen.de/de/doku_pdf/abkommen-zls.pdf (6.12.2006) – in the following ZLS-Treaty – in conjunction with § 2 para. 15 No. 1 b GPSG. The BAuA, as the authorized authority, announces the GS-inspection bodies, § 11 para. 4 GPSG in conjunction with § 2 para. 14, para. 15 No. 1 b) GPSG.

129 The issue of the GS-mark was defined by law for the first time in the amendment from 13.8.1979, Federal Law Gazette (Bundesgesetzblatt) I, 1432 in § 3 para. 4 GSG, but the mark had already been used earlier, *Wilrich*, GPSG, § 7 Rn. 4; *Peine*, Gerätesicherheitsgesetz, 2nd edition 1995, § 3 Rn. 112. For the origin of the GPSG see *Wilrich*, GPSG, § 28 Rn. 6 et seq.

130 Report of the Federal Government on the State of Accident Protection and Events of Accident in the Federal Republic of Germany (Bericht der Bundesregierung über den Stand der Unfallverhütung und das Unfallgeschehen in der Bundesrepublik Deutschland, Unfallverhütungsbericht), BT-Drs. 7/189, p. 165 et seq., 170.

because it was initially supposed to replace the introduced inspection seals from inspection bodies such as the VDE, TÜV or DVGW[131]. The newly introduced GS-mark, which according to the Committee for Work and Social Order was an "increasingly effective instrument for safe products", was supposed to be further promoted by the addition of the respective regulations to the law in 1979[132]. Nowadays primarily large chains of stores pay attention to the GS-mark when purchasing products[133].

Apart from that, the GS-mark has gained significance in preventive work safety[134]. The Equipment Safety Law in the version applicable up to 11/27/2003[135] contained a provision in § 3 para. 1 clause 2, according to which technical equipment could only be put on the market in the area not harmonized by EC law if it "was created according to the recognized standards of technology as well as the work safety and accident protection provisions" to the extent that users or third-parties were protected if the equipment was used properly. The rules on bearing the GS-mark were contained in § 3 para. 4 GSG, which in turn referred in no. 1 to the requirements of para.1. The work safety provisions and above all the accident protection provisions of the *Berufsgenossenschaften* (accident prevention and insurance associations) thus became the standard for inspections for the GS-mark[136]. Affixing a GS-mark to products also was advantageous during official surveillance. According to the general administrative provision on the GSG the authorities could refrain from their own inspection if an inspection certificate from an authorized body existed or the product

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131 Accident Prevention Report (Fn. 130), p. 166, 170. Lawmakers refrained from this in the legal provisions in § 3 para. 4 of the Law on Technical Work Equipment; the GS-mark could be displayed along with inspection body and association seals; see the Beschlussempfehlung zu dem Entwurf eines Gesetzes zur Änderung des Gesetzes über technische Arbeitsmittel, BT-Drs. 8/2824, p. 10.

132 Beschlussempfehlung (Fn. 131) p. 10, 2. In particular, one should attempt to create a means for the surveillance authorities to prevent the misuse of the GS-mark.

133 For the advantages of the GS-mark from the perspective of the manufacturer or the marketer see *Peine*, in: Schulte (ed.), Handbuch des Technikrechts, p. 391 et seq., 417.

134 *Wilrich*, GPSG, § 7 Rn. 2, Introduction, Rn. 4. For the function of the structural requirements as a component of preventive work safety *Wilhelm*, Unfallverhütungsvorschriften, p. 13 et seq.

135 Law on technical work equipment (Gerätesicherheitsgesetz) in version of the announcement from 11.5.2001, BGBl. I, 866 (valid until 27.11.2003).

136 See *Peine*, in: Schulte (ed.), Handbuch des Technikrechts, p. 391 et seq., 418 (411 et seq.). For the significance of accident prevention provisions in work safety law see also *Wilhelm*, Unfallverhütungsvorschriften, in particular p. 115 et seq. for the effects of the new version of the GSG on the environmental protection provisions; p. 128 et seq. for the strategies of the *Berufsgenossenschaften* after the abolishment of the reference to the accident prevention provisions in § 3 GSG (however not in relation to the GS mark).

was marked with an inspection mark[137]. The GS-mark was a voluntary symbol, yet no legal but de facto GS-inspection obligation could arise in this way. The Berufsgenossenschaften also frequently require GS symbol to be affixed to work equipment and attempt to enforce this among employers. To this extent, the GS-mark can also have market-averse effects, because the introduction of products to the market without the GS-marks from the GS bodies officially authorized in Germany, e.g. office furniture, computer accessories, etc., would in fact hardly be possible. This effect of the GS-mark is frequently criticized abroad[138].

2. Inspection of equipment requiring surveillance according to §§ 14 et seqq. GPSG

As a result of the Law to Amend the Equipment Safety Law and Chemicals Law from 27 December 2000[139], the "person-oriented" German technical inspection system for equipment surveillance, which has traditionally been based on officially recognized experts, was transformed to an "organization-oriented" inspection system with recognized inspection bodies[140]. The justification for the bill states that the person-oriented technical inspection system does not correspond with the structures of an organization-oriented inspection system provided for by EC law. The technical inspection system is supposed to be harmonized with the European structures by creating authorized surveillance bodies, "in the interest of the long-term assurance of the competitiveness of the national system of technical surveil-

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137 *Peine*, in: Schulte (ed.), Handbuch des Technikrechts, p. 391 et seq., 417.

138 According to the regulations introduced in 2000 in § 11 para. 3 GSPG (formerly § 9 para. 3a GSG, see *Wilrich*, GPSG, § 11 Rn. 10), bodies abroad can also be notified as GS-bodies under certain conditions. This regulation makes it easier for foreign firms to access the market, because inspection bodies active in their country can also distribute the GS-mark. The procedural legal requirements of § 11 para. 3 GPSG are rather strict though – for example the conclusion of an administrative agreement with the country of headquarters is obligatory. The permissibility of national safety marks like "GS" is often contested due to these market-averse effects; nevertheless the new Regulation does not exlude national consumer safety marking as the GS-Mark, see Art. 30 para. 5 clause 2 Regulation (EC) No 765/2008, according to which "(A)any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired".

139 BGBl. I, 2048.

140 § 17 para. 1 GPSG, § 21 para. 1 BetrSichV. Until 31.12.2005 the inspections of equipment requiring surveillance were to be carried out by official or officially recognized experts. Starting 1.1.2006 authorized surveillance bodies may operate here. Starting 1.1.2008 the inspections will generally be conduced by authorized surveillance bodies, as long as the BetrSichV does not specify otherwise; see the transitional provisions § 21 para. 2 to 5 GPSG.

lance in a European services market"[141]. Besides this clear reference to the change of structures in the inspection system, the regulations on equipment surveillance point to a two-step system of accreditation and notification; they should therefore be presented in the following overview:

The operation of facilities requiring surveillance is governed by the *Betriebssicherheitsverordnung* (BetrSichV)[142], which prescribes inspections before initial operation for certain equipment in § 12[143]: This concerns certain steam boiler systems, elevator systems, equipment in potentially explosive atmosheres, and storage facilities. § 15 BetrSichV stipulates recurring inspections for equipment requiring surveillance. These inspections are carried out by Authorized Surveillance Bodies (zugelassene Überwachungsstellen, ZÜS)[144]. § 17 para. 5 GPSG requires the ZÜS to be notified by the respectively responsible state authorities. A precondition for the notification is that compliance with the requirements to the bodies specified in the GPSG and the BetrSichV is inspected during an "accreditation procedure"[145]. In order to operate as an authorized surveillance body, both accreditation as well as notification is mandatory. The accreditation covers criteria such as independence, availability of the required resources, and equipment, sufficient technical expertise and experience, compliance with the procedures specified for conducting the inspection, exchange of experience among the bodies and additional requirements such as the existence of the requested liability insurance[146].

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141 Bill to amend the equipment safety law and the chemical law (Entwurf des Gesetzes zur Änderung des Gerätesicherheitsgesetzes und des Chemikaliengesetzes) from 2.6.2000, BT-Drs. 14/3491 p. 1, p. 10. See *Wilrich*, GPSG, § 28 for an overview of the history and origin of the GPSG.

142 The BetrSichV replaces the ordinances on facilities requiring surveillance which are based on § 11 GSG, whose content was adopted by the BetrSichV.

143 § 12 para. 2 clause 1 BetrSichV in conjunction with § 1 para. 2 clause 2 BetrSichV. According to § 1 para. 2 BetrSichV the BetrSichV no longer applies to all equipment requiring surveillance in terms of § 2 para. 7 GPSG, rather only for equipment for which the legislator assumes a particularly high danger potential; see *Wilrich*, GPSG, § 14 Rn. 11 et seq.

144 § 17 para. 1 GPSG.

145 § 17 para. 5 clause 2 GPSG.

146 § 17 para. 5 clause 2 No. 1, 2, 3, 6, 8, 4 GPSG, supplemented and further specified by § 21 para. 2 BetrSichV.

The Länder have delegated the accreditation and in part the notification as well to the ZLS[147]. The accreditation is valid in all of Germany[148] under consideration of state-specific accreditation conditions[149]. The notification, in contrast, is generally limited to the Federal State for which it is granted[150]. Some states conduct the notification themselves (two-level procedure). The majority of the states have also transferred the notification decision to the ZLS (so-called one-level procedure)[151]. The ZLS has further specified the requirements for the accreditation of authorized surveillance bodies in special guidelines. They indeed do not make a reference to the harmonized accreditation standards of the series ISO/IEC 17000[152]. However, in practice the accreditation does take place on the basis of these standards, as is the case with the accreditation of authorized bodies and/or Notified Bodies in the scope of the directives based on the New Approach.

The accreditation of authorized surveillance bodies in accordance with the GPSG and the BetrSichV can therefore be regarded as accreditation in line with the definition of section 5.6 DIN EN ISO/IEC 17000[153]. The regulations show, in particular, that a notification decision can be directly based on an accreditation decision which is made by an accreditation body different than the notifying authority.

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147 Agreement on the Central Authority of the Laender for Security Technology (Fn. 128) under "Zuständigkeitsbereiche/Zugelassene Überwachungsstellen".

148 ZLS, Directives on requirements for the accreditation of authorized surveillance bodies (aZLS-VD-026, Stand 23.7.2004), available online at URL: http://www.zls-muenchen.de/de/doku_pdf/anforderungen_zues.pdf (20.3.2006), p. 7.

149 These primarily concern the registration of equipment requiring surveillance by a data-managing institution, see § 17 para. 4 clause 1 No. 3 GPSG. See the overview of the country-specific accreditation conditions compiled by the ZLS under URL: http://www.zls-muenchen.de/ (16.2.2006) under "Antragsverfahren/länderspezifische Akkreditierungsbedingungen".

150 ZLS, Directives on requirements for the accreditation of authorized surveillance bodies (Fn. 148), p. 7.

151 See the overview by the ZLS "Übersicht über den Stand der landesspezifischen Vorschriften zur Benennung von zugelassenen Überwachungsstellen und Führung von Katastern" (version 5.1.2006) at URL: http://www.zls-muenchen.de/de/left/antragsverfahren/uebersicht_stand_landesspez_vorschr_zues.htm (16.2.2006).

152 As far as can be seen, European directives which provide for the inspection of equipment requiring surveillance also contain no assumption of conformity to the benefit of the harmonized requirements for conformity assessment bodies, see e.g. the provision in Art. 9 para. 3 Directive 1999/36 EC on transportable pressure equipment; however, the parallel provision of Art. 8 para. 2 Directive 1999/36 EC on the Notified Bodies (responsible for carrying out the conformity assessment procedure for transportable pressure equipment) also does not include a conformity assumption. This could be related to the fact that the harmonization of the requirements of the bodies is less significant with regard to equipment surveillance due to its more minor importance in facilitating the free movement of goods.

153 Confirmation by a third-party which formally demonstrates that a conformity assessment body has the expertise to carry out certain conformity assessment procedures.

V. Additional areas

Conformity assessment, in particular accreditation is used in numerous additional legal regulations. The German coordination group of the legally regulated sphere ("Koordinierungsgruppe Gesetzlich Geregelter Bereich – KOGB")[154] has drawn up a "Review of the bodies dealing with accreditation, recognitions, notifications, authorization, and evaluations within the context of conformity assessment" in the legally regulated (public) sphere in Germany, which provides a table of the recognition and accreditation bodies with their areas of activity and the applicable legal provisions[155]. We refer the readers to this compilation for the additional areas. Two selected cases shall be presented in the following.

1. Accreditation in the driving licence system

In the driving licence system the driving licence authority can, under certain conditions, request the concerned person to provide an expert opinion in order to demonstrate his/her ability to drive[156]. The expert opinion serves as a preparation for the decision on behalf of the driving licence authority. Bodies or persons who test or assess the ability or authorization to operate a motor vehicle for the purpose of preparing for an official decision must be legally or officially recognized or authorized[157]. The Driving Licence Ordinance (Fahrerlaubnisverordnung, FeV) specifies further details. According to § 72 FeV, bodies assessing driving aptitude, technical inspection bodies on the basis of § 69 FeV and bodies which offer courses for persons wishing to regain their aptitude to drive must be accredited according to DIN EN 45013[158]. The accreditation is carried out by the Federal Highway Re-

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154 On KOGB under B.I.4.b).

155 "Bestandsaufnahme für die in Deutschland im gesetzlichen (öffentlich-rechtlichen) Bereich mit Akkreditierungen, Anerkennungen, Benennungen, Zulassungen, Bewertungen und Notifizierungen befassten Stellen im Rahmen der Konformitätsbewertung" KOGB 12-06 rev. 09, version 9.9.2005, available online at URL: http://www.bundesnetzagentur.de/media/archive/4029.pdf (16.2.2006).

156 § 2 para. 8 StVG, § 11 FeV.

157 § 2 para. 8 StVG.

158 § 6 para. 1 No. 1 d) and k) StVG (the latter in conjunction with § 2 para. 13 StVG) is the legal basis for the stipulation in § 72 FeV to this extent. This constitutes a static reference to DIN EN 45013. More precisely the accreditation obligation refers not to the bodies themselves but to the institutions which are legally responsible for them ("Träger").

search Institute (Bundesanstalt für Straßenwesen - BASt) in accordance with DIN EN 45010[159].

2. *Recognition of competent bodies for the certification of responsible bodies and measures of further vocational training in accordance with SGB III*

The third book of the German Social Law (Sozialgesetzbuch, SGB) regulates the recognition of competent bodies by the Federal Labour Agency (Bundesagentur für Arbeit, BA), which in turn itself certifies responsible bodies for advancement measures as well as the measures themselves. If the responsible body for a measure wishes to offer further education and training which can be funded by the state according to SGB III, the body must be certified. Here the use of certification aims at assuring the quality of the further education activities funded by public money. The certification bodies do not operate within a framework of regulatory control of the citizens' activities, but in an administrative context which is concerned with offering benefits to the citizens (*Leistungsverwaltung*). The bodies are ultimately supposed to ensure that state funds are only spent on effective training measures. The following section provides a more detailed overview:

According to §§ 77 et seq. of SGB III professional training can be funded under certain conditions. To do so, certain responsible bodies for measures are approved along with certain measures, with the result that the expenses of these measures can be covered. The requirements for the responsible bodies and measures are further specified in the Recognition and Authorization Ordinance for Further Training (Anerkennungs- und Zulassungsverordnung Weiterbildung, AZWV)[160]. A prerequisite for the authorization of responsible bodies and measures for vocational training is, among other things, that a private "competent body" has determined that the responsible body has certain features (capacity of the re-

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159 § 72 para. 2 FeV. This constitutes a static reference to DIN EN 45010.

160 § 7 et seq. AZWV. No reference to standards is included; an accreditation board is supposed to draw up recommendations in order to "ensure a uniform Germany-wide certification" § 15 para. 2 AZWV, p. 5 of the justification AZVW; the justification is available online at URL: http://www.arbeitsagentur.de/content/de_DE/hauptstelle/a-5/importierter_inhalt/pdf/AZWV_Begruendung.pdf (17.2.2006).

sponsible body, qualification of the director and the teaching staff, QMS)[161] and has inspected the measures[162].

The competent bodies are recognized by the recognition body of the Federal Labour Agency according to the AZWV[163]. The prerequisites for the recognition are regulated in § 2 AZWV. With regard to the requirements for the bodies, the ordinance contains a generally worded catalogue of criteria and no reference to standards. However, the justification for the AZWV partially refers to DIN EN 45012[164]. The Federal Labour Agency itself refers to the series of standards EN 45000 (45012) and ISO 17000 et seq.[165] in its information offer, as does the "review" of the KOGB[166].

VI. Summary: forms of use in the regulatory sphere

The above considered provisions from various areas of law show that the state can make use of conformity assessment procedures in different ways and in the pursuit of different aims:

In the harmonized European product safety law conformity assessment procedures serve the purpose of organizing products' access to the market without recourse to an official product authorization procedure and thus promoting the free movement of goods in the Internal Market. The supplier's declaration as well as the conformity assessment by third-party bodies are of importance here. With regard to the accreditation and notification of the bodies, it is ensured that the statements of conformity are recognizable across Europe and

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161 § 84 SGB III.

162 § 85 SGB III. The authorization of responsible bodies and measures is applied for by the responsible bodies from the certification body, which decides on this. A certificate is issued upon authorization, § 7 para. 1, § 9, § 10 para. 1, 2 AZWV. The responsible body may freely select the certification body.

163 The responsibility of the recognition body of the Federal Labour Agency (Bundesagentur für Arbeit) results from § 3 para. 1 AZWV.

164 For the responsibilities of the competent body see p. 4 of the justification (Fn. 160); on the quality management system of the competent body p. 5.

165 Informations from the BA at URL: http://www.arbeitsagentur.de/vam/vamController/CMSConversation/anzeigeContent?navId=56987&tl=tlcn&rqc=4&ls=false&ut=0 (17.2.2006) under "Anerkennungsverfahren".

166 KOGB, Bestandsaufnahme (Fn. 155), columns on the recognition body of the BA.

that time- and cost-intensive multiple inspections can be avoided. Therefore, the level of accreditation is of particular significance in this area.

Another important function of conformity assessment is removing the burden from the state during executive tasks such as surveillance, e.g. in equipment surveillance[167]. Thanks to the use of recognized conformity assessment bodies – whether inspection tasks are delegated to them by the authorities or the persons affected by the laws are requested to provide inspection reports – the state authorities can be exonerated from inspection tasks. At the same time, the conformity assessment bodies operating on the market feed their expertise and up-to-date knowledge into surveillance measures. The recognition and accreditation of the bodies fulfils the function of assuring the quality of the inspections which are no longer conducted by the authorities themselves. The regulations of the state in the so-called "regulated environmental area" also show that the accreditation can contribute to the harmonization of inspections and at the same time to the simplification and greater effectiveness of the administration in a federal state.

In individual areas we find conformity assessment procedures or in any case elements of conformity assessment in administrative contexts concerned with distributing benefits (*Leistungsverwaltung*). An example of this is the recognition of competent bodies for the certification of responsible bodies and measures for further education and training in accordance with SGB III which is supposed to ensure that state funds are only spent on effective training measures[168].

Ultimately the state can indirectly pursue certain regulatory objectives through the establishment and/or advancement of (voluntary) conformity assessment systems. Examples of this are the regulations on EMAS (environmental protection) or the GS-mark (consumer protection and work safety).

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167 See above A.II. for the regulatory environmental sphere, further above A.IV.2 on the surveillance of equipment according to the GPSG. The accreditation of bodies in the driving licence system fulfils a similar function, see above A.V.1.

168 See above A.V.2.

What is characteristic for the multitude of used conformity assessment procedures is that they are not exclusively relevant for the regulatory sphere, rather draw on inspection and certification procedures which are also used in the private sphere.

B. Current structure of the German accreditation system

The overview of the forms of use of conformity assessment and accreditation in the regulatory sphere shows that the recognition and accreditation of the bodies plays a significant role in securing the quality of conformity assessment and – to the extent that the conformity assessment systems are geared to do so – the recognizibility of the results. Therefore, the structures of accreditation in Germany shall be examined in more detail in the following. The German accreditation system is currently marked by two features, on the one hand the separation of private accreditation bodies and state accreditation and recognition bodies, and on the other hand the division of the responsibilities of the accreditation bodies according to sectors. It also distinguishes itself from the accreditation systems of other European countries in that there are several accreditation bodies and that they compete or at least are allowed to compete with one another – as long as they are not state bodies. The upcoming segment first outlines how this complex structure of the German accreditation system developed. Secondly, the most important currently active accreditation bodies or recognition and accreditation bodies shall be briefly presented, before the advantages and disadvantages of the current structures are addressed.

I. Development of the structures of the German accreditation system

In Germany, accreditation came about at the end of the 1980s. The establishment of accreditation bodies was partly motivated by the New Approach and the Global Approach for[169], which recommended the establishment of accreditation systems to support the designation and notification procedures by the Member States. In December 1988 the Federal Ministry of Economic Affairs founded the *BAM-Akkreditierungssystem Prüfwesen*, the

169 See above Second Section, B, in particular B.III.1.a).

current *DAP*[170], which initially was intended to offer accreditation in all the areas relevant at that time. However, it soon became evident that there were obstacles to the creation of a uniform accreditation body, on the one hand the efforts by business interest groups to set up their own accreditation bodies in the respective sectors, and on the other hand the division of administrative authority between the Federal Government and the Länder.

1. Accreditation bodies for the non-regulatory sphere

German businesses and business interest groups tended to be adverse to a uniform state accreditation body. One reason for this was that some business associations had reservations towards the institution of accreditation: an accreditation to assure the quality of inspections was frequently regarded as unnecessary. Furthermore, the majority of business interest groups held the view that accreditation could be carried out just as well or even better by accreditation bodies operated by businesses. They thus intended to establish their own accreditation bodies[171]. Initially, *one* accreditation body for the non-regulatory sphere was envisioned, which was supposed to practically function as a placeholder and prevent the potential expansion of the activities of the state accreditation body into the voluntary sphere. The establishment of a uniform accreditation body failed however: in the various areas there were different demands for accreditation and economic sectors which had not yet benefited from accreditation up to this point in time and were not automatically willing to participate in financing the system. Furthermore, the *BAM-Akkreditierungssystem Prüfwesen*/*DAP* already existed, which was also active in the non-regulatory sphere, and it was unlikely that this could be integrated into a uniform accreditation body of the non-regulatory sphere. Consequently, accreditation bodies were founded relatively early by business and professional associations and industrial firms, which were active in certain sectors, e.g. the GAZ in the steel sector (1989) or DATech (1990), DASMIN and DASET (1991) as well as the DACH (late 1992). A cited advantage of such a system is that the associations would have close professional contacts to the conformity assessment bodies active in their area and could thereby offer a more economically oriented and effective

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170 *Deutsches Akkreditierungssystem Prüfwesen GmbH*, see DAP at URL: http://www.dap.de/ (13.2.2006). See also *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 3.

171 See also *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 3; *Wloka et al.*, Anerkennung und Akkreditierung (Module 3), Item 2.1. at the end.

accreditation. The TGA (German Association for Accreditation) was originally supposed to coordinate the activities of the different accreditation bodies and offer accreditation (only) in areas in which no other association-based accreditation was available. This thus led to the development of a sectorally divided accreditation system in the non-regulatory sphere.

2. Accreditation bodies of the Federal Government and the Länder

During the implementation of the directives based on the New Approach the requirements for the Notified Bodies were adopted in the respective area-specific laws, e.g. the Equipment Safety Law (GSG) or the Medical Devices Law (MPG). The recommendation of the directives that the basis of the notification should be an accreditation wherever possible was interpreted to the extent that accreditation – as the basis for the designation or notification – is a state task, which consequently must be carried out by the authorities – in any case as long as it is takes place for designation purposes[172]. This led to the establishment of state accreditation and recognition resp. designation bodies which operated on the basis of the relevant directive. As a rule, the state accreditation bodies carry out accreditation procedures under consideration of harmonized standards, but are also at the same time responsible for sovereign decisions on the notification or recognition of the bodies[173].

As long as the execution of the relevant laws was incumbent on the Länder (this was the case with the Equipment Safety Law for example, in which numerous directives were implemented according to the New Approach, and for the Medical Devices Law), the Länder took claim to the responsibility for accreditation on the basis of Art. 83 GG: the Prime Ministers of the Länder adhered to a resolution from 1989 stating that whenever according to EC law the appointment of executive authorities with responsibilities for all of Germany is required, theses bodies must work within the executive authority of the Länder as long as

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172 However, this was by no means binding. The directives only require an official decision for notification. Developments in other examined countries show that a distinction between the sovereign designation or notification and the accreditation upon which it was based was made from the very beginning. See above Third Section, B.

173 Among other things, this had the effect that in the German recognition and accreditation system a clear distinction was not always made between accreditation on the basis of harmonized standards on the one hand and notification and recognition on the other hand.

- according to the relationship between the Federal Government and Länder at the domestic level - the Länder are responsible for the enforcement of the laws[174]. In order to not have to provide for the required professional expertise in all federal states and to avoid double administrative structures, the Länder decided to centrally organize the accreditation, notification and surveillance of the conformity assessment bodies. In 1989 the Prime Ministers signed an agreement on the establishment of the *Zentralstelle der Länder für Sicherheitstechnik* - ZLS (Central Authority of the Laender for Security Technology) in Munich and on the *Akkreditierungsstelle der Länder für Mess- und Prüfstellen zum Vollzug des Gefahrstoffrechts* - AKMP (Accreditation Body of the Länder for Measuring and Inspection Bodies for the Execution of the Dangerous Substances Law) with headquarters in Kassel[175]. Accordingly, a state treaty was concluded in 1993[176]. In view of directives 93/42 EC on medical devices and 90/385 EEC on active implantable medical devices a decision again had to be made on the division of responsibilities, and an additional state treaty established – under consideration of the Berlin Resolution"[177] – an additional central body for the Länder *Zentralstelle der Länder für Gesundheitsschutz bei Medizinprodukten* - ZLG (Central Authority of the Laender for Health Protection Regarding Medical Devices) with headquarters in Bonn[178].

As long as the Federal Government and not the Länder were generally responsible for the execution of the laws, the Designating Authorities provided for by the directives were based in the area of responsibilty of the area-specific Federal Ministries. For example, the former *Regulatory Authority for Telecommunications and Post* (Regulierungsbehörde für

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174 The resolution is cited in *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 5.

175 *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 5. On the ZLS below a). The AKMP has been dismantled meanwhile. The corresponding section of the treaty (Fn. 128) was abolished by the agreement from 16.12.2003 (published e.g. in GVOBl. Schl.-H. 2004, p. 2).

176 Agreement on the *Zentralstelle der Länder für Sicherheitstechnik* and on the *Akkreditierungsstelle der Länder für Meß- und Prüfstellen zum Vollzug des Gefahrstoffrechts* (ZLS/AKMP) from 16/17 December 1993 (Fn. 128).

177 See *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 5.

178 Nowadays "*Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten – ZLG*" (Central Authority of the Laender for Health Protection Regarding Medicinal Products and Medical Devices), the basis is the "*Abkommen über die Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten*", GV. NRW. 1994 p. 972, as amended and promulgated on 02/09/1999 (GV. NRW p. 54), available online at URL: http://www.zlg.nrw.de (20.2.2006) under "Wir über uns", Abteilung Medizinprodukte: Link "Abkommenstext".

Telekommunikation und Post) became responsible for accreditation and notification in the area of electro-magnetic compatibility and telecommunications[179], the Federal Bureau of Motor Vehicles and Drivers (*Kraftfahrtbundesamt*) for motor vehicles and the Federal Railway Authority (*Eisenbahnbundesamt*) for railway systems[180].

Later, additional bodies came about at the federal and state level which dealt with accreditation and/or the recognition and notification of inspection bodies outside the scope of the directives based on the New Approach in product safety law. For example, at the state level the *Koordinierungsstelle der Länder für Messgeräte - KL-Mess* (Coordination Agency of the Länder for Measuring Devices) must be mentioned or the *AKS Hannover* and the *SAL* with headquarters in Wiesbaden, which are both active for several federal states in the area of food surveillance and organic farming[181].

3. Establishment of the German Accreditation Council – DAR

After it became evident that there would be several accreditation bodies in both the regulatory and non-regulatory sphere, the creation of the German Accreditation Council (*Deutscher Akkreditierungsrat - DAR*) was prepared as of 1989/1990. The objective was to create a common representation of the accreditation bodies, which above all was to represent them externally. The DAR has existed since March 1991 as a committee supported by both the state and businesses, in which accreditation bodies of the regulatory and non-regulatory sphere work together on a voluntary basis[182]. The DAR does not carry out any accreditations or recognitions on its own. Among its tasks is the coordination of the accreditation and recognition bodies active in Germany, as long as they are represented in the DAR and support German interests in national, European and international institutions

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179 The current *Bundesnetzagentur* (Federal Network Agency), in greater detail below B.II.2.b)(i).

180 Responsible in the scope of Directive 96/48/EC (Inter-operability of the trans-European high-speed rail system).

181 In greater detail below. See also the review of the KOGB in the respective column, KOGB, "Bestandsaufnahme für die in Deutschland im gesetzlichen (öffentlich-rechtlichen) Bereich mit Akkreditierungen, Anerkennungen, Benennungen, Zulassungen, Bewertungen und Notifizierungen befassten Stellen im Rahmen der Konformitätsbewertung" (KOGB-12-06 rev 09, last updated 9.9.2005), available online at URL: http://www.bundesnetzagentur.de/media/archive/4029.pdf (22.2.2006).

182 Handbuch des DAR, Section 2, available online at URL: http://www.dar.bam.de/qm2.html (13.2.2005). For more on the DAR see also *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 45 et seqq.

which deal with general accreditation and/or recognition matters. The DAR also maintains a central accreditation and recognition register[183].

The more or less coherent appearance towards the outside of the German accreditation system was supported by the fact that the accreditation bodies represented in the DAR were authorized to use a uniform accreditation certificate of the DAR and the logo of the DAR while the accreditation was issued[184]; the accreditation certificate of the DAR contains, among other things, an illustration of the German Federal Eagle[185].

4. Further development

In this manner, an accreditation system originated in Germany, which – unlike in other countries – transferred accreditation in the regulatory sphere to the state authorities responsible for the sovereign decision on the recognition and designation. However, these bodies did not carry out any accreditations for the non-regulatory sphere, so that the structure of the private accreditation bodies generally supported by business associations active in certain sectors could develop there.

a) Non-regulatory sphere

However, in the course of further developments in the non-regulatory sphere the difficulty arose that the sectors could hardly be distinguished from one another and that the areas of activity overlapped. The integration of additional private accreditation bodies into the system also led to difficulties. The division of the sectors among the accreditation bodies and the coordination activities of the TGA led to concerns with regard to anti-trust laws, which resulted in proceedings at the *Bundeskartellamt* (German Federal Cartel Office)[186]. The consequence of this was that the TGA gave up the task of coordinating the accreditation

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183 For more see the procedural rules of the German Accreditation Council; see the currently applicable version of the document DAR-2-GL 01, Version 7.0, confirmed on 7.9.2005, available online at URL: http://www.dar.bam.de/pdf/dar_2_gl_01.pdf (13.2.2005).

184 Handbuch des DAR (Fn. 182), Section 4.5.

185 See DAR-3-EM-03, Hinweise für die Verwendung der Akkreditierungsurkunde des Deutschen Akkreditierungsrates, Version 7.1, confirmed on 7.9.2005, available online at URL: http://www.dar.bam.de/pdf/dar_3_em_03.pdf (13.2.2006).

186 The procedure was suspended.

bodies in the non-regulatory sphere[187]. In fact, several accreditation bodies of the non-regulatory sphere currently compete with one another. Meanwhile, there are – repeated – efforts to merge the accreditation bodies into a core group of accreditation bodies of the non-regulatory sphere.

b) Regulatory sphere

Several accreditation and recognition bodies from the regulatory sphere have abandoned their membership in the DAR, in particular as a consequence of the anti-trust dispute.[188] These include the ZLS and ZLG which are responsible for broad areas.

In 2001 a coordination group for the legally regulated areas (Koordinierungsgruppe des gesetzlich geregelten Bereichs - KOGB) was formed, which was supposed to fill in the gap between the regulatory and non-regulatory sphere[189]. The KOGB views itself as a part of the German accreditation system under the auspices of the DAR[190]. Membership in the coordination group is open to all public institutions of the Federal Government and the Länder, whose responsibilities include notification, designation, recognition or accreditation as well as drawing up legislation in these areas[191]. The KOGB has set the objective of drawing up recommendations, opinions and suggestions, in particular to define the position of the legally regulated sphere with regard to the national and international accreditation and conformity assessment policy. Furthermore, it shall develop a uniform standard and/or guidelines for the appointment of experts, which enables access to experts for other bodies

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187 The Director of the DAR is currently – temporarily – presiding over the entry of bodies from the non-regulatory sphere into the DAR on the basis of an evaluation of the body by the BAM; to this end, the accreditation bodies conclude an evaluation contract with the BAM. See the procedural rules of the German Accreditation Council (Fn. 183), Item 3.1.

188 According to the member list from March 2006, the following organizations are currently members in the DAR: AKS Hannover, Bundesnetzagentur, DAU, KL-Mess and KBA (Source: based on DAR-2-GL-02, Version 16.0, updated 10.3.2006, available online at URL: http://www.dar.bam.de/pdf/dar_2_gl_02.pdf (20.3.2006); the Internet site of the DAR only mentions the AKS, DAU and KBA in the overview of the accreditation bodies for regulatory sphere, though.

189 For the KOGB see *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 50.

190 Internet site of the KOGB under "Einbindung der Koordinierungsgruppe in den DAR", at URL: http://www.bundesnetzagentur.de/enid/5ded412cd6d74770d5e0b55b01f64a0e,55a304092d09/hg.html (13.2.2006). Not all members of the KOGB are members of the DAR. The offices of the coordination group are currently maintained by the *Bundesnetzagentur* (Federal Network Agency).

191 Internet site of the KOGB under "Mitgliedschaft in der Koordinierungsgruppe", at URL: http://www.bundesnetzagentur.de/enid/5ded412cd6d74770d5e0b55b01f64a0e,55a304092d09/hg.html (13.2.2006). Not all members of the KOGB are members of the DAR.

as well as to exchange experiences and or share mutual information from the legally regulated sphere in the national and international arena.

II. Taking stock: recognition and accreditation bodies in Germany

In the following the accreditation bodies from the non-regulatory sphere and the recognition and accreditation bodies of the regulatory sphere active in Germany shall be described and an overview of their areas of activity provided. However, it is not possible to offer a complete listing[192].

1. Accreditation bodies in the non-regulatory sphere

There are currently seven accreditation bodies in the non-regulatory sphere[193].

a) Overview of the bodies

First of all, this includes the **DAP** – Deutsches Akkreditierungssystem Prüfwesen GmbH, which was founded in 1988 by the Federal Ministry for Economic Affairs as the BAM-Akkreditierungssystem Prüfwesen[194]. It is primarily supported by the Association of Materials Testing Offices (Verband der Materialprüfungsämter). Additional associated partners are the Deutsche Gesellschaft für Zerstörungsfreie Prüfung (DGZfP), the DVS – Deutscher

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192 Here we kindly ask readers to refer to the schematic presentations for the regulatory sphere provided by the KOGB. The KOGB provides three different overviews: The "Bestandsaufnahme für die in Deutschland im gesetzlichen (öffentlich rechtlichen) Bereich mit Akkreditierungen, Anerkennungen, Benennungen, Zulassungen, Bewertungen und Notifizierungen befassten Stellen im Rahmen der Konformitätsbewertung" (KOGB-12-06 rev 09, updated 9.9.2005) presents the accreditation and recognition bodies with their respective responsibilities and the respective legal foundations in a table. The overview KOGB-06-06 rev. 2 (updated 13.7.2005) offers a schematic overview of the accreditation and recognition bodies at the Federal and State level; the overview KOGB-07-06 rev. 8 (updated 30.11.2005) categorizes the bodies according to their responsibilities in the regulatory spheres of the directives based on the New Approach "other decrees and regulations" as well as additional legal foundations. The documents are available online at the website of the offices of the KOGB at the *Bundesnetzagentur* (Federal Network Agency) at URL: http://www.bundesnetzagentur.de/media/archive/4029.pdf (KOGB-12-06), http://www.bundesnetzagentur.de/media/archive/4369.pdf (KOGB-06-06), http://www.bundesnetzagentur.de/media/archive/4370.pdf (KOGB-07-06), (22.2.2006).

193 Information on the bodies and their areas of activity is also contained in the short descriptions of the DAR, available online at URL: http://www.dar.bam.de/ (14.2.2004).

194 DAP at URL: http://www.dap.de/ (13.2.2006). See also *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 3.

Verband für Schweißen und verwandte Verfahren e.V., the Germanischer Lloyd Industrial Services GmbH (GLIS), the Landesgewerbeanstalt Bayern (LGA) as well as the Verband der Technischen Überwachungs-Vereine e.V. (VdTÜV)[195]. It is active in various areas of accreditation.

In the chemistry sector two accreditation bodies existed, the **DACH** – Deutsche Akkreditierungsstelle Chemie GmbH (German Accreditation Body for the Chemical Sector) and the **DASMIN** – Deutsche Akkreditierungsstelle Mineralöl GmbH. (German Accreditation Body for Petroleum). The DACH was established at the end of 1992 by the Verband der Chemischen Industrie (VCI – German Chemical Industry Association), the Gesellschaft Deutscher Chemiker (GDCh – German Chemical Society) and the Deutsches Institut für Normung – DIN and began its accreditation activities in 1994. The Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin (DGKL – Unified German Association for Clinical Chemistry and Laboratory Medicine) has been the successor of the DIN as an associate of the DACH since 2003[196]. The DASMIN GmbH was founded in 1991 by the DGMK - Deutsche Wissenschaftliche Gesellschaft für Erdöl, Erdgas und Kohle e.V. (German Society for Petroleum and Coal), in order to promote quality assurance in its areas of activity, petroleum, natural gasoline, petro-chemistry and coal refinement. It transferred its accreditation activities to the DACH on 1/1/2006[197].

The **DATech** – Deutsche Akkreditierungsstelle Technik e.V. (German Accreditation Body for Technology) and the TGA Trägergemeinschaft für Akkreditierung GmbH (German Association for Accreditation) must also be mentioned. The DATech is active in the area of electrotechnology, engineering, precision mechanics, optics, information and telecommunication technology as well as related areas[198]. The **TGA** accredits conformity assessment bodies that evaluate quality management systems (ISO 9001, QS 9000, SCC, EN 46001/2) and environmental management systems (ISO 14001) or carry out personnel certifications, for example with regard to non-destructive testing, joining technology and

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195 DAP at URL: http://www.dap.de/ (14.2.2006).
196 DACH at URL: http://www.dach-gmbh.de/s_wir.htm (14.2.2006).
197 DASMIN at URL: http://www.dasmin.de/ (13.2.2006).
198 DATech at URL: http://www.DATech.de/ (14.2.2006).

welding, motor vehicle experts, corrosion experts, property appraisers, quality management and environmental management personnel[199].

The **GAZ** – Gesellschaft für Akkreditierung und Zertifizierung mbH (Association for Accreditation and Certification) is active in the steel industry. It was established in 1989, primarily by German firms and associations, but also foreign firms from the steel industry[200].

The **DIAS** – Deutsches Institut für Akkreditierungssysteme GmbH (German Institute for Accreditation Systems) with its headquarters in Stuttgart should also be mentioned. It is a newer firm that accredits inspection bodies in various areas[201].

The Deutscher Kalibrierdienst DKD (German Calibration Service), which is based at the Physikalisch-technischen Bundesanstalt (PTB) (Federal Agency for Physical and Technical Affairs), can additionally be included in the non-regulatory sphere.

The DEKITZ, which was active in the area of information technology, merged with the DATech in 2000. The DASET – Deutsche Akkreditierungsstelle Stahlbau und Energietechnik e.V. (German Accreditation Body for Steel Construction and Energy Technology) has discontinued its activities.

b) Membership in the DAR as well as in EA, IAF and ILAC

The mentioned accreditation bodies of the non-regulatory sphere are members of the DAR[202]. Full members of EA and signatories of the EA-MLA include the DACH, DAP, DATech, TGA and DKD; the same holds for the DASMIN[203]. Upon membership an explanatory remark is made that the mentioned accreditation bodies are members of the DAR. Signatories to a MRA and thus full members of ILAC are DACH, DAP, DATech (signatories to the MRA for the testing segment) as well as the DKD for the calibration

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199 TGA at URL: http://www.tga-gmbh.de/ (14.2.2006).
200 GAZ at URL: http://www.gaz-online.de/ (14.2.2006).
201 Short description of the DAR at URL: http://www.dar.bam.de/kurz/dias.pdf (14.2.2006).
202 Source: DAR-2-GL-02, Mitglieder im Deutschen Akkreditierungsrat, Version 15.3, available online at URL: http://www.dar.bam.de/pdf/dar_2_gl_02.pdf (13.2.2006).
203 Source: List of the signatories of the EA-MLA with a reference to their respective scope, available online at URL: http://www.european-accreditation.org/ (13.2.2006).

segment[204]. DAR is a member of ILAC as a National Coordination Body. IAF lists the DAR as a member "on behalf of" TGA, DAP and DATech. DAP and DATech are included in the IAF MLA for product certification, the TGA in the IAF-MLA for Quality Systems and for Environmental Management Systems[205]. The GAZ and DIAS are not represented in the associations of the accreditation bodies and are not signatories to the MLA.

2. Recognition bodies and accreditation bodies in the regulatory sphere

In the current German system the repartition of competences and thus the affiliation of the accreditation bodies to the state or federal level follows the repartition of competences for the enforcement of the respective laws, which is devided between the states and the federal level (see above Fourth Section B.I.2)[206].

a) Recognition and accreditation bodies of the Länder

(i) ZLS

The Zentralstelle der Länder für Sicherheitstechnik - ZLS (Central Authority of the Laender for Security Technology) with headquarters in Munich was founded in 1989 on the basis of an agreement between the 16 Federal States[207]. The main focus of its activities was initially the area of (preventive) occupational safety[208], and the accreditation and surveillance of inspection and certification bodies which inspect and certify devices, machines and equipment. Meanwhile, more emphasis is placed on the facilitation of the free movement of goods by means of conformity assessment, in particular due to the regulations on marketing products in the directives based on the New Approach. According to Art. 2 para. 2 of the agreement, the ZLS now carries out the tasks of the states in the area of accredita-

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204 ILAC at http://www.ilac.org/ (13.2.2006).

205 IAF at URL: http://www.iaf.nu/ (13.2.2006).

206 The KOGB offers a schematic overview in its stocktaking and the illustrations, see above Fn. 192.

207 *Abkommen über die Zentralstelle der Länder für Sicherheitstechnik und über die Akkreditierungsstelle der Länder für Meß- und Prüfstellen zum Vollzug des Gefahrstoffrechts* (ZLS/AKMP) from 16/17 December 1993 (Fn. 128). On the establishment of the ZLS see also above 2, in greater detail in *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 4 et seq., Rn. 25 et seqq.

208 The responsibility for the recognition and notification of GS-bodies can also be seen in this context, see above A.IV.1.

tion, recognition, and notification[209] as well as the surveillance of conformity assessment bodies in various areas[210], in particular within the scope of the GPSG. It is thus responsible for the accreditation and notification of bodies within the scope of numerous directives based on the New Approach[211], for the accreditation of conformity assessment bodies in various segments of the MRA between the EU and third countries[212], for the accreditation and in part also the notification of authorized inspection bodies for the surveillance of facilities[213] as well as for the recognition and notification of GS- bodies[214].

While notifying bodies within the scope of European directives, the ZLS uses the relevant standards of the series EN 45000 et seqq. resp. ISO/IEC 17000 et seqq.[215].

The ZLS has established a core group of experts for the exchange of experience between the bodies at the national level and several groups in individual sectors for this purpose[216].

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209 As long as no other authority (the responsible area-specific agency of the federal state) is responsible for the notification.

210 Art. 2 para. 2 of the agreement refers to authorized bodies *(zugelassene Stellen)* and authorized surveillance bodies (*zugelassene Überwachungsstellen)* according to the Equipment Safety Law, Notified Bodies and certification bodies according to the medical product law for the area of active medical devices, inspection and certification bodies according to the Law on the Transport of Dangerous Substances in conjunction with § 6 of the Dangerous Substances Ordinance with regard to roads and railways for containers for the transport of gases, Notified Bodies according to the First Ordinance on the Explosives Law, bodies according to the Ship Equipment Ordinance (*Schiffsausrüstungsverordnung-See*), bodies in the area of the Dangerous Substances Law and notified and authorized bodies according to the Directive on transportable pressure equipment. Since the amendment of the Dangerous Substances Ordinance, which came into force on 1.1.2006, the ZLS no longer accepts accreditation applications for the accreditation of measuring bodies according to § 9 para. 6 of the Dangerous Substances Secree (formerly § 18 para. 2 of the Dangerous Substances Ordinance), ZLS at URL: http://www.zls-muenchen.de/de/left/aktuell/pdf/050411_ausstieg_messstellen_gefstoffv.pdf (20.2.2006). The Dangerous Substances Ordinance from 23.12.2004 (BGBl. I, 3759, last amended by Art. 2 of the Ordinance from 23.12.2004, BGBl. I, 3855) only stipulates now in § 9 para. 6 that only those persons may conduct measurements who have the necessary professional expertise and the required facilities. According to clause 2 an employer who mandates an accredited measuring body may assume that the results determined by this measuring body are correct.

211 Overview of the ZLS at URL: www.zls-muenchen.de/de/left/zustaendigkeitsbereich/eg-richtlinien/eg-richtlinien-ix.htm (21.2.2006).

212 Overview of the ZLS at URL: www.zls-muenchen.de/de/left/zustaendigkeitsbereich/mra/mra-ix.htm (21.2.2006).

213 According to §§ 19 et seqq. GPSG and the *Betriebssicherheitsverordnung*, see above A.IV.2.

214 On the GS-bodies above A.IV.1.

215 More on the ZLS at URL: www.zls-muenchen.de/de/left/antragsverfahren/antragsverfahren_gpsg.htm (21.2.2006). For the criteria for the accreditation and recognition/notification of GS-bodies and authorized surveillance bodies, see above A.IV.1, A.IV.2.

216 More on the ZLS at URL: www.zls-muenchen.de/de/left/erfahrungsaustausch/erfahrungsaustausch-ix.htm (21.2.2006).

At least in the scope of the GPSG, existing accreditations of other accreditation bodies – including those from the non-regulatory sphere – may be considered in the recognition and/or accreditation procedure of the ZLS[217].

(ii) ZLG

The *Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten* – ZLG with headquarters in Bonn was established in 1993 by an additional agreement between the Länder[218]. According to Art. 2 para. 3 of the agreement, it carries out in particular the tasks of the Länder in the medical devices sector[219] with regard to the accreditation and notification of conformity assessment bodies for non-active medical devices and in-vitro diagnostics, and also within the framework of agreements between the European Community and third-countries (MRA)[220].

According to the accreditation rules of the ZLG, compliance with the demands of the harmonized standards is a prerequisite for accreditation[221]. However, the requirements of the harmonized standards are supplemented with further demands resulting, for example, from relevant Commission recommendations (e.g. MEDDEV Papers[222]); furthermore, they are in part concretized and supplemented by special accreditation rules which are drawn up by the Accreditation Advisory Board *(Akkreditierungsbeirat)* of the ZLG[223].

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217 § 11 para. 1 clause 2 GPSG is used as a basis for this, in greater detail above A.I.1.c).

218 *Abkommen über die Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten* (Fn. 128). See above B.I.2 for the establishment of the ZLG, in greater detail in *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 2 Rn. 4 et seq., for the tasks see Rn. 34 et seqq.

219 The responsibilities of the ZLG with regard to medicinal products will not be addressed here.

220 According to the language used in the agreement on the ZLS, the term "conformity assessment body" only refers to bodies recognized within the framework of an agreement with a third-country, while the remaining bodies are generally defined as laboratories, certification bodies or notified bodies, see Art. 2 para. 3 No. 8 of the agreement as well as illustration 11 in *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 37.

221 See the General Accreditation Rules of the ZLG, which define compliance with the harmonized standards as a prerequisite for accreditation: ZLG, Allgemeine Akkreditierungsregeln (200_AR01_031031), 1.2, available online at URL: http://www.zlg.de/download/MP/200_AR01_AllgAkkRegeln.pdf (16.2.2006). More on the requirements for accreditation in *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 14 et seqq., *Merten*, Private Entscheidungsträger, p. 188 et seqq.

222 See the Second Section above B.III.3.

223 See above A.I.2 at the end.

The ZLG is the office for the information exchange of the bodies notified under the Medical Devices Law (*EK-Med*)[224]. The ZLG participates in the exchange of experiences at the level of the European Union and in consultations within the framework of the agreements between the EC and third-countries in the medical devices sector[225].

(iii) KL-Mess

The coordination body of the states KL-Mess is active in the measuring sector, currently in particular in the area of non-automatic scales, which are affected by the regulations based on the Directive 90/384 EC. The office headquarters are located in the Thuringia State Office for the Measuring and Calibration System (*Landesamt für Mess- und Eichwesen Thüringen* – LMET). The extent to which the KL-Mess will assume tasks based on the new Measuring Instruments Directive (MID)[226], which provides for conformity assessment procedures based on the New Approach for additional measuring equipment, remains to be seen[227].

(iv) AKS Hannover and SAL

The AKS Hannover and the SAL in Wiesbaden are active in the foods sector[228].

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224 More on the ZLG at URL: http://www.zlg.nrw.de (21.2.2006) under "Medizinprodukte" – Link "Erfahrungsaustausch".

225 More on the exchange of experiences in the medical devices sector at the European and international level above in the Second Section, B.III.3, for the European level see *Soltau*, in: Anhalt/Dieners (eds.), Handbuch des Medizinprodukterechts, § 12 Rn. 51 et. seqq.

226 The directive 2004/22/EC of the European Parliament and the Council of 31 March 2004 on measuring equipment, Official Journal L 135 p. 1 (MID) is supposed to be implemented in Germany by a new Measuring Law with a Measuring Ordinance, which is supposed to replace the Calibration Law (Eichgesetz).

227 In the state measuring system there is a general administrative provision issued by all Federal States "Gesetzliches Messwesen – Allgemeine Regelungen - GM-AR"); the GM-AR compiles normative requirements and interprets them; it attaches great importance to the international recognition of the results of the conformity assessment procedures (GM-AR, p. 5). The GM-AR was already drawn up with respect to the implementation of the MID and the inclusion of conformity assessment procedures in German law, GM-AR p. 2, p. 7, p. 9. The GM-AR is published in the *Bundesanzeiger* (Federal Gazette) No. 108a from 15.6.2002 and available online at URL: http://www.agme.de/News/GM-AR-100402Bundesanzeiger.pdf (20.2.2006).

228 According to Art. 1 et seqq. Regulation (EC) No. 882/2004 (replaces Directive 89/397 EWG) foods and articles of daily use are subject to regular official surveillance. According to Art. 5 Regulation (EC) No. 882/2004, the Member States may transfer certain tasks to control bodies, when it has been demonstrated that the controlling body fulfils certain requirements; among other things, it must be accredited according to EN 45004 (inspection bodies) and the laboratories used must fulfil the requirements of Art. 12 para. 2

The *AKS Hannover* was established by the government of the State of Lower Saxony during the implementation of a resolution of the 65th Conference of Health Ministers (1994) and is active across Germany. According to its own information, it accredits state and private inspection bodies, certification bodies and inspection laboratories "in the interest of the public"; its core activities are in the areas health consumer protection, agriculture, laboratory diagnostics, and veterinary medicine. With regard to inspection laboratories, its core competences apply to the area of biological, chemical, physical and medical-diagnostic examinations of biological material, foods, water, articles of daily use, medicines, animal feed, as well as human bio-monitoring, among other things[229]. According to their own statements, the series of standards EN 45000 and ISO 17000 provide the basis for their activities; the AKS operates according to ISO 17011[230]. The AKS takes accreditations of other accreditation bodies into consideration in some circumstances[231].

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of the Regulation. Art. 11 et seqq. Regulation (EC) No. 882/2004 governs the taking of samples for purposes of analysis. According to Art. 12 Regulation (EC) No. 882/2004 the Member States notify laboratories which may conduct analyses of the legally taken samples. According to Art. 12 para. 2 Regulation (EC) No. 882/2004, the Member States may only notify such laboratories which are accredited according to EN ISO/IEC 17025 and EN 45002 or EN 45003. This may pertain to both official and private laboratories, see also the review by the KOGB (Fn. 192) in the column "AKS" (still referring to Directive 89/397 EEC). Accordingly, all laboratories operating in the foods sector must be accredited on the basis of EN ISO/IEC 17025 or EN 45002, 45003 to ensure a uniform level of security. The Member States are obligated to notify the bodies which conduct the assessment and state whether the laboratory fulfils the requirements of the directive: among others, two accreditation bodies of the Laender are responsible for this in Germany, the AKS Hannover and the SAL in Wiesbaden, see also KOGB, "Bestandsaufnahme" (Fn. 192), columns on AKS and SAL (still referring to Directive 89/397 EEC).

229 According to the presentation of the AKS on the Internet, "Kurzbeschreibung" at URL: http://www.aks-hannover.de/ (4.12.2005).

230 See the document "Ablauf einer Akkreditierung", which mentions ISO 17011 on page 4; available online in the area "Antragsunterlagen" at URL: http://www.aks-hannover.de/ (4.1.2005); see also the download segment for the application documents, which mentions the relevant ISO standard in the headings in parentheses.

231 The document "Ablauf einer Akkreditierung" (Fn. 230) on p. 4 states in this regard: "Berücksichtigt die AKS Hannover die Ergebnisse einer bereits von einer anderen Akkreditierungsstelle gewährten Akkreditierung bzw. durchgeführten Begutachtung, muss gesichert sein, dass die andere Akkreditierungsstelle entsprechend den Anforderungen dieser Internationalen Norm tätig geworden ist. Kooperationsakkreditierungen liegen grundsätzlich Vereinbarungen mit der anderen Akkreditierungsstelle und das Einverständnis der KBS zugrunde. Die AKS ist offen für Kooperationen mit anderen staatlichen und privaten, in- und ausländischen Zulassungs-, Akkreditierungs- und GLP-Stellen". (If the AKS Hannover considers the results of an accreditation already granted and appraisal already conducted by another accreditation body, it must be ensured that the other accreditation body acted in compliance with the requirements of this international standard. Cooperation accreditations are, as a rule, based on agreements with the other accreditation body and the consent of the CAB. The AKS is willing to cooperate with other state and private, domestic and foreign authorizing, accreditations and GLP bodies).

Besides the State in which it is based, Hesse, the *Staatliche Anerkennungsstelle der Lebensmittelüberwachung* – SAL (State Recognition Body for Food Surveillance) is supported by seven other Federal States, which work together on the basis of cooperation agreements with the SAL (Baden-Württemberg, Bavaria, North-Rhine-Westphalia, Rhineland-Palatinate, Saarland, Saxony and Thuringia)[232]. According to its own information, it is a Notified Body on the basis of Article 3 para. 3 of the Directive 93/99/EEC of the Council of 29 October 1993 on additional measures in the area of official food surveillance and a body according to § 1 para. 2 of the Ordinance on the Evaluation and Recognition of Inspection Laboratories as a Requirement of Private Cross-Check Experts for the Analysis of Samples (PrüflabV). Upon agreement, it also carries out the following tasks: the evaluation of inspection laboratories of examination facilities of other Federal States; the evaluation of other inspection laboratories mandated to examine foods; the evaluation of other inspection bodies with areas of inspection which are not subject to the official food surveillance system, but to the LMGB, the Wine Law, or other areas of law that concern food surveillance, as well as the evaluation of third-party inspection laboratories[233]. The accreditation procedures are conducted according to their statements on the basis of DIN EN 45003 or DIN EN ISO/IEC 17025; furthermore, the accreditations issued by the responsible committees of the SAL are to be used in their respectively applicable version[234].

(v) Further competences of the Länder

The Länder bear further competences in the construction sector[235] and in the environmental sector[236] as well as in the organic farming sector[237].

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232 The SAL is based at the Hessian Ministry for Environment, Agrarian Space and Consumer Protection (MULV). The minimization of the expenses for accreditation as a new responsibility of the official food monitoring system is mentioned as a reason for the cooperation and mutual support between the Federal States, see the information of the SAL at URL: http://www.hessen.de/HUMLV (20.2.2006) under "Verbraucher- und Tierschutz/Lebensmittelüberwachung/Akkreditierung".

233 Information from SAL under URL: http://www.hessen.de/HUMLV (20.2.2006) under "Verbraucher- und Tierschutz/Lebensmittelüberwachung/Akkreditierung".

234 See the QM Handbook from SAL, available online through the Internet presenstation of the SAL at URL: http://www.hessen.de/HUMLV (20.2.2006) under "Verbraucher- und Tierschutz/Lebensmittelüberwachung/Akkreditierung".

235 See above A.I.3.b).

236 See above A.II.

237 See the compilation from the KOGB, KOGB-12-06, KOGB-07-06 and KOGB 06-06 (Fn. 192).

b) Recognition and accreditation bodies at the federal level

(i) Federal Network Agency (*Bundesnetzagentur*)

According to the EMVG, the Federal Network Agency is responsible for the recognition of responsible bodies on the basis of § 7 para. 4 clause 1 EMVG, the vesting with public authority *(Beleihung)* as a Notified Body on the basis of § 7 para. 4 clause 2 EMVG and the recognition of conformity assessment bodies within the framework of third-state agreements on the basis of § 1 no. 2c BAnerkV[238]. According to the FTEG it is also responsible for the recognition of Notified Bodies according to § 8 para. 1 FTEG and the recognition of conformity assessment bodies within the framework of third-state agreements on the basis of § 1 no. 1b BAnerkV.

The Federal Network Agency regards the recognition of bodies to be a uniform process, in which the accreditation is also taken into account. During the recognition and/or *Beleihung* it falls back on DIN EN ISO 45011 and/or ISO /IEC 17025[239].

It cooperates with accreditation bodies from the non-regulatory sphere; e.g. staff of the Federal Network Agency are represented in sectoral committees of some accreditation bodies of the non-regulated sphere.

(ii) DAU

The German Accreditation and Authorization Body for Environmental Verificators (*Deutsche Akkreditierungs- und Zulassungsgesellschaft für Umweltgutachter mbH* –DAU) was established in 1995. The task of authorizing and monitoring the environmental appraisers in the EMAS was transferred to it[240]; it is for this purpose vested with public authority (*Be-*

238 See above A.I.3.a).

239 This is mentioned e.g. in the accreditation decisions, among other things; see also the "Bedingungen für die Erteilung, Aufrechterhaltung, Erweiterung, Einschränkung sowie für Erlöschen und Widerruf von Anerkennungen oder Beleihungen der Anerkennungsstelle der Bundesnetzagentur" (Doc. 14.30, updated 10.10.2005), which refer to the criteria of the BAnerkV "under consideration" of the respective standard, the document is available online at URL: http://www.bundesnetzagentur.de/media/archive/4617.pdf (20.2.2006).

240 On EMAS above A. III.

liehene)[241]. The founding partners of the DAU are the Federation of German Industries (BDI), the Association of German Chambers of Industry and Commerce (DIHK), the German Confederation of Skilled Crafts (ZDH), the *Bundesverband Freier Berufe - BfB* as well as nine other large branch associations including the automobile, chemical, electrical, mineral oil, optics, medical and mechatronic, and steel industry as well as the machine and equipment engineering, steel construction and energy technology[242].

(iii) BSI

The Federal Office for Information Security (BSI) offers certificates to confirm the result of safety inspections on IT products[243]. The certification criteria are, for the most part, European or harmonized internationally[244]; the international recognition of the certificates is guaranteed by agreements in which the certifying bodies also participate, thus in this case the BSI[245]. The certification is up to the BSI, but it may delegate the *evaluation* of the product to inspection bodies which it accredits itself[246]. Thus, the state itself offers a service, but outsources the required inspection activities to private bodies.

The accreditation procedure of the BSI combines a basic accreditation in accordance with ISO 17025 for laboratories with a certificate of expertise for the certification according to the applied standard, i.e. the so-called “licensing”, during which the expertise for one of

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241 UAG-Beleihungsverordnung from 18.12.1995. The authorization procedure is further regulated in the UAGZVV. As regards the tasks of the environmental verifieres, the Environmental Verification Committee (*Umweltgutachterausschuss* - UGA) is responsible for the development of interpretative directives on §§ 4 to 18, among other things, § 21 para. 1 No. 1 UAG, see e.g. the UGA-Surveillance Directive (*Aufsichtsrichtlinie*) from 22.2.2004, which regulates in greater detail the use of the surveillance instruments by the DAU. For more on the DAU, see (ii).

242 Information on the DAU under URL: http://www.dau-bonn.de/ (20.2.2006).

243 The legal foundation for the issue of the certificate by the BSI is § 4 BSIG. See also the information of the BSI at URL: http://www.bsi.de/zertifiz/index.htm (20.2.2006).

244 Criteria for the inspection can be: ITS (German criteria scheme), ITSEC (harmonized for Europe) and Common Criteria – CC (harmonized worldwide and now published as ISO 15048).

245 There are agreements on the international recognition of the certificate for ITSEC and CC; the signatories are respective national bodies, in Germany the BSI. More on the *BSI*, BSI certification and BSI-product certification: information for manufacturers and sales departments (BSI 7138), available online at URL: http://www.bsi.de/zertifiz/zert/7138.pdf (20.2.2006); further information also at URL: www.commoncriteriaportal.org (20.2.2006).

246 The applicant may choose the inspection body, see BSI 7138 (Fn. 245), 3.3. He concludes an evaluation contract with the inspection body, but applies for the certification from the BSI, BSI 7138 (Fn. 245), 3.1.1.

the licence areas[247] is inspected[248]. The recognition of accreditations on the basis of ISO 17025 by other accreditation bodies is possible; in such cases only IT specific items are still separately inspected within the framework of the basic recognition[249].

(iv) Additional bodies

Additional accreditation bodies exist on the federal level at the Federal Bureau of Motor Vehicles and Drivers (Kraftfahrtbundesamt)[250], the Federal Railway Authority (Eisenbahnbundesamt)[251], the Federal Labour Agency (Bundesagentur für Arbeit)[252] and the Federal Highway Research Institute (Bundesanstalt für Straßenwesen - BASt)[253].

III. Evaluation of the existing German accreditation system

The German accreditation system distinguishes itself from the accreditation systems of the other analyzed states by its separation of the regulatory and non-regulatory sphere (under 1). This goes hand in hand with a sectoralization of the accreditation facilities (under 2) which has led to competition in the non-regulatory sphere (under 3). The result of this type of structure of accreditation in Germany is that the accreditation system as a whole is only insufficiently incorporated into international structures (under 4).

1. Separation of the regulatory and non-regulatory sphere

However, the separation of the accreditation into a regulatory and non-regulatory sphere does also find considerable support. From the standpoint of the regulatory sphere, the

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247 ITS, ITSEC or CC.

248 For the accreditation procedure, see BSI at http://www.bsi.de/zertifiz/akkred/index.htm (20.2.2006), see the BSI procedure description 7113, available online at URL: http://www.bsi.de/zertifiz/akkred/BSI_7113.pdf (20.2.2006), see also BSI 7138 (Fn. 245).

249 BSI 7113 (Fn. 248), Section 3.2, accreditations by the Federal Network Agency and the DATech come under consideration, BSI 7138 (Fn. 245), 3.1.2.

250 Responsible for the authorization of vehicles and vehicle parts according to the directive 70/156/EEC (Type-approval of motor vehicles).

251 Responsible within the scope of Directive 96/48/EC (Interoperability of the trans-European high-speed rail system).

252 Responsible for the recognition of competent bodies for the certification of institutions and measures for further professional education according to SGB III, see above A.V.2.

253 Responsible for the accreditation of bodies for the driving licence system, see above A.V.1.

evaluation of the competence of bodies for legally stipulated conformity assessment tasks is often considered to be a task which by all means must be carried out by state authorities. From a formal point of view this appears to be essential, because the Member States are not only *entrusted* with the designation and notification of the bodies, but also *responsible* for this, especially within the scope of the directives based on the New Approach where the Member States must assume responsibility for their notification decisions vis-à-vis the other Member States. When the bodies provide testing results which are legally relevant for the market access for products or within the context of official surveillance measures, authorities see a close link to tasks incumbent on them such as health protection, environmental protection or, even more generally, to provide for safety[254]. Therefore, it is viewed as sensible to maintain as much influence as possible on assuring the quality of the conformity assessment and therefore establish official recognition procedures, which indeed are oriented towards the accreditation standards, but otherwise must be regarded more as classic state approval procedures. This appears to be comprehensible from the standpoint of the regulatory sphere and the respective area-specific departments.

With this, however, the path is paved towards the sectoralization of the recognition procedures in the regulatory sphere. To a certain extent, this can cause a greater administrative burden for the authorities altogether[255]. Under certain circumstances this sectoralization can lead to the need for the conformity assessment bodies to be recognized by different official recognition bodies, i.e. double and multiple accreditations/recognitions.

However, another issue seems to be more important: the systems of conformity assessment which are used in the regulatory sphere focus on structures which also exist in or for the non-regulatory sphere. This holds precisely for the level of accreditation. In the areas in which conformity assessment is supposed to facilitate international trade, actors at the European level pursue the goal of organizing market access for products with the least administrative effort. The aim is the principle of *one-stop-testing*. The accreditation systems at the European and international level are to provide an important contribution to this by

254 See *Wloka et.al.* Anerkennung und Akkreditierung (Module 3), Section 4.3. at the end.

255 However, this would be acceptable if the responsibility of area-specific authorities led to a particularly effective surveillance of the bodies.

providing for a uniform evaluation of the conformity assessment bodies and thus indirectly the equivalence of the declarations of conformity. In order to do so, it is necessary for the instrument of accreditation to cover all of the requirements concerning professional (technical) competence and adequacy of the body, so that state authorities can rely on it. Hence, the accreditation bodies must be designed for such tasks and if necessary bound to the state[256]. Therefore, it is at least problematic when accreditation and the sovereign decision on a notification/recognition are equated by means of legal provisions or from the point of view of state authorities. On the one hand, the very effects are eliminated which are supposed to be achieved by basing conformity assessment on structures which exist in the private sector. On the other hand and with regard to the criteria to be fulfilled, this quickly leads to uncertainties (here one might recall the "delta" between an "accreditation for the regulatory or the non-regulatory sphere", which is frequently addressed in the debate but difficult to define). Altogether, the unclear relationship between internationally harmonized accreditation procedures and sovereign recognition procedures leads to less transparency in the accreditation and recognition system – this is disadvantageous with regard to its function and the creation of trust. Solutions must be found here which bring about an appropriate balance between the functioning of accreditation in the international system and the justified interests of the area-specific departments in exerting sufficient influence on the competence and adequacy of the bodies.

Finally, it should be noted that the separation of the accreditation systems in Germany is not a total separation: there are forms of cooperation between bodies from the regulatory and non-regulatory sphere which span from representation in the respective sectoral committees to common assessments onto the consideration of existing accreditations. In the same measure, the public authorities elsewhere indeed believe to be able to accept evaluations by private accreditation bodies for conformity assessment bodies which are integrated into decision-making structures[257]. Altogether it thus depends on developing a structure which harmonizes the justified official interests with the international recognizibility of the statements of conformity.

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256 See Third Section above, and below Part Two, C.

257 See the above Fourth Section, A.II.1.

2. Sectoralization

An additional feature of the German accreditation system is the division according to areas of activity, which exists in both the regulatory and non-regulatory sphere. In the regulatory sphere this is substantiated by the interests of the departments just described. In the non-regulatory sphere it was motivated by the interest of business associations, who wanted to offer their members the most economically oriented and professional accreditation possible[258].

Such sectoralization can also lead to situations in which double or multiple accreditations may be required. The fees collected for this are an economic burden for the conformity assessment bodies, which can cause competitive disadvantages vis-à-vis other bodies, including those from other European countries. The extent to which this is perceived as a burden depends on the one hand on the size and financial resources of the body, and on the other hand on the sector in which it is active – the frequency of multiple accreditations varies from sector to sector, and ultimately from the range of activities covered. Altogether, the debate shows however that the problem of multiple accreditations is in any case not the most urgent problem that a reform of the accreditation system must tackle.

A reference should be made to potential advantages resulting from this sectoralization. Due to the division into different sectors both in the regulatory and non-regulatory sphere, the accreditation and recognition bodies have a high level of professional expertise in their respective area of activity. If one takes into consideration that an accreditation body can also be regarded as an "organization of assessment competence"[259], this also is advantageous. Numerous highly qualified assessors are available to the German accreditation bodies, e.g. through the incorporation of many state agencies and in particular due to the involvement of the area-specific organizations. This is in itself already an advantage, because it contributes to the quality of the accreditation. In view of the future development of accreditation, it might offer additional advantages: the current international system is indeed geared towards offering accreditation services in every country or every region and

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258 See above B.I.

259 This is the description chosen by a director of an accreditation body.

excluding competition between the accreditation bodies. At the same time, however, diverse conformity assessment programs are developing in numerous areas, for example occupational health and safety, the broad area of environmental protection, et al. and not all accreditation bodies will regard it as economically purposeful to offer accreditation in all these areas. Therefore, it cannot be ruled out that there will be a certain degree of specialization of accreditation bodies in the future. Therefore, it appears to be worthwhile to maintain the special expertise created in the sectoral system, wherever possible. This can also contribute to supporting the traditionally strong German inspection system in the midst of competition.

3. Competition at the level of accreditation?

A significant consequence of sectoralization in accreditation is the inevitable competition between the accreditation bodies in the non-regulatory sphere[260]: from a legal standpoint a market exists at the level of accreditation and several accreditation bodies do in fact compete with one another. If we examine the situation of accreditation internationally, this also holds for the accreditation systems of the USA and – as far as can be seen – Japan. Otherwise and in particular in the European Union, Germany finds itself in a special situation with this solution. The advantages and disadvantages that competition can lead to at the level of accreditation have already been thoroughly addressed above[261]. However, one must remember that Germany is isolated in Europe with this kind of structure. From the standpoint of the remaining states and most likely the responsible General Direction Enterprise as well, Germany plays an obstructive role in the revision of the New Approach[262], in any case Germany can only exert very limited influence on the further development of the New Approach.

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260 In comparison to the other examined countries, one may maintain however that the separation of the regulatory and non-regulatory sphere has facilitated this development.

261 For the arguments put forward in the debate see Second Section A.I.3.a).

262 This holds regardless of the extent to which the German position may be correct or instructive when it comes to the issue of competition.

4. Incorporation into international structures and the assurance of a uniform level of accreditation

The international system of accreditation strives to assure a uniform level of accreditation by means of peer evaluation and similar procedures, in order to create the basis for the mutual recognition of the declarations of conformity. Mechanisms like these are required to prevent a drop in quality if the performance of the accreditation bodies is not promoted otherwise, e.g. by means of competition[263]. Furthermore, the cooperation between the accreditation bodies at the European and international level is of crucial significance for the harmonization of the application of the accreditation standards. Therefore, it is problematic when recognition and accreditation bodies from the regulatory sphere do not participate in international procedures to exchange experience and when they are not represented in MLA at the European and international level. It is indeed true that from a strictly formal point of view it is the European directives and not the MLA wich are the legal basis for the recognition of the declarations of conformity in the regulatory sphere. However, the participation in MLA, groups for information exchange in the individual sectors, etc. is of great significance for the recognizibility of the certificates and testing reports and the trust thereby created.

In some sectors it might be possible to replace the cooperation in MLA by close professional cooperation among the authorities of the participating countries, so that the required trust is generated by other means. Nevertheless, lacking participation in MLA at European or international level may raise problems. This became apparent when the MRA between the EC and Australia was concluded. One of the competent German accreditation bodies was indeed a member of DAR, but did not participate in the relevant MLA; a special assessment of the accreditation body thus became necessary[264]. Even though the result was finally positive, this shows that trust in the competence of the conformity assessment bodies at the international level cannot only be created by the fact that the body has been recognized by a state agency[265]. It should also be pointed out that state accreditation bodies

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263 And this is also not the case in Germany in the current situation.

264 *Wloka et. al*., Anerkennung und Akkreditierung (Module 3), Section 2.3 at the end, Section 4.4.

265 See also the reference in *Wloka et al*., Anerkennung und Akkreditierung (Module 3), Section 2.3.

such as the Swiss SAS or the accreditation body of the Austrian BMWA are of course members of EA and signatories of the EA-MLA.

Thus, the participation in international procedures for the exchange of experiences and harmonization is indispensable. This holds, above all, for the accreditation bodies that assess conformity assessment bodies and whose certificates of conformity serve to facilitate the international movement of goods. In the regulatory sphere, these are essentially the conformity assessment bodies within the scope of the directives based on the New Approach; in the non-regulatory sphere this is likely to apply to a majority of the conformity assessment bodies. However, most accreditation bodies here are members of the international cooperative networks anyway. The significance of this network will increase in both the regulatory and non-regulatory sphere to the extent that the inspection system develops as a whole into a European or even international market. An "evaluated" and internationally recognized accreditation offers considerable additional benefits for conformity assessment as a service and thus ultimately for the products certified this way.

The concerns emanating from the German situation cannot be mitigated by referring to the success of the German accreditation system up to now. It is indeed true that the German accreditation system enjoyed a high level of trust abroad, despite its complex structure. This can be traced back to the long tradition of the German testing and inspection infrastructure, and certainly also to the work of the DAR. Before the problems that recently emerged, the DAR understood how to unite the accreditation bodies under one roof despite its relatively weekly developed legal structure and to externally represent it under the DAR logo. If the German conformity assessment infrastructure altogether is held in high esteem, this is primarily due to the commitment of the individual people from the DAR and from individual accreditation bodies and industrial firms, who contribute their specialized expertise to high-ranking committees of EA, ILAC or IAF and the standardization committees, who externally represent the German accreditation "system" and hence stand for the reliability of accreditation and conformity assessment in Germany. However, this is by no means structurally guaranteed in the current system[266]. This is all the more important as the representation of the German accreditation system in the relative committees also secures

[266] A similar view in *Wloka et.al.* Anerkennung und Akkreditierung (Module 3), Section 4.4.

the influence of Germany on the further development of conformity assessment at the European and international level.

Part Two: Conclusions and Recommendations

A. Evaluative approaches

I. Conformity assessment as a private sector system

As the analysis of the structures of conformity assessment and accreditation in the First Part of this study has shown, conformity assessment is not primarily a state or state-mandated activity, rather a system organized and operating in the private sector, in whose functioning the state and the European Community have their own interest. An analysis of options for state action in the field of conformity assessment must take this into consideration:

(1) The distinctive function of every system of conformity assessment is its operation in commercial activities between private parties. To this extent conformity assessment is a service offer. The main task in this regard is, on the one hand, to create trust to facilitate national and in particular international commercial activities and thereby enable the implementation of quality standards on the other hand. However, these goals do not exclusively reflect private interests, they are in the public interest as well: the facilitation of economic activity is the responsibility of the state and an international obligation[1]. The state can therefore take on the task of guaranteeing a functional quality infrastructure, which helps increase the national and in particular international competitiveness of German firms.

(2) As the analysis of the other European states has confirmed, the centrepiece of the state's use of conformity assessment is product safety law on the basis of the New Approach. The main responsibilities in this regard are the creation of trust in a *horizontal* perspective to facilitate trade in goods and services in the Internal Market, on the one hand, and to guarantee the highest possible product safety standards on the other hand[2].

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1 See First Part, Second Section under B.

2 For the horizontal use of conformity assessment see First Part, First Section, B.II.1.

(3) In many areas the transfer of testing and assessment tasks to conformity assessment bodies primarily serves the purpose of relieving the burden from public authorities. Here, the focus is placed on the use of an existing and effective structure with elaborated standards on the use of private bodies for inspection purposes. As the certificates are primarily addressed to the state, horizontal mechanisms for the creation of trust are not the focus of interest to the same extent. The same holds for regulatory areas in which EU law demands the introduction of conformity assessment procedures in order to guarantee a certain uniform quality of the enforcement infrastructure throughout Europe. The results of such conformity assessments – for example in case of EMAS – do not primarily target recognizibility in other Member States, rather the *vertical* assurance of a comparable level of enforcement[3].

These different functions of conformity assessment must be taken into account in the considerations outlined in the following. The provision of a functioning infrastructure, i.e. above all compatible with European and international guidelines, is an urgent matter for the state, in particular in cases in which conformity assessment is used to create trust vis-à-vis other private actors or states from a horizontal perspective (1 + 2). In cases of the vertical use of conformity assessment, the state's agenda is not always concurrent with European and international guidelines (3). For example, actors may have an interest in linking the conformity assessment bodies to the commissioning administrative body to the greatest possible extent, an interest which would be counterproductive in the case of horizontal conformity assessment. This demonstrates that it is not easy to find a common denominator for the state's options to design policies for conformity assessment, when conformity assessment is used for heterogeneous motives. If a decision must be made in this regard though, priority must be given to the use of conformity assessment as a system able to create trust horizontally.

3 See First Part, First Section, B.II.2; Fourth Section, A.VI.

II. Criteria for recommendations

Besides respecting European and international guidelines and taking into account the concerns of the State when using conformity assessment, a future conformity assessment structure in Germany must accommodate, above all, the interests of businesses in economical and effective conformity assessment. The objective here is to minimize the financial and time-related burdens resulting from conformity assessment for firms while sustaining or even increasing the lasting value of certificates by

- making multiple tests unnecessary ("one-stop-principle");
- removing, to the greatest possible extent, the administrative burden which is associated with quality assurance at this level; this means, above all, reducing bureaucracy and avoiding double inspections;
- optimizing the lasting value and international acceptance of the certificates by incorporating the German conformity assessment system into European and international structures in the closest and most transparent manner possible.

1. Pursuit of state regulatory interests and preservation of regulatory options for the state

If the State draws on a private system as in the case of conformity assessment for the pursuit of regulatory interests, it must, on the one hand, respect the rationality of the private system, on the other hand, there is a need for a minimum of State influence in order to guaruantee the functioning of the private system and its orientation towards the aims pursued by the State. The preservation of regulatory options for the state requires sufficient areas of influence for the state, but in particular sufficient feedback mechanisms from the regulated area, so that the state has the necessary regulatory knowledge at its disposal. This provides justification for the state to hold open certain interfaces with the system of conformity assessment, for example by exemplarily operating its own conformity assessment bodies. In equal measure regulatory interests can provide justification for the state to focus on an *accreditation* mechanism and not another autonomous form of assuring the quality and international recognizibility of conformity assessment, for example the mutual recognition of conformity assessment bodies in a peer review procedure (in detail under C II 2).

2. Need for action at the European level

The state actively participates in the design of European product safety law and its use of conformity assessment as a market access instrument. This opportunity for active participation can be used to help improve recognized shortcomings and to adapt the system to the state's own interests. However, European and international guidelines always provide the framework for this.

With regard to the design of European product safety law, it is important to bear in mind that the use of conformity assessment as an instrument of market access can be viewed as the establishment of a new European administrative structure. As such, importance can also be attached to conformity assessment from the perspective of democratic legitimacy because it is supposed to guarantee product safety for the entire European administrative area[4]. One comes to a similar result when interpreting European product safety law to the extent that the thereby prescribed conformity assessment is not a state-mandated administrative activity but rather an element of a self-regulated market access regime which lies in the responsibility of private enterprise[5]. Even then, the regulatory structure established this way would have to guarantee the orientation towards public interests: the promotion of common welfare also must be taken into account in such situations in which the state no longer decides itself, rather transfers the assertion of the public interest to a private, autonomously acting system. Hence, the private actors and the procedural contexts in which they operate must be capable of sufficiently fulfilling their function of carrying out public responsibilities in a manner which promotes common welfare. The establishment of a new administrative structure for this purpose is ridden with prerequisites. One must reflect on the following points, which also were the subject of meanwhile nearly completed discussions at the Community level[6]:

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4 See *Röhl*, Akkreditierung und Zertifizierung, p. 39 et seq., and First Part, Second Section under B.II.4.d).

5 See *Hofmann*, Rechtsschutz und Haftung, p. 28 et seq., in particular footnote 123; *Schmidt-Aßmann*, Ordnungsidee, Kapitel 3 Rn. 57. For a similar view *Peine*, Gerätesicherheitsgesetz, § 9 Rn. 21; following him *Schmidt-Preuß*, VVDStRL 56 (1997), p. 160 et seqq., (p. 167 there footnote 18).

6 The study was finalized in April 2006. During the compilation of the English version the revision of the New Approach within the framework of the "New Internal Market Package for Goods" led to the issue of a horizontal Regulation on the sub-areas of accreditation and market surveillance as well as a Council Decision: Regulation No 765/2008 of 09/07/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93,

a) Material requirements

The Global Approach establishes a new structure for the administration of market access. The foundations of this structure are the Notified Bodies which are, as a rule, private organizations, and in any case do not need to be Member State or European administrative agencies[7]. For this reason, the Notified Bodies do not themselves have the qualities that public administration is commonly associated with, i.e. neutrality, expertise, and the ability to evenly take different interests into consideration. As a decentralized administrative structure though, the set of Notified Bodies requires a mechanism which assures the uniform interpretation and application of the standards which guide their activities. Therefore, Community law and the legal provisions of the Member States must first define and assert the demands to the Notified Bodies.

Up to now, the requirements for Notified Bodies had only been partially defined: the basic requirements for the bodies contained in the Global Approach and the Council Decision 93/465/EEC could be taken as a point of reference[8]. However, only the requirements contained in the directives were ultimately binding. The various directives list as material requirements for designation similar competence criteria which often sligthly differ, sometimes without any particular concern in the matter being recognizible. Consequently, this has led to very different practices and criteria in the Member States[9].

b) Procedures of quality assurance in the Notified Bodies

What appears to be more decisive to us is the problem that *procedures* for and the organization of the selection, designation, and continual surveillance of the Notified Bodies, which are the responsibility of the Member States, have not yet been sufficiently specified.

OJ 2008, No. L 218, p. 30, and Decision No 768/2008/EC of the European Parliament and of the Council of 09/07/2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ 2008, No. L 218, p. 82. For more details on the content of the horizontal legal acts see below, in Particular C.II.3. The Regulation shall apply from 1 January 2010, Art. 44 para. 2 Regulation (EC) No 765/2008.

7 The designation of administrative agencies has not yet been completed, but both the exclusive as well as the competitive designation can lead to legal problems. Along with this comes the requirement to sufficiently separate Designated Bodies from the market surveillance agencies.

8 See First Part, Second Section under B.III.1.

9 See First Part, Third Section under B.

Such specifications on the level of binding European law are indispensable for creating trust in the Notified Bodies, their organization and procedural links in the individual Member States. This is, however, still underdeveloped at the moment[10].

c) Continual surveillance

Besides the non-uniform rules for designation, an additional shortcoming is that specifications for continual monitoring of Notified Bodies do not exist up to now. The directives do prescribe that the Member States must revoke the designation when its requirements are no longer met[11]. However, the creation of the informational basis for such a decision is not yet specified. The Commission does specify surveillance as an obligation of the Member States, but binding guidelines are for this are still lacking. At least accreditation – used in many cases for the purpose of designation – involves regular surveillance[12]. However, accreditation is currently not yet obligatory, and currently it is not very transparent in which cases an accreditation procedure is carried out and thereby continual surveillance guaranteed. In addition, the reassessments carried out by the accreditation bodies seem to differ with regard to intervals, focus and depth of inspection.

d) The actual arrangement: no experiences

The relinquishment of selection, designation and surveillance modalities to the Member States has the consequence that the system of Notified Bodies as a whole is not easy to keep track of. The Commission indeed makes efforts to increase the level of information for all parties by measures such as mutual visits or workshops. However, this cannot suffice: The Notified Bodies authorize products for the entire European Community and thus for every Member State. Thus it is not adequate for it to be merely *possible* to gain knowl-

10 See First Part, Third Section under B.

11 E.g. Art. 12 para. Directive 97/23/EC (Pressure equipment), in a similar manner Art. 16 para. 3 Directive 93/42/EEC (Medical devices).

12 COM (2003) 240 final, p. 12 (under 2.2.5). The new ISO-Accreditation standards prescribe such requirements as regular reassessments, see e.g. ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, 7.11 Reassessment and Surveillance. It should also be mentioned in this regard that the equivalence of the reassessments effectuated by European accreditation bodies is sometimes disputed.

edge on the different designation systems in numerous Member States. What is required are uniform and transparent designation and surveillance procedures.

III. Consequences for the design of the conformity assessment system

The following components of the conformity assessment system hence require further in-depth reflection:

1. Level of conformity assessment

The level of conformity assessment is by principle the responsibility of private bodies. The state's responsibility here is to provide a general legal regime. The state may also participate in the system of conformity assessment by operating conformity assessment bodies itself.

The activities of the conformity assessment bodies are framed by "specified requirements", usually in the form of standards. A high-quality and trustworthy conformity assessment system thus must assure that these standards are applied in equal measure. As the observations have shown[13], this can only be achieved by means of cooperation among the conformity assessment bodies. However, the prerequisites for such cooperation are still lacking at the moment. This pertains both to the instruments to compel the conformity assessment bodies to engage in such cooperation as well as the legal foundations which enable the conformity assessment bodies to partake in such cooperation.

2. Assuring quality and international recognizibility

The assurance of quality and international recognizibility in the system of conformity assessment has proven to be the main focus of activities by the state. For the state, this entails in particular the task of forming an important anchor point in the conformity assessment system through international networking and by utilizing the trust generally placed in the state.

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13 See above First Part, Second Section, B.II.4.c) - on the cooperation between the Notified Bodies within the framework of the directives based on the New Approach.

3. Market surveillance

Conformity assessment is only one, albeit integral component of the system of product safety law. Its effectiveness in guaranteeing safety is closely linked with a functioning system of market surveillance. Even though this is not a fundamental part of this study, it has become clear that the consequences of the use of conformity assessment for market surveillance must be incorporated into any systematic analysis[14].

B. Level of the conformity assessment bodies

I. The conformity assessment contract

In the system of conformity assessment, services involving conformity assessment are, as a rule, provided as private services. The existing private contract law is generally sufficient for the establishment of this legal relationship according to the statements of the experts we have spoken to. The same applies with regard to the recourse to legal instruments for the protection of the conformity assessment marks against misuse. As long as voluntary conformity assessment is concerned, the burdens placed on the contractual partner of the conformity assessment body such as the disclosure of information, the opening of the firm for inspections and surveillance measures by the conformity assessment body or their option to unilaterally remove certificates is based on its private autonomy. If the conformity assessment bodies operate, by contrast, as Notified Bodies in line with the Global Approach, the legal relationship remains based on private law, but the obligation for the manufacturer to turn to the conformity assessment system to gain access to the Internal Market for his/her products shifts the balance. Although the interview partners did not report any problems in this regard, at least the most important competences of the Notified Bodies mentioned above should have a firm basis in the relevant rules and regulations[15].

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14 See the description in the Appendix under Items E.

15 For examples of such regulations in Austria, see Appendix, Third Section under D.I.

II. State conformity assessment bodies

The state itself also operates conformity assessment facilities on a considerable scale. In principle, the standards for conformity assessment do not exclude such state activity.

1. State bodies as providers of conformity assessment

In individual cases, state bodies offer conformity assessment services in the non-regulatory and regulatory sphere. The permissibility of such activities is to be evaluated according to general principles of competition law: particularly critical aspects are competitive advantages which such conformity assessment bodies may receive from direct or indirect financial support by public authorities as well as through income which they gain from their monopolistic status in a public domain. In these cases the activity of the public authorities is only permissible when a substantial public objective is thereby pursued. In exceptional cases such an objective could be that the state must be able to gain practical experience in conformity assessment activities in order to successfully regulate the area.

2. Special features of the regulatory sphere

Due to the increased public interest, this justification applies to the regulatory sphere in particular. An additional factor is that the obligation stipulated by the New Approach to involve a conformity assessment body makes the state the guarantor in those cases in which such a conformity assessment is not offered by the market. In individual cases, public authorities have in fact been entrusted with the function of a Notified Body by law, either as the only Notified Body or in competition with others.

- Due to constitutional law, there are however reservations to the exclusive designation of state agencies, in particular with regard to Art. 12 para. 1 GG, because the access to this segment of commerce remains closed to German firms, without the state being able to ensure the sole responsibility of public bodies for this activity: In view of the fact that Notified Bodies from other Member States may carry out conformity assessments in Germany, a plausible justification for such a regulation must be given which goes

beyond the constitutionally irrelevant interest of the respective state agency to preserve its functions or status[16].

- If public bodies are entrusted by law with the task of a Notified Body[17], they operate in a comparable manner to private Notified Bodies on the market. It is difficult to integrate this solution into the Global Approach if the public conformity assessment bodies are not accredited.
- Additional questions arise with regard to national and European competition law. If a sufficient offer of conformity assessment existed without state involvement, the legal status of the other Notified Bodies and competition law might create pressures for the public body to discontinue the operations. Art. 12 para. 1 GG as well provides substantiation for critically examining the continuation of this service by the public body.

III. Exchange of information and cooperation among the conformity assessment bodies

As an instrument for the implementation of European product safety law, the entirety of the Notified Bodies must guarantee a sufficiently equivalent application of standards, because the mutual recognition of the certificates can only be substantiated in this manner. Thus, effective cooperation among the Notified Bodies is indispensable for guaranteeing uniform implementation, and also for the necessary link between the system of market access on the one hand and market surveillance by public authorities on the other hand[18]. However, in practice the cooperation among the Notified Bodies at the national and European levels as well as their cooperation with the responsible authorities is of very different intensity[19]. Transparent, uniform regulations do not exist, and there is currently uncertainty with regard to what extent the guidance documents and procedural recommendations resulting from the cooperation between the Notified Bodies are of a binding character[20].

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16 See *Röhl*, Akkreditierung und Zertifizierung, p. 69 et seq.

17 The Federal Agency for Material Testing (Bundesanstalt für Materialprüfung) in accordance with § 12c para. 2 clause 1 1. SprengV beyond the type examination.

18 For details see First Part, Second Section B.II.4.c).

19 See First Part, Second Section under B.II.4.c).

20 Draft CERTIF 2005-8 “Creating a network of notified bodies”, Item III p. 3; the document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_8.pdf (4 March

In the Decision on a Common Legal Framework, the regulations on the involvement of the Notified Bodies in the exchange of experiences and in standardization work are incorporated into the catalogue of requirements for Notified Bodies[21]. Accordingly, the bodies are to participate in the relevant standardization activities or at least ensure that their personnel has been instructed on them. The same holds for the participation in the groups of Notified Bodies, which were established within the framework of the respective Directive[22]. With regard to the bindingness of the guidelines thereby drawn up, the decision states in a reserved manner that the bodies apply the work results of these groups in their activities as *general guidance*[23]. To complement this cooperation in the GNB, the bodies are obligated to give other bodies which operate within the scope of applicability of the same directives relevant information on issues relating to negative and, on request, positive conformity assessment results[24]. The practical implementation of these provisions is still problematic.

The legal basis provided by the Decision will thus only partially eliminate the regulatory deficit from which the cooperation among the Notified Bodies suffers. The ensuing implementation in Germany should address this issue more thoroughly. First and above all, uniform and transparent rules are needed. Subsequently, it is also imperative to find an effective form of cooperation, which achieves the best possible results while placing an acceptable burden on the Notified Bodies. This requires precise specifications on the membership of the groups exchanging experiences, while rules of representation among the Notified Bodies are also important[25]. A clear regulation on the relevance and bindingness of the decisions of such groups exchanging experiences is also imperative. Information on practical experiences of the accreditation bodies existing in Germany and, in particular, from the other Member States, exists[26].

2006). See the open wording in *European Commission,* Guide (‘blue’) 6.6, p. 43 "apply as general guidance".

21 Art. R17 para. 11 Decision No 768/2008/EC.

22 For the coordination of the Notified Bodies in the groups of Notified Bodies see Art. R30 Decision No 768/2008/EC.

23 Art. R17 para. 11 Decision No 768/2008/EC.

24 E.g. Art. 16 para. 5 Directive 93/42/EEC (Medical devices), see now Art. R28 para. 2 Decision No 768/2008/EC.

25 Art. R30 para. 2 Decision No 768/2008/EC now explicitly authorizes the representation of Notified Bodies in the GNB.

26 E.g. in the Netherlands, see Appendix, Second Section under D.II.

C. Assuring quality and international recognizibility

I. Assuring the quality and international recognizibility of the certificates as a State responsibility

If conformity assessment is about creating trust, the level of conformity assessment must have a mechanism which assures the quality and uniformity of the conformity assessment and guarantees the international recognizibility of the certificates. Only by doing so, does the conformity assessment business have a structural backbone.

Conformity assessment is an essential element of the value-creating chain, in particular in export-oriented economies. Hence, the state can legitimately assume responsibility for guaranteeing a functioning conformity assessment system in the non-regulatory sphere as well. This state task especially covers the creation or the promotion of mechanisms to assure the quality of conformity assessment and the recognizibility of the certicicates both in the European and the international context, because these mechanisms are imperative components of a functioning conformity assessment system. This would be provided for, for example, if market forces were capable of establishing a sufficient accreditation structure. However, if the market is not capable of such self-regulation, first the support and then the organization of an accreditation system can become responsibility of the state. In the analyzed Member States as well this reasoning justifies the intervention of the state[27].

In the following, the possible options for action for an organization at this structural level will be considered (under II), before the derived solution will be examined with regard to its compatibility with legal provisions (under III). Further thoughts will then be presented on the design of the solution confirmed in this manner (under IV).

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27 See First Part, Third Section under C.III.1.

II. Assuring quality and international recognizibility: organization

The assurance of quality and international recognizibility can take place horizontally at the level of conformity assessment or be established on a functional level above the level of conformity assessment.

1. Quality assurance at the level of conformity assessment

a) Peer-to-peer review in agreement groups

At the level of conformity assessment, peer-to-peer review has been established in certain economic branches as a mechanism to secure the quality and recognizibility of conformity assessment[28]. A separate standard exists for this mechanism, Standard ISO/IEC 17040. Practical experience with these so-called agreement groups primarily exist for the electric branch. This instrument is therein certified as highly effective. However, a functional pre-requisite appears to be a limited number of participants and the personal trust associated with this. Accordingly, it is reported that the effectiveness of the peer-to-peer review as an instrument of quality assurance decreases to the extent that the focus is expanded beyond Europe. An additional factor is that relatively homogenous areas of conformity assessment are concerned. Therefore, such a peer-to-peer review is likely to reach its functional limits as soon as a larger number of divergent thematic areas of conformity assessment are dealt with in the evaluations or a large number of conformity assessment bodies competing with one another participate.

From the perspective of the state, an additional shortcoming must be pointed out: peer-to-peer review is ultimately organized without means for state intervention. Therefore, the monitoring of the implementation of state or European regulatory interests, e.g. product safety, would be difficult. For this reason as well, such a mechanism could hardly be taken into consideration to implement the directives based on the New Approach.

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28 For an in-depth description see First Part, Second Section under A.II.

b) Network of certifying bodies

Among several large, internationally active certification bodies there is an ongoing discussion whether they should establish a peer-mechanism amongst themselves, which is to create trust in the certificates and their international recognizibility by means of the international visibility of these certification bodies *as such*. For the regulatory sphere conformity assessment could not be bolstered in this manner for the just mentioned reasons. For the non-regulatory sphere such an approach is indeed within the realm of possibilities in view of the broad area of activity of these certifying bodies.

This consideration certainly also may be expressed in order to have a potential argument at hand towards the accreditation bodies. This applies in particular to the fact that their requirements as well as the standards applicable to the accreditation are sometimes perceived by the certification bodies as too restrictive. Such arguments are not to be completely refuted, though. However, from a state perspective they are undesirable because such a cartel-like agreement would be insufficient with regard to the state's task of guaranteeing a sufficient conformity assessment infrastructure. On the one hand, the accreditation as an interface between the conformity assessment system and state regulatory interests would be lost. Moreover, this would result in a competitive disadvantage for smaller conformity assessment bodies. Finally, one must doubt whether the dominance of larger institutions, which partly eliminates the competition among the conformity assessment bodies, could be equally effective in quality assurance.

Altogether, such an autonomous infrastructure is not easily compatible with the state's responsibility of guaranteeing a functioning conformity assessment infrastructure. However, the repeatedly stated reference to this possibility indicates for every other solution that it must be designed in a manner that is sufficiently responsive to the interests of the conformity assessment bodies.

2. Accreditation

As a result, the creation of structures at the level of conformity assessment is not taken into consideration as a general instrument. Therefore, such structures must be based on a higher level – and this is the subject of accreditation. However, the German example shows that up to now there is no fully consented model for the organization of accreditation in Europe.

The hitherto practiced accreditation system in Germany is sectorally organized and allows competition in the non-regulatory sphere, while the establishment of a national accreditation body is the rule in other European countries[29].

a) Competition in accreditation

The arguments for and against the organization of accreditation based on competition are presented in-depth above[30]. Resulting from them, there are some reservations against the preservation or even the expansion of competition-based accreditation from the German perspective:

- Competitive accreditation will have to provide for an additional level of quality assurance[31] or other control mechanisms for accrediting bodies. However, an additional level of control would lead to the effect that the various accreditation bodies at national level could only be integrated in European and international accreditation structures by a body representing them. This would complicate the international integration of the accreditation infrastructure, which – as already seen – constitutes a core element in assuring the recognizibility of the certificates. This level would also be difficult to reconcile with the statutes of EA, because according to them accreditation must be the last level for the assessment of technical competence, impartiality and integrity[32].
- According to statements made by most interviewees, the profit to be made by accreditation services is low. As a rule, state subsidies are required at least to fulfil international responsibilities. The international and European debates also tend to rule out profit-oriented accreditation: hence, the members of EA are obliged to carry out their operations as a *non for profit distributing* activity[33]. The introduction to ISO/IEC 17011 stipulates that accreditation bodies "operate in a non-profit distributing manner".

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29 See First Part, Third Section under C.I.

30 See First Part, Fourth Section III.3; see as well First Part, Second Section, A.I.3.; First Part, Third Section B.IV.

31 See the preliminary work on the draft of the accreditation law (status of January 2005).

32 EA-2/01 – S1 Criteria for Membership, 1.2, 1.4; the document is available online at URL: http://www.european-accreditation.org under Publications/General/Procedural and Policy Documents Series 2 (4.3.2006).

33 EA-2/01 – S1 Criteria for Membership (Footnote 32), 1.2, 1.4.

- An accreditation system must assure that an accreditation is offered for every requested area, even if this does not appear to be lucrative for an individual accreditation body due to the low number of requests. To the extent that accreditation bodies offer accreditation services in competition with one another, they are not obligated to provide such an offer as individual bodies. Precisely the handed down system in Germany points out this problem: The TGA had abandoned its role as a mere coordinator, in order to offer accreditations which were not available on the market.

b) Sectoralized accreditation

The greater difficulties associated with the coordination and the international integration are a potent argument against the sectoralization of accreditation[34]. An additional factor is the requirement to also offer accreditation precisely for those cases which emerge outside the existing sectors. Furthermore, the sectoralization poses obstacles to mutual learning between the area-specific levels in general. As the development of accreditation in the too loosely coupled network of the DAR shows, competition between the accreditation bodies can ultimately only be prevented under the auspices of the state due to problems with regard to anti-trust law. The widely successful sectoral accreditation in the medical devices branch (regulatory sphere) is not an argument in favour of sectoralization but a special case[35], in which it was possible to organize a transparent market with a limited number of participants[36].

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34 See First Part, Fourth Section B.III.4.

35 This is also the case in France, for example, see Appendix, First Section under B.I.1, or in the United Kingdom, see Appendix, Sixth Section under B.II.1.

36 For the limited number of Designated Bodies see *Höppner*, in: Anhalt/Dieners, Handbuch des Medizinprodukterechts, § 14 Rn. 2. For comparison: within the framework of the medical devices directive – each having differently large scopes –, 22 bodies are designated in Germany, eight in the United Kingdom, two in the Netherlands, two in Sweden, one in Austria and five bodies in Switzerland; within the framework of the directive on active implantable devices eight bodies in Germany, two bodies in the United Kingdom, two in the Netherlands, none in Sweden, two in Austria and one in Switzerland; within the framework of the directive on in-vitro diagnostics eight bodies in Germany, three in the United Kingdom, one in the Netherlands, none in Sweden, one in Austria, and none in Switzerland; source: list of the registered bodies, which were designated by the Member States and the EFTA-States (EEC-members within the framework of the directives of the "New Approach", Official Journal No. C 302 from 12/12/2003 p. 0001 – 0414 (status of December 2003). The cooperation is also illustrated by Soltau, in: Anhalt/Dieners, Handbuch des Medizinprodukterechts, § 12 Rn., 51 et seq.

3. Debate at the European level

Up to now, the procedures and the organization of the designation and monitoring of the Notified Bodies were not bindingly stipulated at the European level, neither by the Global Approach and the New Approach documents nor by the directives. This was motivated by a deliberate political decision to rely on the principle of mutual recognition and thus keep the designation of the bodies to the greatest possible extent a responsibility of the Member States, including organization and procedures[37]. The result of this restrained approach was the non-uniform handling of accreditation and designation of bodies described in the First Part, which led to different requirements in terms of their competence and expertise[38]. In the meantime this shortcoming has been acknowledged, and the revision of the New Approach has led to the passing of a horizontal Regulation and a Decision on a Common Framework for the Marketing of Products[39]. They thoroughly address the structure and process of accreditation in the individual Member States as well as integration of the national accreditation bodies into a European accreditation structure. Yet the legal acts continue to take a restrained approach with regard to the delicate issue of the relationship between accreditation and notification: according to the Decision, the use of accreditation governed by the future Regulation shall be "encouraged" as an "essential means" for the purposes of notification[40], but it is still not bindingly required.

a) Accreditation as the basis for designation

Art. 29 of the Decision, which governs the notification procedure, does not make accreditation by a national accreditation body a binding prerequisite for notification. From Art. 29 para. 4 of the Decision it follows that the Member States may also notify bodies which do not have an accreditation delivered by a national accreditation body within the meaning of

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37 COM (2003) 240 final version from 7 May 2003, 2.2.3, p. 9, with reference to the principle of subsidiarity. In detail in the First Part, Second Section under B.III.

38 See First Part, Second Section, III.1 See as well Commission Staff Working Document accompanying the proposal for the Regulation, SEC(2007) 173, 2.1 (in particular 2.1.2, p. 15 et seq.).

39 See above footnote 6.

40 Recital 39 Decision No 768/2008/EC.

the Regulation[41]. In view of the extensive efforts to harmonize the accreditation procedures, which are reflected in the Regulation and Decision, this possibility actually should be seen as an exception to the rule. However, such a rule-exception relationship cannot be discerned in the Decision itself[42]. Art. 20 para. 2 of the Decision only stipulates that the Member States *may decide* that the the assessment and monitoring of the bodies shall be carried out by the national accreditation body, without bindingly prescribing this.

The wording of the Decision hence lags behind the working paper CERTIF 2005-16, which understood accreditation as the instrument to be regularly applied in the future, by means of which the technical expertise and the suitability of the body for the activity to be carried out in the scope of applicability of the concrete designation were to be ultimately judged: accordingly, the designation of conformity assessment bodies was to be supported by a "formal accreditation"[43] wherever possible. With regard to the recognition of notifications without previous accreditation, which was conceived much more explicitly as an exception requiring justification in CERTIF 2005-16[44], it was intended that such notifications shall be "verified, recognized, and regularly monitored" in order to "ensure an equivalent level of mutual confidence"[45]. The Decision indeed contains requirements for the notifying

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41 Art. R23 para. 4 in conjunction with Art. R22 para. 2 Decision No 768/2008/EC. In this case the notifying agency authority "shall provide the Commission and the other Member States with the documentary evidence which attests the conformity assessment body's competence and the arrangements in place to ensure that the body will be regularly monitored and will continue to satisfy the requirements laid down in Article [R17]".

42 See Art. R23 Decision No 768/2008/EC, which in paragraph 1 only refers to the compliance with the requirements to Notified Bodies laid down in Article R17, but not to accreditation. Art. R 22 para. 2 of the Decision, which governs the placement of applications for notification, also only prescribes that the conformity assessment bodies present the accreditation certificate of the national accreditation body "where one exists".

43 According to the definition of the term in CERTIF 2005-16 rev. 2 (Footnote 6), Annex I, p. 32, "formal" accreditation is an accreditation, which the accreditation body carries out in compliance with the Standard EN ISO/IEC 17011 and obligates the accreditation bodies to comply with the relevant harmonized standards (as a rule from the series of standards EN 45000/EN ISO/IEC 17000).

44 CERTIF 2005-16 rev. 2 (Footnote 6), C.5.2., p. 13: "in duly justified cases"; C.5.3., p. 14 : "Where, by way of exception, Member States do not make use of formal accreditation…".

45 In the original text of the document In CERTIF 2005-16 rev. 2 the passage is as follows: "Wherever possible, designation of conformity assessment bodies shall be supported by formal accreditation conveying demonstration of their competence to fulfil conformity assessment tasks specified in the applicable Community legislation and policies. In duly justified cases, the Commission, together with the Member States, may accept the notification of a conformity assessment body designated on the basis of competence assessment not using formal accreditation, provided that such notifications are verified, recognised and regularly monitored to ensure an equivalent level of mutual confidence." CERTIF 2005-16 rev. 2 (Footnote 6), C. 5.2, p. 13. For the Designating Authorities, an explicit reference was made for

authorities, which also pertain to the competence of their employees[46]. Unlike the provisions on accreditation though, they are not supported by relevant procedural rules, which would make it possible to demonstrate the evaluative competence of the notifying authorities towards the authorities of the other Member States. The previous practical experiences with designation have shown that from the perspective of the other Member States – whose perspective is ultimately relevant because they are the addressees of the declarations of conformity – trust cannot be created alone by the designation being granted by a national public authority. To establish the aspired equal level for the assessment and monitoring of the competence of the conformity assessment bodies, it will be decisive that the Member States base their notification decisions on an accreditation according to the proposed accreditation Regulation, as aspired by the Commission. At least the newly introduced arrangement differentiates between accreditation-based and other notifications by means of the right of the Commission and Member States to appeal notifications. In the case of notifications not based on accreditation the deadline to appeal is two months instead of the otherwise applicable two weeks[47]. For cases in which the notification carried out by a Member State appears to be not sufficiently trustworthy, the Decision also prescribes that the Commission examines all cases in which it doubts the competence of the notifying body itself or doubts are reported to it. If these doubts are confirmed, it can demand the notifying Member State to carry out corrective measures[48]. With this, at least a procedure to eliminate unrightfully existing notifications has been created. Whether the assignment of this controlling task to the Commission will have a controlling effect in practice remains to be seen.

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such cases to the catalogue of essential requirements, which primarily pertain to their organization, independence and technical expertise, CERTIF 2005-16 rev. 2 (Footnote 6), C.5.2., p. 13.

46 Art. R15 para. 6 Decision No 768/2008/EC, "sufficient number of competent personnel".

47 Art. R23 para. 5 Decision No 768/2008/EC.

48 Art. R26 Decision No 768/2008/EC.

b) Requirements with regard to the organization and procedure of accreditation at the national level

With regard to the accreditation structures at the national level, the Regulation abandons the previously rather reserved Community policy and gives binding guidelines for the organization of accreditation in the Member States[49].

(i) General principles

According to Art. 4 para. 1 of the Regulation every Member State designates a single national accreditation body[50]. Competition between several accreditation bodies at the national level is therewith ruled out[51]. The Regulation also no longer contains any exemption clause to the benefit of an "accreditation system", which would allow for the merger of several accreditation bodies into an umbrella association or a similar organization[52].

With regard to the legal status of the national accreditation body, the Regulation states "that "a Member state shall entrust the national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition"[53]. The Regulation also specifies that the national accreditation bodies may not operate on a profit-oriented basis[54]. The tasks and responsibilities of the national accreditation bodies are to be clearly distinguished from those of other national authorities[55]; furthermore, the accreditation bodies must distance themselves from the sphere of activity of the conformity assess-

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49 Art. 3 et seqq. Regulation (EC) No 765/2008, not without the formula-like reference that the establishment of a uniform national accreditation body should be without prejudice to the allocation of functions within Member States, Recital 11 Regulation (EC) No 765/2008.

50 The Member States are not obligated to establish such an accreditation body, if they regard this as economically unsustainable; in this case they can have recourse to the national accreditation body of another Member State, Art. 4 para. 2, 3. Regulation (EC) No 765/2008.

51 Art. 6 Regulation (EC) No 765/2008, for the background see above CERTIF 2005-16 rev. 2 (Footnote 6), 6.1, p. 16; for more details see Draft CERTIF 2005-12 (Footnote 53), p. 3.

52 The "system of accreditation bodies", permitted in particular in the German situation, (see for example CERTIF 2005-16 rev. 2 [Footnote 6], 6.1, p. 16) is accordingly no longer permissible.

53 Art. 4 Para 5 Regulation (EC) No 765/2008. For the development of this manner see also CERTIF 2005-16 rev. 2 (Footnote 6), 6.4, p. 16; Draft CERTIF 2005-12 S. 12 under II.1; the document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/draft_certif_2005_12.pdf (20 March 2006).

54 Art. 4 para. 7 Regulation (EC) No 765/2008.

55 Art. 4 para. 6 Regulation (EC) No 765/2008.

ment bodies and preserve their independence vis-à-vis the conformity assessment bodies[56]. The Member States must ensure that the accreditation bodies have sufficient financial and personnel resources[57].

These principles apply regardless whether accreditation takes place for the regulatory or the non-regulatory sphere[58]. The Commission communication from 2003 had already lamented that a separation of the regulatory from the non-regulatory sphere had taken place over time – primarily due to the lacking Community law foundations –, even though the applicability of the used structures in both areas was one of their most important features at the time the New Approach was developed[59].

A part of the mentioned principles is reworded in Art. 8 of the Regulation as a requirement for the national accreditation bodies. This pertains, in particular, to the preservation of the independence and objectivity of the accreditation body, the assurance of its competence in conducting evaluations and, not least in the interest of the conformity assessment bodies as well, the assurance of efficient management and suitable internal[60] controls. The responsible Member State is responsible for the compliance of the national accreditation body with these requirements. The Member State must verify this in regular intervals[61]. The peer-review procedure within the framework of EA provided for in Art. 10 in conjunction with Art. 14 of the Regulation plays a central role here. For example, the assumption of conformity with regard to the compliance of the requirements of Article 8 applies when the compliance with the harmonized standards by successfully participating in the peer review procedure of EA has been proven[62].

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56 Art. 4 para. 8 Regulation (EC) No 765/2008.

57 Art. 4 para. 9 Regulation (EC) No 765/2008.

58 Art. 3 Regulation (EC) No 765/2008.

59 COM (2003) 240 final, 2.2.8, p. 14.

60 Although not explicitly mentioned in Art. 8 Regulation (EC) No 765/2008, procedures for handling complaints and objections to accreditation decisions are specified by Art. 5 para. 5 Regulation (EC) No 765/2008. They ensure that the addressees of the accreditation decisions – regardless of the legal form of the accreditation body – have possibilities for recourse against decisions of the accreditation body.

61 Art. 9 Regulation (EC) No 765/2008.

62 Art. 11 para.1 Regulation (EC) No 765/2008.

(ii) Participation in the European accreditation infrastructure and peer evaluation

According to the concept of the Regulation, the regular participation of the accreditation bodies in peer review plays a decisive role with regard to proving their competence[63]. This is all the more crucial because competition between the accreditation bodies as a corrective factor is ruled out due to the decision for the principle of one accreditation body per Member State. The Regulation specifies for the first time the tasks of the European accreditation structure in a binding legal act and governs the participation of the national accreditation bodies, in particular with regard to peer evaluation: for example, Art. 14 of the Regulation provides for the recognition of a relevant organization at the European level, with which the Commission enters into an agreement on tasks, funding and supervision[64]. Art. 14 para. 6 of the Regulation provides for the recognition of EA, provided that it has concluded the mentioned agreement. The Regulation thereby creates the organizational foundation to obligate the national accreditation body of the Member States to participate in the peer evaluation procedure of EA[65]. The results of the evaluations are published by EA and reported to all Member States as well as the Commission[66]. The Commission, in cooperation with the Member States, shall oversee the rules and the proper functioning of peer evaluation system[67].

c) Summary

To a greater extent than previously, the Regulation endeavours to make accreditation a common instrument to create equivalency of declarations of conformity. The trust required for the recognition is to be created by means of the participation of the accreditation bodies in the procedures involving the exchange of experience and peer evaluation, which are

63 See Art. 11 para. 1, 2 Regulation (EC) No 765/2008 on the assumption of conformity to the benefit of the national accreditation bodies, which is based on the participation in the peer review of the EA, and the ensuing obligation of the public authorities to recognize the equality of the accreditation services and subsequent accreditation confirmations as well as the confirmations of conformity from the bodies accredited by them.

64 Art. 14 para. 2 Regulation (EC) No 765/2008; according to paragraph 3 the agreement is to be published; paragraph 5 further specifies that such an agreement may only be entered into with one body respectively. For the requirements placed on the body, see Annex I of the Regulation.

65 Art. 10 para. 1 Regulation (EC) No 765/2008.

66 Art. 10 para. 6 Regulation (EC) No 765/2008.

67 Art. 10 para. 7 Regulation (EC) No 765/2008.

organized within the framework of EA. As "public authorities", the national accreditation bodies are to be associated with the state, firstly to grant them the necessary authority for their activity at the last level of conformity assessment, and secondly to assure their responsibility towards the state and the Commission and to provide a guarantee for the compliance with the obligations incumbent on them. The mutual recognition of the notification decisions and the declarations of conformity in the Community are to be based on this structure in the future, even though according Decision No 768/2008/EC the support of the notification by accreditation is strived for as basic model, but is not bindingly prescribed for the Member States.

4. European comparison

Essentially, the use of accreditation from a single national accreditation body for the purpose of designation would widely correspond with the situation in the other Member States of the EC. Furthermore, it would have the advantage of being able to reduce the still existing divergences despite this fundamental comparability and, above all, to provide for the urgently necessary transparency. In any case, till now the respective situation in a Member State can only be understood after thoroughly studying documents and on the basis of intense contacts with the involved parties. At any rate, according to our experiences the Regulation outlines a common European model with regard to the concentration of accreditation in one national accreditation body. This model has been implemented in Switzerland and all Member States with the exception of Germany[68]. Except for in Germany, none of the interviewed persons reported on a model which differs in the essential features. The organizational separation of the accreditation systems, as has been the case in Germany, is unusual from a non-German perspective and the reasons for this appear to be difficult to comprehend:

- All studied countries have a national accreditation body, which – supported by state authority – provides an extensive accreditation offer in the regulatory and non-regulatory sphere and in different economic sectors.

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68 For a thorough summary of the situation in the studied countries see the First Part, Third Section, C.

- The accreditation bodies are either based within state agencies or are organized according to private law, but associated with the state or individual ministries through agreements or memoranda of understanding.
- The respective national accreditation body has a unique status at the national level and is incorporated into the international structure of accreditation in the form of EA as well as IAF and ILAC.

5. Proposed option: Establishment of a national accreditation body

Looking altogether at the arguments put forward above, the clear trend at the European level and the pan-European accreditation scenario – with the exception of Germany –, our only recommendation can be for Germany to no longer resist the institutionalization of a single national accreditation body[69]. All other organizational models, competitive accreditation or with an additional level as envisioned in the draft on an accreditation law, hardly appear to be realistic. In view of the dominance of the model of one national accreditation body, there are also few prospects for persuading the other Member States or the European Commission to accept an alternative model. On the contrary, there are some indications that Germany has exhausted the political energies in this area by clinging to the passed-down model or by attempting to further develop it and relinquished possibilities for shaping the discussion at the European level.

III. Permissibility of the establishment of a national accreditation body

1. Permissibility of national accreditation in European law

a) Competition law

The restructuring of (at least a part of) accreditation in the form of “national accreditation”, thus a state or state supported offer of accreditation services by a single body, can collide with the competition rules of the Treaty on the Establishment of a European Community

69 In view of the clear ruling in Art. 4 para. 1 Regulation (EC) No 765/2008 there is now a need for action in any case.

(ECT), if accreditation cannot be qualified as a public authority activity, but as an economic activity within the meaning of Art. 81 et seqq. ECT.

(i) Applicability of competition law: undertaking

In this regard, it depends on whether the activity of national accreditation would fall under the term undertaking from Art. 81 et seq., 86 and 87 ECT[70]. A functional understanding of undertaking must be assumed here[71]: According to the definition of the ECJ the concept of an undertaking encompasses "every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed"[72]. Economic activity is any activity which consists in goods or services being offered in a certain market[73]. In the present case it depends precisely on whether a market still exists after the establishment of a national accreditation body or whether the Member States can, by concentrating accreditation in national accreditation bodies, remove certain activities from the market. The opposite term to economic activity is public authority activity ("*eigentliche Staatstätigkeit*"), i.e. the exercise of public authority by the Member States and by the Community[74]. Accordingly, such state or public activity in a narrow sense does not fall under the provisions in Art. 81 et seqq. ECT relating to undertakings. However, the question what "public activity" comprises has been highly variable between the Member States and over time. Hence, a clear definition for the distinction between economic activities and public activities not covered by Art. 81 et seqq. ECT does not exist[75].

In this situation, it is thus recommended to orientate oneself towards the criteria offered in the ECJ's case-law for an overall analysis.

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70 Secondary law and court practice do not answer this question.

71 *Hochbaum*/*Klotz* in: Von der Groeben/Thiesing/Ehlermann/Bieber (eds.), EGV/EUV, Art. 86 EC Rn. 6.

72 ECJ Case C-41/90, Rec. 1991, I-1979 (para. 21) – Höfner and Elser; Case C-159 et al./91, Rec. 1993, I-637 (para. 17) – Poucet and Pistre; Case C-354/92, Rec. 1994, I-43 (para. 61) – Eurocontrol; Case C-244/94, Rec. 1995, I-4013 (para. 14) – FFSA; Case C-309/99, Rec. 2002, I-1577 (para. 46) – Wouters.

73 ECJ Case 118/85, Rec. 1987, 2599 (para. 7) – Commission/Italy; Case C-35/96, Rec. 1998, I-3851 (para. 36) – Commission/Italy; Case C-309/99, Rec. 2002, I-1577 (para. 47) – Wouters.

74 *Emmerich* in: Immenga/Mestmäcker, EG-Wettbewerbsrecht, Art. 85 EGV Rn. 21.

75 Only various points for consideration are mentioned by *Stockenhuber*, in: Grabitz/Hilf, Kommentar zur Europäischen Union, Art. 81 EGV Rn. 70; *Mestmäcker*/*Schweitzer*, Europäisches Wettbewerbsrecht, § 33 Rn. 28 et seq.

- Profit-making: A fundamental element of an economic activity is the orientation towards profit-making. Notwithstanding, a qualification as an economic activity is not excluded by the fact that no intention to make profits exists, according to the prevailing opinion[76]. Conversely, the activity cannot automatically be categorized as an economic activity because it is only carried out for a returned service, for example if a fee is charged for the services[77]. The *possibility* of profit-making does not suffice either as the sole criteria of differentiation from economic activities[78], because the state can remove certain services from the market despite existing profit-making possibilities by organizing their provision as a public authority activity (*hoheitliche Tätigkeit*).
- Public objective: An important element for the categorization as a non-economic entity is the thereby pursued public objective[79]. However, the orientation towards a public objective alone does not exclude the qualification as an undertaking, because public objectives can also be pursued by private parties in competition[80].
- Form of activity: The activity in legal forms under public law alone cannot discharge legal entities from the specifications of Art. 81 et seqq.[81]; a mere change in legal form would make it too easy for the Member State to avoid the applicability of Art. 81 et seqq. ECT. The former German Federal Office for Employment (*Bundesanstalt für Arbeit*) can be viewed as an example of this[82].
- Organization: However, the organization of the relevant entity offers crucial points of reference for its categorization in accordance with Art. 81 et seqq. ECT. The ECJ[83] essentially focuses on how the establishment is structured, whether it is obligated to act in

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76 ECJ Case 209/78 et al., Rec. 1980, 3125 (para. 88) – FEDETAB; Case C-244/94, Rec. 1995, I-4013 (para. 14) – FFSA; *Mestmäcker*/*Schweitzer*, Europäisches Wettbewerbsrecht, § 33 Rn. 21.

77 ECJ Case C-354/92, Rec. 1994, I-43 (para. 28) – SAT ./. Eurocontrol; Case C-343/95, Rec. 1997, I-1547 (para. 24 et seq.) – Calì ./. Servizi ecologici porto di Genova.

78 For this position *Essebier*, Dienstleistungen, p. 65 et seq.

79 ECJ Case C-343/95, Rec. 1997, I-1547 (para. 23) – Calì ./. Servizi ecologici porto di Genova: "exercise of powers relating to the protection of the environment"; Case C-354/92, Rec. 1994, I-43 (para. 27) – SAT ./. Eurocontrol: "tasks in the public interest"; Case C-159 et al/91, Rec. 1993, I-637 (para. 18) – Poucet and Pistre: "exclusively social function".

80 *Mestmäcker*/*Schweitzer*, Europäisches Wettbewerbsrecht, § 33 Rn. 37.

81 ECJ Case C-41/90, Rec. 1991, I-1979 (para. 22) – Höfner and Elser; *Mestmäcker*/*Schweitzer*, Europäisches Wettbewerbsrecht, § 33 Rn. 22.

82 ECJ , l. cit.

83 ECJ Case C-180/98, Rec. 2000, I-6451 (para. 87) – Pavlov; Case C-309/99, Rec. 2002, I-1577 (para. 57 et seq.) – Wouters.

accordance with public interest criteria, and whether the Member State exerts control or envisions other or additional mechanisms to ensure the conformity of actions with the common interest. However, if that is the case, it is also conceivable to vest a private body with public authority. In this case, the legal status as a private body alone does not evoke the characteristic of an economic undertaking.

- Factual situation, historically and in other Member States: Based on these considerations and having regard to the different criteria, importance can equally be attributed to the actual situation and its development in the respective Member State and in the other Member States. In the decision on the exclusive right of employment procurement of the German Federal Office for Employment, the ECJ underlines that such an activity "has not always been, and is not necessarily, carried out by public entities"[84]. The situation in other Member States thus also gains particular significance[85], as it reveals the extent to which the state or market-based provision of services is legitimate.

(ii) The status of a national accreditation body as an undertaking within the meaning of Art. 81 et seqq. ECT

If accreditation is offered by a state accreditation body, this does not lead automatically to the exemption of its activity from the applicability of Art. 81 et seqq. ECT as being the exercise of public authority. Therefore it must be assured by other means that accreditation does not become an economic activity. For national accreditation as a “public authority activity”, as corresponds with the current discussion at the European level[86], that implies:

- Exercise of public authority (*Hoheitlichkeit*): The particularity of “national” accreditation must be specified in the establishing legal act by means of a precise description of tasks: the centralization of the creation of trust, the necessary monopolization with regard to international links and the granting of the German Federal Eagle Seal (*Bundesadler*) which evokes trust precisely in the state are elements which support this characterization as an entity exercising public powers.

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84 ECJ Case C-41/90, Rec. 1991, I-1979 (para. 22) – Höfner and Elser.
85 E.g. *Mestmäcker*/*Schweitzer*, Europäisches Wettbewerbsrecht, § 33 Rn. 23 (at the end).
86 See above under C.II.3.

- Profit-making: The organization of the accreditation body must – in compliance with international standards – ensure that it operates on a non for profit basis.
- Public objective: The public objective of accreditation must be guaranteed, above all, by adequate organization. The state legal act establishing the accreditation body must take precautions so that the definitive international standards for accreditation[87] are respected and applied.
- Development and situation in the other Member States: A comparison with the situation in the other Member States shows that accreditation is organized there either as an activity of public authorities or as an activity of a private entity, which – supported by the state – enjoys a de facto monopoly status[88]. In these states accreditation is generally free of competition and is thus not carried out as an economic activity. It is monopolized either within state agencies or in organizations established under private law with close ties to the state. The qualification of accreditation as an economic activity thus would contradict – with the exception of Germany – the pan-European situation, which has to be considered in the interpretation of Art. 81 et seqq. ECT, as well. It would force all other Member States to remodel their system, to discontinue supporting the present accrediting bodies and allow competition.

b) Compatibility with the freedom to provide services

An infringement on the freedom to provide services stipulated in Art. 49 ECT by the establishment of a national accreditation body only comes under consideration insofar as *foreign* (private) accreditation bodies wish to operate in Germany and thus across borders. The constraint on these foreign accreditation bodies does not result from a regulatory restriction, rather from the fact that national accreditation under certain circumstances could make the market for private accreditation uninteresting, thus from an indirect infringement.

87 In detail above in the First Part, Second Section under A.I.
88 Above First Part, Third Section under C.IV.

The freedom of services stipulated in Art. 49 ECT is also understood as a prohibition of restrictions (*Beschränkungsverbot*)[89]. Measures by one Member State, which constitute an indirect infringement of the freedom of services, could be categorized as restrictions. This would be the case if service providers from another Member State were subject to indirectly more adverse conditions than service providers established in the acting Member State[90]. In the case of the establishment of a national accreditation body, however, there is no such unequal treatment, because private accreditation bodies established in Germany are subject to the same encroachment. Because it does not constitute an economic activity as shown above, the activity of a national accreditation body is not a service for which a foreign private accreditation body could request equal treatment in view of Art. 49 ECT.

2. Compatibility of one national accreditation body with the freedom of occupation of the competitors

In the German debate references are frequently made to the fundamental freedom of occupation (*Berufsfreiheit*) based on Art. 12 para. 1 GG[91], in order to justify why the establishment of one single accreditation body is impossible: it is argued that the private competitors of the state accreditation body are barred from activity, or that they are in any case at a disadvantage amid competition. This allegedly constitutes a violation of their freedom of occupation. The German version of the study thoroughly explains that these concerns are not substantiated. A state or state mandated accreditation body exercises a special form of public activity, which is not accessible to private parties. If this activity is not accessible to private parties, the state therefore does not revoke from them any possibilities of exercising their profession. This character as a special form of public activity primarily results from the necessity to establish the link to the European (EA) and international (IAF and ILAC) accreditation networks. This is only feasible with a single institution, but not with several accreditation bodies operating on a competitive basis.

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89 ECJ Case C-76/90, Rec. 1991, I-4221 (para. 12) – Säger; Case C-398/95, Rec. 1997, I-3091 (para. 16) – SETTG; Case C-266/96, Rec. 1998, I-3949 (para. 56) – Corsica Ferries II.

90 *Holoubek*, in: Schwarze, EGV, Art. 49 Rn. 83.

91 Art. 12 para. 1 of the German Basic Law states: “All Germans shall have the right to freely to choose their occupation or profession, their place of work, and their place of training.”

Altogether, the German accreditation landscape in its current state is a misguided development. A competitive structure was not envisioned for the non-regulatory sphere; rather, a division of accreditation into sectors was intended. As demonstrated, this objective could not be achieved with a structure based purely on private law without state intervention. Only this system, which was originally non-competitive and divided by sectors, made it possible, with the support of the state through the interposition of the DAR, to put into practice the key features of the accreditation "system" described above: the linkage of the accreditation bodies with the European (EA) and international (IAF and ILAC) accreditation networks on the one hand and internal coherence of the accreditation system represented by the DAR accreditation logo on the other hand.

These considerations coincide in entirety with the results of the country comparison conducted during this study: All visited countries have organized accreditation as a state activity or with close associations to the state with the – in any case de facto – exclusion of competition[92]. The fact that the other Member States organize competition-free accreditation makes a potential decision by Germany along these lines appear legitimate. The concept of what is understood as an economic activity in terms of a profession according to Art. 12 para. 1 GG can, in the case of such a European and internationally oriented activity, be interpreted in view of developments in other European countries. Such an interpretation still corresponds with the European perspectives, which have led to a decision for the designation of a single national accreditation body for the regulatory and non-regulatory sphere[93]. As a result, the state action has additional legitimacy here.

However, the activity of private bodies as "accreditation bodies" is affected by the establishment of a national accreditation body insofar as competition for these private bodies arises and they therefore may lose market shares. The encroachment by the state is an indirect-de facto encroachment: Commercial opportunities would be restricted if the state opted to assume a public activity which dries out previously existing areas of enterprise. A majority of views conveyed in German courts' decisions and literature, however, do not regard state competition as an intervention to be judged on the basis of fundamental rights.

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92 See above First Part, Third Section under C.I.

93 Art. 5 para. 1 in conjunction with Art. 3 Regulation (EC) No 765/2008.

This holds, at least, if the state acts as a competitor under the same legal conditions as private competitors do. However, this would not be the case here, because the state accreditation body would be priviledged by the possibility of using its special powers which result from being vested with public authority. The hereby triggered effects on the private accreditation bodies thus constitute an indirect de facto intervention. For such an indirect de facto intervention into Article 12 para. 1 GG a special legal basis is required. However, such a law would be permissible, and in particular not disproportionate, because a more moderate approach which poses a lesser burden on the commercial opportunities of the other private bodies is not discernable. Only the centralization of the accreditation activity can guarantee the necessary networking and creation of trust at the domestic level and is compatible with European guidelines. In any case, the status of private accreditation bodies in the accreditation system was originally designed as part of a quasi-state system. The newly emerging accreditation bodies, by contrast, have only gained access to the state-supported, DAR-organized accreditation market by means of the actually non-intended competition, so that their professional opportunities were indirectly fostered by the state. As a result, Art. 12 para. 1 GG is not in opposition to the establishment of a national accreditation body.

3. Organizational law questions concerning accreditation

German constitutional law also provides organizational guidelines for the establishment of a national accreditation body: the Federation would have to be competent for passing the relevant law ("legislative competence") and, above all, to create such an establishment as a federal agency ("administrative competence"). Moreover, it is questionable whether the Constitution contains organizational guidelines for the relationship to the ministerial administration.

a) Competence of the Federation

As a general *legislative* competence, the Federation may draw on Art. 74 para. 1 No. 11 GG concerning the “law of business and commerce” (*Recht der Wirtschaft*). For individual areas of accreditation in the regulatory sphere the Federation must fall back on more specific competence, for example Art. 73 No. 7 GG for telecommunications law, Art. 74 para. 1 No. 4a GG for explosives law or Nos. 21 to 23 for traffic law. However, the Federation only has the right to legislate if federal legislation is "necessary" according to

Art. 72 para. 2 GG. Whether the prerequisites of Art. 72 para. 2 GG are met is entirely subject to the control of the Constitutional Court; there exists no legislative leeway for assessment[94]. A single accreditation body operating across Germany, which also guarantees the international linkages, can only be governed uniformly for the entire federally structured country. The alternative currently practiced in part by the Federal States, which involves establishing central bodies such as the ZLS or ZLG on the basis of a State Treaty (*Staatsvertrag*), shows that a uniform arrangement is required[95]. Thus the law is necessary in accordance with Art. 72 para. 2 GG for the maintenance of legal unity.

Administrative competence can only be granted to the Federation on the basis of Art. 87 para. 3 clause 1 GG. Art. 87 para. 3 GG provides the Federation administrative competence in a comparatively broad scope[96], namely for all matters on which it has legislative power. Due to the here existing legislative competence, e.g. based on Art. 74 para. 1 No. 11 GG (law of business and commerce, see above), the Federation can therefore operate, as a rule, on the basis of Art. 87 para. 3 GG. Contrary to some opinions expressed in the literature, an exclusive competence of the Federal States for the accreditation tasks in the execution of EC-directives does not exist[97]. Such a competence of the States does not result either from the fact that the States are responsible for the execution of federal law in this area, thus for example on the basis of the MPG or GPSG. The administrative competence of the Federation given, the establishment of a new autonomous higher federal authority (*selbständige Bundesoberbehörde*) or a new federal corporation or institution established under public law (*bundesunmittelbaren Körperschaft* or *Anstalt des öffentlichen Rechts)* would come under consideration. The transfer of new tasks to an existing legal entity established on the basis of Art. 87 para. 3 GG is also possible[98]. However, in view of the current situation the establishment of a new federal agency for the purpose of accreditation appears to be impracticable:

- a large part of the infrastructure in the non-regulatory sphere is vested in private bodies,

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94 BVerfGE 106, 62 (135 et seq).
95 For the development see *Soltau*, in: Anhalt/Dieners, Handbuch der Medizinprodukte, § 12 Rn. 5.
96 Critique of this in *Britz*, DVBl. 1998, p1167 et seqq.
97 See e.g. *Soltau*, in: Anhalt/Dieners, Handbuch der Medizinprodukte, § 12 Rn. 4.
98 *Lerche*, in: M/D, GG Art. 87 Rn. 175; *Burgi*, in: v. Mangoldt/Klein/Starck, GG, Art. 87 Rn. 116.

- as signatories to the EA-MLA, private accreditation bodies are introduced to the international structures; a newly founded federal agency would have to take great efforts to take on this role, if possible at all.

It would therefore be conceivable to entrust a private accreditation body - potentially a body resulting from a merger of several private-sector accreditation bodies - with the tasks of accreditation, and, for this purpose, to vest this body with public authority (*Beleihung*). It is however disputed whether the vesting of a private body with public authority on the basis of Art. 87 para. 3 GG is possible. The view is sometimes put forward that Art. 87 para. 3 GG deliberately provides a conclusive list of permissible organizational forms[99], so that the vesting of a private body with public authority not mentioned there does not come under consideration. The likely most widespread view, by contrary, assumes that Art. 87 para. 3 clause 1 GG does not ultimately mention all potential forms of organization[100] and that this is rather an exemplary list[101]; according to this view, organizational forms based on private law are also permissible[102]. The latter view is convincing: Art. 87 para. 3 GG serves to protect the States from the intervention of the Federation into their administrative responsibilities. The ban on organizational forms other than those mentioned is only required insofar as they would intervene further into the sphere of competences of the Federal States than the establishment of a federal higher authority as an independent administrative organization. However, such an intervention in the States' competences is not necessarily associated with an organizational form based on private law, so that no general concerns can be raised against this. Concluding information with regard to organizational law can instead only be found in Art. 83 et seq. GG insofar as special terms referring to the organizational form are used, for example the term *bundeseigene Verwaltung* (federal administrative authorities) in Art. 86, Art. 87 para. 1 GG[103]. On this basis, the Federation can appeal to Art. 87 para. 3 clause 1 GG in order to entrust legal persons governed

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99 *Sachs* in: Sachs, GG, Art. 87 Rn. 69f.

100 *Boergen*, DVBl. 1971, 869, 876; *Weberling*, WissR 1990, 226 (229).

101 *Burgi*, in: v. Mangoldt/Klein/Starck, GG, Art. 87 Rn. 106 et seq.

102 *Dittmann*, Die Bundesverwaltung, 1983, p. 154; *Hermes*, in: Dreier, GG, Art. 87 Rn. 93.

103 For the previous situation of the German Federal Railway see *Schmidt-Aßmann*/*Röhl*, DÖV 1994, 577 (578); *Lerche*, in: Maunz/Dürig, GG, Art. 87 Rn. 15, 81 et seq.; Art. 87d GG has not changed any part of this judgement, see ibid. Rn. 40.

by private law with federal administrative tasks[104]. Such an authorization of the vesting of a private body with public authority as a legal instrument also corresponds with ongoing practice of the Federation[105], which corresponds with practical demands[106]. If the Federation wishes to make use of the option of Art. 87 para. 3 GG, the specifications in Art. 72 para. 2 GG are not applicable. The provision in Art. 87 para. 3 clause 1 GG constitutes an exclusive legislative power of the Federation. Hence, its application is not dependent on the prerequisites which the German Basic Law stipulates for the case of concurrent legislative power of the Federation for the area specific regulation. Furthermore, there is only talk of a "special need" in para. 3 clause 2[107].

b) Principle of ministerial autonomy

The principle of ministerial autonomy (*Ressortprinzip)* is often also mentioned as justification for a sectoral organization of accreditation. It is based in Art. 65 clause 2 GG, according to which every federal minister conducts the affairs of his ministry independently and under his/her own responsibility. It is argued that from the responsibility of the ministries for the notification decisions taken within their respective scope of competence it follows that decision-making powers – regarded as such – cannot be transferred to an accreditation body on which the respective ministry has no direct influence.

However, the independence of the accreditation body, as is required in the relevant standards, should exclude such interventions of the ministries with regard to substance and content of accreditation anyway. In addition, in the concept of an accreditation-based designation procedure in the regulatory sphere, accreditation is supposed to be the professional assessment of competence, which is still followed by a sovereign decision of the responsible ministry ("designation"). Thus, it is more a matter of the extent to which the

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104 *Lerche*, in: Maunz/Dürig, GG, Art. 87 Rn. 201 et seq. – understood as an analogue application.

105 *Lerche*, in: Maunz/Dürig, GG, Art. 87 Rn. 204.

106 For examples of private entities being vested with public authority by the Federal Government see e.g. § 44a para. 3 BHO (private subsidies mediators); § 31a LuftVG (flight route coordinator); § 7 para. 1 investment security and investor compensation law (private compensation body vested with public authority); § 3 para. 1 of the Law on the certification of retirement fund contracts (private certification bodies) offer several examples of this. The vesting of the DAU with public authority on the basis of § 28 UAG (authorization body based on EMAS) comes closest to the problem dealt with here.

107 BVerfGE 14, 197 (214).

respective Ministry is willing to trust the assessment by the accreditation body. This reasoning becomes even less convincing if we look at the actual the situation in Germany: in important areas accreditation is entrusted to central accreditation bodies created by the Federal States (e.g. ZLG, ZLS), which can apparently operate without direct influence of each responsible State ministry, without any doubts arising thereby with regard to constitutional law.

IV. Organization and international networking of the accreditation

By establishing a national accreditation body the state assumes responsibility for its proper functioning. This state support is documented by the right to bear the Federal Eagle Seal (*Bundesadler*) and forms the basis of the trust created by this body. The establishment act itself or regulations passed on its foundation must ensure that the national accreditation body operates in compliance with the requirements derived above from European competition law or the the freedom of occupation based in Art. 12 para. 1 GG. Above all though, the national accreditation body must commit itself to respecting international standards. Finally, it must keep pace with the state of the debate at the European level[108]. In detail:

1. Finances

One of the elements which must be imposed on a potential private body vested with public authority as the carrier of the accreditation is, among other things, financial control, in order to prevent accreditation from being degraded to a commercial activity[109]. In non-lucrative areas and wherever necessary for international tasks as well, the state must make the required means available if need be.

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108 Above in C.II.3.

109 The accreditation standards only note in this regard that accreditation bodies "usually do not operate in a profit-oriented manner", DIN EN ISO/IEC 17011:2004, Introduction; see above First Part, Second Section, A.I.3 b. Provisions for financial control exist, for example, for COFRAC: Art. 4 para. 3 of the framework agreement (see Appendix, First Section, Footnote 55); The legal foundation for surveillance is the Décret n° 55-733 from 25 May 1955 in the respectively applicable version, see also Art. 14.2 of the *Statuts* of COFRAC (COFRAC, Statuts, GEN REF 01 Revision 03 – Juin 2005, online at URL: http://www.cofrac.fr (16 February 2006)). In Sweden, for example, the amount of fees must first be agreed with the respective Swedish authorities (*Ekonomistyrningsverket*). However, these arrangements may also be related to the fact that the mentioned accreditation bodies receive state funds to finance, for instance, the external representation of the national accreditation system, albeit on a small scale.

2. Incorporation of the economic sectors

An important condition for the accreditation to succeed is the successful incorporation of the concerned economic sectors and the expertise of the authorities as well as commercial actors in the respective sectors. It appears beneficial here to transform to some extent the external plurality, on which the German accreditation system is based hitherto, into an internal plurality. This is to be supported by the effective involvement of all interested parties as required in the standards, which is above all supposed to ensure the impartiality of accreditation[110], but also – together with the maintenance of a pool of highly competent assessors and the establishment of an assessment committee[111] – contributes professional expertise to the accreditation.

However, to do so, it does not suffice for a national accreditation body serving only as an overarching structure to delegate accreditation tasks to sectoral accreditation bodies by means of sub-orders. The subcontracting of the assessment is indeed possible according to the accreditation standards[112], but the accreditation body may not sub-contract the decision-making itself, rather must assume full responsibility for all subcontracted assessments and have the expertise to take the decision itself[113]. Only in this manner can the accreditation body actually take responsibility for the accreditations issued by it in the international system and thereby ensure trust and international recognizibility.

3. Responsiveness towards clients

The discussion on the competitive structure of accreditation has shown that a national accreditation body also must take measures to assure quality.

- In this regard, it is regarded as desirable by foreign accreditation bodies, among other things, that there exists an adequate organization of and cooperation with conformity

110 DIN EN ISO/IEC 17011:2004, Section 4.3.2, see also the Guidelines on the ISO/IEC Guide 61, under G 2.1.5 - 2.1.10.

111 See DIN EN ISO/IEC 17011:2004, Sections 6, 4.2.6.

112 See DIN EN ISO/IEC 17011:2004, Section 7.4.

113 DIN EN ISO/IEC 17011:2004, Section 7.4.1, 7.4.2.a). From the perspective of the standard as well, a "mediatisation" of the monitoring of accreditation control by the involvement of too many levels of control ought to be avoided; this would inevitably occur if the accreditation body were able to sub-contract the assessment and decision.

assessment bodies, which – acting as clients of the accreditation body – can assess its services and e.g. gain insights on the fee structure of the accreditation body by means of a corresponding representation. An organizational model to this end could consist in the mediation of client interests by structuring the participation of the interested parties.

- A further development of this notion is the participation of the newly established "User Council" *(Gebruikersraad)* of the RvA in determining the prices for accreditation[114], by means of which the specific client interests are separated from the professional consultations in the sectoral committees.
- SAS in Switzerland[115] and UKAS in the United Kingdom[116] have been conducting client surveys among the conformity assessment bodies for some time now, in order to evaluate, among other things, their accreditation services and to receive feedback on the benefit of the accreditation proportionately to the costs.
- In the Memorandum of Understanding UKAS is obligated to regularly undergo an audit, in which the compliance of the accreditation activities with the internationally harmonized requirements and the Memorandum of Understanding is inspected[117].
- Finally, the *peer review* among the European accreditation bodies can provide an important contribution in this respect.

4. European networking

The core mechanism for creating trust at the European level is the networking of the accreditation bodies within a European accreditation infrastructure. Certif 2005-16 had stated in this regard that the European infrastructure for accreditation should serve to create and preserve trust in the conformity assessment bodies[118] and bring together all nationally recognized accreditation bodies into a network-like structure, in order to promote the equiva-

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114 For more details on this see Appendix, Second Section, under D II 1.d).

115 *SAS*, Jahresbericht 2004, p. 23 et seq.; available online at URL: http://www.sas.ch/de/print/jb-sas/2004/JBsas2004_d.pdf (22 August 2005).

116 A summary of the results of the first survey in April 2005 is available at URL http://www.ukas.com/news/2005/CSI_Survey.asp (8 August 2005).

117 Memorandum of Understanding, Art. 10 clause 2; the text of the memorandum is available at URL: http://www.ukas.com/Library/downloads/About_UKAS/MOU.pdf (10 May 2006).

118 This is viewed as a task of public interest, CERTIF 2005-16 rev. 2 (Footnote 6), C.6.4, p. 20.

lency, transparency, and efficiency of accreditation[119]. To this end, it should operate a strict and transparent peer evaluation system, which is in accord with international practice, and thereby promote the mutual recognition of the declarations of conformity, both in the regulatory as well as the non-regulatory sphere[120].

Compared with this important function, the previous safeguarding of standards within the present cooperative structures in the EA framework is still insufficient[121]. Thus, EA is an association governed by private law, whose implementation instruments used vis-à-vis the national accreditation bodies are only weakly developed[122]. Its legal status vis-à-vis the Member States and the Commission is only loosely defined, and at the national level there is no legal connection to membership in EA. The only indication in a legal act in this regard can be found in the EC-Switzerland MRA[123]. Hence, it was crucial and imperative to legally anchor the legal status of the European accreditation infrastructure vis-à-vis the Commission and the Member States and, in particular, to put their competences vis-à-vis the national accreditation bodies on a solid legal basis[124]. The national regulations on accreditation must therefore abide by the corresponding rules.

The Regulation now underlines the central function of accreditation in facilitating the mutual recognition of declarations of conformity[125] and obligates the national accreditation bodies to be members in EA and to regularly participate in the peer reviews[126]. The responsibility for compliance with the requirements for national accreditation bodies stated in Art. 4 and 8 of the Regulation is imposed on the respective Member State, which also must guarantee that corresponding corrective measures are taken in cases of non-fulfilment of

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119 CERTIF 2005-16 rev. 2 (Footnote 6), 6.4, p. 16.

120 CERTIF 2005-16 rev. 2 (Footnote 6), 6.4, p. 16.

121 See also the description of the problem in Commission Staff Working Document accompanying the proposal for the Regulation, SEC(2007) 173, 2.1.4 (p. 19).

122 As an example for the lacking executive capacity of the EA, references are made time and time again in the discussions to the long-lasting process which is required to exclude an accreditation body, which no longer meets the requirements of the EA, from the circle of European accreditation bodies.

123 See Appendix, Fifth Section, under B.IV.2.

124 For the considerations expressed during the revision of the New Approach see the Discussion Paper Draft CERTIF 2005-5: The development of the European infrastructure for accreditation; from 16 June 2005; the document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/certif_2005_05.pdf (15 March 2006).

125 Recitals 8 et seqq. Regulation (EC) No 765/2008, esp. No. 9, 10, and 20.

126 Art. 4 para. 10, Art. 10 para.1 Regulation (EC) No 765/2008, see above C.II.3.b)(ii).

the requirements[127]. If the responsibility for corrections to the accreditation practice thus lies with the Member States and not the European accreditation structure or EA itself, there is less need for the strengthening of the enforcement of the executive mechanisms of EA vis-à-vis the national accreditation bodies mentioned above. With regard to the horizontal creation of trust, it is however imperative that the Member States carry out the inspection of their own accreditation body in a manner that is *transparent* towards the other Member States. The communication of the results of the obligatory peer assessment to the Commission and all Member States and the information requirements towards the Commission with regard to corrective measures taken by the Member States, which are provided for in Art. 10 para. 6 of the Regulation[128] are thus a step in the right direction.

5. Continual surveillance

The verification of the competence of the conformity assessment bodies by the Member States entails the obligation for the latter to define and carry out procedures which ensure that the conformity assessment bodies continuously fulfil all requirements resulting from the special conformity assessment procedures in combination with the product categories for which the body has applied for the designation. Therefore the Notified Bodies must be regularly and effectively monitored in accordance with the international standards[129]. If the notification in this respect is supported by continual surveillance within the framework of the accreditation, the national accreditation bodies must be vested with the legal foundations which allow for effective surveillance in accordance with these specifications[130].

6. Relationship between designation and accreditation

Rules on a national accreditation body would also have to provide for clear specifications on the relationship between designation and accreditation and clear usage of the terminol-

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127 Art. 9 para. 1 Regulation (EC) No 765/2008.

128 Art. 9 para. 1 Regulation (EC) No 765/2008.

129 In particular with regard to sub-contracting and various forms of cross-border activity; CERTIF 2005-16 rev. 2 (Footnote 6), C. 5.2, p. 13, on the state of domicile principle as well. For sub-contracting see Art. R20 Decision No 768/2008/EC.

130 For the surveillance obligation concerning the accreditation bodies see Art. 5 para. 3 Regulation (EC) No 765/2008; for the limitation or revocation of the confirmation of accreditation see Art. 5 para. 4 Regulation (EC) No 765/2008.

ogy in this context. The lack of a clear demarcation between accreditation and designation and the unclear requirements for them are the main obstacles to generating trust internationally.

a) Comparison of law

However, this observation can be also be made in most European states, in which the designation and surveillance of the conformity assessment bodies is supported by the accreditation by a (national) accreditation body. In these systems as well uncertainties arose, in particular with regard to the relationship between the requirements laid down in the Directives and the criteria of the series of standards EN 45000 et seqq. and EN ISO/IEC 17000 et seqq.[131] This coincides with the fact that the international certification bodies claim to have accreditations and designations in several Member States despite largely identical scopes of activity[132], because in practice requirements for notifications resp. accreditation differ between Member States despite theoretically equivalent requirements.

b) The debate in Europe: The relationship between accreditation rules and harmonized standards

CERTIF 2005-16 did not contain any specifications on how the respective area-specific requirements of the Directives are to be related to the international accreditation standards[133]. However, the document assumed that this can take place by means of more specific accreditation rules: The Member States were supposed to "determine or approve the accreditation rules or criteria against which assessment of competence is performed by the nationally recognised accreditation body on the basis of the relevant European and international standards and application documents for accreditation"[134]. The Regulation now stipulates that the Commission can call on EA to develop sectoral accreditation schemes, which ensure compliance with the requirements defined in the directives by means of cor-

131 For more details see First Part, Second Section, B III.1.b).
132 First Part, Third Section, B.II.
133 In-depth thoughts on this still in Draft CERTIF 2005-6, 2.2 (a), p. 4. The document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/certif_2005_06.pdf (15 March 2005).
134 CERTIF 2005-16 rev. 2 (Fn. 6), C.6.1, p. 17.

responding technical specifications[135]. The uncertainty with regard to the documentation of the requirements for bodies to be notified by the international accreditation standards is still reflected in the wording of the rules on the assumption of conformity to the benefit of the Notified Bodies: according to Art. 24 of the Decision the conformity assessment bodies are to be granted an assumption of conformity with regard to the fulfilment of all requirements in Art. 23 if they comply with the harmonized standards, "insofar as the applicable harmonized standards cover these requirements"[136]. Moreover, this regulation does not include any specifications that would imply that such an assumption of conformity only exists when the confirmation of compliance with the international standards was issued by an accreditation body that is integrated into an international accreditation system; in consideration of the accreditation structure in the Community provided for in the Regulation[137] this will normally be the case though.

c) Recommendation

An accreditation law establishing a national accreditation body could play an exemplary role due to its universal approach, even if initially only some areas of the regulatory sphere are likely to be covered. To this extent, it could provide for clarity with regard to the relationship between accreditation, on the one hand, and the sovereign recognition or designation act on the other. Equally important here, however, is that the legal provisions on the European level clarify this core issue in order to bring about unambiguous solutions to this question.

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135 Art. 13 para. 2 lit. b) Regulation (EC) No 765/2008. See additionally para. 3: "The Commission shall ensure that sectoral schemes identify the technical specifications necessary to meet the level of competence required by Community harmonisation legislation in fields with specific technology, or health and safety or environment related requirements or other public interest protection."

136 Art. R18 Decision No 768/2008/EC states: "Where a conformity assessment body can demonstrate its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article [R17] insofar as the applicable harmonised standards cover these requirements."

137 See above C.II.3.b).

D. Market surveillance

At least in the regulatory sphere, the issue of market surveillance is inseparable from that of conformity assessment[138]. All consulted experts in Germany and abroad have underscored the particular significance of effective market surveillance as a necessary supplement to or – stated negatively – as an "open flank" for a functioning conformity assessment system. This is due to the fact that European product safety law, on the basis of the New Approach, makes fundamental changes to the tasks of the Member State authorities. They no longer have the instrument of preventive control and rely on risk prevention measures in the so-called post-market phase. However, the separation between, on the one hand, the conformity assessment bodies which open access to the market and, on the other hand, the market surveillance authorities proves to be a critical issue. Accordingly, it is first of all the conformity assessment bodies who have the information and the knowledge on potential dangers. In addition, the national market surveillance authorities frequently lack the necessary financial resources. Further problems rise from the fact that now Europe-wide market surveillance must be organized by a broad array of authorities of different provenance.

I. Challenges

1. Information and knowledge

One possibility for lawmakers to react to situations of typical or potential risks is using the instrument of authorization, thus the official approval of a product. The person who has possession of a potential source of danger, thus e.g. a product, is forced to first produce information on this potential source of hazard and then share it with the authorities. The manufacturer, who has something to gain, i.e. market access, provides the information on his/her own incentive in this situation. The authorization requirement thus solves, in particular, this information problem with regard to which products in what condition are put on the market. Market surveillance by Member State authorities is now faced with pre-

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138 See Recital 8 Regulation (EC) No 765/2008, which describes conformity assessment and market surveillance as parts of "an overall system".

cisely this *information problem*, because no systematic information about the products on the markets are at their disposal and the entire market for a certain product is much more difficult to observe than merely the market access. Although it is the task of the Member States to take all necessary measures to ensure that products are only put on the market and in operation when they either do not present a danger[139] or meet the demands of the directive[140]. However, to fulfil this task, sufficient information is lacking as long as no concrete information on sources of hazard exists. Precisely for more complicated products though, it is difficult to determine sources of hazard without inspection. If measures taken to identify these hazards are not permissible without concrete evidence, this reduces the chances of effective market surveillance, in particular for products with a large hazardous potential for damage.

At least some directives based on the New Approach stipulate that the conformity assessment bodies must inform the Notifying Authorities about the suspension and revocation of certificates or other relevant conformity assessment results, which then pass these onto the market surveillance authorities[141]. The public authorities can additionally be incorporated into the flow of information through the experience-exchange groups of the Notified Bodies[142]. To a certain extent, the information deficit of the market surveillance authorities can be countered in this manner. However, such feedback mechanisms between the levels of conformity assessment and market surveillance must be enhanced[143]; they also must not restrict themselves to individual cases (regarding the trustful relationship between the conformity assessment body and client), rather must provide precisely for a systematic transfer of knowledge on risk potentials between the now separated areas.

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139 e.g. Art. 2 para. 1 Directive 98/37/EC (machines).

140 E.g. Art. 2 Directive 93/42/EEC (medical devices).

141 For example Annex IV Part 1 Module B1 No. 7 Directive 1999/36/EC (Transportable pressure equipment) on EC design-examination certificates, Annex V A No. 7, B No. 7 Directive 95/16/EEC (Lifts directive) with regard to the EC type-examination; see the preliminary remarks on the Designated Bodies Art. 16 para. 5 Directive 93/42/EEC (medical devices).

142 For medical devices law see *Höppner*, in: Anhalt/Dieners, Handbuch des Medizinprodukterechts, § 14 Rn. 5.

143 See also 2005-6 rev. 2 The document is available online at URL: http://europa.eu.int/comm/enterprise/newapproach/pdf/certif_2005_06.pdf (15 March 2005), C.5.3, p. 14.

2. Resources

The abolishment of the authorization requirement and the restriction on preventive controls is additionally linked with a *resource problem*: public funding for establishing own inspection capacity for hazardous products is often lacking[144]. Subsequently, the required knowledge on handling hazardous products can no longer be produced within the state organizations. As a result, the state authorities, which lack their own capacities, also draw on the resources of conformity assessment bodies on specific occasions. In such cases, precaution must be taken as in hazardous situations as the quality of the engaged conformity assessment body is always questioned, and now a competing firm has been called on to offer its assessment.

3. Cooperation at the national and European level

At the national level, the coordination of market surveillance is impeded by the general allocation of responsibilities for market surveillance to different administrative levels, in particular to the municipal level as well[145]. An additional factor in Germany is that the Federal States (*Länder*) are, as a rule, responsible for market surveillance. However, for effective market surveillance, it is important that the various authorities at the national level cooperate and that a strategy is developed and adjusted to the respective product sectors, which allows for the identification of non-conform products even beyond municipal and Federal States' boundaries.[146] Thus an "interstate" level must be established for coordination. A similar situation applies to the cooperation at the European level due to the Community-wide marketability of products with the CE-marking. Enhanced cooperation

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144 As stated already in the Commission communication "Enhancing the Implementation of the New Approach Directives", Commission (2003) 240 final, under 2.5.1.

145 The sections on the analyzed countries in the Appendix, respectively under E, provide an overview on the organization of market surveillance.

146 The initial steps towards drawing up surveillance concepts are outlined in § 8 para. 2 GPSG. *Klindt* calls for the strengthening of efforts at overarching coordination between the German federal states, NJW 2004, 465 et seq, 470. The PSG in Austria calls for a yearly coordination meeting between the responsible authorities, which is envisioned, among other things, to draw up and coordinate strategies and establish sectoral surveillance programs, see Appendix, Third Section, E.I. at the end. The Council for Market surveillance in Sweden also will draw up an annual plan for market surveillance, in greater detail in the Appendix, Fourth Section, E.II.1.

between the market surveillance authorities is also urgently necessary due to the scarce resources.

II. Approaches in Europe

Sweden is pursuing an interesting coordination approach at the national level. The fifteen sector-specific authorities responsible for market surveillance are represented in a Market Surveillance Council, which is to draw up an annual action plan for market surveillance. The council is based in the Swedish accreditation body SWEDAC, which is also responsible for the coordination of market surveillance[147]. In Austria a product safety advisory board was created to advise the responsible minister during market surveillance, among other things[148]. It also serves to promote the exchange of experiences and can offer recommendations which are to be published by the Minister[149].

In the United Kingdom as well, a special coordination approach has been developed for the market surveillance authorities based at the local level, which is to improve market surveillance above all at the national level. Its centrepiece is the so-called *Home Authority Principle*. This is a mechanism for the coordination and cooperation between local authorities for dealing with firms that market their products in an area which spans beyond the competence of the local authorities. According to the Home Authority Principle the agency in whose area of jurisdiction the headquarters of a firm are located is responsible for the surveillance of the products and services of this firm. Thus, the Home Authority becomes the main point of contact, on the one hand for the firm itself, and on the other hand for other local authorities that are confronted with products or services of the firm. This should make it possible for a responsible authority to make agreements with firm which apply within the entire firm[150]. Other authorities are, as a rule, to first consult the responsible

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147 More details in the Appendix, Fourth Section, E.II.1.

148 For information on the committee membership, including representatives of the social partners, interest associations and state agencies, see § 20 PSG 2004, more in Appendix, Third Section, E.I.

149 § 21 para. 1 No. 4, para. 4 PSG 2004 – in particular by way of publication on the Internet.

150 See *LACORS*, An introduction to the Home Authority Principle and how it operates, p. 1; available online at URL: http://www.lacors.gov.uk/tempBE/Download1.pdf (2 August 2005); *DTI*, Market Surveillance in the UK – UK Policy on enforcement of European Product Safety regulations, November 2003 (URN 03/1577), Item 5; the document is available online at URL:

Home Authority before they take their own measures[151]. The Home Authority Principle puts into practice the notion of cooperation with the firm. It also enables the authorities to build up technical competence in certain areas. Finally, it supports the cooperation among the authorities and can hence contribute to improvements in terms of the effectiveness of surveillance altogether, primarily for the national market though[152].

At the community level the Regulation, for the first time, addresses the relationship between the market access regime based on conformity assessment and market surveillance in a systematic manner. The Regulation envisions the creation of a community-wide legal framework for market surveillance[153], which provides for, among other things, an improvement of the coordination between the Member States and the Community and between the Member States as well as the improved use of and sharing of resources[154]. This goes hand and hand with a stronger conceptualization of market surveillance in the Member States, who are obligated to draw up market surveillance programs[155]. At the German federal level this must result in a cross-national strategy for market surveillance. An additional element of the community-wide legal regulations is the establishment of a common information management system[156], which could build on the already established ICSMS database[157]. The increased usage of Rapex systems is also provided for[158]. The rules are

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http://www.dti.gov.uk/strd/marketsurveill.pdf (2 August 2005). Besides the Home Authority there is also the Originating Authority, which is responsible for goods produced and services provided for in its field of responsibility; see *LACORS*, An introduction to the Home Authority Principle and how it operates, p. 2.

151 *LACORS*, Home Authority Principle – Standards, p. 6. Available online at URL: http://www.lacors.gov.uk/tempBE/Download2a.pdf.

152 More on market surveillance in the United Kingdom in Appendix, Sixth Section, E.

153 See the heading of Section 2 Regulation (EC) No 765/2008.

154 Art. 24, 25 Regulation (EC) No 765/2008.

155 Art. 18 para. 5 Regulation (EC) No 765/2008.

156 Art. 23 Regulation (EC) No 765/2008.

157 The ICSMS database is not explicitly mentioned in the Regulation, though. ICSMS is an Internet-based system for the exchange of product information. It consists of a closed and a public area. The closed area is reserved fort he market surveillance authorities, customs, and the EU Commission and makes available product information, testing results, information on official measures taken, etc. The public area can also be accessed by consumers and manufacturers. It contains, for example, official information on hazardous products, but also voluntary recalls by the industry as well as information on fake products. More on ICSMS at URL: http://www.icsms.org (6 June 2006).

158 Art. 22 para. 4 Regulation (EC) No 765/2008.

supplemented by provisions on the more effective incorporation of the customs authorities when monitoring the products entering the Community market[159].

E. Summary of the conclusions and recommendations

The starting point for any analysis must be the existence of conformity assessment as a self-supporting system based in the private sector. The utilization of this system for state regulatory objectives in order to create horizontal trust (in particular product safety) or in a vertical manner (expert activities in particular in the environmental sector) leads to different functional logics and ultimately to a diversification. A comprehensive regulatory strategy thus cannot be discerned for the moment – instead, it is a matter of taking action in those areas which urgently require action. Firstly, this includes private sector conformity assessment, whose international integration should be supported by strong and enduring support by the state. Secondly, this includes the incorporation of conformity assessment into the European regulatory strategies based on the New Approach, which demands action at all levels and is imperative for devising a stringent policy. By contrast, the need for action is much lower in the other areas of conformity assessment which are in the interest of the state and do not rely on international recognizibility to the same extent. The need for action currently appears to be most urgent with regard to the organizational design of accreditation. The study recommends that measures be taken to establish a national accreditation body in a first step.

I. Action at the national and European level

The objective at the national level is, firstly, to enforce a more stringent conformity assessment policy, which initially may also be restricted to narrower areas. Secondly, German representatives should – based on an open-minded stance towards European needs – actively participate in the design of a consistent European conformity assessment policy, which is at the same time compatible with national structures.

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159 Art. 27 et seqq. Regulation (EC) No 765/2008.

II. Legal clarity

The revision of the legal regulations on the use of conformity assessment at the national and European level offers the opportunity to rectify the inadequate legal situation at all levels of action and create transparent and sensible structures for the system of conformity assessment. This includes:

- A more precise regulation of the requirements for the designation of the Notified Bodies, in particular the role of accreditation in this context.
- A manageable distinction between accreditation on the one hand and the sovereign recognition or designation act as well as a clear classification of the criteria to be used at these levels.
- Sustainable support for EA as well as the effective integration of the national conformity assessment systems in this structure of European networking.

III. Accreditation as a backbone

The instrument of accreditation can be attributed a significant role in the system of conformity assessment. It provides the most important interface with state regulatory interests, and the state is simultaneously required at this position as an authority to reinforce the trust in the accreditation body and thus the conformity assessment bodies as well. Consistent with the European and international specifications and in agreement with the analyzed Member States, we recommend the establishment of a single national accreditation body, if need be in several steps. The establishment of such a national accreditation body, which does not compete with others and has a unique status for the regulatory and non-regulatory sphere, would be permitted by German law.

(1) In the current situation it is indispensable to strengthen accreditation as a mechanism to guarantee the quality and recognizibility of the certificates of conformity and to consolidate accreditations procedures and organizations at the national level, as well. Firstly, an effective mechanism of quality assurance is necessary in a system of conformity assessment, so that the system can create trust in the certificates from within. To do so, the international conformity assessment system places emphasis on accreditation. Secondly, the horizontal legal acts at the Community level will grant the formal accreditation procedure an important role in the previously inadequate harmonization of the designation proce-

dures[160]. An accreditation system should be present in Germany, which is integrated into the European structures, is transparent and can thereby gain and maintain the trust of the authorities in the other Member States.

(2) Competition at the level of accreditation is not necessary. The German accreditation system as well was not originally based on competition between the accreditation bodies[161]. From a legal perspective, it is permissible to exclude competition from accreditation. This applies both from the perspective of European competition law as well as from the standpoint of German constitutional law[162]. The renunciation of competition bears disadvantages insofar as the competition no longer is a means of identifying non-compliance, which leads to increases in quality and greater consideration of the concerns of the users of accreditation. This gap will have to be filled with other mechanisms of quality assurance consistent with the European plans, such as an intensification of cooperation in EA, regular peer reviews among the accreditation bodies and corrective measures in case of non-conformities detected in the review process.

(3) The regulatory sphere and non-regulatory sphere should be consolidated into one accreditation body. In the interest of an export-oriented economy, the state can take on the task of assuring the recognizibility of the certificates of conformity. It fulfils this task by providing an "anchor point" for the systems for assuring quality and recognizibility in the form of an accreditation body for conformity assessment bodies in the non-regulatory sphere. The state administration is particularly well suited to guarantee the functional capability of such an anchor point due to its high capacity for neutrality and the existing monitoring structures. In the countries analyzed in this study these considerations, in particular, have led to the establishment of a uniform accreditation body for the regulatory and non-regulatory sphere[163]. From an economic standpoint the consolidation of accreditation activities in one body generates synergy effects for the conformity assessment bodies, for example because it can help avoid multiple inspections of the same requirements and significantly reduce administrative expenses.

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160 See above C.II.3 a).
161 See above First Part, Fourth Section, B.I., in particular B.I.4.a).
162 In greater detail above, C.III.
163 See above, C.I.

(4) The different economic sectors should be consolidated in one national accreditation body. The other studied countries have had positive experiences with the consolidation of various sectors in one accreditation body, because this ultimately leads to the already discussed synergy effects. This applies not only with regard to the required administrative expenses, but also with regard to a service offer geared towards the conformity assessment bodies, on the one hand, and the public authorities on the other hand as users of accreditations. Moreover, this service offer would include accreditation in all areas in which there is a demand for it. A national accreditation which has been established on these foundations also can be more easily integrated into the international system of accreditation. This is significant because *effective* mutual control also must be achieved in the international system. The high degree of professional competence, which doubtlessly exists in the sectoralized accreditation bodies of the present German accreditation system, could be integrated into a uniform national accreditation body organized along these lines.

(5) The establishment of a central accreditation body at the federal level is also permitted by German law[164]. The Federation has the necessary legislative competence as well as the administrative competence on the basis of Art. 87 para. 3 GG. It would also be permissible to establish an independent superior federal agency or a new federal corporation or institution established under public law *(bundesunmittelbare Körperschaft* or *Anstalt des öffentlichen Rechts).* A private body could also be vested with public authority over accreditation tasks. The vesting of a private body with public authority seems to be the more viable option because a large part of the infrastructure is already based in private bodies and – in particular – because private bodies of the current German accreditation system are incorporated into international structures through their membership in the MLA of EA, IAF and ILAC.

[164] In greater detail above, C.III.3.

Appendix

Conformity Assessment and Accreditation in Other European Countries: Country reports

The appendix shall present the insights on conformity assessment and accreditation in the countries that were analyzed in this study. The country reports are based primarily on an evaluation of the respectively applicable legal foundations and documents, which take the situation as of March 2006 into account*.

The selection of the European countries was carried out with respect to their economic significance as well as their particular legal structures. The analysis focused first on the bordering countries Austria and Switzerland, where there are specific legal regulations for accreditation. As a non-EU member and partner within the framework of a MRA, Switzerland is worthy of particular attention. We additionally analyzed conformity assessment and accreditation in Sweden, which – like Austria and Switzerland – has horizontal legal regulations. France, the Netherlands, and the United Kingdom also are of particular economic significance for conformity assessment, not least because they are large trading partners of Germany. The analysis of conformity assessment and accreditation in the United Kingdom and the Netherlands was also worthwhile because both countries have a particularly well documented conformity assessment *policy*, which enabled a fruitful comparison. An additional aspect of the selection was the active role and visibility of the examined countries in the European and international conformity assessment and accreditation policy.

The compilation of the country reports would not have been possible without the talks and interviews conducted with representatives of the respective ministries, accreditation bodies and conformity assessment bodies on location between October and December 2004. They clarified to us the importance of many provisions, pointed out numerous aspects and enabled us to gain an overall picture, which we would like to present in the following country reports. We would also like to thank our interviewees for reviewing the drafts of the indi-

* Unfortunately, it was not possible to update the information for the English version of this study.

vidual segments with great patience and effort, which in turn has enabled us to hopefully provide a sufficiently adequate picture of conformity assessment in respective countries. Wherever assessments are presented in the text, they illustrate the state of the discussion at the time of the interviews. The preliminary work with regard to the further development of the New Approach was much less advanced at this point in time and therefore only to a limited extent a topic of the conversations.

The country reports should, above all, serve to facilitate the comparison of the German conformity assessments system with the structures in other European countries. With view to the conclusions drawn in the Second Part of the analysis they concentrate on the use of conformity assessment in the regulatory sphere. The respective reports begin with an overview of the significance and the areas of applicability of conformity assessment. After that, its use in the regulatory sphere will be examined in greater depth, while particular attention will be dedicated to the role of accreditation in the designation and notification procedure. This is followed by comments on the organization of the accreditation body and the role of conformity assessment. The segments conclude with several remarks on the organization of market surveillance. Market surveillance was not a subject of this analysis, and the relevant regulations were not extensively analyzed. However, the talks have shown that the organization and procedure of market surveillance are closely related to conformity assessment and are of crucial significance for guaranteeing the aspired level of safety.

First Section: Conformity Assessment in France

After a brief overview of the use of conformity assessment in France, its relevance in the regulatory sphere shall be demonstrated on the basis of selected examples; particular attention will be given to the role of accreditation in the approval procedure and the surveillance of conformity assessment bodies by public authorities. Furthermore, the organization and status of COFRAC, the French accreditation body, will be described, followed by several remarks on the activities of the conformity assessment bodies. The section is concluded with a brief outlook on the role of market surveillance in relation to conformity assessment.

A. Overview of the use of conformity assessment

In France, there is no comprehensive legal regulation on the use of conformity assessment and accreditation. In the regulatory sphere, the use of conformity assessment is primarily motivated by safety regulations now mostly under European law. France has special provisions on conformity assessment in consumer protection law, which are supposed to provide for transparency on the market for voluntary certifications.

I. Conformity assessment as a regulatory instrument

For France, there is no evidence that conformity assessment is used as regulatory instrument in a targeted manner and on a large scale[1]. Nevertheless, accreditation is quite often mandatory for laboratories performing measurements required by law and conformity assessment is widely used in product safety law, now regulated by the corresponding directives based on the New Approach[2]. However, conformity assessment is indeed viewed as a regulatory element, which relieves the state from various activities and allows for an ap-

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1 This may be due to the fact that product safety policy and standardization existed in parallel in France before the development of directives based on the New Approach. From the standpoint of product safety policy, certification was subsequently factored out. Further information in *Joerges/Falke/Micklitz/Brüggemeyer*, Sicherheit von Konsumgütern, p. 66 et seq.

2 Formerly, conformity assessment was offered either by specialised public bodies (*service public*) or by recognised third party bodies.

proximation of legal demands and market demands[3]. Meanwhile, efforts are being made to resort to certification and accreditation in non-harmonized areas as well during the introduction of new regulations if the object of regulation is appropriate for doing so, e.g. when measuring asbestos pollution[4]. Additional examples are the inspection of measurement bins, water and sediment analyses by approved enterprises, or regulations on the transport of hazardous substances by rail.[5] Regulations on the application of conformity assessment procedures can thus also be found nowadays outside the areas affected by directives based on the New Approach; however, unlike in the Netherlands, for example, there is no comprehensive conformity assessment policy in France.

Once conformity assessment is applied to guarantee the safety of products, maintaining a certain level of safety is viewed as a state task. The commitment on behalf of the state to create a uniform accreditation body available for both the non-regulatory and regulatory sphere is viewed as a component of this. In France, the transparency of the conformity assessment system is viewed as an important precondition for the trust, which the affected persons place in the system. Against this background, particular emphasis is placed on the incorporation of all interested parties[6].

II. Regulations on certification in the Code de la Consommation

The regulations for conformity assessment in France primarily distinguish themselves from those of the other analyzed countries by the fact that there are provisions in consumer protection law on product certification, which are supposed to create transparency with regard to the information on the labels.

The stipulations of the *Code de la Consommation* include the voluntary third-party certification of services and products with the exception of certain product groups such as food

3 *Couret/Igalens/Penan*, Certification, p. 10.
4 Further details on this under B.II.2.
5 More on the fields of application of the conformity assessment in the regulatory sphere under B.I.
6 Observers still see a need for improvement here at the European level.

and nutrients as well as agricultural or medical devices[7]. Thus, the provisions only concern certification services for voluntary certification[8]. The essence of the regulation is the obligation of providers of certification services to notify the responsible ministry of industrial affairs of such activities[9]. The certification takes place on the basis of so-called *référentiels.* These product-specific certification schemes are drawn up with the participation of the interested groups and validated in a specific procedure[10]. The validation of the *référentiels* is published in the Journal Officiel de la République Française[11]. During the notification procedure, the certification body must provide evidence of its independence and competence. The declaration required for this is provided through a simplified procedure if the conformity assessment body has an accreditation from a recognized accreditation body[12]. The accreditation is thus not obligatory here, but simplifies the procedure, as the conformity assessment body must only present less comprehensive documentation. The *Comité Français d'Accréditation* (COFRAC) is recognized as an accreditation body according to this law[13].

The forerunner to the modern-day regulations in the *Code de la Consommation* was the so-called *Loi Scrivener* from 1978[14]. The objective of the law was above all consumer protection, as the number of markings, labels, and certificates had increased and their respective

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7 Code de la Consommation, Partie Legislative, Art. L115-27 to L115-33, Partie Réglementaire, Art. R115-1 to R115-12.

8 See DIGITIP/SQUALPI, La Certification des produits industriels et des Services en 7 questions, 2001, online at URL: http://www.industrie.gouv.fr/pratique/certification/certif7q.pdf (16.2.2006), p. 2.

9 Art. L115-28 para. 1 in conjunction with Art. R115-1 of the Code de la Consommation. Instead of the mere notification, the *Loi Scrivener* (Fn. 14) provided for state approval (*agrément*) of the certification activity, Art. 22 para. 2 of Loi n° 78-23 du 10 janvier 1978. This was perceived to be too cumbersome, in particular because at that time France was the only European country that required an approval, *Couret/Igalens/Penan*, Certification, p. 12.

10 Art. R115-1 Code de la Consommation.

11 Art. R115-11 Code de la Consommation.

12 Art. 115-6 in conjunction with Art. R115-1 Code de la Consommation.

13 Arrêté du 30 mars 1995 portant reconnaissance du Comité français d'accréditation en tant qu'instance d'accréditation des organismes certificateurs de produits industriels et de services, NOR: ECOC9500027A, J.O n° 81 du 5 avril 1995 page 5439. The approval does not formally grant COFRAC a monopoly; however, no other accreditation bodies were approved. For the position of COFRAC, see C.I below, in particular C.I.3.b.

14 Loi n°78-23 du 10 janvier 1978 sur la protection et l'information des consommateurs de produits et de services (dite "loi Scrivener"); the text is available online at ULR: http://www.admi.net/jo/loi78-23.html (16.2.2006).

meanings had become difficult to grasp.[15] The objective of the regulation was to create transparency, in particular in the interest of consumers, by validating the *réferentiels* and notifying the certification activity. Accordingly, the regulations can be found today in the *Code de la Consommation* under the first title "Consumer Information"[16].

The applicable version of the *Code de la Consommation* can be traced back to a law from 1994[17]. In view of the free movement of goods and the New Approach this regulation simplified the provisions from 1978 and adjusted them to European requirements[18]. Upon the introduction of the CE-marking, the question was raised to what extent the conformity indications on the basis of the *réferentiels* are permissible alongside the CE-marking; as a rule this is only possible, when there is no possibility of confusing the markings, i.e. in particular when the indications display information which goes beyond that of the CE-marking. Accordingly, the validation of the *réferentiels* requires the information on the label to not restrict itself to merely complying with legal provisions, but also to contain further features. For example, this might entail combining the certification with the surveillance of the manufacturing process[19].

B. The use of conformity assessment bodies in the regulatory sphere

In France the approval of conformity assessment bodies for the regulatory sphere is usually described with the terms *agrément*, *reconnaissance*, *désignation* or *habilitation*[20]. As a

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15 *Couret/Igalens/Penan,* Certification, p. 11; *Joerges/Falke/Micklitz/Brüggemeyer,* Sicherheit von Konsumgütern, p. 92 et seq.

16 Code de la Consommation, Partie Législative, Livre Ier, Titre Ier, Chapitre V, Section 4 Certification des services et des produits autres qu' alimentaires (Articles L115-27 à L115-33). As for this aim, there are similarities with the regulations on marks of quality in Austria and Germany, where the transparency of the certification schemes also plays a role for consumers. Unlike the marks of quality, the regulation in the Code de la Consommation seems to be less concerned with the positive marketing effects of such indications.

17 Loi no 94-442 du 3 juin 1994 modifiant le code de la consommation en ce qui concerne la certification des produits industriels et des services et la commercialisation de certains produits, NOR: ECOX9300172L, J.O n° 128 du 4 juin 1994 page 8072.

18 *Couret/ Igalens/Penan,* Certification, p. 11 et seqq., 14 et seqq., 38.

19 DIGITIP/SQUALPI, La Certification des produits industriels et des Services en 7 questions (Fn. 8), p. 2 et. seq.

20 See the description in the preamble of the framework agreement between the state and COFRAC. The framework agreement is available online at URL:

rule, the term *notification* refers to the information of the European Union on the designation of the accreditation body. The approval or designation and notification of conformity assessment bodies generally is incumbent upon the ministries in charge[21]. An accreditation by the national accreditation body COFRAC is not always a legally binding prerequisite for this. In practice, though, this is done very frequently. The criteria to be fulfilled for approval can exceed those examined during an accreditation. COFRAC is responsible for the surveillance of the agencies, as long as this is covered by the assessment programme of accreditation. Otherwise, it is carried out by the responsible ministry.

I. Role of accreditation during the competence evaluation by the state

The accreditation by COFRAC is not always a legally binding prerequisite for approval or designation, but it is frequently used. Whether an accreditation is required, depends on the pertinent law or the responsible ministry. In France the view prevails that its situation corresponds with the legal situation in Europe, to the extent that the directives based on the New Approach have not – yet – defined accreditation as obligatory. Accreditation is regarded by the responsible department of the ministry of economic affairs as the appropriate instrument for the evaluation of the adequacy of a certification body for notification. One would welcome a European regulation, which would require the accreditation as a prerequisite for notification. In practice, the approaches of the different ministries currently vary, sometimes even within the same ministry. This will be demonstrated in the following on the basis of selected examples.

1. The implementation of directives based on the New Approach

When examining selected legal provisions for the implementation of the New Approach, it becomes evident that the accreditation by the national accreditation body COFRAC is used

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http://www.industrie.gouv.fr/portail/pratique/index_normalisation.html (16.2.2006); more on the framework agreement under C.I.2.

[21] The notification is generally carried out by an *arrêté* of the responsible minister; sometimes the ministries also draw up contracts with the notified agencies, though. With regard to transportable pressure equipment, for example, see the Arrêté du 2 décembre 2003 portant habilitation d'organismes pour l'application du décret n° 2001-386 du 3 mai 2001 relatif aux équipements sous pression transportables, NOR INDI0402270A, J.O n° 14 du 17 janvier 2004 page 1310; for example, contracts on notification are concluded within the scope of the construction products directive.

in different ways. The regulations on lifts[22], pressure equipment[23] and medical devices[24] have been singled out:

According to Art. 8 al. 1 of the decree on lifts, the ministers in charge of industry, construction and housing are collectively responsible for the designation of bodies. Art. 8 al. 1 of the decree refers to the criteria in Annex VII of the decree for the designation requirements. This contains minimum criteria which are inspired by those in the EU directive. The decree does not contain regulations on the observance of accreditation. Similar regulations exist for pressure equipment. However, the provisions here include a presumption, stating that the bodies, which are accredited by COFRAC or an equally recognized accreditation body, comply with the relevant requirements[25].

In the area of medical devices, the Agence Française de Sécurité Sanitaire des Produits de Santé (Afssaps) is responsible for the designation[26]. The Afssaps is a state authority which is subordinate to the ministry of health[27]. According to Art. R5211-55 al. 3 of the Code de la Santé Publique, the requirements for conformity assessment bodies are presumed to be fulfilled when harmonized norms are complied with. Afssaps conducts the evaluations of the competence of the conformity assessment bodies in their entirety on its own and does not fall back on an accreditation from COFRAC[28]. However, it should be noted that France

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22 Décret n° 2000-812 du 24 août 2000 relatif à la mise sur le marché des ascenseurs, NOR EQUX0000110D.

23 Décret n° 99-1046 du 13 Décembre 1999 relatif aux équipements sous pression, NOR ECOI9900400D ; Loi du 28 octobre 1943 relative aux appareils à pression de vapeur employés à terre et aux appareils à pression de gaz employés à terre ou à bord des bateaux de navigation maritime, Journal officiel "Lois et Décrets" du 29.10.1943, p. 2791 in the respective relevant version.

24 Code de la Santé Publique, in particular Nouvelle Partie Législative Livre 2 Art. L5211-1 et suivants ; Livre 3 Art. L5311-1 et suivants (AFSSPS), Livre 4 Art. 5461-1 et suivants; Nouvelle Partie Réglementaire Livre 2 2 Art. L5211-1 et suivants ; Livre 3 Art. L5311-1 et suivants (AFSSPS), Livre 4 Art. 5461-1 et suivants.

25 Art. 21 II al. 1 of the decree on pressure equipment (Fn. 23).

26 Art. R5211-54 Code de la Santé Publique.

27 It has the classical functions of a surveillance agency, see Livre 3 Titre 1 Code de la Santé Publique.

28 See the description from G-Med, URL: http://www.gmed.fr (27.4.2005). For comparison: with regard to the Medical Devices Directive, 22 bodies have been designated in Germany, eight in the United Kingdom, two in the Netherlands, two in Sweden, one in Austria, and five in Switzerland, all of them with a different scope; for the directive on active implantable medical devices, there are eight bodies in Germany, two in the United Kingdom, two in the Netherlands, none in Sweden, two in Austria and one in Switzerland. As for the directive on in-vitro diagnostic medical devices there are eight bodies in Germany, three in the United Kingdom, one in the Netherlands, none in Sweden, one in Austria, and none in Switzerland. Source: List of notified bodies designated by the Member States and the EFTA Countries

has only designated one conformity assessment body within the scope of the medical devices directive, the directive on actively implantable devices and the directive on in-vitro diagnostics: G-Med[29].

2. Further areas of application

In other legal areas as well, accreditation is used as a requirement for the approval of conformity assessment bodies. It is often stipulated as compulsory. This holds, for example, for the assessment of the competence of firms conducting measurements on asbestos pollution in compartment air. It is legally compulsory to carry out such measurements[30]. The enterprises who wish to conduct these measurements must apply for state approval (*agrément*)[31]. In order to obtain the approval, they must be accredited by COFRAC or another accreditation body represented in EA[32]. The accreditation is based, firstly, on the norms EN 45001 and 45004, and secondly on the accreditation program No. 144 from COFRAC or an equivalent program[33]. The approval (*agrément)* is issued for a maximum of three years. The bodies are required to take part in intercomparison programmes and to provide the ministry with an annual report on their activities[34].

A similar regulation exists for the authorization of firms for the inspection and approval of measurement repositories, like for example glass bottles for the transport of liquids. In this case, certain inspection activities were transferred to authorized bodies. During the official surveillance of the measurement repositories, the responsible authority can request the

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(Members of the EEA) under the New Approach directives, Official Journal No. C 302 from 12.12.2003 p. 0001 – 0414 (updated December 2003).

29 G-Med (Groupement pour l'évaluation des dispositifs médicaux) is a GIE (groupement d'intérêt économique), which is carried nowadays by LCIE and LNE. The GIE G-Med was founded in 1994; at that time, its partners were not only LCIE and LNE but also the ministry of health and industry.

30 Décret no° 96-97 du 7 février 1997 relatif à la protection de la population contre les risques sanitaires liées à une exposition a l'amiante dans les immeubles bâtis, NOR: TASP9620056D, J.O no° 33 du 8 février 1996 page 2049, Art. 4 , third dash.

31 Décret no° 96-97 du 7 février 1997 relatif à la protection de la population contre les risques sanitaires liées à une exposition a l'amiante dans les immeubles bâtis (Fn. 30), Art. 5 al. 1er.

32 Arrête du 21 décembre 1998 relatif aux conditions d'agrément des organismes habilités à procéder aux mesures de la concentration en poussières d'amiante des immeubles bâtis, NOR MESP9824014A, J.O du 26 décembre 1998 page 19560, Art. 1 al. 1er.

33 Arrête du 21 décembre 1998 relatif aux conditions d'agrément des organismes habilités à procéder aux mesures de la concentration en poussières d'amiante des immeubles bâtis (Fn. 32), Art. 1 al. 2.

34 Arrête du 21 décembre 1998 relatif aux conditions d'agrément des organismes habilités à procéder aux mesures de la concentration en poussières d'amiante des immeubles bâtis, (Fn. 32), Art. 4, 5, 6.

owner of the repository to have it examined by an approved body[35]. The approval of a body for such testing activities requires accreditation by COFRAC, based on the norm EN 45001 and a corresponding accreditation program[36]. Comparable regulations exist for the transport of hazardous substances by rail[37] or the authorization of certain water and sediment analyses[38].

II. Requirements for approval or designation and notification

The requirements for the approval or designation and notification of bodies are regulated by the respective laws. In addition to the criteria examined by an accreditation on the basis of international accreditation standards, there may be further requirements for approval or designation and notification. In France, the view prevails that the bodies are not entitled to approval even when all requirements have been met.

1. Criteria of the accreditation standards and further requirements

In France, too, the question arises to what extent the criteria examined during an accreditation are sufficient to demonstrate the competence and adequacy of a body for carrying out the conformity assessment procedure for the regulatory sphere. In some areas the legal foundations stipulate additional criteria for the approval of bodies. They demand, for example, sufficient experience on behalf of the body with tasks regarding conformity assessment in certain areas, the participation of the body in national and international standardization activities or in the exchange of experiences between the bodies. Furthermore, the bodies may be requested to sustain a certain minimum level of activity within the

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35 Arrêté du 28 septembre 1990 relatif aux récipients-mesures utilisés pour le transport routier ou ferroviaire des produits liquides a la pression atmosphérique, J.O n° 245 du 21 octobre 1990 page 12763, NOR INDD9000680A, Art. 35-1 as amended by the Arrété du 21 juin 1996, NOR INDB9600460A.

36 Arrêté du 28 septembre 1990 relatif aux récipients-mesures utilisés pour le transport routier ou ferroviaire des produits liquides a la pression atmosphérique (Fn. 35), Art. 35-2 para. 1 as amended by the Arrété du 21 juin 1996, NOR INDB9600460A.

37 Regulations on the approval of bodies and accreditation as a prerequisite in Arrêté du 5 juin 2001 relatif au transport des marchandises dangereuses par chemin de fer (dit arrêté « RID »), NOR: EQUT0100810A, J.O n° 159 du 11 juillet 2001 page 11062, Art. 31.

38 Regulations on the approval of agencies and the accreditation by COFRAC or an accreditation body organized in EA in Arrêté du 12 Novembre 1998 portant modalités d'agrément des laboratoires pour certains types d'analyses des eaux ou des sédiments, NOR ATEE9870411A, J.O n° 302 du 30 décembre 1998 page 19985, Art. 2 para.. 1.

ambit of an approval. Such requirements or obligations are partially further specified in the provisions for the implementation of European directives[39] and imposed on the bodies during the designation procedure. The practices of the responsible ministries do not appear to be uniform. For example, a decision by the ministry of economic affairs in favour of designating three conformity assessment bodies for transportable pressure equipment contains a detailed catalogue of obligations[40]. Among other things, the enterprises are obligated to participate in the exchange of experiences in France and at the European level, to take part in the national and European standardization activities, and to report the revocation of certifications to the responsible ministry and other bodies designated within the scope of the concerned directive or to provide the ministry a yearly report on the activities conducted within the framework of the approval[41].

The assessment of the conformity assessment bodies on the basis of such criteria is basically incumbent upon the responsible ministries[42]. However, it could also be transferred to

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39 See, for instance, the regulation on transportable pressure equipment, Décret n°2001-386 du 3 mai 2001 relatif aux équipements sous pression transportables et pris pour l'application du 1° de l'article 2 du décret n° 97-34 du 15 janvier 1997 relatif à la déconcentration des décisions administratives individuelles NOR:ECOX0000186D, J.O du 6 mai 2001 page 7149 in the consolidated version, Art. 14. An overview of the applicable directives based on the New Approach and the corresponding French implementation guidelines can be obtained under the title "Libre circulation des produits - Fiches relatives aux textes communautaires organisant la libre circulation des marchandises en Europe (janvier 2002)" from the French ministry of economic affairs, online at URL: http://www.industrie.gouv.fr/portail/pratique/index_normalisation.html under Nouvelle Approche/Les directives Européennes under the link "Fiches relatives aux textes communautaires" (16.2.2005).

40 Arrêté du 2 décembre 2003 portant habilitation d'organismes pour l'application du décret n° 2001-386 du 3 mai 2001 relatif aux équipements sous pression transportables (Fn. 21).

41 Arrêté du 2 décembre 2003 portant habilitation d'organismes pour l'application du décret n° 2001-386 du 3 mai 2001 relatif aux équipements sous pression transportables (Fn. 21), Art. 2 no. 3, 4, 7, 8 and 14. Sometimes the ministries also draw up contracts with the bodies to be notified, which – among other things – contain obligations for participation in the exchange of experiences or the standardization activities; this takes place, for example, when the bodies are notified under the construction product directive.

42 In the debate on the improvement of the designation and notification procedure, France had advocated a clarification of the criteria, whose assessment was intended to be reserved to the national authorities. A harmonization was only necessary in the former case, in order to harmonize the notification procedure at the European level. Among the areas covered by the accreditation were, for example, the technical qualifications of the body, the organization of the sub-contracting of tasks, or systems of internal quality control. Among the criteria only assessed by the responsible authorities were the assessment of the scope of activity, the references, and the experience of a conformity assessment body, which applies for a certain scope of accreditiation within the scope of a directive. Furthermore, the consideration of the participation of a body in the standardization activities in the concerned area, the willingness of the body to participate in the exchange of experiences at the national and European level, as well as the consideration of the economic situation and the competition in the affected area are incumbent on the authorities. These additional criteria might in part be related to the fact that bodies do not have a right to approval or designation in France and that the responsible authorities want to keep other options open.

COFRAC. Corresponding agreements between the ministries and COFRAC are plausible. The accreditation rules from COFRAC can be expanded with requirements which result from the legal stipulations for a legally compulsory accreditation[43]. As for differences in the competence assessment depending on whether it is conducted for the activities of a body in the regulatory or non-regulatory sphere, it has been pointed out that the precise knowledge of the legal regulation is required in the regulatory sphere. During an accreditation for the regulatory sphere, this is also inspected.

2. No right to approval or designation and notification

From the French standpoint, conformity assessment bodies do not have a right to be approved, designated or notified. France wants to keep open the possibility of restricting the number of approved bodies in a specific area. This is regarded as necessary for the sake of monitoring the bodies effectively and organizing the exchange of experiences. This possibility of limitation is apparently used to different extents in the different sectors. Bodies notified by other countries would not be affected by such a limitation, because they can provide their service across Europe on the basis of the notification.

III. Surveillance of the Notified Bodies

As a rule, COFRAC is responsible for the surveillance of the bodies, as long as this is covered by the assessment programme of accreditation. The surveillance procedure and the time interval between the different surveillance measures are specified by the corresponding accreditation rules[44]. For accredited bodies that certify products and services, the interval between two surveillance audits is a maximum of eighteen months[45].

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43 See the description in COFRAC, Règlement d'accreditation, Document LAB Ref 05 (Révision 01 – Décembre 2003), Section 8.2 first paragraph, online at URL : http://www.cofrac.fr/doc/docs/1_laboratoires/lab%20ref%2005.pdf (16.2.2005).

44 For the certification of products and services, see *COFRAC*, Règlement d'accreditation, Document CPS Ref 05 (Révision 05 – Juillet 2004), Section 10, online at URL: http://www.cofrac.fr/Doc/Docs//Certification%20de%20produits%20industriels%20et%20services/CPS%20%20REF%2005.pdf (16.2.2006); for laboratories COFRAC, Règlement d'accreditation, Document LAB Ref 05 (Fn. 43), Section 9.2.

45 COFRAC, Règlement d'accreditation, Document CPS Ref 05 (Fn. 44), first paragraph; online at URL: http://www.cofrac.fr/fr/documentation/fics.mpi?s1=INDUS&repbase=Certification%20de%20produits%20industriels%20et%20services%5C (24.5.2005).

For the rest, the responsible ministry is in charge of surveillance[46]. In some cases, the pertinent laws allow the responsible surveillance agencies to accompany the bodies while conducting inspections and require them to provide an annual activity report[47]. If the designation requirements are not fulfilled, the designation can be suspended or revoked[48]. From the French standpoint, the surveillance of the bodies must provide a decisive contribution to assuring the quality of the service and the further harmonization of national and European conformity assessment practices[49]. Furthermore, increased cooperation among the authorities in monitoring the bodies is viewed as desirable.

C. Organization and status of the accreditation body

The French accreditation body COFRAC is organized as an association under private law and operates on the basis of a framework agreement with the government. It is active in both the regulatory and non-regulatory sphere and is de facto the only organization of its type. COFRAC currently estimates the proportion of accreditations for the regulatory sphere to be approximately 50 %. The number of accreditations for the regulatory sphere is purportedly increasing, because the ministries are increasingly falling back on the accreditation procedure[50].

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46 In some cases, one can also find regulations which grant the concerned public authority the responsibility for monitoring the bodies which stipulate the observance of surveillance measures during the accreditation; see e.g. the regulation on inspecting measurement repositories in Arrêté du 28 septembre 1990 relatif aux récipients-mesures utilisés pour le transport routier ou ferroviaire des produits liquides à la pression atmosphérique, J.O n° 245 du 21 octobre 1990, NOR INDD9000680A, Art. 35-5 as amended by the Arrêté du 21 juin 1996, NOR INDB9600460A. The scenario is not entirely uniform here either.

47 See e.g. the regulation on transportable pressure equipment, Décret n°2001-386 du 3 mai 2001 (Fn. 21), Art. 23 al. 3; Regulation on pressure equipment, Décret n° 99-1046 du 13 Décembre 1999 (Fn. 23), Art. 22 al. 1.

48 See, e.g. the regulation on transportable pressure equipment, Décret n°2001-386 du 3 mai 2001 (Fn. 21), Art. 24; Regulation on pressure equipment, Décret n° 99-1046 du 13 Décembre 1999 (Fn. 23), Art. 23.

49 In this regard, France had proposed a revision of the Code of Conduct in the year 2000. This was intended to deal, for example, with the maintenance of the required skills, the decisions of the accreditation bodies on remarks, suspensions or the revocation of the accreditation, the proof of the measures actually carried out and the participation in the exchange of experiences as well as the consequences of compliance with notification requirements. For the Code of Conduct, see Code of Conduct for the functioning of the system of notified bodies, Certif 97/1 Rev. 3.

50 For the number of accreditations issued see COFRAC's annual report for 2004, online available at URL: http://www.cofrac.fr/fr/documentation/Rapports/Rapport_2004.pdf (15.3.2004).

I. Status of the accreditation body

1. Foundation and legal form

COFRAC was founded in 1994 and is organized as a registered association (*association déclarée*) on the basis of the law from 1 July, 1901[51]. Its foundation was a result of the revision of the legal framework for certification by the law from 3 June 1994[52]. Previously, accreditation systems already existed in France in certain areas, for example testing laboratories in the Réseau national d'essais – RNE, for calibration laboratories in the Bureau national de métrologie – BNM-FRETAC[53]. The objective for establishing COFRAC was to create an accreditation system that is compatible with European and international demands[54].

2. Framework agreement from December 2003

In December 2003, France concluded a framework agreement with COFRAC for the regulatory sphere[55]. COFRAC's contracting parties are four ministries[56]. The scope of the agreement includes accreditation for the certification of products and services, quality management systems and persons, the certification of environment management systems as well as the areas laboratories and inspection on the basis of the relevant European or international accreditation standards[57].

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51 Loi du 1er juillet 1901 relative au contrat d'association, J.O du 2. Juillet 1901 page 402 ; on the legal form *COFRAC*, Statuts, GEN REF 01 Revision 03 – Juin 2005, Article 1, online at URL: http://www.cofrac.fr (16.2.2006) under Documentation Générale, GEN REF 01.

52 Loi no 94-442 du 3 juin 1994 modifiant le code de la consommation en ce qui concerne la certification des produits industriels et des services et la commercialisation de certains produits, NOR: ECOX9300172L, J.O n° 128 du 4 juin 1994 page 8072, see above A II. (at the end).

53 *Couret/Igalens/Penan*, Certification, p. 19.

54 See the description at COFRAC, URL: http://www.cofrac.fr/fr/cofrac/vocation.htm (16.2.2006), *Couret/Igalens/Penan*, Certification, p. 19.

55 The framework agreement is online at URL: http://www.industrie.gouv.fr/portail/pratique/index_normalisation.html (22.3.2005).

56 Le Ministre de l'Economie, des Finances et de l'Industrie, le Ministre de l'Equipement, des Transports, du Logement, du Tourisme et de la Mer, la Ministre de l'Ecologie et du Développement durable, le Ministre de l'Agriculture, de l'Alimentation, de la Pêche et des Affaires rurales, see the top of the framework agreement (Fn. 88).

57 Art. 1 of the framework agreement (Fn. 88); the accreditation standards are listed respectively; the reference is designed as a dynamic reference, so that COFRAC must gear its activities towards the respec-

The state recognizes COFRAC as a national accreditation body[58]. COFRAC is mandated to promote the French accreditation system and make European and international institutions familiar with it. To do so, COFRAC participates in multilateral agreements within the framework of EA, ILAC, and IAF[59]. Art. 6 of the framework agreement calls on COFRAC to consult of the affected departments of the ministries on the general orientation of its activities. Art. 7 of the framework agreement allows for the possibility of additionally concluding separate contracts with individual ministries. In such contracts, formal procedures for the consideration of the accreditation for approvals and designations in the regulatory sphere can be specified or certain accreditation programs established which the affected ministry deems necessary. According to Art. 3 para. 2 of the framework agreement, the state can monitor compliance with the agreement by means of inspections and audits. Should COFRAC infringe upon the framework agreement, the state may terminate it, Art. 9 para. 2.

3. COFRAC's de facto monopoly

There is no legal provision, which would formally grant COFRAC a monopoly for accreditation. However, COFRAC has an exclusive status both in the regulatory as well as the non-regulatory sphere.

a) Reasons for the unique status of COFRAC

In France, the view prevails that there should only be one accreditation body. The notion of competition between accreditation bodies is decidedly rejected.The accreditation body is at the top of the conformity assessment system, ensuring the quality of the conformity assessment service: if competition was the rule, another body would be necessary as an upper control level. It is noted that competition would also not be wise for economic reasons, regarding the small size of the the market. The main arguments for establishing a uniform accreditation body active in both the regulatory and non-regulatory sphere are the advantages it would offer in terms of competence and effectiveness. Furthermore, multiple ac-

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tively applicable standards, see also the clarification in the second paragraph of Art. 1 of the framework agreement.

58 Art. 3 para. 1 of the framework agreement (Fn. 88) "instance nationale d'accréditation".

59 Art. 4 of the framework agreement (Fn. 88).

creditations could be avoided. Another argument for a non-profit single accreditation body associated with the state to a certain degree is that if the state relies on accreditation, it must be assured that accreditation is offered in all relevant areas. It is not possible to leave this up to the market, because from an economic standpoint accreditation should not be profitable in many areas.

At the European level as well, there is not supposed to be any competition between the accreditation bodies. In France, a straightforward clarification that accreditation is a service of general economic interest is advocated. France supports strengthening the link between EA and the EU, which already exists in the Advisory Board (EAAB). However, EA is not supposed to be at the head of the European accreditation bodies, but rather organizes its activities in a network-like framework.

b) Wording of the legal regulations

The framework agreement thus grants COFRAC a unique status, as COFRAC is recognized as a "national accreditation body"[60]. However, it is not stipulated that it must act as the sole accreditation body.

It cannot be inferred from the laws relevant to the implementation of the directives based on the New Approach that COFRAC enjoys a legally guaranteed unique status. The provisions in part explicitly refer to an accreditation by COFRAC or "accreditation bodies recognized as equivalent" and contain a presumption of conformity with the requirements to Notified Bodies upon presentation of such an accreditation[61]. However, only the national accreditation bodies of other states organized in EA are "recognized as equivalent"; no other accreditation body exists in France.

For the scope of the *Code de la Consommation*, the Decree No. 95-354 from 30 March 1995 on the certification of industrial products and services envisages the approval of an

60 Art. 3 para. 1 of the framework agreement (Fn. 88) "instance nationale d'accréditation".

61 See e.g. the regulation on transportable pressure equipment, Décret n°2001-386 du 3 mai 2001 (Fn. 21), Art. 15 al. 2 ; Art. 21 II al. 1 of the decree on pressure equipment, Décret n° 99-1046 du 13 Décembre 1999 relatif aux équipements sous pression, NOR ECOI9900400D.

accreditation body by the ministers responsible for consumer protection and industry[62]. Only COFRAC has been approved as such[63]. Upon the introduction of the regulation, the approval of only one accreditation body was not legally stipulated. The wording of the *Code de la Consommation* would also permit the establishment of multiple accreditation bodies[64].

Up to now, it appears that no private enterprises have expressed the wish to become active in the accreditation sector. As for the approval of an accreditation body for matters concerning the *Code de la Consommation*, Art. 7 of the decree No. 95-354[65] is likely to pose a significant obstacle. The provision stipulates as a prerequisite for approval not only sufficient technical and financial resources, but also the well-balanced composition of the accreditation body, which ensures the representation of all interested groups. In its preamble, the framework agreement from December 2003 focuses on the representation of the concerned groups in similar fashion. Public authorities, professionals, laboratories, accredited bodies and consumer protection organizations are mentioned among others. At the moment, only COFRAC is in a position to ensure this in practice by means of its organizational structure[66].

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62 Art. 6, 7 Décret no 95-354 du 30 mars 1995 relatif à la certification des produits industriels et des services ; NOR: ECOC9500026D ; J.O n° 81 du 5 avril 1995 page 5437.

63 Arrêté du 30 mars 1995 portant reconnaissance du Comité français d'accréditation en tant qu'instance d'accréditation des organismes certificateurs de produits industriels et de services, NOR: ECOC9500027A, J.O n° 81 du 5 avril 1995 page 5439.

64 Art. R115-6 al. 1 Code de la Consommation: “une instance d’accreditation, reconnue, par arrêté…”; see also Art. 7 Décret no 95-354 du 30 mars 1995 relatif à la certification des produits industriels et des services ; NOR: ECOC9500026D ; J.O n° 81 du 5 avril 1995 page 5437; the provision provides the approval requirements for an accreditation body.

65 Décret no 95-354 du 30 mars 1995 relatif à la certification des produits industriels et des services ; NOR: ECOC9500026D ; J.O n° 81 du 5 avril 1995 page 5437.

66 For more on the participation of the interested groups, see below D.II. See the corresponding requirement of the standard ISO/IEC 17011, 4.3.2.

II. Organization of the accreditation body

1. Institutions

COFRAC consists of a *Structure Permanente*, which is responsible for carrying out the accreditation. It is headed by a general director[67]. On the basis of Art. 13 (1) of the *Statuts*, COFRAC may employ delegated public officials[68] to a limited extent in certain positions, e.g. as a general director. COFRAC also holds general assembly meetings and has an Internal Auditing Commission, and Board of Directors (Conseil d'Administration)[69]. The Conseil d'Administration does not participate directly in the accreditations, but does appoint, for example, the (non-executive) president of COFRAC and the presidents and members of the sectoral committees, who are responsible for overviewing the framework of the accreditation process (documents to be used, tariffs etc.) and for appeals against COFRAC decisions[70]. Only a reimbursement of expenses is generally paid for the latter mentioned activities, not remuneration[71].

2. Membership structure

The membership structure of COFRAC is intended to ensure the participation of the groups interested in conformity assessment[72]. The members of COFRAC are divided into active and associated members[73]. The active members belong to different Councils; Council A includes accredited bodies or their associations, while Council B comprises enterprises that make use of the services of the accredited bodies. Council C consists of consumer organizations, etc. and Council D includes representatives of the state[74]. The

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67 *COFRAC*, Organigramme, online at URL: http://www.cofrac.fr/fr/cofrac/organigramme/default2.htm (22.3.2005).

68 The correct designation is: "*des fonctionnaires en position de détachement*".

69 See *COFRAC*, Statuts (Fn. 51), Art. 7,8,9.

70 See *COFRAC*, Statuts (Fn. 51), Art. 9,1.

71 *COFRAC*, Règlement Intérieur REF 02 (Révision 01 – juin 2005), Art. 9, online at URL: http://www.cofrac.fr/Doc/Docs/0%5Fdocuments%20g%E9n%E9raux/GEN%20REF%2002.pdf (16.2.2006).

72 See the corresponding requirement in ISO/IEC 17011, section 4.3.2.

73 *COFRAC*, Statuts (Fn. 51), Art. 5.

74 COFRAC, Statuts (Fn. 51), Art. 6. The members are listed in the annual report. For 2003 COFRAC, Rapport d'activité 2003, p. 26 et seq.; online at URL: http://www.cofrac.fr/fr/documentation/RAPPORTS.HTM (16.2.2006).

Conseil d'Administration is made up of seven representatives of Council A, six representatives of Council B and four representatives of Councils C and D each plus one competent person[75].

3. Sections and assessors

COFRAC operates with four different sections, which are each headed by a section committee (*Comité de Section*): *Laboratoires, Certification d'Entreprises, de Personnel et Environnement, Certification de produits et services* and *Inspection*[76]. Regulations on the composition and tasks of the committees are contained in Art. 10, Sections 10.1 and 10.2. of the *Statuts*; supplemental regulations can be found in Art. 7 of the *Règlement Intérieur*. The members of the section committee are listed in the annual report[77]. Regulations on the qualification and selection of the assessors are compiled in a corresponding document entitled "Qualification et Suivi des Experts/Auditeurs techniques"[78].

4. Financing

COFRAC is basically financed by accreditations fees and by members' contributions. Art. 5 of the agreement stipulates that the state can finance certain activities of COFRAC in which it has a particular interest. COFRAC currently estimates the proportion of state resources in the financing at approximately 6%. To that effect, COFRAC is subject to the economic and financial oversight of the state[79].

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75 COFRAC, Statuts (Fn. 51), Art. 8.

76 See the description of *COFRAC*, Le Cofrac – LES SECTIONS, online at URL: http://www.cofrac.fr/fr/sections/default.htm (16.2.2006).

77 For 2003 see *COFRAC*, Rapport d'activité 2003 (Fn. 74), p. 28 et seqq.

78 COFRAC, Qualification et Suivi des Experts/Auditeurs techniques, Document n° GEN CGQA REF 03, Revision 1 – May 2004, online at URL: http://www.cofrac.fr/Doc/Docs/0%5Fdocuments%20g%E9n%E9raux/GEN%20CGQA%20REF%2003.pdf (16.2.2006).

79 Art. 4 Para. 3 of the framework agreement (Fn. 88); the legal basis for surveillance is the Décret n° 55-733 from 25 May 1955 in the version applicable at that time, see also Art. 14.2 of the *Statuts* from COFRAC (Fn. 51).

III. Legal relationship between COFRAC and conformity assessment bodies

1. Private law contract

The relationships between COFRAC and the accredited bodies are governed by a contract based on private law. This holds regardless of whether the accreditation is conducted for the regulatory and non-regulatory sphere[80]. The contract divides the accreditation relationship into a Phase 1, which concerns the rights and obligations of the participants in order to obtain accreditation, and Phase 2, in which the rights and obligations for the duration of the accreditation are stipulated[81]. In the second phase, COFRAC is obligated, among other things, to keep the accreditation system in compliance with the applicable international standards, in order to facilitate the international recognition of the issued certificates. The accredited body is obligated, among other things, to allow for and support the surveillance by COFRAC; this also entails allowing for *witness audit*s. Inspection laboratories also pledge to participate in inter-laboratory tests at the national and international level to a certain extent[82].

2. Requirements for accreditation and monitoring

The requirements and procedures of the accreditation are further specified in special accreditation rules. They provide references to the pertinent international accreditation standards and the interpretation documents used[83]. The period of validity of an accreditation amounts to a maximum of 60 months, except for the initial period of validity, which is 48 months[84]. Monitoring audits are carried out in intervals of a maximum of 18 months[85]. If the requirements of the accreditation are not complied with, the contract allows for the

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80 See COFRAC, Règlement d'accreditation, Document LAB Ref 05 (Fn. 43), Section 9.1.2 first paragraph, Section 3.

81 Further details on the sequence of the accreditation procedure are included in the respective Règlements d'accreditation of the COFRAC, see e.g. for the certification of products and services COFRAC, Règlement d'accreditation, Document CPS Ref 05 (Fn. 44); for laboratories COFRAC, Règlement d'accreditation, Document LAB Ref 05 (Fn. 43).

82 See COFRAC, Règlement d'accreditation, Document LAB Ref 05 (Fn. 43), Section 11.2 first paragraph.

83 *COFRAC*, Règlement d'accreditation, Document CPS Ref 05 (Fn. 44), Section 2.1.

84 *COFRAC*, Règlement d'accreditation, Document CPS Ref 05 (Fn. 44), Section 9.

85 *COFRAC*, Règlement d'accreditation, Document CPS Ref 05 (Fn. 44) Section 10. As regards an extended accreditation, the interval can amount to up to 18 months, see Section 10 para. 2.

suspension or revocation of the accreditation[86]. If the accreditation takes place in the regulatory sphere, the responsible agencies are informed upon request[87].

3. Defence and recovery options of the accredited bodies

COFRAC has a structured procedure for dealing with complaints and appeals from its clients[88]. If no amicable solution can be reached, the *Comité de Section* handles the appeal in a first step. If the accreditation body is not satisfied with its decision, it can turn to the *Conseil d'administration* in a second step. The body filing the appeal is then heard by the Comité or Conseil[89]. If this does not settle the dispute, the complaining body can go to the courts to challenge the decision. The civil court is generally responsible here, in particular cases the administrative court as well[90].

D. The activities of the conformity assessment bodies

From the standpoint of German administrative law, consulting private bodies for state authorization or surveillance activities raises questions about their legal standing, on the one hand regarding the state authorities and on the other hand in relation to their clients. In France, this question is not debated to the same extent. As a result, only the following observations apply.

I. Legal relationship between the conformity assessment bodies and their clients

The conformity assessment bodies conclude a contract on the conformity assessment based on private law with their clients. The possibility of limiting or revoking certificates, etc.

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86 Regulations on the suspension and revocation of the accreditation in *COFRAC*, Suspensions, Résiliations et Retraits, Document n° GEN Proc 03 – Révision 00 – Decembre 2003, online at URL: http://www.cofrac.fr/Doc/Docs/0%5Fdocuments%20g%E9n%E9raux/GEN%20PROC%2003.pdf (16.2.2006).

87 *COFRAC*, Suspensions, Résiliations et Retraits (Fn. 86), Section 7.4 para. 2.

88 Traitement & gestion des Appels, Document n° GEN PROC 04, Révision 01, online at URL: http://www.cofrac.fr/Doc/Docs/0%5Fdocuments%20g%E9n%E9raux/GEN%20PROC%2004.pdf. (16.2.2006).

89 See *COFRAC*, Traitement & Gestion des Appels (Fn. 88), Section 6.3, 6.4, 6.5.

90 See the choice of forum agreement in *COFRAC*, Traitement & Gestion des Appels (Fn. 88), Section 6.6.

only arises from this contract. The same holds for the rights to information and access during surveillance. The mentioned authorities are not regulated by law.

II. Cooperation between the conformity assessment bodies at national and international level

The participation in national or international meetings in which experiences are exchanged can be made a prerequisite for the approval or designation and notification[91]. The authorities have a right to participate in the national groups set up for the exchange of experiences. According to the experiences of the conformity assessment bodies, the scope and effectiveness of the exchange of experiences differ significantly.

E. The role of market surveillance in relation to conformity assessment

The function of market surveillance in relation to conformity assessment was also a topic of the discussions in France. Market surveillance cannot be dealt with comprehensively in this report. However, the impressions gathered on this shall be briefly presented here.

I. Organization of market surveillance

In France, the responsibility for market surveillance for various product areas is incumbent on the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes* (DGCCRF), which is in charge of monitoring the quality of services and products as well as consumer protection and assuring fair competition[92]. For the scope of the *Code de la Consommation* Art. L 215-1 specifies who is responsible for monitoring the provisions of the *Code de la Consommation* on the conformity and security of products and services. In no. 1 it mentions the inspectors of the DGCCRF, the inspectors of the customs authorities and the taxation authorities. Numbers 2 through 9 of Art. L 215-1 of the *Code de la Consommation* designate other authorities, who are granted monitoring authority in

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91 See above. B.II.1.

92 For more on the DGCCRF see URL: http://www.finances.gouv.fr/DGCCRF/01_presentation/missions.htm?ru=01 (16.2.2006).

their specific area of responsibility. The Articles L 215-3 through L 215-8 include competences for determining and identifying infringements as well as urgent measures. Market surveillance is financed by taxes. Financial difficulties due to the abolition of fees for product authorizations and the like are not provided for. This might be ascribed to the fact that before the restructuring of the product safety law by introducing the directives based on the New Approach the main focus of the supervision of product safety law was placed on repressive post-market control[93], which is why the authorities still have sufficient personnel and financial resources.

II. Division of tasks, authority, and responsibilities between conformity assessment and market surveillance

One question was concerned with the extent to which the outsourcing of inspection activities by the authorities to private conformity assessment bodies leads to the previously responsible authorities not having the required personnel, skills and qualification as well as the necessary inspection facilities and results in complications for market surveillance by the authorities. In France this is not viewed as being particularly problematic. In many areas it is not profitable for the state to maintain its own laboratories. As a rule, private enterprises can more easily keep pace with technical developments. It is imperative to be on the market in order to acquire expertise. Against this background, the subcontracting of inspection activities to private enterprises is viewed as a viable option. The Laboratoire National de Métrologie et d'Essais (LNE) sees itself in a special role, in that it can provide the government with quick and independent inspection results even in urgent cases. In less urgent cases, market surveillance authorities can issue an invitation to tender on the inspection activities. Furthermore, the market surveillance authorities have the possibility of requesting information on certified products from the Notified Bodies[94].

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93 A more detailed analysis in *Joerges/Falke/Micklitz/Brüggemeyer*, Sicherheit von Konsumgütern, p. 77 et seqq.

94 Sometimes the certified agencies are required to cooperate with the authorities and pass on information upon request during the notification procedure, see e.g. Arrêté du 2 décembre 2003 portant habilitation d'organismes pour l'application du décret n° 2001-386 du 3 mai 2001 relatif aux équipements sous pression transportables (Fn. 21), Art. 2 no. 9, 10.

With regard to the market surveillance agencies, the sensitization of the inspectors is decisive from the French perspective, so that they can detect security-related factors. This is essentially guaranteed by the high degree of specialization of the market surveillance agencies, the more so because in most areas new products are not put on the market too frequently so that the inspectors could not keep pace with developments. As regards pressure equipment, for example, a central commission with representatives of the state, the manufacturers, the designated bodies, the users and experts has been established at the ministry responsible for industry[95]. This also contributes to the exchange of information.

95 Art. 27 of the Decree on Pressure Equipment, Décret n° 99-1046 du 13 Décembre 1999 relatif aux équipements sous pression, NOR ECOI9900400D.

Second Section: Conformity Assessment in the Netherlands

In the Netherlands, conformity assessement is used in various areas especially in the regulatored sphere. First, the basic options for the use of conformity assessment will be presented. Particular attention will be given to the role of accreditation in the procedure of approval and surveillance of the conformity assessment bodies by state authorities as well as the legal classification of the activities of the conformity assessment bodies. Then. the organization and status of the accreditation body, the RvA, will be described, followed by a brief outlook on market surveillance in relation to conformity assessment.

A. Overview of the use of conformity assessment

In the Netherlands conformity assessment procedures are used in numerous areas, both in the regulatory and non-regulatory sphere. Already at the beginning of the 1990s, there were considerations on the chances and risks of using conformity assessment as a regulatory instrument.

I. Areas of use of conformity assessment

A study by the University of Tilburg mandated by the Ministry of Economic Affairs revealed that at the time of analysis there were eighty different regulations in the regulatory sphere alone, which drew on the instrument of conformity assessment in different ways[1]. Besides the provisions for implementing the European directives based on the New Approach, there are also several regulations in the regulatory, non-harmonized sphere, for example with regard to work health and safety, the environment and health care[2]. The possible applications of conformity assessment vary considerably, though. There are provisions which make the certification by an independent third-party body compulsory, e.g. to

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1 *Eijlander/Evers/van Gestel*, De inkadering van certificatie en accreditatie in beleid en wetgeving – Een onderzoek in opdracht van het Ministerie van Economische Zaken, Universiteit te Tilburg – Centrum voor Wetgevingsvraagstukken, 2003, p. 10; the study is available from the Ministry of Economic Affairs of the Netherlands at URL: http://www.minez.nl, see: home.EZ.nl/Kamerbrieven/kamerbrieven 2003/Oktober (20.5.2005).

2 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 10; for more on the regulations stipulated there, see p. 88 et seqq.

demonstrate the qualification of firms specializing in asbestos removal or crane operators[3]. There are also provisions which envisage certification as a potential means to demonstrate compliance with legal requirements; examples from construction law can be cited here[4]. These can be distinguished from forms of certification which do not serve to demonstrate compliance with legally binding provisions, but which are instead used by enterprises on a volutary basis. However, legal consequences can be attached to the participation in such programs by means of state oversight or surveillance activities. The environmental certification in accordance with ISO 14000 or EMAS has been noted as an example of this[5].

There are numerous areas of application for certification in the non-regulatory sphere as well. For example, the certification with regard to health at the workplace according to the standard OHSAS or VCA is of increasing importance[6]. Numerous non-obligatory certification schemes also exist with regard to the certification of foods – e.g. according to HACCP or for organically grown products - or with regard to sustainable forestry.

II. Conformity assessment as a regulatory instrument

1. Thoughts on the use of conformity assessment

In the Netherlands conformity assessment procedures have been used since the late 1970s. Conformity assessment in conjunction with the free movement of goods is regarded as an important factor in economic growth. Promoting the certification infrastructure thus is in the interest of the state. This holds, in particular, with respect to the regulatory sphere, in

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3 For the certification of firms specializing in asbestos removal, see the report created by the B&A Groep (J. van Erp, S. Verberk) "Discussienotitie Handhaving & Certificering", p. 44 et seqq., published by the Ministerie van Justitie, Expertisecentrum Rechtshandhaving, Den Haag 2003; the document is available online at URL: http://www.justitie.nl/themas/rechtshandhaving/publicaties/Discussienotitie_Handhaving_en_Certificering.asp (21.7.2005). Regulations of the qualification of crane operators can be found in the work health and safety law, more under B I 3a. See also *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 25.

4 More on the recognized quality declarations in Dutch construction law in *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 26; see *Evers*, Blind vertrouwen?, p. 133 et seqq.

5 *Eijlander/Evers/van Gestel*, De inkadering van certificatie, p. 26.

6 The certification in accordance with the VCA (Veiligheids Checklist Aannemers) is a certification system used in the area of work health and safety. It was originally introduced by the Dutch chemical industry. It is primarily based on an evaluation of the management system, which aims for safe working conditions for the firm as a whole as well as a personnel certification which focuses on the individual safety-related capacities of the individual employees. More information on the VCA from the Stichting SSVV at URL: http://www.ssvv.nl/intro/default.htm (25.7.2005).

which the use of conformity assessment relieves the state from such tasks. Another cited advantage is that the instrument of conformity assessment can draw on the existing expertise of the market participants, which leads to better results. At the same time, firms are relieved from administrative obligations. In this respect, conformity assessment systems in the non-regulatory sphere can also be of significance for the state when conformity assessment promotes indirect goals which are in the interest of the state, e.g. with regard to the environment or health protection[7].

Since the beginning of the 1990s, the Dutch government has increasingly dealt with various aspects of standardization and conformity assessment[8]. An interministerial commission for standardization and certification has already existed within the Ministry of Economic Affairs since 1992 (*Interdepartementale Commissie voor Normalisatie en Certificate – ICN).* The commission's task is to advise the affected ministries on matters concerning standardization, certification and accreditation and to coordinate strategies in this policy area among the various ministries, in particular with regard to the relationship to legislation on the one hand and standardization, certification and accreditation on the other hand[9].

Firstly, the motive for these considerations was the use of conformity assessment at the European level by the directives based on the New Approach. Secondly, conformity assessment was regarded as a potential regulatory instrument during the deregulation debate. Within the framework of the large-scale initiative "Marktwerking, deregulering en wetgevingskwaliteit – MDW", the government appointed various working groups, among others a working group for standardization and certification. One objective of the investigation was to determine the extent to which standardization and certification can be used as an alternative to legislation (*wetgeving*). In 1996 the MDW Report "Normalisatie en Certificatie" was presented which provided a categorization of conformity assessment

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7 See *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 57.

8 As far as can be seen, the first recapitualtory document in this context is a report from the Ministry of Economic Affairs from 1995 entitled "Normen, certificaten en open grenzen" (NCOG-Nota). The report was continued with the additional report "Internationaal is de norm" (IN-Nota); this report is available online at URL: http://192.87.114.76/nl/act/specials/kenb/internationaal.pdf (22.7.2005).

9 *Ministerie van Economische Zaken*, Jaarverslag 2001 en 2002 van de Interdepartementale Commissie voor Normalisatie en Certificatie, Juni 2003, Inleiding, p. 4; see also the overview by the Dutch government at URL: http://almanak.overheid.nl/WPSServlet?action=document&id=12885 (21.5.2005).

regulations and dealt with the advantages and disadvantages of their use in the regulated sphere[10].

The study by the University of Tilburg drew on the MDW Report and systematized the existing conformity assessment regulations in the Netherlands. An essential result of the study was the perception that the practices of the various ministries in using conformity assessment regulations do indeed vary considerably[11]. This was demonstrated, on the one hand, by the structure of the legal regulations, which – as indicated above – differed substantially with regard to the meaning of the certification. Furthermore there were differences concerning the use of accreditation to assess the competence and independence of the bodies as well as in fulfilling oversight functions by the ministries. The study identified 15 different ways of applying conformity assessment and developed on this basis several options for the use of the certification[12].

2. Legal framework of the conformity assessment system

The government readdressed the results of the study in a Cabinet's position from November 2003[13] and drew up guidelines for dealing with conformity assessment in the future. A clear division of the responsibilities between the ministries, the accreditation body and conformity assessment bodies is intended to lead to more consistency during conformity assessment. Accordingly, the Cabinet's position describes three basic options for the use of conformity assessment[14]. These are supposed to provide a basic orientational structure for future regulations. By these means, a harmonization of the diverse options is to be achieved in the medium-term. A systematic revision of the existing regulations is not envisaged; instead the regulations are to be adjusted step by during regular revisions.

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10 The report was published as a part of the program "Marktwerking, Deregulering en Wetgevingskwaliteit" by the first *Kok* government, see Kamerstukken Tweede Kamer, vergaderjahr 1995-1996, 24 036, No. 15; it is available online at URL http://192.87.114.76/nl/act/specials/kenb/mdw.pdf (21.5.2005).

11 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 19 et seq., 59 et seqq., in particular 63 et seqq.

12 More on the options in *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 49 et seqq.

13 The cabinet's position from 14 November 2003 is printed in: Kamerstukken Tweede Kamer, vergaderjahr 2003/2004, 29 304, No. 1.

14 Cabinet's position 2003 (Fn. 6), p. 12, 19 et seqq.

B. The use of conformity assessment in the regulatory sphere

The different practices of the ministries when using conformity assessment and accreditation are to be harmonized on the basis of three basic options, which are specified in more detail in the Cabinet's position. The incorporation of accreditation into the decision on the approval and designation of the body as well as the surveillance over it play a particularly important role. A horizontal legal regulation on conformity assessment and accreditation is currently not planned. As a result, the provisions on the use of the conformity assessment bodies can still be found in the respective area-specific laws.

I. The structure of the conformity assessment regulations on the basis of the cabinet's position of November 2003

The Cabinet's position describes three basic options for the use of conformity assessment: the *zelfreguleringsvariant*, the *toezichtsondersteuningsvariant* and the *toelatingsvariant* [15].

1. Zelfreguleringsvariant (self-regulation option)

The self-regulation option comprises forms of conformity assessment which do not originate in the regulatory sphere and primarily pursue private objectives[16]. Conformity assessment does not serve to demonstrate compliance with legally binding requirements and does not entail legal consequences. The participation in such certification programs is voluntary. However, such programs may indirectly serve purposes which are of public interest, such

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15 Cabinet's position 2003 (Fn. 6), p. 12, 19 et seqq. The cabinet's position uses the concept of certification as an overall concept to describe different forms of conformity assessment. Certification is defined as the totality of activities on the basis of which an independent, competent and trustworthy body determines and indicates in writing that they have substantiated confidence that a certain object (a product, process, or system or the competence of an individual) fulfils certain requirements. Certification in this context comprises activities such as (type) tests, probes, tests, chemical analyses, inspections, calibrations and systems for testing the competence of individuals, Cabinet's position 2003 (Fn. 6), p. 25, 5. The options are based upon the four options proposed in the study by the University of Tilburg and combine the following proposed options *erkenningsvariante* and *toezichtsvariante* under the designation *toelatingsvariant* (authorization option); see *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 49 et seqq.; Cabinet's position 2003 (Fn. 6), p. 12.

16 The *zelfreguleringsvariant* corresponds with the *marktordeningsvariant* of the study by the University of Tilburg, *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 56 et seqq.

as safety and health protection[17]. Thus, enhancements to the certification infrastructure are considered in this framework, in particular to increase transparency in the service sector and hence increase the contribution of the certification regulation to the realization of public objectives. This option is to be used when the state opts to rely on the self-regulatory forces of the market or promotes deregulatory measures[18]. The certification schemes for organically grown products are an example of this[19].

2. Toezichtsondersteuningsvariant (option to support surveillance measures)

According to this option, the participation in the certification program is also voluntary. The certificate functions as an indicator hihglighting the efforts that a firm has made to comply with legal guidelines, for example. During authorizations, oversight or surveillance measures, the state can revert to the certificate[20]. The certification in accordance with ISO 14001 or EMAS for the environment are cited as examples of this option[21]. For example, the law on environmental protection stipulates that the existence of an environmental report can be taken into consideration when issuing the required authorizations. In this case, the authorization can be restricted to the specification of goals and objectives; the means for reaching the goals, e.g. production capacities, certain production processes, etc. can be freely selected by the firm[22]. One of the mentioned reasons for using this option is that the

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17 These certification regulations should be distinguished from those that do not directly serve the public interest, such as a majority of the certifications in accordance with ISO 9000; Cabinet's position 2003 (Fn. 6), p. 20.

18 Cabinet's position 2003 (Fn. 6), p. 12, 20.

19 For example, the certification of organically grown products by Skal. More on this in *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 56 et seqq. Skal certifies agricultural products on the basis of different certification schemes; e.g. the EC-organic farming directive (Council Regulation EEC No. 2092/91 of the Council of 24 June 1991 on the organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs), additionally on the basis of a certification scheme for organically grown products regulated by Dutch law and a certification scheme from the voluntary sector, see Skal under http://www.skal.nl/ (24.7.2005) under "Accreditation". Whether the cabinet intends for state support of certification schemes to go so far as to create a legal framework for voluntary schemes, remains unanswered. A difference to the *Toezichtsvariant* also exists in the legally stipulated certification schemes, though, because according to the *Zelfreguleringsvariant* the transparency created by the certification primarily serves the consumer and the state does not attach any legal consequences to the existence of the certificate.

20 Cabinet's position 2003 (Fn. 6), p. 20.

21 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 91.

22 For the legal foundations, see Art. 8.12 para. 4 in conjunction with Art 12.4 para. 5, 12.5 Wet milieubeheer - Wet van 13 juni 1979, houdende regelen met betrekking tot een aantal algemene onderwerpen op het gebied van de milieuhygiëne; the law is available online at URL: www.wetten.overheid.nl. More on this procedure of so-called "Vergunning op hoofdzaak" at URL: http://www.iso14000.nl/wetten.html (24.7.2005).

certification regulation contributes to the awareness market participants with respect to the demands posed to their product and to allow for more effective state oversight[23].

This option does not call for an approval or designation of the conformity assessment bodies by state agencies. The index effect is only supposed to apply to the certificate if it was issued by a body which in turn has been accredited by the RvA[24].

3. Toelatingsvariant (authorization option)

The authorization option comprises regulations, in which the certification is designated to demonstrate compliance with legally stipulated requirements[25]. The certificate can be a compulsory prerequisite for starting a certain activity or substantiate a presumption for the fulfilment of legal requirements. The Cabinent's position distinguishes between two sub-options, the *onvoorwaardelike* (approximately "unconditional") and the *voorwaardelijke* (approximately "conditional") authorization option[26].

a) Onvoorwaardelike toelatingsvariant

This option is frequently used when the certificate is supposed to attest for the qualification of an individual. The proof of qualification for crane operators based on work safety law can be cited as an example of this. The *Arbeidsomstandighedenbesluit* stipulates that cranes at construction sites may only be operated by persons who possess a certificate, attesting their qualification[27]. The requirements for issuing the certificate are stipulated in the *Arbeidsomstandighedenregeling*, which refers to the applied certification schemes[28].

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23 Cabinet's position 2003 (Fn. 6), p. 20.

24 Cabinet's position 2003 (Fn. 6), p. 20.

25 Cabinet's position 2003 (Fn. 6), p. 12, 21.

26 The options differ as to the point of reference of potential surveillance measures; more on this below. The options *onvoorwaardelike* and *voorwaardelijke toelatingsvariant* were described in the study by the University of Tilburg as *Erkenningsvariant* and *Toelatingsvariant*, *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 50 et seq., 52 et seq.; Cabinet's position 2003 (Fn. 6), p. 20.

27 Department 5 § 2 Art. 7.32 para. 1a of the *Arbeidsomstandighedenbesluit* - Besluit van 15 januari 1997, houdende regels in het belang van de veiligheid, de gezondheid en het welzijn in verband met de arbeid (Arbeidsomstandighedenbesluit); the resolution is available online at URL: http://wetten.overheid.nl (25.7.2005).

28 Paragraaf 7.3 Art. 7.7 para. 2 *Arbeidsomstandighedenregeling* - Regeling houdende bepalingen ter uitvoering van bij en krachtens de Arbeidsomstandighedenwet en enige andere wetten gestelde regels; the regulation is available online at URL: http://wetten.overheid.nl (25.7.2005).

According to the "unconditional option", state bodies conduct surveillance to examine only whether the individual has the required certificate[29]. The attributes or skills which are considered to be demonstrated by the certificate are no longer verified[30].

b) Voorwaardelijke toelatingsvariant

According to this option, the certificate provides a (refutable) presumption that the legal requirements have been fulfilled. The oversight/surveillance *(nalevingstoezicht*) can also be aimed at determining whether the requirements examined during certification have actually been fulfilled. This option is used, in particular, during the implementation of the directives based on the New Approach in product safety law. An example of this is the implementation of the pressure equipment directive into Dutch law: Art. 7 of the *Warenwet*[31] arranges for the prohibition of the trade and use of certain technical products if the testing procedures stipulated by regulations are not complied with. This authorization was used in Art. 4 of the *Warenwetbesluit drukapparatuur*[32], which subjects the trade and use of certain pressure equipment to conditions for authorization. Art. 10 of the *Warenwetbesluit drukapparatuur* contains a conjecture that pressure equipment which complies with harmonized standards fulfils the Essential Requirements of the pressure equipment directive. According to Art. 11 paragraphs 1 and 2 of the *Warenwetbesluit drukapparatuur* the manufacturer must subject the products to a conformity assessment[33]. The surveillance of the products is regulated in Art. 27 et seqq. of the *Warenwet*. Art. 27 para. 1 of the *Warenwet* states that the persons responsible for oversight can inspect the products again. If the result of the inspection is negative, they can file an objection resulting in the loss of validity of the mark of inspection or conformity validation issued for the product. Subsequently,

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29 According to § 2 Art. 7.32 para. 2 of the Arbeidsomstandighedenbesluit, the crane operator is obliged to carry the certificate with him.

30 Similar to the motor vehicle driving licence, it is thus only examined whether the person possesses a valid proof of qualification, not whether he or she in fact (still) has the certified qualifications.

31 Wet van 28 december 1935, houdende voorschriften betreffende de hoedanigheid en aanduiding van waren; the law is available online at URL: http://wetten.overheid.nl (25.7.2005).

32 Besluit van 5 juli 1999 tot vaststelling van een algemene maatregel van bestuur ter uitvoering van de Wet op de gevaarlijke werktuigen, de Brandweerwet 1985, de Mijnwet 1903, de Mijnwet continentaal plat, de Wet milieubeheer en de Stoomwet met betrekking tot drukapparatuur (Besluit drukapparatuur), the resolution (besluit) is available online at URL: http://wetten.overheid.nl (25.7.2005).

33 The applied procedure is based on the assignment of products to the risk categories and appendix 3 of the pressure equipment directive which follows up on this, Art. 11 para. 2 *Warenwetbesluit drukapparatuur*. The designation of the conformity assessment bodies which in part become active here is regulated in Art. 7a of the *Warenwet.*

the presumptive effect of Art. 10 of the *Warenwetbesluit drukapparatuur* no longer applies.

According to both sub-options, the certification by a third party can be stipulated as compulsory, but can also be non-obligatory. The Cabinet's position considers certificates stipulated as compulsory as regulations under which the certificate is a necessary requirement e.g. for taking up an activity or putting a product on the market[34]. In the case of a certificate stipulated as non-obligatory, the law provides for additional possibilities to attest for compliance with the legal requirements[35]. According to both sub-options, the certification bodies are designated by the respective minister on the basis of statutory requirements[36]. In order to increase the state's trust in the results of the certification activities, the state must observe or monitor the quality of the activities of the certification bodies[37]. The improper exercise of the certification activity can lead to the revocation of the designation by the minister[38].

II. Conformity assessment bodies as administrative bodies

The incorporation of the conformity assessment bodies into the realization of public duties led observers in the Netherlands to question whether conformity assessment bodies can be classified as *bestuursorganen* (administrative bodies). This question is also of practical interest, because their categorization as administrative bodies has consequences for both the legal relationship between the conformity assessment bodies and the state and for the relationship with their clients. Whether a conformity assessment body is to be categorized as a *bestuursorgan*, essentially depends on whether it exercises public authority.

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34 This is the case for the proof of qualification of the crane operator, for example; see above B.I.3.a).

35 Cabinet's position 2003 (Fn. 6), p. 21.

36 Cabinet's position 2003 (Fn. 6), p. 21.

37 Cabinet's position 2003 (Fn. 6), p. 22. For example Art. 7b of the *Warenwet* stipulates that the responsible minister is in charge of monitoring whether the bodies carry out their task lawfully and purposefully. According to Art. 7d of the *Warenwet*, the Minister can give the body general instructions. For the division of tasks between the ministry and the accreditation body during surveillance of the bodies, see under D III 3.

38 Cabinet's position 2003 (Fn. 6), p. 22. The details are regulated by the specific law, see e.g. Art. 7a para. 3 of the *Warenwet* in conjunction with Art. 22c para. 2, 3 *Warenwetbesluit Drukapparatuur*.

1. Conformity assessment bodies as bodies vested with public authority

a) Uncertainty on the exertion of public authority

In Dutch law, the categorization of a non-state institution as an administrative body can be based on Art. 1:1 para. 1 no.1b of the Algemene Wet Bestuursrecht (AWB). Accordingly, persons who are vested with public authority (*openbaar gezag*) are conceived as administrative bodies[39]. This is the case when they are authorized by public law to define the rights and obligations of other legal entities. This is generally assumed when they are authorized to carry out legal acts under public law[40]. Whether this is the case with the conformity assessment bodies is difficult to judge, in particular because the options for using conformity assessment bodies in the regulatory sphere are very diverse in the Netherlands.

In the debate, a first distinction is made about whether the law attaches legal consequences to the existence of the certificate or whether the certificates only play a role during the administrative activities, e.g. the surveillance of firms, without this being explicitly stipulated by law.

In the first case, there is a broad consensus that the conformity assessment body exercises public powers if the certificate is a necessary requirement for issuing an authorization and if there is no other possibility to obtain the authorization. In cases in which it is obligatory to acquire the certificate, the certification body is categorized as an administrative body[41]. This categorization is disputed when the certificate is indeed stipulated by law, but if there are other possibilities to demonstrate compliance with the legal requirements, for example when the certificate is thus not a necessary, but a sufficient requirement for issuing an authorization. The MDW Report already assumes the existence of a public activity if the law

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39 "Openbaar gezag" also means agency or authority.

40 Cabinet's position 2003 (Fn. 6), p. 16.

41 *de Moor-van Vugt/van Ommeren*, Certificering als reguleringssysteem?, SEW 3 (1999), 89 (93); *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 44; MDW-Rapport (Fn. 10), p. 37; see also Cabinet's position 2003 (Fn. 6), p. 16. What is decisive here is that the certificate is a necessary prerequisite; whether a decision by the authority on issuing a licence takes place is not addressed. The MDW-Rapport also assumes that this can at least potentially be categorized as a public activity when the certificate is not legally compulsory, but when there is a factual requirement for obtaining the certificate, MDW-Rapport (Fn. 10), p. 39.

attaches legal consequences to the mere possession of the certificate[42]. Others contest such a broad interpretation and admit the existence of an administrative body without an explicit legal basis only in exceptional cases[43]. The MDW Report makes an additional distinction according to whether the law attaches direct legal consequences to the existence of the certificate or whether an additional official decision follows after the certificate is presented. In the latter case, the certification body is not supposed to exercise public powers, because the sovereign decision is only made by the state authority. However, this does not apply when the certificate is the only requirement for authorization and the state authority no longer has any discretion for its decision[44].

When the law does not directly attach consequences to the existence of the certificate and these only result from a governmental practice (that is not legally compulsory), e.g. during the surveillance of firms, the certification does not constitute a public activity, because the point of reference is not the certificate, but the official practice as such[45].

In the Cabinet's position from 2003 it is evident that there is still uncertainty with regard to the categorization of such case groups[46]. Thus, in future legal regulations it should be explicitly clarified whether the conformity assessment bodies called on obtain the status of an administrative body. An approval of the body by the minister should always be a prerequisite for obtaining this status. The act of approval offers the possibility to explicitly require the bodies to comply with the demands resulting from their status as administrative bodies[47].

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42 MDW-Rapport (Fn. 10), p. 38.

43 *de Moor-van Vugt/van Ommeren*, Certificering als reguleringssysteem?, SEW 3 (1999), 89 (94); in terms of the result, see also *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 44.

44 MDW-Rapport (Fn. 10), p. 37 for compulsory certificates according to the report; on cases in which the certificate is provided for by law, but not a necessary requirement see p. 38 et. seq.

45 MDW-Rapport (Fn. 10), p. 39.

46 Cabinet's position 2003 (Fn. 6), p. 16; "as a precaution", Cabinet's position assumes that the accreditation body is an administrative body in the case of obligatory certificates.

47 Cabinet's position 2003 (Fn. 6), p. 16. For the consequences of the categorization as an administrative body, see under 3.

b) Assumption of public authority for the *toelatingsvariant*

With regard to the forms of use of certification in the regulatory sphere elaborated in the Cabinet's position, we can infer from this view that the categorization of certification bodies as administrative bodies only comes into question for the *toelatingsvariant*[48]. Here the Cabinet's position specifies that all conformity assessment bodies are to be approved by the state. As for the *onvoorwaardelijke variant*, which only calls for the existence of the certificate, the conformity assessment bodies are regarded as administrative bodies. In the case of the *voorwaardelijke variant*, in which the certificate is the basis of the assumption that the legal requirements have been fulfilled, the conformity assessment bodies are categorized as administrative bodies, when the certificate is the only possibility of providing proof of compliance or when the conformity assessment bodies assess the product directly on the basis of the specifications of the European directives or the national implementation laws, because no harmonized standards exist[49]. With respect to the *voorwaardelijk* option, in particular, it is emphasized that the area-specific legal regulation must create clarity as to the status of the conformity assessment bodies. For some regulations this is currently the case[50].

2. Consequences of the classification as zelfstandig bestuursorgan

If one assumes that a conformity assessment body executes public authority, it is a *zelfstandig bestuursorgan* (independent administrative body), but only for the specific task given by the ministry. *Zelfstandige bestuursorganen* are characterized by the fact that they are vested with public authority, but are not hierarchically subordinate to a minister[51].

If a conformity assessment body is categorized as a *zelfstandig bestuursorgan*, this has consequences for the legal relationship both between the body and the state, as well as with

48 For the *toelatingsvariant* and both sub-options see above under B I 3.

49 See Cabinet's position 2003 (Fn. 6), p. 21 et. seq.

50 For example, for the pressure equipment the Risa makes it clear that the designated bodies are *zelfstandige bestuursorganen*; RISA-Scheme PED (Fn. 66), item 1.3 paragraph 3.

51 On the concept, see *Van Wijk/Konijnenbelt/Van Male*, Hoofdstukken van Bestuursrecht, p. 85; in more detail *Zijlstra*, Zelfstandige Bestuursorganen, p. 75 et seqq. see also the bill for a framework law on *zelfstandige bestuursorganen* as amended on 26.5.2002, *Eerste Kamer der Staten-Generaal*, Regels betreffende zelfstandige bestuursorganen (Kaderwet zelfstandige bestuursorganen), Vergaderjaar 2001–2002 No. 276 (27426).

regard to its rights and obligations towards its clients. As for the legal relationship to the state, it is of significance that the body conducts public tasks, without being incorporated into the hierarchical structure of the administration in the traditional manner. This raises questions as to how the execution of the public task can be sufficiently authorized. To do so, it is particularly imperative to create a relationship of accountability which allows for the appropriate control of the activities of the bodies. This relationship of accountability is generally established by the instruction and control rights vested in higher levels of administration. In the case of the conformity assessment bodies, mechanisms must also be defined which allow for the supervision of their activities. This matter will be further addressed when discussing the approval and surveillance of the bodies[52]. In relationship to the clients, a particularly important consequence of the categorization as *zelfstandig bestuursorgan* is that the conformity assessment body is subject to the obligations of administrative law. This has implications for structuring the activities of the bodies, e.g. in terms of dealing with applications or the clients' options for filing complaints or lawsuits[53].

III. Role of the accreditation during the competence assessment by the state

The approval or designation of the bodies is conducted by the responsible minister. The Dutch government concluded an agreement with the Dutch accreditation body, the RvA, according to which every approval or designation of a body is to be preceded by an accreditation or assessment by the RvA in the future[54].

1. Approval or designation by the responsible minister

The responsible minister is in charge of the approval or designation of bodies. The approval/designation is carried out by *besluit*. Legal action against this can be taken on the basis of administrative law[55].

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52 See below B.III.1, B.III.4.

53 More on this under C.I.

54 More on the agreement from 15.6.2005 under D.I.3.a).

55 See the indication in the revised agreement between the Dutch government with the RvA in the section *Toelichting*, under *Bestuurlijke status van de RvA* (p. 13); the agreement is available online at URL: http://www.rva.nl/pdfdoc/30062005.pdf (3.7.2005).

If one considers the conformity assessment bodies in the regulatory sphere as *zelfstandige bestuursorganen*, the approval or designation of bodies by a state institution is already required for the sake of creating a sufficient link between the bodies and the minister and thus granting them legitimacy. The approval decision of the minister makes it possible to explicitly obligate the bodies to comply with the requirements placed on them. It allows the minister to intervene, when the bodies fail to fulfil their legally compulsory tasks[56].

2. Assessment by the RvA as a decisive criterion

During the approvals or designation procedure the competence and independence of the body must be inspected. The agreement of 15/6/2005 assumes that, as a rule, every approval or designation is preceded by an assessment by the RvA[57]. The assessment report of the RvA is supposed to play an important role in the decision of the responsible minister on approving the body[58]. It is not binding for the minister, though. This provision might have to do with the fact that a categorization of the activities of the RvA as governmental is avoided in these cases and that the approval constitutes the definitive legal act in the relationship between the state and the approved body[59].

3. Accreditation and assessment criteria in the regulatory sphere

In the regulatory sphere the question arises to what extent the compliance with general the accreditation standards may serve as a basis for an approval. The agreement between the RvA and the Dutch state assumes that the use of the standards of the series EN 45000 and ISO 17000 is not sufficient in all cases. The level of training and the experience of the personnel are examples of additional criteria to be taken in to account[60]. Against this back-

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56 Cabinet's position 2003 (Fn. 6), p. 22; *Overeenkomst* (Fn. 55), *Toelichting* under *Verantwoordelijkheden* (p. 12 et. seq.).

57 *Overeenkomst* (Fn. 55), *Toelichting* under *Europese context*, p. 12.

58 *Overeenkomst* (Fn. 55), section 2 paragraph 5 clause 3, *Toelichting* under *Bestuurlijke status van de RvA* (p. 13).

59 See also the *Overeenkomst* (Fn. 55), *Toelichting* under *Bestuurlijke status van de RvA* (p. 13). Otherwise, the RvA would also be categorized as an administrative body if the arguments in favour of governmental activities by the conformity assessment bodies were taken as a basis.

60 *Overeenkomst* (Fn. 55), *Toelichting* under *Afstemming activiteiten*, p. 12. This considers the views of some ministries, according to which the criteria examined during the accreditation are not always sufficient for guaranteeing the required quality while fulfilling tasks provided for by law, see *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 64.

ground, the agreement distinguishes between the consideration of an *accreditation* by the RvA and an *assessment (beoordeling)* by the RvA within the framework of the approval/designation.

a) Distinction between accreditation and assessment

The agreement defines a*ccreditation* as an assessment by the RvA on the basis of European or international standards[61], and *assessment* as an assessment by the RvA on the basis of criteria stipulated by the responsible minister[62]. If the responsible minister falls back on an accreditation during the approval of a body, the assessment by the RvA is conducted on the basis of the relevant accreditation standards. The extent, to which additional criteria are taken into account during the sovereign approval decision, is primarily up to the minister[63]. In contrast, the assessment (*beoordeling*) by the RvA during an approval procedure takes place on the basis of criteria which are stipulated by legal provisions for the concerned regulated area. As a result, the ministry has the option of having the RvA inspect additional items which it deems necessary during the regulatory use of of conformity assessment[64].

With this distinction, the agreement is reacting to previous experiences with the use of the accreditation during the competence assessment. Frequently the concerned ministers did not have sufficient knowledge of the criteria which were covered by the accreditation. As for the RvA, it was often uncertain which additional assessment criteria the different ministries wished for. A terminological distinction between accreditation and assessment (*beoordeling*) can increase clarity here.

b) Supplementing accreditation rules with additional criteria

(i) Risa and Wesa

In the Netherlands, the difference between accreditation standards and assessment standards for the regulatory sphere had been a topic of debate for some time. In order to cover

61 *Overeenkomst* (Fn. 55), Section 1 lit. b.
62 *Overeenkomst* (Fn. 55), Section 1 lit. c.
63 *Overeenkomst* (Fn. 55), *Toelichting* under *Afstemming activiteiten,* p. 12.
64 See *Overeenkomst* (Fn. 55), *Toelichting* under *Afstemming activiteiten,* p. 12.

the additional need for assessment that had been detected, a system of directive and law-specific accreditation standards was developed[65]. At the same time, special accreditation programs for certain areas were elaborated within the framework of an agreement between the responsible ministry and the RvA and fitted to the criteria of the directives the national laws[66]. The programs contain, for example, clarifications with regard to the areas of applicability of the provisions, the applied assessment procedures, etc. Professionals from the participating groups are involved in the development of the programs. The certification bodies accredited according to the programs must join a *Centrale College van Deskundigen*[67], which provides for participation of all stakeholders[68]. The accreditation by the RvA during the approval procedure is then conducted on the basis of the specific accreditation scheme[69].

(ii) Assessment criteria according to the agreement

Within the framework agreement between the RvA and the state the *assessment* of bodies in the regulatory sphere is to be conducted by the RvA in accordance with statutory criteria (stipulated by the minister), which may take the special needs of the regulatory sphere into account[70]. The criteria are defined by the responsible ministries. They are to be based on internationally harmonized accreditation standards to the greatest possible extent[71].

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65 See the article by *van Malkenhorst*, "The Dutch System Of Directive-specific Accreditation (RISA)" presented during a workshop of the EOTC on 21 February 2001 in Brussels, available at URL: http://www.eotc.be/Events/Eotc/NBs/Downloads/9-Public%20_van%20Malkenhorst_%20Dutch%20System%20-%20RISA.pdf (3.7.2005); see also *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 69 et seq., p. 64.

66 See for example the Risa for the scope of the pressure equipment directive, RISA-Schema PED, Richtlijn Specifiek Accreditatie Schema voor de Richtlijn 97/23/EG van het Europees Parlement en de Raad van 29 mei 1997 inzake de onderlinge aanpassing van de wetgevingen der lidstaten betreffende Drukapparatuur, available at URL: http://docs.szw.nl/pdf/135/2005/135_2005_1_9415.pdf (3.7.2005). The Risa and Wesa are public documents, which are published in the *Staatscourant*.

67 More on the *Colleges van Deskundigen* under C.II.

68 See e.g. the RISA-Scheme PED (Fn. 66), Section 3.1.

69 Apparently, the practices of the different ministries differed significantly here. As regards pressure equipment, there is a reference to the Risa PED, for example, in the decision to approve the certification body Kiwa N.V. It is determined in the initial considerations that Kiwa is willing to maintain an accreditation in accordance with the Risa PED; see e.g. Besluit van de Staatssecretaris van Sociale Zaken en Werkgelegenheid, M. Rutte, van 28 mei 2003, Directie A&G, nr A&G/W&P/03 42690 houdende aanwijzing van Kiwa N.V. als keuringsinstantie voor drukapparatuur ter uitvoering van artikel 5, eerste, tweede en vierde lid, van de Wet op de gevaarlijke werktuigen, Staatscourant 2003, 112 p. 17.

70 Risa ans Wesa are beeing renamed and improved.

71 *Overeenkomst* (Fn. 55), Section 1 lit. c., *Toelichting* under *Afstemming activiteiten* (p. 12).

4. Surveillance of the conformity assessment bodies

a) Role of the RvA

Previously, the practices for monitoring the designated bodies differed greatly. While several ministries left the surveillance entirely up to the RvA during the accreditation procedure, others conducted the surveillance on their own. As was the case with the initial appraisal, there was sometimes uncertainty with regard to the criteria inspected by the RvA. Consequently, additional or direct surveillance by the responsible ministries themselves was regarded as necessary.

If one considers the conformity assessment bodies in the regulatory sphere to be administrative bodies, the rules on the surveillance of the bodies must create a point of reference for their supervision by the responsible minister. If the RvA were interposed as a supervisory authority, mechanisms must be created which allow the ministries sufficient influence on the bodies. The restructuring of the surveillance in the agreement between the government and the RvA from 15 June 2005 must be viewed in this context. According to this, the regular surveillance of the approved bodies is to be conducted by the RvA. It provides for a yearly assessment during the assessment and accreditation procedure. The report on the results of the assessment is to be passed on not only to the approved body, but also to the respective ministry within one month at the latest. The ministries shall obligate the approved bodies to authorize the RvA to give a thorough account of any irregularities. Details with respect to the content and the frequency of the surveillance can be coordinated separately between the ministries and the RvA[72].

b) Annual reports of the conformity assessment bodies

The annual reports of the conformity assessment bodies also provide a contribution to the state's means of control. Some ministries require the conformity assessment bodies to present an annual report on the activities which they conducted during the approval[73]. The

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72 *Overeenkomst* (Fn. 55), Section 2.

73 See e.g. the decision to approve Kiwa (Fn. 69), Article 3 Letter h in conjunction with the appendix. Annual reports are a significant instrument for the oversight of independent administrative bodies for all *zelfstandigen bestuursorganen*, see e.g. the bill for the *Kaderwet zelfstandige bestuursorganen* (Fn. 51),

annual report must contain information on the conducted inspections, notices on changes to the basic criteria, as well as information on experiences with subcontracting and cooperation with other conformity assessment bodies etc[74]. The report provides the ministries insights on the activities of the body and can therefore serve as a point of reference for any additional measures.

C. The activities of the conformity assessment bodies

The conformity assessment bodies offer their services on the free market and conclude a contract with their clients based on private law. As a rule, this also holds for the regulatory sphere. In this situation, the independence of the bodies is of particular importance for creating confidence in the validity of the certificate. The independence of the bodies is enhanced in the Netherlands by a special institution, the *Colleges van Deskundigen*, which also play an important role in the harmonization of the interpretation and application of the certification schemes. In the Netherlands, there is a branch organization of certification bodies, the Vereniging Overleg van Certificatie-instellingen (VOC)[75].

I. Legal relationship between the conformity assessment bodies and their clients

In the Netherlands as well, the legal relationship between the conformity assessment bodies and their clients is generally based on a private law contract. It stipulates, in particular, the requirements for issuing a certificate as well as the certification procedure, the surveillance of the certified establishments, the guidelines for determining non-conformities, the revocation of the certificate and options for clients to file a complaint[76]. As a rule, the contract contains the authorization for the conformity assessment body to unilaterally with-

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which provides for annual reports in Chapter 3 under the heading “information measures, administration and oversight” (Art. 18) .

74 For the content of the annual report, see the appendix of the decision to approve Kiwa (Fn. 69).

75 It apparently does not have an internet site.

76 See for example the general regulations of the conformity assessment body Kiwa for product certification, *Kiwa*, Kiwa-Reglement voor Productcertificatie:2004, Sections 2.6, 3, 4, in particular 4.3, 5.1 and 7; the document is available online at URL: http://www.kiwa.nl/uploadedFiles/Kiwa_website/01_Certificatie_en_Keuringen/303_Reglementen/Reglement%20Productcertificatie%202004.pdf (18.7.2005).

draw the certificate in the case of continuous non-conformities[77]. Furthermore it often stipulates the authorization of the accreditation body to accompany the conformity assessment body during its activities (witness audits)[78].

A special situation arises when the conformity assessment body has the status of a *zelfstandig bestuursorgan*[79]. When the body is assigned public powers by these means, the applicability of the Law on General Administrative Law *(Algemene Wet Bestuursrecht - AWB)* has implications for the legal relationship between the body and the clients. For instance, the freedom of contract can be restricted and there may be maximum limits for the duration for processing applications. It is also possible to set maximum prices for the service offered[80]. The decision to issue the certificate takes place on the basis of the legal form of the *besluit*. Legal objections to the *besluit* can be initiated by means of administrative process law. The internal complaints procedure by the bodies must be coordinated on this basis. Some bodies react to such a categorization as an administrative body by drawing up supplementary regulations for these fields of activity, which are incorporated into the contracts with the clients[81].

II. The role of the Colleges van Deskundigen

According to the standardized requirements for the conformity assessment bodies the bodies must have a documented structure which assures their impartiality. This structure must allow for the participation of all involved parties in drawing up regulations on the content and method of operation of the certification system[82]. In the Netherlands, a uniform structure was developed for complying with these requirements, the *College van Deskundigen*

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77 See also *Kiwa*, Kiwa-Reglement voor Productcertificatie: 2004 (Fn. 76), Section 5.1 in conjunction with 4.3.1.

78 See for example *Kiwa*, Kiwa-Reglement voor Productcertificatie:2004 (Fn.76), Section 2.1.5.

79 See above B III.

80 The Cabinet's position provides for this possibility for the Toelatingsvariant, Cabinet's position 2003 (Fn. 6), p. 21; see the decision to approve Kiwa (Fn. 69), Art. 4.

81 See e.g. *Kiwa*, Aanvullend Reglement voor Wettelijke Certificatieregelingen from 25.1.2001; the document is available online at URL: http://www.kiwa.nl/uploadedFiles/Kiwa_website/01_Certificatie_en_Keuringen/303_Reglementen/AanvulReglWettCertRegl(gedownload).pdf (18.7.2005).

82 See e.g. General requirements for bodies operating product certification systems, EN 45011 Item 4.2.e; General requirements for bodies operating assessment and certification/registration of quality systems, EN 45012 Item 2.1.2.e; General requirements for bodies operating certification for persons, EN ISO 17024, Item 4.2.2.

(Council of Experts). The members of the *College van Deskundigen* represent the businesses, which make use of the conformity assessment as a service, as well as concerned authorities and other affected groups, depending on the type of certification scheme[83].

1. Organization of the Colleges van Deskundigen

According to the RvA's interpretation, every certification body generally must have a *College van Deskundigen* for every area in which it is accredited in order to fulfil the requirements of the accreditation standard[84]. This results from the requirements of the accreditation standards, which demand a representation of all involved parties[85]. If the conformity assessment body has established such a committee within its own organizational structure, it constitutes a *College van Deskundigen (CvD).* The composition of the CvD is examined by the RvA to determine whether all involved parties are represented. The CvD must convene at least twice per year[86]. If several conformity assessment bodies operate in one area, a CvD can be active for several bodies.

However, it is much more customary to establish a common committee in each sector, which centrally monitors the certification scheme for all bodies, e.g. for the certification according to ISO-14000, EMAS, OHSAS, asbestos removal or similar. These *Centrale Colleges van Deskundigen (CCvD)* are generally established within foundations, which were created for this purpose or fulfil coordination tasks in the concerned sector. For example, the *Stichting Persoonscertificatie Deskundig Toezichthouder (STIPDT)* was originally founded for the certification of firms specializing in the removal of asbestos; nowadays ist is also active in related areas of personnel certification[87]. Another example is the *Stichting Coördinatie Certificatie Milieu- en Arbomanagementsystemen (SCCM),*

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83 See e.g. the list of members of the CCvD for asbestos removal at URL: http://www.stipdt.nl/basis.asp (18.7.2005) under *Organisatie/Centraal College van Deskundigen* as well as for the areas environment and work health and safety at URL: http://www.sccm.nl/01_Achtergrond/1_1_organisatie/index.htm (18.7.2005), both under *Centraal College van Deskundigen Milieu* and *Arbo*.

84 See *Evers,* Blind vertrouwen?, p. 103.

85 If for example the bodie fulfils the requrements for certification bodies in Section 2.1.2 e) EN 45012, according to which the body must have a documented structure, assuring the participation of all relevant interested parties, this requirement is satisfied. For Section 2.1.2 e) EN 45012 see IAF Guidance on the Application of ISO/IEC Guide 62:1996 (on which EN 45012 is based), Section G.2.1.16 et seq.; see as well IAF Guidance on the Application of ISO/IEC Guide 65:1996, Section G.4.11 et seqq.

86 *Evers,* Blind vertrouwen?, p. 103.

87 More information on the foundation at URL: http://www.stipdt.nl/basis.asp (18.7.2005)

which is active in the areas environment and work safety[88]. The conformity assessment bodies conclude a contract with the foundations, in which they obligate themselves to follow the interpretation of the certificate rules by the CCvD. In return, they are authorized to offer the certification system and use the marks of the foundation, where applicable[89]. The RvA examines whether the CCvD fulfil the requirements of the conformity assessment standards for the representation of the concerned parties. To do so, a formalized procedure for the approval of CCvD exists[90]. Among others, a prerequisite for approval is that the CCvD is open to all bodies, which are accredited by the RvA for the area supervised by the CCvD or have applied for an accreditation[91]. Regular tests are conducted by the RvA during the four-year duration of the approval of a CCvD[92]. Currently 24 CCvDs operate and have been approved by the RvA[93].

2. Function of the Colleges van Deskundigen

The task of the CvD and CCvD is to participate in the elaboration of certification schemes and arrange for the continual update of existing schemes[94]. This applies, above all, to branch-specific certification schemes and those which have not been internationally harmonized. As for the internationally harmonized schemes, the main focus is placed more on drawing up interpretation documents and the like. As long as the methods of examination and the frequency of the assessment have not already been laid down in the certification standards, they are also determined by the CvD and CCvD[95]. They can impose binding

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88 The foundation runs a CCvD for the environment and another for the area work health and safety. More information on the foundation at URL: http://www.sccm.nl/01_Achtergrond/index.htm (18.7.2005); in particular on the incorporation of the foundation and the CCvD in the accreditation and conformity assessment structure *SCCM* at URL: http://www.sccm.nl/01_Achtergrond/1_2_Werkwijze/index.htm (25.7.2005).

89 *Evers*, Blind vertrouwen?, p. 103.

90 The procedure is specified in *RvA*, De Beoordeling en Acceptatie van Centrale Colleges van Deskundigen – RvA-R13, available online at URL: http://www.rva.nl/pdfdoc/rva-r13-debeoordelingenacceptatievancentralco.pdf (15.5.2005).

91 *RvA*, De Beoordeling en Acceptatie van Centrale Colleges van Deskundigen – RvA-R13 (Fn. 90), Item 2.2. third dash.

92 *RvA*, De Beoordeling en Acceptatie van Centrale Colleges van Deskundigen – RvA-R13 (Fn. 90), Item 3.3.

93 Updated on 1.7.2005. A list of the approved CCvD is available online at URL: http://www.rva.nl/nl/rccvd.html (18.7.2005). Many of the CCvDs supervise certification schemes from the non-regulatory sphere. More information on the CCvD is available from the respective foundations.

94 *Schalekamp*, Zicht op Certificatie, p. 30. The brochure can be obtained from www.kiwa.nl.

95 See e.g. the description of tasks for CvD of the conformity assessment body Kiwa in *Kiwa*, Kiwa-Reglement voor de Advisie-Colleges: 2004, Item 2.2.3, the document is available online at URL:

provisions on the conformity assessment body for carrying out the certification and for the interpretation of the certification standards. The body can only deviate from these provisions in exceptional cases and must comply with a certain procedure. The CCvD have an especially important role. Their purpose is to bring together all stakeholders in a certification scheme in only one committee and to assure at national level that all certificates have the same value.

The representation of all participating groups in the CvD and CCvD prevents the conformity assessment bodies from unilaterally orienting their activities towards the needs of their clients. They thus contribute to guaranteeing the independence of the bodies[96]. In the regulatory sphere they grant the responsible authorities a possibility to exert a certain degree of influence over the further development and, in particular, the application of the certification schemes as well. By drawing up interpretation documents, they ultimately provide an important contribution to the harmonization of the interpretation and application of the certification schemes.

D. The role of the accreditation body

The RvA (Stichting Raad voor Accreditatie) was founded in 1995 as a result of a merger of existing accreditation bodies. The RvA is a foundation based on Dutch law, which operates without the intention to realize profits. It currently has approximately 50 employees and works with around 400 internal and external assessors. Its yearly turnover is approximately 6 million Euros. The RvA has been appointed as the national accreditation body in an agreement with the government. In the non-regulatory sphere as well it has a de facto monopoly.

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http://www.kiwa.nl/uploadedFiles/Kiwa_website/01_Certificatie_en_Keuringen/303_Reglementen/Reglement%20Adviescolleges%202004.pdf (18.7.2005).

96 Kiwa designates this system as “scheiding van beleid en uitvoering”.

I. Status of the RvA

1. Establishment and legal form

The RvA originated in 1995 through the merger of existing accreditation organizations. These included the *Raad voor Certificatie*, an accreditation body for certification bodies founded in 1981, and the foundation NKO/STERLAB/STERIN (NSS). The NSS had emerged from a merger of the Dutch Organization for Calibration (Nederlandse Kalibratie Organisatie – NKO) and STERLAB/STERIN, an accreditation body for laboratories and inspections bodies[97]. The merger of the bodies to the RvA was encouraged and supported by the Ministry of Economic Affairs[98]. The RvA is a private-law foundation with its headquarters in Utrecht[99]. The legal foundations based on private law were deliberately selected during the establishment of the RvA, even though the accreditation bodies were state or semi-state organizations in other countries[100]. At the same time, it was also assumed in the Netherlands that the state is jointly responsible for the proper functioning of the accreditation organization, firstly because it also serves public interests, and secondly, because surveillance over the accreditation by the state is necessary[101].

2. Areas of activity of the RvA

The RvA operates in nearly all accreditation areas and accredits certification and inspection bodies, testing and calibration laboratories as well as organizers of proficiency tests in the regulatory and non-regulatory sphere[102]. The proportion of accreditations issued for the regulatory sphere is quoted at approximately 40 %[103].

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97 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 59.

98 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 59.

99 Art. 1 of the *Articles of Association* of the RVA; the Articles of Association are available in Dutch at URL: http://www.rva.nl/pdfdoc/rva-r01nlstatuten.pdf (22.6.2005), in English translation at URL: http://www.rva.nl/pdfdoc/rva-r01ukarticlesofassociation.pdf (22.6.2005).

100 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 59.

101 *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 59.

102 *RvA* at URL: http://www.rva.nl/uk/rmisuk.html (22.6.2005); *RvA*, Regulation for Accreditation – RvA-R2 (Version from 15.3.2002), available at URL: http://www.rva.nl/pdfdoc/rva-r02ukregulationforaccreditation.pdf (24.6.2005). Section 3.4.1.

103 *Overeenkomst* (Fn. 55), *Toelichting* under *Werkingssfeer*, (p. 11).

In 2004 the RvA listed 538 accredited bodies, of them 207 in the area of testing, 187 in the area of certification, 70 calibration bodies, 68 inspection bodies as well as six proficiency testing bodies[104]. In the area of certification, in particular, many of the bodies are accredited for several areas of certification. The focus is placed here on the certification of management systems, followed by product certification, environmental certification and personnel certification[105]. With regard to the certification of management systems, the focus is placed on the certification according to ISO 9000, followed by the certification schemes QS 9000, VCA and HACCP[106].

Similar to UKAS, the RvA conducts a significant part of its activities abroad, in particular in Asia. In the area of certification 57 % of the accredited bodies come from the Netherlands und 8 % from the rest of Europe, 19 % from Asia and 12 % from the United States and Canada[107]. As a rule, though, the accreditation of bodies with headquarters outside the Netherlands does not come under consideration, when the accreditation body of the country of headquarters is a partner of a MRA[108].

3. Unique status of the RvA as an accreditation body

The RvA has been explicitly recognized by the government as the national accreditation body of the Netherlands for the regulatory sphere. In the non-regulatory sphere it enjoys a unique status in practice.

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104 *RVA*, Jaarverslag 2004, p. 22; the annual report of the RvA is available online at URL: http://www.rva.nl/pdfdoc/jvsl2004.pdf (19.7.2005), in English at URL: http://www.rva.nl/pdfdoc/jvsl2004uk.pdf (22.6.2005).

105 *RVA*, Jaarverslag 2004 (Fn. 104), p. 22.

106 *RVA*, Jaarverslag 2003, p. 7. The annual report is available from the RvA. The certification according to VCA (Veiligheids Checklist Aannemers) is a certification system in the area of work health and safety. It was originally introduced by the Dutch chemical industry. It is primarily based on an evaluation of the management system which aims for safe working conditions for the firm as a whole as well as a personnel certification, which targets the individual safety-relevant skills of the individual employees, *RVA*, Jaarverslag 2003, p. 2; the HACCP (Hazard Analysis and Critical Control Point) is system to guarantee food safety.

107 *RVA*, Jaarverslag 2003 (Fn.106), p. 6; see for the year 2004 the description broken down according to the different areas of accreditation under *RVA*, Jaarverslag 2004 (Fn. 104), p. 22.

108 More on the *cross-frontier-policy* of the RvA *RvA*, Detailing RvA's policy on cross-frontier accreditations, at URL: http://www.rva.nl/uk/rcrossfrpolicy.html (24.6.2005).

a) Status of the RvA in the regulatory sphere

Since 1994 the Dutch government has maintained an agreement with the RvA, which defines the mutual rights and obligations. The agreement was revised following the cabinet resolution from November 2003[109]. In the agreement from 15 June 2005 the government grants the RvA the status of a "national accreditation body"[110]. The cabinet's position and the agreement with the RvA assume that in the future every designation of a body should be based on an accreditation or assessment by the RvA[111]. The status of the RvA as a private law organization is maintained. The new agreement intends to promote in particular communication between the accreditation body and the state authorities, which is in need of improvement according to the study by the University of Tilburg and the Cabinet's decision. This is to be achieved e.g. by means of a clearer description of tasks by the responsible ministries, parameters to measure the quality of the performance of the RvA and reporting obligations[112]. If necessary, the agreement is to be supplemented by additional agreements with individual ministries[113].

Hence, the RvA has an exclusive status in the regulatory sphere, which is only guaranteed by the private law agreement with the government, though[114]. Following up on a suggestion in the study by the University of Tilburg, it was debated whether a law should grant the RvA a "concession" for the medium-term for the accreditation activities[115]. However, for the time being, the agreement has only been revised, as provided for by the cabinet's position.

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109 *Ministerie van Economische Zaken, Raad voor Accreditatie*, Overeenkomst Staat – Raad voor Accreditatie, available at URL: http://www.rva.nl/pdfdoc/30062005.pdf (3.7.2005).

110 *Overeenkomst* (Fn. 55), section 2 paragraph 2, *Toelichting* under *Europese Kontext* (p. 11); see also Cabinet's position 2003 (Fn. 6), p. 24 (no. 28).

111 Cabinet's position 2003 (Fn. 6), p. 21, *Overeenkomst* (Fn. 55), *Toelichting* under *Europese Kontext* (p. 12). On the relationship between accreditation and designation or approval, see under B.III.

112 *Overeenkomst* (Fn. 55), *Overwegende* under h, see the reporting and publication obligations in Section 6 of the agreement, performance indicators in Section 7, the regulation on the evaluation in Section 8, on the designation of contact persons in Section 9 as well as *Toelichting* under *Aanleiding voor deze nieuwe overeenkomst* (p. 10), and under *kwaliteitsimpuls* (p. 13); see also Cabinet's position 2003 (Fn. 6), p. 4 (no. 8).

113 *Overeenkomst* (Fn. 55), *Overwegende* under j; see also Cabinet's position 2003 (Fn. 6), p. 4 (no. 11).

114 For the classification of the agreement as private law, see Cabinet's position 2003 (Fn. 6), p. 21 (no. 29).

115 Cabinet's position 2003 (Fn. 6), p. 24 (no. 28, 29). See the potential roles of the RvA discussed in the study in *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 80 et seqq.

b) Status of the RvA in the non-regulatory sphere

The allocation of an exclusive status to the RvA in the agreement with the government only refers to its activities for purposes within the regulatory sphere[116]. According to the responsible ministry, the state cannot prevent other bodies from offering accreditation activities on the market in the non-regulatory sphere. As far as can be seen, at least one additional accreditation body exists in the Netherlands, the Centrale Accrediterings Raad (CAR), which has only issued a few accreditations, though[117]. In order to mitigate potential disadvantages for competitors, the RvA is supposed to make a clear distinction between the tasks defined in the agreement and its other activities[118].

4. Reasons for a uniform, national accreditation body

In the Netherlands a national accreditation body has been deliberately established, which is active in all branches and in the regulatory and non-regulatory sphere.

a) An accreditation body for the regulatory and non-regulatory sphere

One cited advantage of a uniform accreditation body active in the regulatory and non-regulatory sphere is that it prevents multiple accreditations and reduces costs. Furthermore, it is said to more effectively guarantee that in the regulatory sphere as well the accreditation rules keep pace with technical developments. This purportedly improves the transparency of the entire conformity assessment system, for end consumers as well.

b) No competition over the accreditation

In the Netherlands there has not always been a consensus that there should be no competition over the accreditation. There were fears that the pricing system would be difficult to monitor if the accreditation body had a monopoly and that the accreditation body would have no incentive to continually improve the quality of its service. Another topic of discus-

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116 See *Overeenkomst* (Fn. 55), *Toelichting* under *Europese Kontext* (p. 11).

117 According to the statements at its Internet site, the body has currently accredited four conformity assessment bodies. More information on the CAR at URL: http://www.accreditatie.com/index.html (18.7.2005).

118 *Overeenkomst* (Fn. 55), section 10 paragraph 4.

sion was the circumstance that a monopoly of the accreditation body virtually leads to an obligation to contract for the bodies interested in the accreditation. This was deemed as particularly problematic in cases in which the accreditation is of significance during a designation procedure. According to popular view, the conformity assessment bodies must always have another possibility to prove their competence and obtain a designation, apart from accreditation[119].

This was challenged by the notion that the accreditation plays a substantial role in assuring the quality of conformity assessment. In particular in areas, in which conformity assessment is used to meet objectives such as public safety, the accreditation is said to be of great significance. This purportedly holds in particular when the government resorts to conformity assessment on a large scale, as is the case in the Netherlands, and leaves responsibilities up to the market through extensive deregulation policies. Accordingly, it must be assured that such a system which places emphasis on the self-regulatory forces of the market indeed does function. A uniform accreditation body linked to the state supposedly offers the possibility of guaranteeing this. It is also emphasized that the quality of conformity assessment created by the accreditation is significant for commerce, in particular in an export-oriented country like the Netherlands. In a small market such as that of the Netherlands it is difficult for several accreditation bodies to acquire the sufficient size to develop the necessary competence.

Thus, the view prevails that the RvA should be at the tip of the pyramid of conformity assessment. This is clearly demonstrated in the new agreement by the allocation of the status of a national accreditation body[120]. Even in a system without competition, there are conceivable factors which contribute to quality assurance during the accreditation. These include, for example, the participation of the newly established "Client Council" (*Gebruikersrat*) of the RvA in setting the prices for accreditation[121]. The new agreement

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119 See *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 62. Nowadays, the solution to the problem of the obligation to contract, which is regarded as impermissible, is that the bodies that are not seeking accreditation also must allow for an evaluation of their competence and independence to be carried out. This is also done by the assessors of the RvA, albeit not on behalf of the conformity assessment body, rather on behalf of the responsible ministry during the designation and approval procedure.

120 *Overeenkomst* (Fn. 55), *Toelichting* under *Europese Kontext* (p. 11), see also the Cabinet's position 2003 (Fn. 6), p. 24 (no. 28).

121 More on this under D.II.1.d).

between the government and the RvA provides for performance indicators such as customer satisfaction[122]. The peer review among the European accreditation bodies, which is determined obligatory by the agreement[123], could also provide an important contribution.

Concerning the European level, it is assumed in the Netherlands that the national accreditation body provides a service of general economic interest in terms of Art. 86 para. 2 of the Treaty Establishing the European Community[124]. The primary role of EA is viewed to be the harmonization of the accreditation procedures, which are supposed to provide the foundations for the designation of the bodies by the Member States. As a rule, the existing system at the European level has been viewed as satisfactory, because it is indeed able to enforce the demands towards the accreditation body. However, closer ties between EA and EU would also be welcomed.

II. Organization of the RvA

The RvA introduced a new administrative structure, effective as of 2 January 2003. Among other things, the means of influence of the groups affected by the accreditation have been restructured accordingly.

1. Institutions

The RvA is run by a Board of directors (*bestuur)*. The Board of directors appoints an Executive Director, who is responsible for carrying out the accreditations. The RvA has a Supervisory Board (*Raad van Toezicht*), a User Council (*Gebruikersraad*) as well as various advisory committees.

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122 *Overeenkomst* (Fn. 55), section 7 paragraph 5.

123 *Overeenkomst* (Fn. 55), section 5 paragraph 2.

124 See *Overeenkomst* (Fn. 55), *Overwegende* under h, *Toelichting* under *Europese Kontext* (p. 11). For the categorization of this solution according to competition law, see *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 93 et seqq.

a) Board of directors – bestuur

The Board of directors manages the foundation. It determines the long-term orientation of the RvA and oversees the implementation of the accreditation policy[125]. It consists of seven members from the government, manufacturers, suppliers as well as persons with particular professional knowledge and experience in the area of accreditation and certification[126]. The members of the Board of directors are listed in the respective annual report[127]. The Board of directors elects a chairperson and his/her deputy from among its members[128].

b) Executive Director

The Board of directors designates an Executive Director, who is responsible for managing the RvA and conducting accreditation activities[129]. The Executive Director is not a member of the Board of directors[130] and is an employee of the RvA[131]. He/she makes the decision on the accreditation of a body[132].

c) Supervisory Board– Raad van Toezicht

The Supervisory Board oversees the business policy of the RvA and can set guidelines for its areas of focus[133]. It currently consists of eleven members, which are selected from representatives of the public authorities, consumers, manufacturers, and suppliers[134]. The members of the Supervisory Board are supposed to represent as many areas of accreditation and conformity assessment as possible, because this committee serves to ensure the representation of all involved groups[135]. The members of the board are listed in the respec-

125 Art. 4 no. 1, 2 of the Articles of Association of the RvA (Fn. 99); *RVA*, Jaarverslag 2003 (Fn.106), p. 11.
126 *RVA*, Jaarverslag 2003 (Fn.106), p. 11.
127 For the year 2004 *RVA*, Jaarverslag 2004 (Fn. 104), p. 39.
128 Art. 3 no. 1 clause 4 of the Articles of Association of the RvA (Fn. 99).
129 Art. 4 no. 4 in conjunction with Art. 11 of the Articles of Association of the RvA (Fn. 99).
130 Art. 4 no. 4 of the Articles of Association of the RvA (Fn. 99).
131 See Art. 11 no. 1 clause 2 of the Articles of Association of the RvA (Fn. 99).
132 Art. 11 no. 5 of the Articles of Association of the RvA (Fn. 99) – as recommended by the accreditation commission, see below D.II.1.c).
133 *RVA*, Jaarverslag 2003 (Fn.106), p. 11.
134 Art. 6 no. 1 clause 4 of the Articles of Association of the RvA (Fn. 99).
135 *RVA*, Jaarverslag 2003 (Fn.106), p. 11.

tive annual report[136]. Since 2003 representatives of the accredited bodies are no longer represented in the Supervisory Board, but in the User Council.

d) User Council – Gebruikersrad

The User Council introduced in 2003 consists of representatives of direct clients of the RvA. These include the conformity assessment bodies from the different areas (testing, calibration, certification, and inspection bodies), but also public authorities[137]. It is chaired by the Executive Director[138]. The committee advises the Executive Director with regard to the prices of accreditation as well as the scope and quality of the services offered[139]. The User Council consists of six members and convenes twice annually[140]. It reports to the Board of directors once per year[141]. If no agreement is reached with the managing director on the prices or the service offer of the RvA, the council may refer to the Board of directors[142].

e) Accreditation Committee – Commissie Accreditaties

The Accreditation Committee consists of three members and advises the Executive Director on decisions concerning the accreditation[143]. As for decisions on the issue, extension, expansion or revocation of the accreditation, the Commission issues a recommendation. If the Executive Director wishes to deviate from this, he/she must effectuate a decision by the board of the directors[144]. The Commission convenes on a monthly basis and analyzes more than 150 accreditation reports annually[145].

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136 For the year 2004 *RVA*, Jaarverslag 2004 (Fn. 104), p. 39.
137 Art. 8 no. 1 of the Articles of Association of the RvA (Fn. 99).
138 Art. 8 no. 2 of the Articles of Association of the RvA (Fn. 99).
139 Art. 9 no. 1 of the Articles of Association of the RvA (Fn. 99).
140 *RVA*, Jaarverslag 2003 (Fn.106), p. 11.
141 Art. 9 no. 3 of the Articles of Association of the RvA (Fn. 99).
142 Art.9 no. 4 of the Articles of Association of the RvA (Fn. 99).
143 *RvA*, Reglement Commissie Accreditatie – RvA-07 section 2 paragraph 1, section 3; available at URL: http://www.rva.nl/pdfdoc/rva-r07nlreglementcommissieaccreditaties.pdf (24.6.2005); *RVA*, Jaarverslag 2003 (Fn.106), p. 7.
144 *RVA*, Jaarverslag 2003 (Fn.106), p. 7.
145 *RVA*, Jaarverslag 2003 (Fn.106), p. 7; *RVA*, Jaarverslag 2004 (Fn. 104), p. 32. *RvA* at URL: http://www.rva.nl/uk/rcommuk.html (24.6.2005).

f) Advisory committees in the areas of accreditation

The advisory committees support the board of directors of the RvA in further developing the areas of accreditation and improving the accreditation processes, in order to make them transparent and understandable for all participants[146]. For each of the four areas of accreditation, there is an *AfdelingsAdviesCommissie (AAC).* It is supposed to contribute to harmonizing the accreditation activities in the concerned sector[147]. The supervisors and secretary of the *AvdelingsAdviesCommissies* form the *AccreditatieBeleidsadvies-Commissie (ABC),* which advises the board of directors of the RvA[148].

g) Committee for International Affairs– Comissie International Overleg

In the Committee for International Affairs, representatives of the concerned groups and the RvA discuss international developments in the area of accreditation[149].

2. Sections and assessors

The RvA works in four different areas of accreditation: certification, inspection, and laboratories as well as calibration and proficiency testing. The accreditations are carried out by approximately 400 assessors, of which the majority are external assessors[150]. Several times a year, the RvA organizes meetings with the assessors, which are supposed to promote the exchange of knowledge and experiences and thus contribute to the harmonization of the assessment[151].

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146 *RVA*, Jaarverslag 2004 (Fn. 104), p. 9; see also *RvA* at URL: http://www.rva.nl/uk/rcommuk.html (24.6.2005); more on the commissions *RvA*, AccreditatieBeleidsadviesCommissies – RvA-R12, available at URL: http://www.rva.nl/pdfdoc/rva-r12nlaccreditatiebeleidsadviescommissie.pdf (24.6.2005).

147 *RvA*, AccreditatieBeleidsadviesCommissies – RvA-R12 (Fn. 146), Section 4.

148 *RvA*, AccreditatieBeleidsadviesCommissies – RvA-R12 (Fn. 146), Sections 2, 3.

149 *RVA*, Jaarverslag 2004 (Fn. 104), p. 9, 10; more on the composition and tasks of the commission *RvA*, Reglement Commissie Internationaal Overleg – RvA R08, available at URL: http://www.rva.nl/pdfdoc/rva-r08nlreglementcommissieinternationaaloverleg.pdf (24.6.2005).

150 *RVA*, Jaarverslag 2003 (Fn.106), p. 12.

151 *RVA*, Jaarverslag 2003 (Fn.106), p. 12.

3. Financing

The RvA is a non-profit foundation based on Dutch law[152]. Its yearly turnover amounts to approximately 6 million Euros[153]. The RvA is primarily financed from fees for accreditation and from members' dues[154]. The agreement between the RvA and the state includes an indexation clause for the activities of the RvA in the regulatory sphere, which limits increases to the daily rates[155]. The RvA receives a state allowance for its representation as the Dutch national accreditation organisation in international accreditation organizations and the reporting and publishing activities of the RvA for the regulatory sphere[156]. In 2003 and 2004 the allowance amounted to 223,000 Euros[157].

III. Legal relationship between the RvA and the conformity assessment bodies

The RvA concludes a contract on accreditation based on private law with the bodies seeking accreditation. The contract stipulates the mutual rights and obligations. This holds regardless whether the accreditation is conducted for the regulatory or non-regulatory sphere[158]. General regulations on the legal relationship established by the contract are contained in the *Reglement voor Accreditatie (Regulation for Accreditation)*[159].

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152 See *RvA*, Regulation for Accreditation – RvA-R2 (Version 15.3.2002), Section 2 clause 1; the document is available at URL: http://www.rva.nl/pdfdoc/rva-r02ukregulationforaccreditation.pdf (24.6.2005).

153 For the year 2003 6,175,000 Euros, *RVA*, Jaarverslag 2003 (Fn.106), p. 17.

154 Art. 13 no. 1 of the Articles of Association of the RvA (Fn. 99); *RVA*, Jaarverslag 2003 (Fn. 106), p. 17. The amount of fees is stipulated in *RvA*, Tarieven – RvA-R05, available under http://www.rva.nl/pdfdoc/rva-r05nltarievenrva.pdf (3.7.2005).

155 *Overeenkomst* (Fn. 55), section 10 paragraph 2. This regulation is in conjunction with the exclusive status granted to the RvA in the regulatory sphere, *Overeenkomst* (Fn. 55), *Toelichting* under *kwaliteitsimpuls* (p. 13).

156 *Overeenkomst* (Fn. 55), Section 10 paragraph 3; more in *Overeenkomst* (Fn. 55), *Toelichting* under *Financiering RvA* (p. 11).

157 *RVA*, Jaarverslag 2003 (Fn. 106), p. 17; *RVA*, Jaarverslag 2004 (Fn. 104), p. 29. Currently there is a discussion whether the state should provide a one-time financial allocation to further improve the infrastructure of the RvA; *Overeenkomst* (Fn. 55), *Toelichting* under *Financiering RvA* (p. 11).

158 See *Overeenkomst* (Fn. 55), Section 2 paragraph 2, according to which the accreditation and assessment must always be conducted at the application and expense of the assessed body.

159 *RvA*, Reglement voor Accreditatie – RvA-R2 (Version 15.3.2002), available in Dutch at URL: http://www.rva.nl/pdfdoc/rva-r02nlreglementvooraccreditatie.pdf (24.6.2005), in English at URL: http://www.rva.nl/pdfdoc/rva-r02ukregulationforaccreditation.pdf (24.6.2005).

1. Requirements for accreditation

The RvA accredits bodies, which offer one of the following activities: testing, calibration, inspection, certification, verification, confirmations or the organization of proficiency testing[160]. As a rule, the RvA refers bodies based outside the Netherlands to the national accreditation body of their country of basis, in particular in those countries, whose accreditation bodies take part in a MRA[161].

For the requirements of the accreditation, Section 3.1 of the *Regulation for Accreditation* refers to the national, European, and international accreditation standards in their relevant version. According to Section 3.2., recognized interpretational guidelines are to be used to the greatest possible extent to interpret the standards; specific national interpretations are regarded as an obstacle for the concept of "one-stop"[162]. If the accreditation is conducted for the regulatory sphere, the assessment may call for additional criteria not included in the standards. These are based on the specific accreditation schemes drawn up for the area[163]. The standardized requirements to conformity assessment bodies prescribe that conformity assessment bodies must have a documented structure, which guarantees their impartiality. In the Netherlands, the *College van Deskundigen* and *Centrale College van Deskundigen* were developed to comply with this requirement. During the accreditation, the RvA examines whether the bodies have such a structure[164].

2. Accreditation procedure

The accreditation procedure begins with the registration of the body seeking accreditation. This is followed by a preliminary investigation, which is then followed by the actual assessment[165]. Besides the examination of the relevant documents, Section 4.3.1 of the *Regu-*

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160 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 3.4.1 paragraph 1.

161 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 3.4.2. More on the cross-frontier-policy of the RvA *RvA*, Detailing RvA's policy on cross-frontier accreditations, at URL: http://www.rva.nl/uk/rcrossfrpolicy.html (24.6.2005).

162 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 3.2 paragraph 1 at the end.

163 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 3.2 paragraph 2. More on the accreditation programs, directives and law-specific accreditation schemes for the regulatory sphere above under B.III.3.b).

164 *RvA*, De Beoordeling en Acceptatie van Centrale Colleges van Deskundigen – RvA-R13 (Fn. 90), Item 1 (p. 2).

165 Näher *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.

lation for Accreditation prescribes an examination of the operating site to determine how the quality management systems have been implemented, as well as witness audits, targeted interviews with the employees and the consultation of results from proficiency testing. The Accreditation Committee gives a recommendation on the basis of the final report of the accreditation team[166]. The Executive Director decides when the accreditation is issued. Without a positive recommendation of the Accreditation Committee, it can only issue an accreditation after the consent of the Board of directors of the RvA[167]. If the accreditation is issued, the RvA concludes an accreditation contract with the body and the body receives the accreditation certificate[168]. In the past the long duration of accreditation procedures posed difficulties in certain areas of accreditation. The agreement from 15 June 2005 between the RvA and the state includes performance indicators, whose observance is to lead to improvements in the services of the RvA. For instance, it stipulates deadlines, within which the RvA must process applications and arrange for a study on customer satisfaction, which is to be carried out every two years[169].

3. Monitoring the accredited bodies

The accreditation is valid for four years[170]. Within this timeframe, three assessments are conducted, which are less comprehensive than the tests conducted when the accreditation is first issued[171]. A re-assessment follows in the forth year[172]. Should the RvA detect any significant or numerous non-conformities in the course of the assessments, it may conduct additional inspections – even without advance notice[173]. Additional tests can also be carried out due to complaints or other information, e.g. instructions from state authorities[174]. The bodies are committed to allow the RvA to conduct the inspections and notify it of

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166 Art. 13 no. 1 of the Articles of Association of the RvA (Fn. 99), *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.3.5. Number 2.

167 Art. 11 no. 5 of the Articles of Association of the RvA (Fn. 99), *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.3.5. Number 3.

168 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.5.

169 *Overeenkomst* (Fn. 55), Section 7, in particular paragraphs 1 through 3, 5, 5.

170 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.4.2 clause 1.

171 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.4.1 paragraph 1.

172 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.4.2 clause 2.

173 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.4.3. paragraphs 1 and 2.

174 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 4.4.3 paragraph 3.

relevant changes[175]. Section 6 of the *Regulation for Accreditation* contains provisions on the suspension of the accreditation and Section 7 provisions on the revocation of the certificate. Suspensions and revocations are reported on the homepage of the RvA[176].

4. Legal protection options of the accredited bodies

The procedural rules of the RvA provide for several ways of settling disputes. The agreement with the state obligates the RvA to observe certain minimal requirements during the complaints procedure such as a contradictory procedure, which ends with a substantiated written decision, as well as the specification of appeal options[177].

a) Internal procedures for the settlement of disputes

According to the accreditation rules of the RvA, there are internal procedures for the settlement of disputes concerning, on the one hand, the interpretation of the requirements of a standard and, on the other hand, the procedure of the RvA; the head of the accreditation department makes a decision on this after having heard the parties and, where applicable, experts[178]. The quality manager of the RvA makes the decision in the case of complaints on the conduct of the RvA and its assessors[179]. The accredited bodies can also initiate a formal complaint procedure against decisions of the RvA[180]. This constitutes a contradictory procedure, in which written opinions are exchanged, followed by an oral hearing[181]. The *College van Beroep* (*Board of Appeal)*, which has been established within the RvA, makes the decision on the complaint[182]. It consists of three independent members, which

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175 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 5.1, in particular 5.1.2 and 5.1.4.

176 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Sections 6.4, 7.4. A list of the revoked certificates is available at URL: http://www.rva.nl/uk/rintrekuk.html (24.6.2005), a list of the suspended certificates at http://www.rva.nl/uk/rschorsuk.html (22.6.2005).

177 *Overeenkomst* (Fn. 55), Section 7 paragraph 8. The following statements pertain to the procedure applicable on 1.7.2005.

178 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 8.1.

179 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 8.2.

180 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 8.3. The complaints procedure is regulated in greater detail in *RvA*, Regulation for Appeal – RvA R4 - Summary, available at URL: http://www.rva.nl/pdfdoc/rva-r04ukregulationforappealsummary.pdf (24.6.2005); complete version of the document in Dutch at URL: http://www.rva.nl/pdfdoc/rva-r04nlreglementvanberoep.pdf (24.6.2005).

181 *RvA*, Regulation for Appeal – RvA R4 (Fn. 180), Section 5.

182 Art. 10 no. 1 of the Articles of Association of the RvA (Fn. 99).

are appointed by the supervisory board at the proposal of the board of directors[183]. The body filing the complaint has a right to be consulted during the selection of the members[184].

b) Legal defence and recovery

As the legal relationship between the RvA and the accredited bodies is based on private law, legal action can be taken in the civil courts in the case of disputes.

c) Mediation procedures between accredited bodies and third parties

The RvA also conducts mediation procedures. Mediation is offered when accredited bodies dispute with third-parties, e.g. their clients, matters related to the confirmations provided by the RvA to the accredited body[185].

E. The role of market surveillance in relation to conformity assessment

I. Organization of market surveillance

In the Netherlands, market surveillance is carried out by the authorities responsible for the respective sectors. This responsibility is based on the area-specific laws[186]. The powers of the market surveillance authorities are generally regulated in the General Law on Administrative Law (*Algemene Wet Bestuursrecht - AWB*)[187]. The embodied information and access rights etc. can be supplemented by the area-specific laws. Responsibilities for market surveillance are currently divided into approximately nine different inspection services. The inspection services are subordinate to different ministries and are financed by their budget.

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183 Art. 10 no. 2 of the Articles of Association of the RvA (Fn. 99).

184 *RvA*, Regulation for Appeal – RvA R4 (Fn. 180), Section 4.

185 *RvA*, Regulation for Accreditation – RvA-R2 (Fn. 159), Section 8.3; more on the mediation procedure *RvA*, Regulation for Mediation – RvA-R11, available at URL: http://www.rva.nl/pdfdoc/rva-r11ukregulationformediation.pdf (24.6.2005).

186 For example, the law on medical devices stipulates the responsibilities for surveillance, see Art. 11 Wet op medische hulpmiddeleln, Wet van 15 januari 1970, houdende regelingen met betrekking tot medische hulpmiddelen, the law is available online at URL: http://wetten.overheid.nl/ (22.7.05).

187 Section 5.2 AWB.

II. Cooperation with conformity assessment bodies

Due to scarce financial resources, increased cooperation with market participants or conformity assessment bodies appears to be desirable in the Netherlands. One possibility of supporting market surveillance by means of conformity assessment bodies is passing on information to the monitoring authorities. The regulations on conformity assessment sometimes grant the ministries the possibility to link the decision on the approval or designation of bodies with certain conditions. For example, these might entail that the conformity assessment bodies inform the responsible ministry and other conformity assessment bodies on the revocation or the denial of certifications while specifying the reasons[188]. In the cabinet's position, the government assumes that the conformity assessment can play a supportive role during oversight or market surveillance. However, there must be clarity among the certification bodies, the RvA, the certified firms, and the monitoring authorities with regard to their respective responsibilities. Certification is by principle a service which is provided on the basis of a private law contract. On the other hand, the oversight or market surveillance provided exclusively by the state is based on a hierarchical relationship[189]. It is emphasized that information obligations of the conformity assessment bodies towards the state should basically be restricted to essential items, such as the issue, limitation, or the revocation of certificates, in order to avoid unnecessary bureaucracy. In individual cases they allegedly can make use of the possibility to request further information. According to the cabinet's position, the authorities also may pass on information to the conformity assessment bodies, as long as this is permissible in view of the rights of the certified firms[190]. The integration of conformity assessment bodies into oversight activities is also viewed critically, though. Due to the relationship with its clients generally based on private law, the conformity assessment bodies can encounter tensions between the service relationship on the one hand and conformity assessment as a public responsibility as well as integration into market oversight, on the other hand. This can also have disadvantageous effects[191].

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188 See e.g. the decision to approve Kiwa (Fn. 69), Article 3 Letter c clause 3.
189 See Cabinet's position 2003 (Fn. 6), p. 17.
190 Cabinet's position 2003 (Fn. 6), p. 18.
191 A critical view in *Eijlander/Evers/van Gestel*, Certificatie en accreditatie, p. 45 et seq.

Third Section: Conformity Assessment in Austria

After an initial overview of legal regulations on accreditation, the use of conformity assessment in the regulatory sphere shall be further examined on the basis of selected legal provisions; particular focus will be placed on the involvement of accreditation. Furthermore, the organization and status of the accreditation body of the Federal Ministry for Economic Affairs (BMWA) will be described, followed by several remarks on the activities of the conformity assessment bodies. The section concludes with a short outlook on the organization of market surveillance.

A. Overview of legal regulations on accreditation

Like Sweden and Switzerland, Austria has a horizontal legal regulation on accreditation, the Accreditation Law (Akkreditierungsgesetz/AkkG). In view of the state authorization of private enterprises as inspection bodies, this regulation can fall back on a long tradition.

I. Regulatory content of the Accreditation Law

As a horizontal provision the Accreditation Law (AkkG)[1] regulates the accreditation of inspection, surveillance and certification bodies[2]. It essentially specifies the requirements of accreditation with regard to personnel, the configuration and organization of the body, the duties while conducting the activities, the official surveillance of the bodies, the revocation resp. the expiration of the accreditation as well as the recognition of foreign inspection and surveillance reports and certificates. The Accreditation Law applies to those areas

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1 Federal Law on the Accreditation of Inspection, Surveillance and Certification Bodies (Bundesgesetz über die Akkreditierung von Prüf-, Überwachungs- und Zertifizierungsstellen), with which the Trade and Industry Laws/Gewerbeordnung 1973, Federal Law Gazette (Bundesgesetzblatt) No. 50/1974, the Boiler Law/Kesselgesetz, Federal Law Gazette (Bundesgesetzblatt) No. 211/1992, and the Measurement and Calibration Law/Maß- und Eichgesetz, Federal Law Gazette (Bundesgesetzblatt) No. 152/1950 last amended by Federal Law Gazette (Bundesgesetzblatt) No. 213/1992, is modified (Acceditation Law - AkkG), last modified in Federal Law Gazette (Bundesgesetzblatt) I No. 85/2002.

2 § 1 paragraph 1 AkkG.

in which the federal government is responsible for the legislation and its execution[3]. It is complemented by three decrees dealing with the use of the accreditation label, the insurance requrements for the bodies and the fees to be charged for accreditation[4]. According to the Accreditation Law, the Federal Minister for Economic Affairs (BMWA) is the responsible accreditation body[5].

II. Development of the legal rules on accreditation

At a very early period in time Austria had a procedure for authorizing private firms as inspection bodies. The foundations for this were provided by the law from 9 September 1910 concerning the technical examination, proving and materials testing system, the so-called Lex Exner[6], which was in force until the restructuring by the Accreditation Law in 1992. According to § 1 of the Lex Exner, independent technical testing and materials testing institutes could be granted the right to issue certificates on the result of their examinations, which were to be viewed as public records. According to § 1 para. 2 this right could also be granted to non-state agencies, provided they demonstrate their professional aptitude and

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3 § 1 para. 2 clause 1 AkkG. With regard to construction products, the states (Laender) – together with the federal government – claim the authority for the accreditation of the bodies. They recognize among each other the certificates of accredited bodies as well as the certificates of accredited bodies from other Member States of the EU. However, the accreditation by the Federal Ministry for Economic Affairs according to the Accreditation Law is only recognized by some of the federal states, so that double accreditations are sometimes necessary. In more detail see *Brigitte Gutknecht*, Kompetenzrechtliche Grundlagen für die Umsetzung der Bauproduktenrichtlinie, 2001; the advisory opinion by order of the Federal Ministry for Economic Affairs is available online at: http://www.bmwa.gv.at/NR/rdonlyres/DFC521AB-2ADD-4236-9ED4-BBE790B1748D/1220/Gutachten_endg_BauprodRLGA.doc (18.8.2005).

4 Decree of the Federal Minister for Economic Matters on the administrative tasks for the official acts to be carried out according to the Accreditation Law (Accreditation Fees Decree/ Akkreditierungsgebührenverordnung - AkkGebV), Federal Law Gazette (Bundesgesetzblatt) No. 70/1994, last modified by Federal Law Gazette (Bundesgesetzblatt) II No. 490/2001; Decree by the Federal Minister for Economic Matters on the flat rate amount covered by insurance carriers of accredited bodies (Accreditation Insurance Decree/Akkreditierungsversicherungsverordnung - AkkVV), Federal Law Gazette (Bundesgesetzblatt) II No. 13/1997, modified in Federal Law Gazette (Bundesgesetzblatt) II No. 490/2001; Decree of the Federal Minister for Economic Affairs on the Definition of Marks (Logos) for accredited inspection, surveillance, and certification bodies (Accreditation Marks Decree / Akkreditierungszeichenverordnung - AkkZV), Federal Law Gazette (Bundesgesetzblatt) II No. 186/1997.

5 § 8 AkkG; the department I/12 is responsible in the Federal Ministry for Economic Affairs; contact and consultants under URL: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1700_akk_ansprech.htm (17.8.2005).

6 Gesetz vom 9. September 1910, betreffend das technische Untersuchungs-, Erprobungs- und Materialprüfungssystem Government Law Gazette/Regierungsgesetzblatt No. 185/1910. The law is named after its author Wilhelm Franz Exner (1840-1931). Five paragraphs, which comprised approximately one printed page, were sufficient.

the existence of the necessary facilities. The Federal Minister for Economic Affairs was responsible for the execution of the Lex Exner.

The restructuring of the conformity assessment system in the Accreditation Law of 1992 was motivated by the coming into force of the Tampere Convention on the Mutual Recognition of Inspection Certificates and Proof of Conformity within the framework of the EFTA[7] and the accession negotiations with the EC. The authorization procedure of the Lex Exner for inspection bodies had to be adapted to the there stipulated procedures. The Accreditation Law created criteria for the accreditation of surveillance and certification bodies, for which there was no legal regulation up to then[8].

B. The use of conformity assessment in the regulatory sphere

Together with the area-specific laws, the Accreditation Law regulates the requirements for conformity assessment bodies during official procedures to evaluate the competence of inspection, surveillance and certification bodies – the means and manner by which the accreditation by the accreditation body of the Federal Ministry for Economic Affairs (BMWA) is incorporated in these evaluation procedures varies.

I. Interplay between the Accreditation Law and area-specific laws

1. Requirements of the Accreditation Law

The Accreditation Law (AkkG) defines the requirements for accreditation with regard to personnel, equipment, and the organization of the body, the duties when carrying out the activities, the official surveillance of the bodies, the withdrawal or expiration of the accreditation as well as the recognition of foreign inspection and surveillance reports and/or

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7 Agreement on the mutual recognition of inspection certificates and proof of conformity with appendixes and report on the application of the agreement on the mutual recognition of inspection certifications and proof of conformity on the Principality of Liechtenstein, Federal Law Gazette (Bundesgesetzblatt) No. 593/1990. The Tampere Convention required the Republic of Austria to designate inspection bodies to be inspected in accordance with the then applicable ISO-Directives 25 and 38 (later replaced by EN 45001 and 45002).

8 Government bill on the Accreditation Law, quoted according to *Österreichisches Normungsinstitut (ON)*, Akkreditierungsgesetz, 1992, p. 13, p. 14.

certificates. The bill on the Accreditation Law as well as the applicable version of the law themselves contain no specific reference to the international and European standards on the accreditation of conformity assessment bodies. The bill on the Accreditation Law, however, was oriented towards the standards existing at the time of origin and defines the requirements on the basis of these[9]. The relevance of the accreditation standards of the series ISO 17000 et seqq. for the accreditation according to the Accreditation Law results from the basic guidelines issued by the accreditation body of the BMWA[10].

2. Regulations in the area-specific laws

The Accreditation Law applies in subsidiary manner in relation to the area-specific regulations, i.e. corresponding rules on the competence evaluation of testing, surveillance and certification bodies in area-specific laws have priority over the Accreditation Law[11]. The manner and means by which the Accreditation Law is referred to in the area-specific laws varies. This shall be illustrated on the example of rules from the law governing trade and industry, the boiler law as well as the Medical Devices Law:

a) Law governing trade and industry (Gewerbeordnung)

With regard to the products which fall under the laws governing trade and industry (*Gewerbeordnung*), e.g. machines or lifts, an official decision is taken on the authorization and/or notification of bodies for inspections provided for by law[12]. A requirement for this authorization or notification is – among other things – that the body has been accredited by

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9 In the statements on the government bill it is emphasized that the law is based on the ISO-Directives and the standards of the series EN 45000, Government bill on the Accreditation Law / Regierungsvorlage zum Akkreditierungsgesetz, quoted according to *Österreichisches Normungsinstitut (ON)*, Akkreditierungsgesetz, 1992, p. 15.

10 More under B.III.2.

11 § 1 para. 2 AkkG.

12 Regulations on the conformity assessment procedure designated as a "coordination procedure" for machines are contained, for example, in Section II of the Machine Safety Decree (Decree of the Federal Minister for Economic Affairs on the Marketing and Supply of Machines and on the Basic Safety Requirements for Machines - Machine Safety Decree/Maschinen - Sicherheitsverordnung, MSV), StF: Federal Law Gazette (Bundesgesetzblatt) No. 306/1994, last modified in Federal Law Gazette (Bundesgesetzblatt) II No. 62/2006 (Revision in process). § 5 para. 5 MSV contains the regulations on the conformity assumption and the reference to the harmonized standards, which provided the basis of the assumption of compliance with the Basic Safety Requirements.

the BMWA[13]. Various decrees have been issued on the basis of the law governing trade and industry (*Gewerbeordnung*), which further specify its stipulations. For example, the machine safety decree (Maschinen-Sicherheitsverordnung/MSV)[14] specifies the minimum criteria for accredited bodies in its Section IV. The regulations concern, above all, the impartiality and independence of the bodies and/or their personnel and their technical expertise as well as insurance obligations. The lifts safety decree (Aufzüge-Sicherheitsverordnung/ASV) is written in a similar manner[15].

b) Medical Devices Law

The Medical Devices Law (Medizinproduktegesetz/MPG) also provides for the use of Notified Bodies during conformity assessment procedures for the implementation of the corresponding directives[16]. The Federal Minister for Health and Consumer Protection is responsible for the notification of the bodies according to § 36 para. of the 2 MPG. According to § 36 para. 2 of the MPG, the prerequisite for notification is that the body was accredited by the BMWA in accordance with the Accreditation Law for the related area of responsibilities, whereas "it must be taken into account that the criteria of § 37 have been fulfilled"[17]. According to § 69 of the MPG the bodies are subject to surveillance; if accredited bodies are concerned, this is carried out by the Federal Minister for Health and Con-

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13 § 71 para. 5 clause 1 GewO stipulates that, in accordance with the Accreditation Law, appropriate accredited bodies are to be authorized by the Federal Minister for Economic Affairs for the inspection whether the machines, devices, equipment, etc. meet requirements defined by decree.

14 Decree of the Federal Minister for Economic Affairs on the Marketing and Supply of Machines and on the Basic Safety Requirements for Machines (Machine Safety Decree/Maschinen- Sicherheitsverordnung, MSV), StF: Federal Law Gazette (Bundesgesetzblatt) No. 306/1994, last modified in Federal Law Gazette (Bundesgesetzblatt) II No. 62/2006 (Revision in process).

15 Decree of the Federal Minister for Economic Affairs and the Federal Minister for Labour and Social Affairs on the Safety of Lifts/Verordnung des Bundesministers für wirtschaftliche Angelegenheiten und des Bundesministers für Arbeit und Soziales über die Sicherheit von Aufzügen (Lifts Safety Decree / Aufzüge-Sicherheitsverordnung 1996 - ASV 1996), StF: Federal Law Gazette (Bundesgesetzblatt) No. 780/1996, last modified in Federal Law Gazette (Bundesgesetzblatt) II No. 464/2005 (Revision in process).

16 See § 27 in conjunction with § 28 MPG – Federal Law concerning Medical Devices/Bundesgesetz betreffend Medizinprodukte (Medical Devices Law/Medizinproduktegesetz - MPG), StF: Federal Law Gazette (Bundesgesetzblatt) No. 657/1996, last modified in Federal Law Gazette (Bundesgesetzblatt) I No. 153/2005.

17 § 37 MPG defines once again the minimum criteria for notified bodies, which concern the impartiality and independence of the bodies and/or their personnel, its technical expertise, subcontracting, as well as insurance requirements.

sumer Protection in understanding with the Federal Minister for Economic Affairs within the framework of § 13 AkkG[18].

c) Regulations on pressure equipment

With regard to pressure equipment in the boiler law (Kesselgesetz)[19] an "issue of authority" already exists at the national level for the legally stipulated inspections; these "authorized" bodies can be notified within the scope of the pressure equipment directive. The boiler law prescribes certain tests, recurring examinations and inspections for pressure equipment[20]. These are conducted by so-called initial testing bodies (*Erstprüfstellen*) and boiler inspection bodies (*Kesselprüfstellen*) as well as user inspectorates (*Werksprüfstellen*). On request, the BMWA issues the bodies the authorization to carry out the activities of an initial testing body and/or boiler inspection body[21]. The boiler law stipulates the requirements which the initial testing bodies and/or boiler inspection bodies must meet[22]. According to § 25 a para. 5 of the boiler law, the Sections II to VI of the Accreditation Law must additionally be applied to initial and boiler inspection bodies, as long as the boiler law does not contain any special regulations, therefore the provisions on the accreditation procedure, certification bodies, accreditation requirements and obligations of the bodies and the end of accreditation may apply. According to § 20 para. 5, initial testing bodies can be designated to participate in international inspection agreements if the scope of their authorization issued by the Federal Ministry for Economic Affairs covers the scope of the inspection according to the international agreement; the Federal Ministry for Economic Affairs is also responsible for this designation[23]. The recognition of foreign testing bodies is governed by § 24 of the boiler law.

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18 § 69 para. 2 MPG.

19 Federal Law on Safety Measures for Boilers, Pressure Equipment, Shipping Containers and Pipelines/Bundesgesetz über Sicherheitsmaßnahmen für Dampfkessel, Druckbehälter, Versandbehälter und Rohrleitungen (Kesselgesetz), StF: Federal Law Gazette (Bundesgesetzblatt) No. 211/1992, last modified in Federal Law Gazette (Bundesgesetzblatt) I No. 84/2003.

20 § 11 et seqq. Boiler Law.

21 §§ 20 para. 4, 21 para. 4 Boiler Law.

22 §§ 20 para. 1 to 3 and 22 para. 1 to 3 Boiler Law.

23 This regulation facilitates, in particular, the designation of initial inspection bodies as inspection bodies within the scope of the pressure equipment directive and the directive on transportable pressure equipment.

In summary, the previous section has shown that the legal provisions require the accreditation of the bodies (law governing trade and industry, Medical Devices Law) or at least an inspection comparable to the accreditation according to AkkG (regulations of the boiler law). At the same time, the provisions frequently contain their own regulations on the requirements for conformity assessment bodies. It is not always conclusively recognizable whether these requirements go beyond those of the Accreditation Law or the relevant European directive.

II. Accreditation according to the Accreditation Law

The Accreditation Law defines the requirements and the procedure of accreditation as well as the surveillance of the bodies by the accreditation body of the Federal Ministry of Economic Affairs. The following statements equally apply to the non-regulatory sphere, because the accreditation body of the Federal Ministry of Economic Affairs is responsible for both areas and applies the same rules.

1. Distinction between inspection and surveillance bodies and certification bodies

The Accreditation Law is marked by a distinction between inspection and surveillance bodies, on the one hand, and certification bodies on the other hand, which is relevant for various provisions of the law. For example, the inspection reports from the inspection and surveillance bodies are regarded as public records as was already the case with the Lex Exner[24]. Inspection and surveillance bodies are accredited on the basis of a decision (Entscheid), while certification bodies are accredited by decree (*Verordnung*)[25]. The reason for this distinction is that it was assumed upon the enactment of the law that the number of certification bodies in a certain area should be limited. The declarations on the government bill state that it was international practice to only permit and notify a restricted number of certification bodies in (product-) specific areas[26]. In order to assure this, arrangements were made for the certification bodies to be accredited by decree, to which the body is not auto-

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24 On the Lex Exner s.o. A.II.

25 §§ 9 para. 1, 17 para. 1 AkkG..

26 Government bill on the Accreditation Law / Regierungsvorlage zum Akkreditierungsgesetz, quoted according to *Österreichisches Normungsinstitut (ON)*, Akkreditierungsgesetz, commentary on § 17, p. 39.

matically entitled[27]. However, as far as can be seen, the possibility of limiting the number of certification bodies has yet to be used. Nevertheless, the Accreditation Law still shows the difference between inspection and surveillance bodies, on the one hand, and certification bodies, on the other hand.

2. Requirements for accreditation

The requirements for accreditation are based on the Accreditation Law and the more concrete guidelines of the accreditation body.

According to § 11 para. 1 and § 17 para. 2 of the AkkG, the bodies must fulfil the requirements of §§ 18 to 21 of the AkkG, which concern the independence of the body, the qualification of the personnel, the premises and facilities as well as the quality management system. For the sake of specificity, the Guidelines for the Accreditation Application of an Inspection and Surveillance Body (L 05)[28] refer to the pertinent international standards as a basis of the accreditation. For certification bodies, § 17 para. 2 of the AkkG standardizes additional requirements which are drawn from international standards and which concern, for example, the recognizibility of the certificates, the organizational structure of the body or its internal complaint procedure. The Guidelines on the Accreditation of Certification Bodies draw on the respective guidelines of the IAF/EA on the relevant standards[29].

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27 § 17 para. 1, 5 AkkG; Government bill on the Accreditation Law / Regierungsvorlage zum Akkreditierungsgesetz, quoted according to *Österreichisches Normungsinstitut (ON)*, Akkreditierungsgesetz, commentary on § 17, p. 39.

28 Federal Ministry for Economic Affairs, Guidelines for Accreditation Application for an Inspection and Surveillance Body / Leitfaden für den Akkreditierungsantrag einer Prüf- und Überwachungsstelle (L 05), Version 09/05, available online at: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1900_akk_news.htm (18.8.2005).

29 Federal Ministry for Economic Affairs, General Requirements for Bodies which operate Product Certification Systems/Allgemeine Anforderungen an Stellen, die Produktzertifizierungssysteme betreiben (L 07), Version 02/2004; General Requirements for Bodies which evaluate and certify Quality Management Systems/Allgemeine Anforderungen an Stellen, die Qualitätsmanagementsysteme begutachten und zertifizieren (L 08), Version 07/2005; Guidelines for the Accreditation of Bodies which certify Persons/Leitfaden für die Akkreditierung von Stellen, die Personen zertifizieren (L 09), Version 04/2004; the documents are available online at: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1900_akk_news.htm (18.8.2005).

3. Procedure

According to § 11 para. 1 of the AkkG, inspection and surveillance bodies are accredited by decision, while certification bodies are accredited by decree according to § 17 para. 2 of the AkkG[30]. In accordance with § 17 para. 5 of the AkkG certification bodies are not automatically entitled to the issue of such a decree. However, in practice this limitation has yet to take effect; all applying certification bodies were accredited upon fulfilment of the requirements.

The bodies are evaluated by the external assessors contracted by the accreditation body. The accreditation board (Akkreditierungsbeirat) discusses their report. The applicants may fall back on the legal remedies of the administrative procedure law to dispute the ultimate decision of the accreditation body. After the accreditation occurs, the bodies are authorized by § 4 AkkG to bear the federal seal and the respective accreditation sign of the Federal Ministry for Economic Affairs which corresponds with the type of body.

If the conformity assessment bodies are active across borders, the Federal Ministry for Economic Affairs creates an evaluation program, which is supposed to guarantee the surveillance of the local business branches abroad. Their surveillance is performed by the Federal Ministry for Economic Affairs or the local accreditation body if it has signed the IAF-MLA[31].

4. Surveillance of the conformity assessment bodies

According to § 13 of the AkkG conformity assessment bodies are subject to surveillance by the accreditation body. According to § 13 para. 2 of the AkkG an inspection is possible at any time when there are important reasons for doing so. § 13 para. 3 of the AkkG governs the authorities granted to the accreditation body for the purpose of inspection. The

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30 For the background of this distinction, see above B.II.1.

31 Federal Ministry for Economic Affairs, Guidelines on Measures in the case of cross-border accreditation and certification/Leitfaden über Maßnahmen bei grenzüberschreitender Akkreditierung und Zertifizierung (L 09), Version 01/2005, available online at: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1900_akk_news.htm (18.8.2005).

intervals for the period of inspection of the bodies and the re-accreditation are based on § 13 AkkG and Point 7 of the Guidelines L 05 (inspection and surveillance bodies) as well as Part C Point 7 of the Guidelines L07, L08, L09 (certification bodies)[32]. The resulting surveillance cycles are presented in an overview[33]. Inspection and surveillance bodies are additionally obligated to present an activity report every year[34].

C. The status of the accreditation body

Austria has opted to have the accreditation in the regulatory and non-regulatory sphere carried out by an accreditation body based within the Federal Ministry for Economic Affairs[35].

I. Tasks

The accreditation body of the Federal Ministry for Economic Affairs issues accreditations both for the regulatory as well as the non-regulatory sphere. A large share of the accreditations is requested for the non-regulatory sphere, in particular with regard to the certification bodies. The accreditation body of the Federal Ministry for Economic Affairs has accredited approximately 160 inspection and surveillance bodies as well as 42 certification bodies[36]. It participates in the international exchange of experiences[37] and the Federal Min-

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32 Federal Ministry for Economic Affairs, Guidelines for the Accreditation Application of an Inspection and Surveillance Body/Leitfaden für den Akkreditierungsantrag einer Prüf- und Überwachungsstelle (L 05), Version 09/05, available online at: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1900_akk_news.htm (18.8.2005), for the sources of the remaining guidelines, see Fn. 29.

33 Available at URL: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1150_pue.htm (18.8.2005).

34 Guideline/Leitfaden L 05 (Fn. 28), Item, 5.10.2; on the contents Federal Ministry for Economic Affairs, Guidelines for Writing Activity Reports on Accredited Inspection Bodies / Leitfaden für die Abfassung von Tätigkeitsberichten akkreditierter Prüfstellen (L 03), Version 3/2004, available online at: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1900_akk_news.htm (18.8.2005).

35 See on this the statements on the government bill on the Accreditation Law, quoted according to *Österreichisches Normungsinstitut (ON)*, Akkreditierungsgesetz, p. 15.

36 Last updated 22.8.2005 on the basis of the lists of the Federal Ministry for Economic Affairs, available at URL: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1800_akk_liste.htm (1.9.2005).

istry for Economic Affairs is a signatory of the various international agreements within the framework of EA, ILAC and IAF. The accreditation body of the Federal Ministry for Economic Affairs is not permitted to conduct accreditations outside Austria[38].

II. National, state accreditation body

Besides the accreditation body of the Federal Ministry for Economic Affairs there are no other accreditation bodies, except for the Austrian Institute for Construction Technology (Österreichisches Institut für Bautechnik/OIB), which carries out accreditations for inspection, surveillance and certification bodies for construction products on the basis of state (*Laender*) law[39]. One cited advantage of a state accreditation body is that it is better able to guarantee its independence than a private body because it does not rely on fees for the accreditation procedures to cover its expenses. The bodies to be accredited also purportedly regard the state support of the accreditation as an advantage. As for a single accreditation body for the regulatory and non-regulatory sphere, it is alleged that the national market could not sustain a second accreditation body and that the same group of people would have to be consulted as assessors anyway[40].

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37 § 12 para. 2 AkkG.

38 Federal Ministry for Economic Affairs, Guidelines on measures in the case of cross-border accreditation and certification (L 19), Version 01/2005, Item 1; the document is available online at: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1900_akk_news.htm (18.8.2005).

39 With regard to construction products the federal government and states (Laender) claim the authority for the accreditation of the bodies. The states mutually recognize the certifications of accredited bodies as well as the certifications of accredited bodies from other Member States of the EU. However, the accreditation by the Federal Ministry for Economic Affairs according to the Accreditation Law is only recognized by some of the federal states, so that double accreditations are sometimes necessary. In more detail, see *Brigitte Gutknecht*, Kompetenzrechtliche Grundlagen für die Umsetzung der Bauproduktenrichtlinie, 2001; the expert opinion by order of the Federal Ministry for Economic Affairs is available online at: http://www.bmwa.gv.at/NR/rdonlyres/DFC521AB-2ADD-4236-9ED4-BBE790B1748D/1220/Gutachten_endg_BauprodRLGA.doc (18.8.2005).

40 For mandating experts by the accreditation body of the Federal Ministry for Economic Affairs, see under B.II.3.

III. Organization of the accreditation body

1. Accreditation Advisory Board

The accreditation advisory board (*Akkreditierungsbeirat*) is supposed to ensure the coordination of the interests of the federal ministries involved in the accreditation procedure and other entities in the accreditation procedure. It advises the accreditation body during the individual accreditation procedures. An extended accreditation council (*erweiterter Akkreditierungsbeirat*) was established for consultation on strategic manners in conjunction with the accreditation[41].

2. Assessors

The accreditation body mandates external assessors for conducting the assessment of the bodies on site[42]. The accreditation body has recorded the requirements for the assessors in guidelines on the qualification of experts and additional guidelines on their activities[43]. Austria, Germany and Switzerland mutually recognize the qualification of experts within the framework of D-A-CH cooperation[44].

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41 Federal Ministry for Economic Affairs at URL: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1300_akk_beirat.htm (18.8.2005).

42 See Art. 10 para. 1 AkkG.

43 Federal Ministry for Economic Affairs, Guidelines for the Qualification of Experts during the Accreditation Procedure/Leitfaden für die Qualifikation von Sachverständigen im Rahmen von Akkreditierungsverfahren (L 01), Version 02/2004; Guidelines for the Activities of Experts during the Assessment of Inspection, Surveillance and Certification Bodies/Leitfaden für die Tätigkeit von Sachverständigen bei der Begutachtung von Prüf-, Überwachungs- und Zertifizierungsstellen (L 02) Version 04/2005, the documents are available online at: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1900_akk_news.htm (18.8.2005). As far as can be see, the decree authorization in Art. 10 para. 3 AkkG has yet to be used up to now.

44 More on DACH-Cooperation BMWA at URL: http://www.bmwa.gv.at/BMWA/Themen/Unternehmen/TechnikAkkreditierung/Akkreditierung/1500_akk_international.htm (18.8.2005) under the keyword DACH-Cooperation.

D. The activities of the conformity assessment bodies

I. Legal relationship between the conformity assessment bodies and their clients

The activities of the conformity assessment bodies are based on a private law contract with their clients, but are influenced in the regulatory sphere by various provisions which reinforce the legal status of the clients vis-à-vis the bodies on individual items.

The private law treaty contains the authorization of the conformity assessment bodies to carry out surveillance measures and suspend, revoke, etc. certificates and attestations if the requirements are not complied with. These authorizations are in part also provided for by law, though. For example, § 29 para. 3 MPG contains information rights of the Notified Bodies vis-à-vis their contracting entity. § 37 para. 10 MPG stipulates that a body suspends or revokes the certificate or imposes limitations on its owner when it determines that the relevant requirements are not met. In § 37 para. 10 MPG the Notified Bodies are obligated to comply with the principles of proportionality [45].

Due to the function of the conformity assessment bodies in the regulatory sphere, the legal relationship is also influenced by special provisions in other aspects: for instance, some laws restate the limitation of the period of validity of certificates already stipulated by the standards[46]. Moreover, the conformity assessment bodies are obligated to pass on information on the issue, suspension or the revocation of certificates to the responsible authorities and in part also to other conformity assessment bodies[47]. As for the notice to other bodies, the Accreditation Law contains in § 5 para. 3 an exception from the otherwise applicable

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45 § 37 para. 10 clause 1 MPG.

46 § 7 para. 1 clause 1 Decree of the Federal Ministry for Health and Women on the Conformity Assessment of Medical Devices/Verordnung der Bundesministerin für Gesundheit und Frauen über die Konformitätsbewertung von Medizinprodukten, StF: Bundesgesetzblatt / Federal Law Gazette. II No. 57/2004.

47 According to § 10 MSV the Notified Body along with the applicant must inform the ministry about the rejection of, withdrawal of or addition to a construction prototype certificate, and other authorized bodies upon its request. According to § 37 para. 9 MPG the Notified Body instructs the ministry on all suspended or revoked certificates, on request on issued or refused certificates as well; see para. 10 on the notification of the outcome of later surveillance measures. According to § 15 para. 1 ASV all decisions which limit the marketability of a lift are to be reported to the Federal Ministry of Economic Affairs and the other authorized inspection bodies; the application requirement is even inapplicable when notifying other inspection bodies.

obligation to maintain secrecy, which should facilitate cooperation between the accreditation bodies in this regard[48]. The bodies are sometimes required to offer justification for negative decisions on the issue of a certificate, etc.[49]. This justification obligation can be seen in relation to the fact that the accredited bodies are subject to surveillance by the responsible ministry when conducting their activities[50]. The laws governing trade and industry and the decrees issued on the basis of them stipulate that the clients of the conformity assessment bodies may file a surveillance complaint (*Aufsichtsbeschwerde*) against decisions of the bodies to the ministry[51]. According to the boiler law, initial and boiler inspection bodies must process applications from their clients within a certain period of time[52]. The boiler inspectors appointed for recurring inspections of pressure equipment carry an official boiler inspection identification card (*amtlicher Kesselprüferausweis*)[53]. In conclusion, it should also be pointed out that according to § 2 para. 2 of the AkkG the inspection reports of accredited inspection and surveillance bodies are public records, as was already the case with the Lex Exner[54].

The close incorporation of accredited conformity assessment bodies into state measures to guarantee product safety is also apparent in the new product safety law 2004[55]. According to § 5 para. 5 Clause 1 PSG 2004, it suffices for a product to be evaluated as dangerous when one domestic or foreign accredited inspection, surveillance and certification body has ascertained security deficits on the product. Official measures according to the PSG 2004 can immediately follow the categorization of a product as dangerous: for example, the determination of a danger emanating from the product by an expert opinion from an accred-

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48 Statements on the government bill on the Accreditation Law, EB on § 5, quoted on the basis of *Österreichisches Normungsinstitut (ON)*, Akkreditierungsgesetz, p. 15.

49 See e.g. § 10 para. 5 MSV, § 15 ASV.

50 See e.g. § 69 MPG, § 71 para. 5 clause 6 GewO, § 20 para. 4 DGVO, §§ 5 para. 7, 6 para. 7 ODGVO.

51 § 71 para. 5 clause 7 GewO, § 15 para. 2 ASV, § 10 para. 6 MSV, here upon the stipulation of a time period of 14 days. A surveillance complaint is a legal remedy, which aims to compel the surveillance authority to make use of its right to oversight. However, they are not automatically entitled to intervene and have no objective obligation to make substantial decisions; from *Walter/Mayer*, Grundriß des Österreichischen Verwaltungsverfahrensrechts, Margin no. 494.

52 §§ 20 para. IV, 23 para. 2 Boiler Law.

53 § 21 para. 4 no. 3 Boiler Law.

54 This is primarily associated with a shifting of the burden of proof in the proceedings. The provision does not hold for certificates from accredited certification bodies.

55 More on the PSG 2004 under E.

ited inspection body suffices for preliminary measures, according to § 15 para. 1 no. 1 PSG, among others.

II. Cooperation between the conformity assessment bodies at the national and international level

In Austria authorized and accredited testing centres and inspection, surveillance, notification, calibration and certification bodies have merged into one association, *austrolab*. The association currently has about 60 members. Among the objectives of austrolab are the representation of common interests at the national and international level, guaranteeing a high level of quality of the members, the uniform implementation of the requirements for the conformity assessment bodies as well as the establishment of a forum for the exchange of information and opinions between the members and the users of their services[56]. The association is currently placing particular focus on accreditation matters. On the one hand, it aims to make the value of the accreditation more publicly acknowledged, both among the clients of the accredited bodies as well as among state agencies. On the other hand, it advocates to the accreditation body, in particular, an acceptable cost-utility-ratio for the accreditation from the viewpoint of the bodies[57]. According to § 12 para. 2 of the AkkG the accreditation body also must provide for the exchange of experiences among the accreditation bodies. Since the product safety law came into force in 2004, austrolab is represented in the expanded product safety council of the accreditation body, which was established for the sake of market surveillance[58].

E. The role of market surveillance

In Austria market surveillance for the area of consumer products was reorganized by the Federal Law for Protection from Dangerous Products (*Bundesgesetz zum Schutz vor gefährlichen Produkten - PSG 2004*), which takes a strong preventive approach and contains

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56 austrolab, Annual Report 2004, p. 4, available online at: http://www.austrolab.at/Deutsch/index.htm (22.8.2005).

57 austrolab, Annual Report 2004 (Fn. 56), p. 5, 6 et. seq.

58 § 20 para. 2 no. 10 PSG 2004, more on this under E.I.

above all important strategies for coordinating activities among the responsible authorities and for integrating external expertise.

I. Market surveillance for consumer products according to the PSG 2004

The Federal Law for Protection from Dangerous Products (*Produktsicherheitsgesetz 2004 – PSG 2004*)[59] serves to implement the product safety directive[60] and adapts the product safety law from 1994 to its guidelines. Drawing on the product safety directive, it basically only pertains to consumer products[61]. It applies in subsidiary manner vis-à-vis other federal law provisions, but §§ 7 to 29 PSG also apply supplementarily so that the provisions, for example, can also be applied when security requirements are formulated in other laws, but sufficient means for execution are lacking[62]. The PSG 2004 does not apply when the specification of security requirements is the responsibility of the states (Laender), i.e. with regard to state law regulations on construction products, for instance[63].

As was already the case after the PSG 1994, responsibilities for carrying out market surveillance were granted to the state governor (Landeshauptmann), who must specify specially trained product safety surveillance organs for doing so[64]. The number of these institutes significantly varies in the individual federal states, as evidenced by the government bill for the PSG 2004. Nevertheless, the law refrains from a more precise specification, but does instruct the surveillance institutes to be sufficiently equipped[65]. Particular

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59 StF: Bundesgesetzblatt / Federal Law Gazette I No. 16/2005.

60 RL 2001/95/EG, EC Official Journal No. L 11 from 15.1.2002.

61 Thus, not only products which are put on the market exclusively for professional purposes and are used accordingly, fall under this; § 2 para. 1 in conjunction with § 3 Number 1 PSG 2004; Government bill on the PSG 2004 - 512 d.B. (XXII. GP) Product Safety Law 2004 - Ad § 2 first paragraph (p. 4); Ad § 3 third paragraph (Page 5). The government bill is available online at URL: http://www.parlament.gv.at/pls/portal/docs/page/PG/DE/XXII/I/I_00512/FNAMEORIG_021377.HTML (23.5.2005).

62 § 2 para. 2 PSG 2002, in more detail in the government bill on the PSG 2004, (Fn. 61), Ad § 2 (p. 5).

63 § 2 para. 3 PSG 2004, government bill on the PSG 2004 (Fn. 61), Ad § 2 last paragraph (p. 5).

64 § 13 para. 1 PSG 2004.

65 § 13 para. 2 PSG 2004.

emphasis is placed on the training and further education of the surveillance organs[66]. Their powers greatly coincide with those already contained in the PSG 1994[67].

The interactions between manufacturers and/or marketers, authorities and third parties play a particular role in ensuring the effectiveness of market surveillance during the evaluation of dangers stemming from the products. § 7 para. 5 of the PSG 2004 contains an obligation on behalf of the marketers to cooperate with the responsible authorities. § 8 PSG 2004 stipulates notification obligations for medical services for the collection of accident data[68], as well as notification obligations for the carriers of the accident insurance and other state executive organs as well as passive information requirements for the customs authorities. The PSG 2004 abolished the notification obligation for directors of accredited inspection bodies, which had hardly been noticed anyway[69]. § 9 PSG 2004 governs the automated processing of the data, and § 10 PSG 2004 the data transfer to foreign and international authorities as well and feeing them into databases; besides the Rapex-system mentioned in § 10 para. 1 PSG, the ICSMS database is also envisioned in § 10 para. 2 of PSG 2004[70].

The product security advisory board which has been enlarged by the PSG 2004 is also likely to play an important role in the incorporation of external expertise in the assessment of dangers and the development of appropriate measures. Until then, the advisory board was purely occupied by social partners[71]; experts were only consulted as appropriate. According to the new regulation, the experts are taken more into account and, for example, representatives of austrolab or the standardization institute are admitted to the advisory board. The advisory council was complemented with representatives of the market surveillance authorities, who are supposed to contribute their experiences to the execution of the law, as well as with a common representative of the states (Laender)[72]. The task of the advisory council is to consult the Federal Minister for Social Security, Generations and Con-

66 § 13 para. 5 PSG 2004.
67 § 14 PSG 2004, Government bill on the PSG 2004 (Fn. 61), Ad § 14 (p. 10).
68 According to the PSG 2004 now only as a passive notification requirement, though, see § 8 para. 1 PSG 2004, Government bill on the PSG 2004 (Fn. 61), Ad § 8, 9 (p. 8).
69 This is explained by the bill with the business relationship between the body and its contracting entities, Government bill on the PSG 2004 (Fn. 61), Ad § 8, 9 (p. 8).
70 Government bill on the PSG 2004 (Fn. 61), Ad § 10 (p. 8 et seq.).
71 See § 16 para. 2 of the PSG 1994.
72 § 20 PSG 2004, Government bill on the PSG PSG 2004 (Fn. 61), Ad § 20 (p. 12).

sumer Protection on basic issues of consumer protection and accident protection as well as market surveillance, support in risk assessment and conformity assessment, and the exchange of experience and knowledge[73]. It may offer recommendations on this, which are to be published by the minister[74].

The cooperation between the executive authorities was also reorganized. According to § 13 para. 7 of the PSG 2004 the authorities shall inform each other appropriately about their market surveillance activities; once again, the use of a database is envisioned here. A coordination session between the responsible authorities, which takes place at least once yearly, was introduced and should serve to facilitate the exchange of experience from market surveillance as well as scientific and technical knowledge on the safety of products, draw up and coordinate approaches and to decide on sectoral surveillance programs.

II. Further areas

No horizontal regulation comparable to the PSG exists for the surveillance of products designated for professional use and for traditional surveillance of industrial equipment. The responsibilities and powers of the surveillance authorities as well as the procedures to be followed are based on the respective area-specific laws. In many areas the regional administration authorities (*Bezirksverwaltungsbehörden*) are responsible for market surveillance, in part on the basis of the trade and industry laws, and in part according to the respective area-specific laws[75]. The Federal Ministry for Economic Affairs is responsible for the coordination of market surveillance.

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73 § 21 para. 1 PSG 2004.
74 § 21 para. 1 Number 4, para. 4 PSG 2004 – in particular by publication on the Internet.
75 E.g. § 32 of the Boiler Law.

Fourth Section: Conformity Assessment in Sweden

After a short overview of the use of conformity assessment in Sweden, its significance in the regulatory sphere will be discussed; particular focus will be placed on the horizontal regulations in Swedish law and the responsibilities of the Swedish accreditation body SWEDAC in the process of approving and monitoring conformity assessment bodies. Furthermore, the organization and status of SWEDAC will be described, followed by several remarks on the activities of the conformity assessment bodies. The section is concluded with an overview of the organization and orientation of market surveillance in Sweden.

A. Overview of the use of conformity assessment

In Sweden, the signing of the Tampere Convention[1] as well as the accession negotiations with the European Union and the coming into force of the Agreement on the European Economic Area in 1994 gave an impetus for the adoption of conformity assessment rules into Swedish law. In 1992 the previously applicable regulation was superseded by the *Lag om teknisk kontroll* (Law on Technical Control)[2], which enables a system of private conformity assessment bodies, which compete with one another – a concept which is also applied in the non-harmonized sphere in Sweden.

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1 Agreement on the mutual recognition of test certificates and proof of conformity including appendixes and report on the application of the agreement on the mutual recognition of test certificates and proof of conformity to the Principality of Liechtenstein, [published e.g. in "Amtliche Sammlung des Bundesrechts der Schweiz "AS 1990 1704].

2 Lag (1992:1119) om teknisk kontroll from 12 December 1992, last change SFS (2005:780). Swedish legal provisions can downloaded under their SFS number (here 1992:1119) from the Swedish service Rixlex, URL: http://www.riksdagen.se/debatt/sfst/index.asp (28.4.2005).

I. The "open system" concept since 1992

1. Development

The *Lag om teknisk kontroll* (Law on Technical Control), which came into force in 1992, created a so-called "open system"[3] for conformity assessment in the regulatory sphere. Accordingly, activities such as analyses, tests, calibration, certification and inspections are carried out by accredited conformity assessment bodies, which compete with one another. The *Lag om teknisk kontroll* applies to conformity assessment activities, as long as these are stipulated by law or have been imposed by a decision by a public authority or to the extent that the conformity assessment has special legal effects in some other respect due to legal provisions[4]. Previously, tests on products were conducted by so-called *Riksprovplatser*[5]. These were laboratories, which were maintained by public authorities or incorporated companies under the influence of the state. They were active in a certain sector respectively[6], over which they held a monopoly. As a rule, tests stipulated as legally binding had to be conducted by these laboratories[7].

2. Conformity assessment in the regulatory, non-harmonized sphere

It is noteworthy that during the introduction of conformity assessment regulations on the basis of the principles drawn up in the EC, Sweden opted not only to apply the New Approach and Global Approach to the directives based on the New Approach, but also to those based on the "old" approach to the greatest possible extent[8]. In 1992 the Swedish

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3 SWEDAC at URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (3.6.2005) under "Activities/Open Systems".

4 § 2 Lag (1992:1119) om teknisk kontroll.

5 Lag (1989:164) om kontroll genom teknisk provning och om mätning from 27 April 1989.

6 § 2 Lag (1989:164) om kontroll genom teknisk provning och om mätning.

7 At the time of the restructuring on the basis of the *Lag om teknisk kontroll* there were seven such *Riksprovplatser*. The designation of such *Riksprovplatser* was the responsibility of the government, § 2 Lag (1989:164) om kontroll genom teknisk provning och om mätning. As a rule, they conducted tests which then served as a basis for the responsible authority's decision on the authorization or market entry of products by the responsible authorities. These are, for the most part, tests in the form of a prototype test. A production test generally did not take place and market surveillance also only played a very minor role.

8 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives, Section "Background and legal base", online at URL: http://www.swedac.se/sdd/swinternet.nsf/webAttDoc/ADMR-64ZHF3/$File/Notified%20bodies.pdf (28.4.2005).

Parliament also took the principal decision that all mandatory conformity assessment should be based on accreditation. This means that conformity assessment bodies, which are accredited on the basis of the applicable international standards, are even used in all non-harmonized regulatory sphere. The regulations on ladders and scaffolding are an example of this. As work equipment, they fall under the scope of the directive 89/655/EC concerning the minimum safety and health requirements for the use of work equipment by workers at work, a directive which does not belong to the directives based on the New Approach[9]. The requirements of this directive are implemented in Sweden by a regulation of the agency responsible for work safety[10]. For certain types of scaffolds, the provision stipulates that they must be subject to a test[11]. This test must be carried out by bodies which are accredited according to the requirements of the *Lag om teknisk kontroll*. The test can also be carried out by a body which is accredited in another state of the EEA if the accreditation has been conducted on the basis of the series of norms EN 45000[12]. A similar regulation exists for ladders[13].

The implementation of the directive in Sweden thus envisions the use of accredited bodies in areas, in which this is not stipulated by European directives. Further examples can be cited from metrology and vehicle inspection, which have yet to be harmonized.

II. Use of the terms notification and accreditation

In Sweden, the term notification generally describes the procedure of assessing the competence of a conformity assessment body and subsequently reporting this body to the Euro-

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9 For the inspection of work equipment, the directive does not envision the use of the designated bodies, which work on the basis of harmonized technical standards. Instead Art. 4a para. 1 RL 89/655/EC, obligates the employer to make sure that the work equipment is subject to an inspection "by competent persons within the meaning of national laws and/or practices". According to Art. 4a para. 4 of Directive 89/655/EC, the Member States themselves stipulate the formalities of the inspection.

10 *Arbetsmiljöverket*, Ställningar - Arbetarskyddsstyrelsens kungörelse med föreskrifter om ställningar samt allmänna råd om tillämpningen av föreskrifterna, AFS 1990:12; the regulation is available online at URL: http://www.av.se/regler/afs/1990_12.pdf (19.7.2005).

11 AFS 1990:12, § 6 para. 1.

12 AFS 1990:12, § 6 para. 3.

13 *Arbetsmiljöverket*, Stegar och arbetsbockar - Arbetsmiljöverkets föreskrifter om stegar och arbetsbockar samt allmänna råd om tillämpningen av föreskrifterna - AFS 2004:3, Art. 4; the regulation is available online at URL: http://www.av.se/regler/afs/2004_03.pdf (19.7.2005).

pean Commission. As a rule, the term accreditation pertains to the appraisal of the competence of a conformity assessment body outside the notification procedure, thus in the regulatory non-harmonized sphere and in the non-regulatory sphere[14]. In practice, this terminological distinction does not play a significant role, because the competence assessment during the notification procedure and the accreditation of SWEDAC are conducted according to the same rules[15]. According to the predominant Swedish language use, a distinction will be made in the following, wherever possible, between accreditation (competence assessment in the regulatory non-harmonized sphere and in the non-regulatory sphere) and notification (regulatory harmonized sphere). In order to differentiate the confirmation of the competence of the accreditation body from the subsequent reporting of the body to the EU-Commission during the notification procedure, the term "designation" will also be used for the former[16].

B. The use of conformity assessment in the regulatory sphere

The requirements for the accreditation and/or notification of conformity assessment bodies are based on the *Lag om teknisk kontroll* and the *Förordning om teknisk kontroll*, and are complemented by specific legal regulations. The national accreditation body SWEDAC is responsible for the accrediting, notifying and monitoring the bodies.

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14 For instance, § 14 of the Lag om teknisk kontroll defines the term accreditation as a declaration that a body is qualified to carry out the activities covered by the accreditation. The definition can be found in the section "Accreditation by SWEDAC". The notification of bodies to the EU is regulated by a previous section "Bodies to be reported to the EU". In this section § 4 para. 2 of the Lag om teknisk kontroll stipulates that before the notification SWEDAC must carry out a "bedömning" (assessment) whether the body fulfils the relevant requirements. Like in § 3 of the Förordning om teknisk kontroll, the term accreditation is not used here for the competence assessment of the body, rather "bedömning" (assessment). For the terminology, see also the description by *Sjögren* on the role of SWEDAC in the assessment and notification of bodies in the context of the EU directives. At the end of the section "Assessment procedure" *Sjögren* formally differentiates the accreditation from the assessment during the notification procedure, even if the same respective regulations are applied to the competence assessments; *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8). However, the use of the terms is not uniform, see for example the description on the homepage of SWEDAC under "Open conformity systems", which mentions accreditation in both cases (in the English version); URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (28.4.2005), in the Swedish version of the site as well.

15 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "Assessment procedure" at the end; their use is not uniform, though, see above Fn. 14; for more on the relationship between accreditation and competence assessment during the notification procedure, see B.III.1.

16 In the language of the *Lag om teknsik kontroll*, notified bodies are referred to as *anmält organ*, literally "registered bodies", see § 4 of the Lag om teknisk kontroll.

I. Interplay between horizontal regulations and area-specific regulations

The activities of the conformity assessment bodies in the regulatory sphere result from the interplay between the horizontal regulations on the conformity assessment, i.e. the *Lag om teknisk kontroll* and the *Förordning om teknisk kontroll,* and regulations for specific areas.

1. Lag om teknisk kontroll and further horizontal regulations

The *Lag om teknisk kontroll* comprises conformity assessment activities, as long as they are statutory or have been imposed by an official decision or to the extent that the conformity assessment otherwise takes legal effect due to any legal stipulations[17]. Among other things, the law contains regulations on notifying the EU of Notified Bodies, the accreditation of bodies by SWEDAC and monitoring the bodies. One peculiarity is that SWEDAC is not only a national accreditation body, but in its function as a national agency is also responsible for assessing, designating and notifying bodies under new approach directives to the EU[18].

The law is further substantiated by the *Förordning om teknisk kontroll* (decree on technical control)[19], which regulates in detail the requirements to designated bodies and the notification procedure. It authorizes SWEDAC to issue complementary regulations on the accreditation. The *Förordning med instruktion för Styrelsen för ackreditering och teknisk kontroll* (the decree with further provisions on SWEDAC) includes further regulations on SWEDAC[20]. Provisions on applying the CE-marking are contained in the *Lag om CE-märkning*[21].

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17 § 2 Lag (1992:1119) om teknisk kontroll.

18 § 3 Lag (1992:1119) om teknisk kontroll in conjunction with § 5 Förordning (2005:894) om teknisk kontroll.

19 Förordning (2005:894) om teknisk kontroll from 1 December 2005, come into force 1 January 2006, replacing Förordning (1993:1065) om teknisk kontroll from 23 September 1993.

20 Förordning (1996:81) med instruktion för Styrelsen för ackreditering och teknisk kontroll from 15 February 1996, last change SFS 2005:895.

21 Lag (1992:1354) om CE-märkning from 17 December 1992, amended by SFS 1994:1588.

2. Area-specific regulations

With regard to the area-specific regulations, there are generally a law, a more concrete decree, as well as supplementary provisions, which the state agency responsible for the concerned sector issues. The area-specific regulations contain the product and service requirements, etc. To inspect whether these requirements are met, they stipulate the use of conformity assessment bodies, whose qualification has been demonstrated in accordance with the horizontal regulations on the conformity assessment. For scaffolds, for example, Art. 6 AFS 1990:12 stipulates that these must be inspected by bodies, which are accredited in accordance with the requirements of the *Lag om teknisk kontroll*[22].

II. Responsibility for accreditation and notification

In Sweden, the national Swedish accreditation body SWEDAC always carries out the evaluation of the qualification of conformity assessment bodies[23]. This is the case regardless of whether the competence assessment is conducted for the sake of notifying a body to the EU or whether an accreditation in the regulatory, non-harmonized sphere is concerned.

One distinctive feature is that SWEDAC, as a state agency, is also responsible for notifying conformity assessment bodies to the EU and carries out the appraisal (*bedömning*) of the competence of the bodies for this purpose. § 5 para. 1 of the *Förordning om teknisk kontroll* stipulates that before taking a decision SWEDAC must consult the responsible public authority for the concerned sector. When the responsible public authority has the required technical qualification, it is generally invited to send a representative to the assessment team as an expert. In each case, the agencies are invited to send representatives as observers. This adds to the transparency of the assessment procedure and is supposed to increase

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22 AFS 1990:12 (Fn. 10). For the regulatory harmonized sphere, see for example the corresponding regulation on the implementation of the Lifts Directive in Chapter 3 § 1 BFS 2003:10; *Boverket*, Föreskrifter om ändring av Boverkets föreskrifter och allmänna råd om hissar och vissa andra motordrivna anordningar - BFS 2003:10; the document is available online at URL: http://www.boverket.se/novo/filelib/arkiv06/hiss9200310.pdf (19.7.2005).

23 SWEDAC is a state agency, which is subordinated to the Ministry of Foreign Affairs. More on SWEDAC under C. In this exceptional case, the government bears responsibility for the notification, when a state agency applies for the notification. SWEDAC provides for the competence assessment here as well, but the government makes the decision on notification, § 5 para.. 2 Förordning (2005:894) om teknisk kontroll.

the trust of the responsible administrative agencies in the competence of the designated bodies[24].

III. Requirements for notification and accreditation

1. Procedures according to the Lag om teknisk kontroll and Förordning om teknisk kontroll

The requirements for the notification and accreditation result from the horizontal regulations on the conformity assessment, thus the *Lag om teknisk kontroll* and the Förordning om teknisk kontroll, as well as the area-specific regulations. According to §§ 2 et seqq. of the *Förordning om teknisk kontroll*, the procedure for judging the competence and adequacy is to be conducted according to international accreditation standards, unless regulated otherwise in area-specific laws; § 3 *Förordning om teknisk kontroll* refers to the series of norms EN 45 000. According to § 3 of the *Förordning om teknisk kontroll* there can be additional prerequisites for the notification. These can result from the EU directives and the laws for their implementation as well as from regulations in the area-specific laws in the non-harmonized sphere.

For the notification of a body, it is not necessary for the body to have been previously accredited by SWEDAC in a separate procedure[25]. § 2 of the *Lag om teknisk kontroll* only specifies that the body must have the necessary qualification and otherwise be adequate. If an accreditation already exists, it is assumed that the body fulfils the corresponding requirements[26]. If no accreditation exists, SWEDAC conducts an appraisal of the competence and adequacy of the body, which corresponds with the assessment during the accreditation procedure[27]. Due to the simultaneous responsibility of the accreditation body for the notification, there is no need to structure the accreditation as a prerequesite for a

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24 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "Assessment procedure".

25 See the justification for the original bill for the Lag (1992:1119) om teknisk kontroll, Prop. 1991/92:170, Page 55; *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "Assessment procedure" at the end.

26 § 4 para. 2 clause 2 Lag (1992:1119) om teknisk kontroll.

27 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "Assessment procedure" at the end.

state designation, as is the case in other countries. Since activities exclusively in the regulatory harmonized sphere are often not economically wise and since the requirements frequently overlap each other, Notified Bodies also generally received one or more accreditations from SWEDAC. If the requirements are fulfilled, the bodies are entitled to notification[28].

In a further regulation[29], STAFS 2002:6[30], SWEDAC stipulated the requirements for the notification of the bodies in binding fashion. STAFS 2002:6 contains, among other things, rules on the competence and independence of the bodies, on sub-contracting, as well as the obligations of the bodies to cooperate and exchange information[31]. SWEDAC requires the Notified Bodies to participate in the respective groups, which exchange experiences at the European level. However, the bodies can delegate a common representative. Furthermore, the conformity assessment bodies must report to SWEDAC on their activities as Notified Bodies[32].

2. Notification of conformity assessment bodies of state agencies

Conformity assessment bodies, which are based within state agencies, can also be notified. SWEDAC is once again responsible for the assessment of their competence, although the government makes the decision on the notification[33]. The agency must specify the special reason why it wishes to carry out the conformity assessment activities as a public agency. Furthermore, potential conflicts of interest and the position of the agency in competition with the conformity assessment bodies from the private sector must be taken into consid-

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28 This results from § 4 para. 1 of the Lag (1992:1119) om teknisk kontroll, according to which bodies are to be notified if they fulfil the relevant requirements.

29 SWEDAC, Styrelsens för ackreditering och teknisk kontroll föreskrifter för organ anmälda till uropeiska unionen för uppgifter i samband med bedömning av överensstämmelse under EG-rättsliga bestämmelser - STAFS 2002:6; the document is available online at URL: http://www.swedac.se (20.7.2005) under the category *Föreskrifter*.

30 SWEDAC is authorized to issue further rules for the notification and accreditation, §§ 7, 9 Förordning (2005:894) om teknisk kontroll.

31 §§ 4, 5, 9 and 10 STAFS 2002:6.

32 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "How is competence established?".

33 § 5 Abs. 2 Förordning (2005:894) om teknisk kontroll.

eration[34]. In organizational terms, the activity as a Notified Body must be separated from the other activities of the agency[35]. In practice, state bodies have only been notified extremely seldom in Sweden[36].

IV. Monitoring conformity assessment bodies

The surveillance of Notified Bodies is regulated by §§ 17 and 18 of the *Lag om teknisk kontroll*. § 18 of the *Lag om teknisk kontroll* contains access rights and information requirements. Surveillance measures can be carried out without advance warning. With regard to Notified Bodies, § 15 STAFS 2002:6 stipulates that the bodies shall allow SWEDAC to conduct surveillance measures at any point in time. As far as can be seen, the intervals for monitoring the Notified Bodies are not specified, but in practice are likely to correspond with those of the accreditation. From time to time, SWEDAC conducts *witness audits*[37]. If the inspection reveals that the requirements for notification are no longer met, the body is granted the opportunity to state its position and or remedy the insufficiencies. If this does not take place, the notification can be revoked[38]. In practice, this occurs extremely seldom.

Not SWEDAC, rather the government is responsible for the revocation of the notification. This thus differs from when the notification is issued[39]. However, SWEDAC ascertains the conditions for the revocation of the notification in this case as well[40].

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34 § 5 Abs. 2 Förordning (2005:894) om teknisk kontroll.

35 § 3 STAFS 2002:6 (Styrelsens för ackreditering och teknisk kontroll föreskrifter för organ anmälda till Europeiska unionen för uppgifter i samband med bedömning av överensstämmelse under EG-rättsliga bestämmelser).

36 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "Background and legal base"at the end.

37 *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "How is competence established?"

38 § 4 Section 3, clause 2 of the Lag (1992:1119) om teknisk kontroll.

39 § 4 Section 3, clause 2 of the Lag (1992:1119) om teknisk kontroll; this regulation is likely related to the depth of the intervention of such measures; up to now however, the provision has yet to take on a significant practical meaning, because the affected bodies voluntarily returned their notification or found another solution.

40 See § 6 Förordning (2005:894) om teknisk kontroll; *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "Background and legal base" at the end.

C. The role of the accreditation body

SWEDAC (Styrelsen för ackreditering och teknisk kontroll)[41] is the national accreditation body of Sweden and conducts appraisals of the competence of the conformity assessment bodies regardless of whether this is done for the sake of the notification procedure or during an accreditation for the regulatory, non-harmonized sphere or the non-regulatory sphere. SWEDAC is a state agency, which is subordinate to the Ministry of Foreign Affairs[42] and already existed before the restructuring of the Swedish conformity assessment system in 1992[43]. SWEDAC has accredited approximately 466 laboratories, 58 certification bodies and more than 1800 inspection bodies and notified 57 bodies to the EU[44]. Besides its function as the national accreditation body, SWEDAC also assumes further sovereign duties.

I. Duties of SWEDAC

Firstly, SWEDAC is entrusted with tasks regarded as sovereign or official. Among the official activities with a direct reference to the conformity assessment are SWEDAC's character as a central administrative body for matters concerning conformity assessments, the notification of bodies in the framework of the directives based on the New Approach and its participation at the European and international level to facilitate the international recognition of the results of the conformity assessment[45]. Furthermore, SWEDAC is,

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41 § 14 Lag (1992:1119) om teknisk kontroll.

42 SWEDAC, SWEDAC's Duties, URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (28.4.2005).

43 In 1989 it was granted the task of monitoring the *Riksprovplatser* (see above A.I.1.). However, at this point in time, this was not yet associated with a comprehensive assessment of the technical competence and the professional quality of their work. SWEDAC did not perform accreditation activities until 1990.

44 Figures compiled on the basis of the annual report of SWEDAC, Activities 2003, available at URL: http://www.swedac.se/sdd/SwDokument.nsf/webDoc/BROH-69XKGS/$File/Activities%202003.pdf. (6.3.2006) ; for the figures of 2004 see the annual report for 20042004 (Arsredovisning 2004), p.25 et seq., available at URL: http://www.swedac.se/sdd/SwDokument.nsf/webDoc/BROH-69XKEG/$File/SWEDAC_arsredovisning.pdf (3.6.2006). The large number of inspection bodies results from the accreditation of more than 1000 bodies dealing with cooling units as well as 500 workshops for vehicles and vehicle parts.

45 SWEDAC, SWEDAC's Duties, URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html.

among other things, responsible for the coordination of market surveillance activities in Sweden[46] and monitoring legal metrology[47].

Along with that, the legal regulations grant SWEDAC the role of the "national accreditation body" within the scope of the *Lag om teknisk kontroll*[48]. SWEDAC accredits laboratories, certification and inspection bodies, EMAS-controllers as well as assessors dealing with public contracting procedures[49].

II. Unique position of SWEDAC as the national accreditation body

In Sweden SWEDAC is viewed as the state accreditation body, which uses its professional competence in the private, non-regulatory sphere as well to offer accreditation services. From the standpoint of the state, accreditation by SWEDAC is a service which the state body provides for the market participants. ·

In the regulatory (harmonized) sphere, SWEDAC is solely responsible for determining and assessing the competence and the subsequent notification, §§ 3, 4 para. 2 of the *Lag om teknisk kontroll*, § 5 para. 1 Clause 1 of the *Förordning om teknisk kontroll*[50].

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46 More on this under E.

47 The tasks of SWEDAC are specified in the Förordning (1996:81) med instruktion för Styrelsen för ackreditering och teknisk kontroll (Fn. 20), §§ 1, 2.

48 § 14 Abs. 2 Lag (1992:1119) om teknisk kontroll; § 1 para. 2 Förordning (1996:81) med instruktion för Styrelsen för ackreditering och teknisk kontroll from 15 Februar 1996.

49 See the description in SWEDAC "Accreditation - Accreditation areas", URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (11.5.2005).

50 This results from a comprehensive look on the mentioned regulations: According to § 3 of the Lag om teknisk kontroll, the government or an agency designated by it determines the bodies for notification, after SWEDAC has conducted an assessment of the their compliance with the relevant requirements, § 4 para. 2 of the Lag om teknisk kontroll. According to § 5 para. 1, clause 1 of the Förordning om teknisk kontroll, SWEDAC designates the bodies for notification. This understanding of the law and decree can be explained by the fact that the government was initially responsible for the notification of the bodies in Sweden as well and SWEDAC only conducted the mandatory ascertainment and assessment of the competence of the bodies. During a later revision of the notification procedure, the task of notifying the bodies was transferred to SWEDAC; *Sjögren*, Swedac's role in assessing and notifying bodies under various EU directives (Fn. 8), Section "Background and legal Base". However, SWEDAC is not responsible for the revocation of the notification; this is still done by the government or the responsible ministry, § 4 para. 3, clause 2 of the Lag om teknisk kontroll, for more details, see above B.IV at the end. On the responsibility of the government for the notification of state bodies, see above B.III.2.

SWEDAC practically enjoys an exclusive status in the non-regulatory sphere as well. It is uncertain whether this is supported by § 14 para. 2 of the *Lag om teknisk kontroll*[51]. One can only infer from the justification for the law that SWEDAC did not have a formal monopoly before the introduction of the *Lag om teknisk kontroll*. Whether this was supposed to change with the introduction of the *Lag om teknisk kontroll*, remains uncertain. After all, the justification for the law states that a concentration of accreditation activities within one sole body would be desirable[52]. Sweden had yet to be confronted with the problem of additional accreditation bodies wanting to offer these services on the market. From the Swedish perspective, however, there is no need to take measures which would prevent this either; the result of the level of quality of SWEDAC's work is that its services are accepted by the market participants. Furthermore, the goal of rationalizing the accreditation process also played a role in the decision for just one accreditation body.

III. Organization and financing

1. Organization of the accreditation body

SWEDAC has a Board and a General Director, who runs the agency[53]. The General Director is appointed by the government[54]. The Board consists of representatives of other administrative authorities as well as industries, consumers, conformity assessment bodies, who are appointed by the government[55]. Here efforts are made to ensure the required representation of the interested groups in accordance with the accreditation standards[56].

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51 § 14 para. 2 of the Lag om teknisk kontroll further mandates SWEDAC with the accreditation of inspection or measuring laboratories, certification bodies for products, quality management systems, or persons as well as inspection bodies. According to the wording predominantly used in the Swedish regulations, this is supposed to refer to the regulatory, non-harmonized sphere. There is no mention of delegating the – exclusive – competence for the non-regulatory area as well in § 14 of the Lag om teknisk kontroll, because the provision in para. 1 initially defines accreditation for "the objective of this law". However, according to § 2, the Lag om teknisk kontroll only includes within its scope the conformity assessment in the regulatory sphere.

52 Prop. 1991/92:170, Bilaga 11, p. 59.

53 §§ 4, 5 Förordning (1996:81) med instruktion för Styrelsen för ackreditering och teknisk kontroll.

54 § 3 Förordning (1996:81) med instruktion för Styrelsen för ackreditering och teknisk kontroll in conjunction with § 32 of the Verksförordning (1995:1322) from 30.11.1995.

55 § 33 Verksförordning (1995:1322). Information on its current composition can be obtained from SWEDAC, About Swedac, Organisation, SWEDAC's Board, URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (11.5.2004).

56 See the corresponding requirement in Section ISO IEC 17011, 4.3.2.

The Technical Department is responsible for the competence assessment during the notification procedure and the accreditation. It is divided into six sub-departments: industry, environment and food, health, equipment vehicles and certification[57]. SWEDAC has various technical committees, which have an advisory function in the different accreditation areas[58]. SWEDAC currently has approximately 100 employees[59].

2. Financing

According to its own information, SWEDAC is financed approximately 25% by public resources, otherwise by fees resulting from its accreditation activities. The turnover for the year 2003 amounted to 114.7 million SEK, or approximately 12.46 million Euros. Of that, 19.5 million SEK (approximately 2.12 million Euros) came from allocations from the government[60]. However, it should be noted that SWEDAC also conducts numerous other activities besides accreditation, for example in conjunction with the state metrology system or market surveillance (see above). The competence assessment for notification and the accreditation activities are financed by fees paid by the conformity assessment bodies[61]. The amount of fees paid must be coordinated in advance with the responsible Swedish agency (*Ekonomistyrningsverket*)[62].

IV. Accreditation rules

1. Requirements for the accreditation

§ 14 para. 3 of the *Lag om teknisk kontroll* stipulates that the applicable European or international standards must be respected during accreditations by SWEDAC. SWEDAC sub-

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57 Organization chart of SWEDAC available at URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (11.5.2005).

58 Listing from SWEDAC under About SWEDAC, Organisation, Technical Committees, URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (11.5.2005).

59 SWEDAC, Årsredovisning 2003, p. 43; available at URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index.html (11.5.2005).

60 SWEDAC, Verksamheten/Activitiers 2003 (Info 03:8), Cost Expenditure on different activities, available at URL: http://www.swedac.se/sdd/SwDokument.nsf/webDoc/BROH-69XKGS/$File/Activities%202003.pdf (11.5.2005).

61 § 20 Lag (1992:1119) om teknisk kontroll.

62 § 15 Förordning (2005:894) om teknisk kontroll.

stantiates this in the accreditation rules, which each cover certain types of certification, e.g. the certification of products, quality management systems, or personnel[63]. § 3 of the respective provision defines the accreditation standard which the conformity assessment bodies must fulfil, e.g. the standard EN 45011:1998 for product certification, the standard 45012:1998 for the certification of quality management systems or SS-EN ISO/IEC 17024:2003 for the certification of persons. Accreditation is valid until further notice, subject to re-assessment every fourth year[64].

2. Monitoring the accredited bodies

The accreditation rules contain additional rules on the surveillance of accredited bodies. A re-assessment is generally conducted every four years[65]. The regular surveillance takes place once every year[66]. For the rest, the surveillance conditions are substantiated by the accreditation decision[67]. SWEDAC sometimes conducts *witness audits* during the surveillance activities. The conformity assessment bodies are called upon to enable the participation of SWEDAC in the conformity assessment procedure for the sake of surveillance[68]. The *Regulations* also include SWEDAC's authorization to suspend, restrict or revoke the accreditation, when the conformity assessment body no longer fulfils the accreditation re-

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63 SWEDAC, STAFS 1999:12 The Swedish Board for Accreditation and Conformity Assessment's Regulations for Accredited Bodies that certify products from 29 November 1999; STAFS 2002:3 The Swedish Board for Accreditation and Conformity Assessment's Regulations for Accredited Bodies that Certify Quality Management Systems from 7 June 2002; STAFS 2004:1 The Swedish Board for Accreditation and Conformity Assessment's Regulations for Accredited Bodies that certify persons from 17 February 2004; documents available online at URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (21.12.2005) under the category: Regulations/SWEDAC's regulations. For more on the special rules for the notification of bodies, see B.III.1., Fn. 30.

64 Rules for product certification in § 6 para. 2 STAFS 1999:12 (Fn. 63); for a general overview, see SWEDAC under "Accreditation/How Accreditation is performed – Surveillance", URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (11.5.2005).

65 Rules for the product certification in § 6, para. 2 of the STAFS 1999:12 (Fn. 63); see the general description from SWEDAC under "Accreditation/How Accreditation is performed – Re-assessment", URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (11.5.2005).

66 See the description from SWEDAC under "Accreditation/How Accreditation is performed – Surveillance", URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (11.5.2005).

67 § 6 para. 1, clause 2 STAFS 2002:3 (Fn. 63); § 7 para. 1, clause 2 STAFS 2004:1 (Fn. 63).

68 See, for example, the explanation in the guidelines for § 6 STAFS 2002:3 (Fn. 63), § 7 STAFS 2004:1 (Fn. 63); the guidelines are an integral part of the respective STAFS documents.

quirements[69]. Unlike the revocation of the notification, the accreditation is revoked by SWEDAC itself[70]. Legal action based on administrative law can be initiated against the surveillance measures and the revocation of the accreditation[71].

D. The activities of the conformity assessment bodies

The legal relationship between the conformity assessment bodies and their clients in Sweden is judged as being based on private law. In order to promote the exchange of experiences, conformity assessment bodies from different areas have founded branch organizations.

I. Legal relationship between the conformity assessment bodies and their clients based on private law

The conformity assessment bodies conclude with their clients a contract on the conformity assessment, which is based on private law.

During the restructuring of the conformity assessment system in 1992, it was debated whether the activities of the conformity assessment body are sovereign activities, because at least in certain cases they took the place of the previously required sovereign product authorization in terms of their function. However, the rationale behind the bill for the *Lag om teknisk kontroll* makes it clear that designated bodies do not carry out administrative activities, and in particular do not make any decisions on behalf of the Swedish state or the EU[72]. The main motive for this arrangement was the consideration that the conformity assessment body only determines the compliance of a product with certain requirements. This was qualified as a purely technical assessment, in contrast to a sovereign decision on the legal admissibility of putting an item on the market. From the Swedish perspective, this

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69 § 7 STAFS 1999:12 (Fn. 63); § 7 STAFS 2002:3 (Fn. 63); § 8 STAFS 2004:1 (Fn. 63), partially in reference to the Lag (1992:1119) om teknisk kontroll.

70 § 15 para. 2 of the Lag (1992:1119) om teknisk kontroll.

71 § 23 para. 1 of the Lag (1992:1119) om teknisk kontroll.

72 Prop. 1991/92:170, Bilaga 11, Page 60.

arrangement was also significant for setting up a system of open competition among private conformity assessment bodies.

This arrangement goes hand in hand with a strong focus on the responsibility of the manufacturers, which is viewed as an advantage of the system[73].

II. Cooperation between the conformity assessment bodies at the national and international level

In Sweden, conformity assessment bodies offering testing, inspections, and certification cooperate in a branch organization, SWETIC – Swedish Association for Testing, Inspection and Certification[74]. The association serves to promote the exchange of experiences and information between the bodies. For this purpose, SWETIC maintains different technical committees[75]. The 27 current members of the organization are accredited by SWEDAC[76]. designated bodies are obligated to participate in the groups exchanging experiences at the European level; see above.

E. The Role of market surveillance in relation to conformity assessment

I. Organization of market surveillance in Sweden

The current system of market surveillance in Sweden came about when Sweden joined the EEA[77]. In light of the experiences in implementing the sectoral directives on product safety

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73 The manufacturer or the person in charge of putting the item on the market remained primarily responsible for the safety of the product. If a conformity assessment body certifies, for example, a non-conforming product, the manufacturer remains responsible for resulting damages. Liability on behalf of the conformity assessment body also might come under consideration if errors are made in the certification procedure. However, the state is not regarded as being liable (see Prop. 1991/92:170, Bilaga 11, page 60), for example because SWEDAC had created a certain element of trust with the decision on the accreditation or notification.

74 www.swetic.org (13.5.2005).

75 Organization chart at URL: http://www.swetic.org/Kontakt (13.5.2005).

76 The index of members with information on areas of activities, accreditation, and notification can be consulted at URL: http://www.swetic.org/Medlemsmatrikel (13.5.2005).

77 Statens offentliga utredningar, Tillsyn för säkra varor och öppna marknader, SOU:2004:57, page 15.

as well as the product safety directive[78], Sweden deemed an investigation necessary and carried out a comprehensive examination of market surveillance measures in 2003 and 2004[79]. The study resulted in an ordinance on market surveillance which provides for clearer responsibilities and demands on relevant authorities concerning market surveillance activities, cooperation and coordination[80]. Market surveillance is defined here as "measures by public authorities to ensure that a product made available on the market is in compliance with all legal requirements[81].

1. Sectoral organization

In Sweden the consumer agency[82] and SWEDAC are active in the area of market surveillance at the horizontal level. SWEDAC assumes coordination functions[83]. Thus, the actual market surveillance measures are organized in a sectoral manner in Sweden. The responsibility for monitoring products on the market is incumbent on the area-specific agencies, which incidentally are also responsible for administrating the respective regulatory sphere[84]. For instance, the Electrical Safety Board (Elsäkerhetsverket) is responsible for implementing the legal regulations on electro-magnetic compatibility, while the Medical Devices Agency (Läkemedelsverket) is in charge of medical devices. Consequently, the responsibilities for market surveillance are divided among 15 different agencies[85]. This division of responsibilities according to sectors shall be maintained after the restructuring on the basis of the decree, in particular due to the expertise of the agencies and the close association with their other activities.

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78 Directive 2001/95/EG.

79 The study has been published with the title "Statens offentliga utredningar, Tillsyn för säkra varor och öppna marknader", SOU:2004:57.

80 Förordning (2005:893) om marknadskontroll av varor, published 1 Decmber 2005.

81 § 1 Förordning (2005:893) om marknadskontroll av varor.

82 The consumer protection agency is responsible, among other things, for the surveillance according to the provisions of the product safety directive. For the competences of the consumer protection agency see SOU 2004:57, p. 86 et seqq.

83 More on this under E.II.1.

84 SWEDAC, Marknadskontrollen i Sverige – En rapport om de svenska myndigheternas marknadskontroll år 2002, SWEDAC REP 03:7, page 4.

85 A list of the agencies can be found in Förordning (2005:893) om marknadskontroll av varor, Bilaga.

One problematic aspect of this constellation is that some of the sectoral agencies do not have a sub-structure which spans to the local level. This makes the implementation of market surveillance measures more difficult. The decree proposal underlines the responsibility of the central area-specific agencies and enjoins them to develop forms of cooperation with the municipalities, other agencies, or private entities, in order to ensure effective market surveillance.

2. Market surveillance procedure

The scope, quality and procedures of market surveillance vary significantly between the different agencies[86]. Sometimes more passive strategies are applied such as following up on complaints. Other times, both active as well as passive strategies are pursued[87]. The penalties which the agencies can enforce differ due to the different legal foundations. They span from recalling products to fines as well as prison sentences. However, the implementation of the product safety directive by means of the *Produktsäkerhetslag*[88] was instrumental in simplifying manners to a certain degree.

II. Coordination of market surveillance

1. National sphere

Because of this sectoral system there is a strong need for coordination of market surveillance activities and SWEDAC is the responsible authority for this. The coordination is mainly conducted through a Market Surveillance Council. The Council and its functions were formally established by the new ordinance on market surveillance[89]. The Council

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86 SWEDAC, Marknadskontrollen i Sverige – En rapport om de svenska myndigheternas marknadskontroll år 2002, SWEDAC REP 03:7, page 6.

87 More details from SWEDAC, Marknadskontrollen i Sverige – En rapport om de svenska myndigheternas marknadskontroll år 2002, SWEDAC REP 03:7, page 6.

88 See §§ 24 et seqq. of the Produktsäkerhetslag (2004:451) from 27.5.2004 with regulations on the documentation obligations of the firms, access rights of the agencies and penalty options.

89 §§ 4 bis 10 Förordning (2005:893) om marknadskontroll av varor. Nach § 1 Abs. 2, § 2 Abs. 1 no. 8, Abs. 2 Förordning (1996:81) med instruktion för Styrelsen för ackreditering och teknisk kontroll (version in force until 1 January 06), SWEDAC had already been responsible for the coordination of market surveillance to a certain extent, see now § 2 a Förordning (1996:81) med instruktion för Styrelsen för ackreditering och teknisk kontroll in the version in force 1 January 06.

now consists of the representatives of the 15 sector authorities, the Swedish Customs and the National Board of Trade[90]. Business and consumer organisations etc. are no longer represented in the Council, different to the Council established within SWEDAC before[91]. But the ordinance states that cooperation with these organisations as well as with other organisations and authorities should take place[92]. The Council will draw up action plans for market surveillance[93].

2. International cooperation

According to SWEDAC, most Swedish market surveillance agencies participate in various forms of European cooperation, for example in the sector-specific Administrative Co-Operation Groups at the EU level or the Market Surveillance Operations Group, MSOG, which was established by the Enterprise General Directorate for the medical devices sector[94]. SWEDAC also advocates an increased exchange of experiences and a harmonization of the regulations on market surveillance at the international level, in particular within the sphere of the EU[95].

III. Financing

Market surveillance in Sweden is currently financed for the most part by budgetary funds. In one of the reports on market surveillance, SWEDAC made lacking financial resources responsible for the fact that market surveillance measures were frequently not carried out to the desired extent[96]. The total expenses for market surveillance are currently estimated at

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90 Responsible for the information procedures for technical regulation according to Directive 98/34/EG.

91 Fn. 90.

92 § 9 Förordning (2005:893) om marknadskontroll av varor.

93 § 4, 4. Förordning (2005:893) om marknadskontroll av varor.

94 SWEDAC, Marknadskontrollen i Sverige – En rapport om de svenska myndigheternas marknadskontroll år 2002, SWEDAC REP 03:7, page 7.

95 SWEDAC, Activities/ Market Surveillance, URL: http://www.swedac.se/sdd/System.nsf/(GUIview)/index_eng.html (13.5.2005).

96 SWEDAC, Marknadskontrollen i Sverige – En rapport om de svenska myndigheternas marknadskontroll år 2002, SWEDAC REP 03:7, page 6.

up to 40 million SEK. According to the study on market surveillance, more than twice that amount would be necessary to conduct satisfactory market surveillance measures[97].

IV. Relationship to conformity assessment

In Sweden, the systems of market surveillance and conformity assessment are not formally associated. There is no organized procedure for forwarding information from the conformity assessment system to the market surveillance system; there are, in part, informal contacts between the agencies and the conformity assessment bodies. In Sweden as well public agencies frequently do not maintain their own testing facilities. If required, testing activities can be assigned to private bodies.

Since the market surveillance agencies are also responsible for regulation in the respective area, this separation of conformity assessment and market surveillance does not lead to a lack of specialized knowledge in the market surveillance agencies.

97 SOU:2004:57, page 111.

Fifth Section: Conformity Assessment in Switzerland

After a short overview of the areas of application of conformity assessment its use in the regulatory sphere shall be further examined, including a review of the mode of operation of the Switzerland-EC MRA. Particular focus will be placed on the role of accreditation during the competence assessment of conformity assessment bodies as well as the organization and status of the Swiss accreditation body SAS. The section concludes with a short outlook on market surveillance in relation to conformity assessment.

A. Overview of the use of conformity assessment

In Switzerland procedures of conformity assessment have gained importance with the increase in cross-border trade after the Second World War. With the Law on Technical Trade Obstacles (*Gesetz über technische Handelshemmnisse*) and the Accreditation and Designation Decree (*Akkreditierungs- und Bezeichnungsverordnung*), Switzerland has horizontal legal provisions which are viewed as foreign trade policy instruments[1] and which regulate conformity assessment in terms of avoiding technical trade obstacles. The Swiss accreditation system is supposed to facilitate the recognition of test results and certificates of conformity for the regulatory and non-regulatory sphere, which is also in the interest of the Swiss export oriented economy.

I. Areas of application of conformity assessment

In Switzerland as in other countries there are numerous conformity assessment schemes in the non-regulatory sphere. Besides the core area of product certification, conformity assessment schemes exist for the evaluation of persons, services or procedures. In the regulatory sphere the conformity assessment procedures which fall under the scope of the

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1 For this classification see the statements by the State Secretariat for Economic Affairs, SECO, for the law on technical trade obstacles (Gesetz über technische Handelshemmnisse/THG) see URL: http://www.seco-admin.ch/themen/aussenwirtschaft/warenverkehr/massnahmen/unterseite00005/index.html?lang=de (6.1.2006).

Switzerland-EC MRA constitute a majority of the applications. However, regulations on the use of accredited bodies can now also be found in Swiss national law. For example, the inspection bodies of the dairy farming inspection and consultation services responsible for monitoring quality assurance must be accredited by the Swiss accreditation body SAS[2]. With regard to agricultural subsidies, farmers who apply for direct payments must provide proof that they have organized the establishment according to certain eligible requirements; the conformation from an accredited inspection body constitutes such proof[3]. Fairground entertainers must offer proof of the facilities they operate in an authorization procedure; an inspection by an accredited inspection body is required for this[4]. Sometimes the state makes use of accreditation to ensure the quality of the services it uses itself. For instance, forensic DNA analyses can only be produced by recognized testing laboratories for genetic engineering; among the requirements for the recognition is the accreditation by the SAS[5]. Similar provisions apply for laboratories which conduct examinations ordered by the police according to the laws dealing with the prevention of epizootics[6]. Rules on the accreditation and certification of bodies can additionally be found in the provisions on electronic signatures; in this case the Swiss accreditation body SAS accredits those bodies which recognize the providers of certification services[7]. If this is all included in the regulatory sphere[8], one can observe that at least the instrument of accreditation is gaining signifi-

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2 Art. 9 para. 2 Decree on Quality Assurance and Quality Control in Dairy Farming (Milchqualitätsverordnung – MQV), SR 916.351.0.

3 Art. 16 Decree on Direct Payments to Agriculture (Direktzahlungsverordnung, DZV), SR 910.13.

4 Art. 21 para. 1, 22 para. 1 Decree on Travelling Commerce (Verordnung über das Gewerbe der Reisenden), SR 943.11.

5 Art. 2 para.. 1, para.. 2 letter a) Decree on the Use of DNA Profiles in Criminal Procedures and to Identify Unknown or Missing Persons (DNA-Profil-Verordnung), SR 363.1.

6 Art. 312 para. 1 Epizootics Decree (Tierseuchenverordnung - TSV), SR 916.401.

7 Art. 1 Decree on the Certification Services for Electronic Signatures (Verordnung über Zertifizierungsdienste im Bereich der elektronischen Signatur - VZertES), SR 943.032; with regard to the terminology one should bear in mind that in this case the “recognition” by recognition bodies is at the same level as conformity assessment, while “certification” pertains to the issue of digital certificates; thus, certification is a service here, whose quality is confirmed with the recognition. So legal regulations on the certification do exist, but the use of certification and subsequently the use of the accreditation bodies are purely voluntarily, though. Therefore this form of certification and recognition should not be classified in the regulatory sphere – as done by the SAS, arguably due to the existence of legal regulations on the certification of electronic signatures; see SAS, Jahresbericht 2003, p. 10; the report is available online at URL: http://www.sas.ch/de/print/jb-sas/index.html (30.8.2005).

8 According to the use of the term by the SAS.

cance here[9]. The SAS has ascertained that accreditation is used today in over 25 laws and decrees[10].

II. Development of the legal regulations on conformity assessment

In Switzerland the furtherance of the conformity assessment system by the development of a corresponding infrastructure – in particular in the area of accreditation – was primarily motivated by foreign trade considerations: Initially provisions existed on the state recognition of inspection and calibration bodies in the form of a decree from 1986[11]. The signing of the Tampere Convention on the mutual recognition of inspection certificates and proofs of conformity within the framework EFTA[12] in 1990 provided the occasion for the adaptation of the regulations, as was also the case in Sweden and Austria. In 1991 the Decree on the Swiss Accreditation System (*Verordnung über das Schweizerische Akkreditierungssystem*)[13] was issued and the Swiss accreditation body founded[14]. In 1993 Switzerland finalized an action program which aimed to adapt the Swiss technical regulations to those of the EC in order to remove trade obstacles[15]. When the EEA Agreement came into force on 1 January, 1994 the significance of the Tampere Convention decreased[16]. After the accession to the EEA Agreement was rejected, there was a perceived need to minimize technical trade obstacles in the form of product provisions or authorization and conformity assess-

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9 According to *SAS*, Jahresbericht (Annual Report) 2004, p. 7. The annual report is available online at URL: http://www.sas.ch/de/print/jb-sas/2004/JBsas2004_d.pdf (30.8.2005).

10 *SAS*, Jahresbericht 2004 (Fn. 9), p. 7.

11 Decree on Calibration and Inspection Services (Verordnung über Kalibrier- und Prüfstellendienste), AS 1986 953. The standard for the professional expertise of the bodies here was still conducting the activity according to the "current state of science and technology", Art. 9 para. 1 of the Decree.

12 Agreement between the EFTA Countries on the Mutual Recognition of Testing Certificates and Proofs of Conformity, AS 1990 1704, effective for Switzerland as of 1 October 1990.

13 Verordnung über das Schweizerische Akkreditierungsystem from 30 October 1991, SR 941.291.

14 See Dispatch on a Federal Law on Technical Trade Obstacles (Botschaft zu einem Bundesgesetz über die technischen Handelshemmnisse - THG) from 15 February 1995, Federal Journal of the Swiss Confederation (Bundesblatt der Schweizerischen Eidgenossenschaft), 22nd Federal Journal, 147th year, Volume 22, Number 95.013, p. 521 et. seq., 593.

15 See the Explanatory Report (Erklärender Bericht) of the EDA/EVD for the consultation on the Switzerland-EC sectoral agreement from 16 March 1999, Chapter 2.3 on the agreement on the mutual recognition of conformity assessment bodies in the version of the corrigendum, under number 2.3.1, document available at http://www.europa.admin.ch/ba/off/vernehm/d/ab_consult_corr.pdf (25.9.2004); explanatory report available at http://www.europa.admin.ch/ba/expl/factsheets/d/fs2002.pdf (25.9.2004).

16 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 537.

ment regulations on the basis of autonomous law[17]. Subsequently, the Federal Law on Technical Trade Barriers (*Bundesgesetz über die technischen Handelshemmnisse/THG*)[18] was passed in 1995, supposed to introduce horizontal principles for the until then predominantly product-specific structured area, in order to create competitive overall conditions for the Swiss economy[19]. Internationally harmonized requirements for conformity assessment, the registration[20] and authorization of products were regarded as a main prerequisite for their cross-border marketability[21]. Subsequently, the Swiss conformity assessment system emerged, which is framed by the THG and the Accreditation and Designation Decree renewed in 1996.

Switzerland concluded an agreement with the European Community on the mutual recognition of conformity assessments, which came into force in 2002. The Switzerland-EC MRA[22] significantly facilitates the market entry of products in the sectors covered by the agreement[23]. Switzerland concluded additional MRAs with the EER/EFTA states as well as with Canada[24]; MRAs with other states are currently in preparation[25].

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17 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 526 et seqq.

18 Bundesgesetz über die technischen Handelshemmnisse (THG) from 6 October 1995, SR 946.51.

19 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 540.

20 The "registration" ("Anmeldung") of products is a procedure which corresponds with the notification procedure (Anzeigeverfahren) in German administrative law, see Art. 3 Letter m THG, Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 575.

21 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 590.

22 Agreement between the Swiss Confederation and the European Community on the Mutual Recognition of Conformity Assessments, concluded on 21 June 1999, effective as of 6 June 2002, EC Official Journal 2002 L 114/369; SR 0.946.526.81; accepted by decision by the Commission on 4 April 2002 (2002/309/EC, Euratom), approved by the Federal Assembly (Bundesversammlung) on 8 October 1999, AS 2002 1527, amended by resolution No. 2/2002 from 8 January 2003 of the Committee to amend appendix 1 of the agreement established with the agreement between the European Community and the Swiss Confederation on the Mutual Recognition of Conformity Assessments and by resolution No. 2/2005 of the Committee to amend Chapter 3 in Appendix 1 established with the agreement between the European Community and the Swiss Confederation (2005/352/EG).

23 More on this in B.II.

24 More detailed information on these MRA at the site of SECO at URL: http://www.seco-admin.ch/themen/aussenwirtschaft/seiten/00033/index.html?lang=de (6.1.2006).

25 SECO at URL: http://www.seco-admin.ch/themen/aussenwirtschaft/seiten/00033/index.html?lang=de (1.6.2006).

III. Special use of terms and concepts

The Swiss regulations conceive conformity assessment as the "systematic examination of the extent to which products … fulfil technical provisions or norms"[26]. This definition of the term does not include *testing* as a "procedure to determine certain properties of a product according to a specified procedure", because this does not necessarily entail an assessment of the agreement of these properties with provisions or standards[27]. However, for the sake of practicability the term "conformity assessment" or "conformity assessment bodies" shall be used in the following in a broad sense which includes testing, as long as not specified otherwise.

The Swiss regulations conceive "accreditation" as the formal recognition of the expertise of a body to conduct certain inspections or conformity assessments[28]. The term "designation" ("*Bezeichnung*") signifies the formal recognition within the framework of an international agreement that a body fulfils the requirements to conduct certain inspections according to the requirements of the concerned agreement and/or effectuate registrations or authorizations[29]. The term "designation" was deliberately selected to differentiate from the term "notification", which is used within the EC for the recognition of bodies. The motive for this specification is that within the framework of the directives based on the New Approach bodies are notified to the Comission and added to the list of Notified Bodies without any further assentment of the other Member States or the Commission, while in the ambit of the Switzerland-EC MRA the joint committee decides on the admission of the bodies. The term "designation" shall clarify that the admission to the list of registered bodies does not automatically follow the designation of the body by the responsible authority, as is the case within the EC, rather that the inclusion of the body in the annex of the MRA constitutes a bilateral procedure[30].

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26 Art. 3 Letter h THG.

27 Art. 3 Letter f THG, see Dispatch on a Federal Law on Technical Trade Obstacles (Botschaft zu einem Bundesgesetz über die technischen Handelshemmnisse / THG) from 15 February 1995 (Fn. 14), p. 573.

28 Art. 3 Letter o) THG. As the accreditation body in Switzerland is a state agency, this constitutes a decision governed by public law; more on this in B.IV.1.

29 Art. 3 AkkBV.

30 More on this in B.IV.2.a.

B. The use of conformity assessment in the regulatory sphere

The incorporation of conformity assessment procedures into the regulatory sphere takes place in the national sphere on the basis of the Law on Technical Trade Obstacles and the Accreditation and Designation Decree in conjunction with the respective area-specific laws. The mutual recognition of test reports and certificates in the international sphere is facilitated by Multilateral Recognition Agreements such as the Switzerland-EC MRA. Accreditation plays an important role in the assessment of the expertise and independence of the bodies as well as for their surveillance.

I. An overview of national regulations

Conformity assessment bodies are used in the regulatory sphere as a result of the interplay of the horizontal regulations on conformity assessment, thus the THG and the Accreditation and Designation Decree (AkkBV), with area-specific regulations.

1. Law on Technical Trade Obstacles (THG)

The Law on Technical Trade Obstacles (*Gesetz über technische Handelshemmnisse* - THG) shall create uniform foundations in order to avoid or remove technical trade obstacles in the regulatory areas covered by federal legislation[31]. Thus, the THG applies to all areas in which the federal government draws up technical provisions[32]. Cantonal regulations no longer play a role since the federal drug law (*Heilmittelgesetz*)[33] and the construction product law (*Bauproduktegesetz*)[34] came into force in 2000 and 2001 respectively.

In Article 18 the THG regulates the recognition of test reports and conformity certificates for the regulatory sphere, as long as testing[35] or conformity assessment by a third party is

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31 Art. 1 para. 1 THG.

32 Art. 2 para. 1 THG.

33 Federal Law on Medicinal Products and Medical Devices (Bundesgesetz über Arzneimittel und Medizinprodukte - Heilmittelgesetz, HMG) from 15 December 2000, SR 812.21.

34 Federal Law on Construction Products (Bundesgesetz über Bauprodukte - Bauproduktegesetz, BauPG) from 8 October 1999, SR 933.0.

35 According to the use of the term in the Swiss legal provisions, testing is not counted as conformity assessment, see above A.III.

not prescribed by area-specific provisions. According to Art. 18 para. 1 of the THG, the test reports and certificates are recognized as evidence when they are from a body which is either accredited in Switzerland, recognized by Switzerland in the framework of an international agreement[36] or is authorized by Swiss law by other means[37]. According to Art. 18 para. 2 of the THG, the recognition of test reports and certifications of foreign bodies comes under consideration even without state treaty foundations if the body can demonstrate that the applied procedures satisfy the Swiss requirements and that it has equal qualifications. This underlines a unilateral, autonomous opening of Swiss law, which only is limited by Art. 18 para. 3 of the THG to the extent that the State Secretary for Economic Affairs (SECO) can make the recognition dependent on the existence of mutuality[38]. Switzerland deliberately opted for a recognition-friendly regulation, which should facilitate market access for products in a small national, but highly internationally integrated market[39]. For the proof of the qualification of the bodies Switzerland trusts above all the international accreditation system: the Dispatch on the THG states that an equivalent qualification would namely be accepted in such cases when the foreign body is accredited by the accreditation body of its country of headquarters, as long as the foreign accreditation body complies with international requirements; in this context a reference is made to the *peer reviews* among the accreditation bodies[40].

With Art. 10, the THG ultimately creates a basis for the regulation of a Swiss accreditation system which comprises conformity assessment with regard to products, persons, services or procedures. The Federal Council made use of this authorization in the Accreditation and Designation Decree, which was rewritten in 1996.

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36 For example within the framework of the Switzerland-EC MRA, see below B.II, B.IV.2.

37 More on the role of accreditation in the recognition of bodies in B.III.

38 This has yet to be used up to now.

39 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 608 et. seq.

40 See Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 608 et seq., in particular 145.

2. Accreditation and Designation Decree (AkkBV)

The Accreditation and Designation Decree (*Akkreditierungs- und Bezeichnungsverordnung/*AkkBV)[41] regulates the accreditation of bodies for the regulatory and non-regulatory sphere and the designation of bodies within the framework of international agreements. The accreditation serves to formally recognize the expertise of a body to carry out certain testing activities or conformity assessments[42]. The designation confirms that a body fulfils the requirements to conduct testing activities or conformity assessments or effectuate declarations or authorizations in accordance with the requirements of the concerned agreement[43]. The existence of an accreditation according to the AkkBV can substantiate the assumption of the fulfilment of the prerequisites for designation[44]. The AkkBV stipulates which bodies can be accredited[45] as well as the requirements for accreditation and the accreditation procedure,[46] the effects of the accreditation[47] and the surveillance of the bodies[48]; the same holds for the designation[49]. It also establishes the Swiss accreditation body SAS as the national accreditation body[50].

3. Interplay between horizontal laws and area-specific laws

According to Article 2 para. 2, the THG applies in subsidiary manner in conjunction with area-specific regulations which contain deviating or more extensive provisions[51]. This shall be clarified in the following using the example of the Law on the Safety of Technical Fa-

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41 Decree from 17 Jun 1996 on the Swiss Accreditation System and the Designation of Inspection, Conformity Assessment, Registration and Authorization Bodies (Akkreditierungs- und Bezeichnungsverordnung, AkkBV), AS 1996 1704, SR 946.512; last amended by the Decree from 10 March 2006, AS 2006 1089.

42 Art. 2 AkkBV, Art. 3 Letter o) THG.

43 Art. 3 AkkBV.

44 Whether this is the case is determined by the respective agreement, Art. 25 para. 2 AkkbV. More on the Switzerland-EC MRA below in B.IV.2.b.

45 Art. 4 AkkBV.

46 Art. 7, 8 et seqq. AkkBV.

47 Art. 15 et seqq. AkkBV.

48 Art. 19 et seqq. AkkBV.

49 Art. 24 et seqq. AKkBV. More on the requirements and procedures of accreditation and designation under B.IV.

50 Art. 5 et. seq.AkkBV.

51 Art. 1 para. 2 THG; in greater detail in the Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 547 et seq., 563.

cilities and Devices (*Gesetz über die Sicherheit von technischen Einrichtungen und Geräten* - STEG)[52]. Machines, gas appliances, personal protective equipment, lifts or pressure equipment, for example, fall under the scope of the STEG. The law contains in Art. 4a a reference to technical standards to concretize the security requirements and in Art. 4b para. 2 an assumption rule in favour of complying with technical standards[53]. The law is supplemented by the Decree on the Safety of Technical Facilities and Devices (*Verordnung über die Sicherheit von technischen Einrichtungen und Geräten* - STEV)[54], which refers to the appendixes of the respective European directives for the Essential Requirements[55] and further regulates the conformity assessment procedures. For the requirements for the conformity assessment bodies, Art. 6 of the STEV falls back on the wording of Art. 18 of the THG: the bodies which are to be involved must be accredited by the Swiss accreditation system, authorized by federal law by other means, or recognized by Switzerland within the framework of an international agreement. This regulatory mechanism can also be found in numerous other laws, for example in the pressure equipment decree[56], the lift decree[57] or in the drug law and the medical devices decree passed on the basis of the latter[58].

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52 Bundesgesetz über die Sicherheit von technischen Einrichtungen und Geräten (STEG) from 19 March 1796, SR 819.1.

53 Art. 4 b para. 3 of the STEG explicitly maintains that the fulfilment of the standards is not mandatory for the proof of compliance with the essential safety requirements and that the proof can also be demonstrated by other means.

54 Verordnung über die Sicherheit von technischen Einrichtungen und Geräten from 12 June 1995, SR 819.11.

55 See also the Decree on the Procedures of the Conformity Assessment of Technical Facilities and Devices/Verordnung über die Verfahren der Konformitätsbewertung von technischen Einrichtungen und Geräten from 12 June 1995, SR 819.115, which outlines the procedures.

56 Art. 5, 7, 9 et seqq. of the Decree on the Safety of Pressure Equipment/Verordnung über die Sicherheit von Druckgeräten (Druckgeräteverordnung) from 20 November 2002, SR 819.121.

57 Art. 5, 7, 9 et seqq. of the Decree on the Safety of Lifts/Verordnung über die Sicherheit von Aufzügen (Aufzugsverordnung) from 23 June 1999, SR 819.13, Art. 5, 7, 9 et seqq.

58 Art. 45 et. seq.Federal Law on Medicial Products and Medical Devices/Bundesgesetz über Arzneimittel und Medizinprodukte (Heilmittelgesetz, HMG) from 15 December 2000, SR 812.21; Art. 4, 10, 11 Decree on Medical Devices/Medizinprodukteverordnung (MepV) from 17 October 2001, SR 812.213.

II. Mode of operation of the Switzerland-EC MRA

The agreement on the mutual recognition of conformity assessments between Switzerland and the EC[59] enables the market entry of products through the recognition of declarations of conformity and test results or certificates of conformity. The area of application of the agreement comprises a majority of the product sectors regulated in the EC by the directives based on the New Approach[60]. It consists of a general section, the appendix 1, which contains 15 sector-specific chapters on the individual product sectors, and the appendix 2, which stipulates general principles for the designation of the conformity assessment bodies. The Switzerland-EC MRA has two different levels of mutual recognition, depending on whether the material requirements for the products have been harmonized or whether different requirements still exist.

1. No equivalent regulations ("classic MRA")

In product sectors in which a harmonization of the legal requirements for products between Switzerland and the EC has not yet taken place or the equivalence of the legal provisions has yet to be ascertained (pressure vessels, gas appliances and boilers, certain measuring instruments and prepackages), the products must be inspected for market entry in the area of the respective other party according to the legal requirements of the latter. However, this can also be conducted by a conformity assessment body based in the exporting state if it is listed in the appendix of the MRA, see Art. 1 para. of the MRA. According to this classic form of mutual recognition, an additional assessment is thus required for market access in the respective other country; however, this can be carried out by the same body which also conducts the assessment for market entry in the exporting state[61].

For pressure equipment, for example, the equivalence of the provisions has yet to be established and to be recognized in the agreement between Switzerland and the EC, so that the Swiss product must undergo a conformity assessment on the basis of the pertinent Euro-

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59 See Fn. 22.

60 Appendix 1 Switzerland-EC MRA (Fn. 22).

61 In practice, these only constitute supplementary inspections, because the differences in the requirements are often slight.

pean regulations. This can also be carried out by a Swiss body listed in Appendix 1 of the MRA, though. If the use of a conformity assessment body is not required, the supplier's declaration of conformity is recognized. The CE-marking affixed on these foundations provides authorization for market entry in the EC. Conversely, an EC product must undergo a conformity assessment according to Swiss law, which again can be conducted by a body listed in Appendix 1 of the agreement. Suppliers' declarations of conformity are recognized. The advantage of the mutual recognition primarily lies in the fact that the assessment can be conducted by a single body on the basis of the legal provisions of both states.

2. Equivalent regulations

In those areas in which the legislation of Switzerland and the EC is regarded as equivalent, only one inspection according to the legal provisions of the EC *or* Switzerland is necessary. The contract parties recognize the certificates of the conformity assessment bodies listed in the appendix as well as the declarations of conformity by the manufacturers, see Art 1 para. 2 of the MRA. The areas in which equivalence is assumed are determined by the committee established by the MRA, Art. 1 para. 3 of the MRA in conjunction with Art. 10 of the MRA[62].

Since the regulations are recognized as equivalent in the medical devices sector, for example, a conformity assessment according to Swiss or EC provisions suffices for the market entry of the Swiss product in the Member States of the EC. This authorizes the manufacturer to affix the CE-marking. Hence, the product is directly marketable in the EC. The same holds for the manufacturer from the EC Member State: his/her product is also marketable in Switzerland when the CE-marking is affixed[63]. This simplified form of mutual recognition thus allows a body to assess the conformity of a product on the basis of the

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62 They are designated in the agreement by the reference in the sector-specific chapters of the Appendix 1 to Art. 1 para. 2, while Art. 1 para. 1 is mentioned when no equivalence exists.

63 Art. 46 HMG stipulates that before the marketing of the medical device it must be demonstrated that the corresponding conformity assessment procedure has been conducted. According to Art. 11 para. 1 of the MepV, the conformity assessment bodies active in this process can also be those that are recognized by Switzerland within the framework of an international agreement. Thus, it suffices for market entry in Switzerland when a conformity assessment procedure is carried out by bodies listed in Appendix 1 of the MRA. According to Art. 8 of the MepV, all products which are put on the market in Switzerland must bear a mark of conformity. According to Art. 8 para. 4 MepV in conjunction with Appendix 2 this also may be the CE-marking .

respective national legislation. Hence, only one assessment according to the legislation of one of the contract parties is necessary, as it is the case within the EC.

III. Role of accreditation during the competence assessment by the state

In Switzerland the accreditation as a procedure to assess the competence and adequacy of the bodies plays a decisive role, both in the national sphere as well as for purposes with regard to international agreements. According to Article 18 of the THG, accreditation is indeed not the only means of demonstrating competence –Art. 18 para. 1 Letter c of the THG stipulates that other procedures can also be taken into consideration. According to the Dispatch on the THG, though, this shall only affect special areas, in which an accreditation is not possible or appears to be disproportional in an international comparison[64]. The regulation in the AkkBV and in the area-specific laws in many cases distinguishes itself by the fact that the accreditation by the state accreditation body is not followed by a further decision by an area-specific agency on the recognition of the body[65]. For example, the Decree on the Safety of Technical Facilities and Devices (STEV) stipulates that the involved conformity assessment bodies must be accredited (or authorized by other means)[66]. In this manner the assessment of the competence and adequacy of the bodies is concentrated in the SAS. The consideration of potential special requirements of the regulatory sphere is guaranteed by the involvement of the area-specific agencies in the accreditation procedure[67]. In practice, the designation of bodies is regularly based on the accreditation by the SAS.

IV. Requirements and procedures of accreditation and designation

The Accreditation and Designation Decree stipulates the requirements and the procedure for the accreditation by the SAS as well as for the designation of bodies in the framework of international agreements.

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64 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 607.

65 Unlike the case of the designation which is carried out by the area-specific agency.

66 Art. 6 para. 1 STEV. The same regulatory mechanism can be found, for example, in Art. 11 para. 1 of the MepV.

67 Art. 11 of the AkkBV.

1. Acceditation according to the AkkBV

In Switzerland the SAS is always responsible for the accreditation[68]. The accreditation is open to testing and conformity assessment bodies in private hands as well as state testing and conformity assessment bodies[69]. Under certain conditions foreign bodies can be accredited after consulting the SECO[70]. According to Art. 7 para. 1 of the AkkBV, a requirement is that the bodies "fulfil the decisive international requirements"; for this the provision "particularly" refers to the international standards of the series ISO 17 000 et. seq. and EN 45 000 et. seq. and the corresponding ISO/IEC Guidelines listed in Appendix 2 of the AkkBV. In the regulatory sphere it is also required for the body to be able to apply the respective legal provisions and, if necessary, fulfil additional requirements contained within[71].

The procedure of accreditation is regulated by Art. 9 et. seq. of the AkkBV. In the regulatory sphere representatives of the responsible state agency can be involved to evaluate the body[72]. This allows for the early involvement of the concerned agencies in the evaluation of the bodies and, where necessary, the consideration of specific demands of the regulatory sphere[73]. The evaluation by the SAS is followed by the opinion of the Swiss Federal Accreditation Committee, AKKO[74]. The director of the SAS decides on the accreditation by order (*Verfügung*)[75]. The bodies may take legal action on the basis of administrative law against the decisions of the SAS; the legal relationship between the accreditation body and its clients is governed by public law[76].

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68 By way of an exception, the EJPD decided in cases in which areas of the METAS – e.g. inspection bodies – were to be accredited, Art. 14 para. 1, 2 of the AkkbV. Art 14 para. 2 of the AkkBV was replaced by decree from 10.3.2006 AS 2006 1089 during the incorporation of the SAS into the SECO .

69 Art 4 para. 1 of the AkkBV.

70 According to the provisions of Art. 4 para. 2 of the AkkBV.

71 Art. 7 para. 2 of the AkkBV.

72 Art. 11 of the AkkBV.

73 If the bodies apply foreign law – e.g. in the area of application of Art. 1 para. 1 of the Switzerland-EC MRA to non-equivalent regulations – a representative of the responsible body in the concerned state should be involved wherever possible, Art. 11 para. 3 of the AkkBV.

74 More on the AKKO in C.IV.

75 Art. 14 para. 1 of the AkkG.

76 See also Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 594.

2. Designation and Notification within the framework of the Switzerland-EC MRA

The requirements for the notification of bodies arise from the MRA and are implemented by Switzerland and the EC Member States by means of the respective national legislation.

a) Requirements of the MRA

The criteria for the designation of the conformity assessment bodies are defined in Art. 6 para. 1 of the MRA in conjunction with Appendix 2 of the MRA, and supplemented where necessary with particular provisions in the sector-specific chapters. The same holds for suspension and revocation. According to Art. 6 para. 1 of the MRA the Designating Authorities follow the designation principles set out in Appendix 2, "subject to" the sections IV of the Appendix 1. The sections IV of the Appendix 1 refer to the pertinent legal provisions of the contract parties, i.e. for the EC to the respective directive in the product sector. As a result, the minimum criteria of the directives on the notification of the bodies must first be complied with.

However, one can induce from the use of the term "subject to" that the criteria of the Appendix 2 remain decisive, as long as the directives do not contain any more extensive or special requirements. This is interesting because the MRA explicitly focuses on the *peer evaluation* and the exchange of experiences of the accreditation bodies in Appendix 2, while the internal regulations within the EC have yet to explicitly address this and only fall back on the factually existing structures in EA[77]: Appendix 2 prescribes that the criteria for the professional expertise of the bodies are to be based to the greatest possible extent on internationally recognized documents, in particular the series of standards EN 45 000 or equivalent standards[78]. An assumption prevails that the bodies have the technical competence to apply the demands stipulated by the other contract party if the responsible accreditation bodies respect the relevant international provisions on accreditation (Standards EN 45 000 et seq. and ISO/IEC-Guidelines) and if they are signatory to a multilateral agree-

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77 There are now also efforts to accordingly concretize the role of accreditation for the notification of bodies by the Member States, see Part Two, C.II.3.

78 Appendix 2 A. 4 of the MRA.

ment under which they are subject to *peer evaluation* or participate in programs for the exchange of experiences under the surveillance of a Designating Authority[79].

According to Art. 7 of the MRA, the contract parties instruct each other on the applied procedures for assessing the bodies' competence and compare the methods used: the respective accreditation systems can be drawn on for this comparison[80]. According to Art. 11 of the MRA, the Committee decides on the admission of a conformity assessment body to the list in Appendix 1 of the agreement upon the request of a contract party. If the other contract party consents to the request or if it does not raise any objections, the proposal is considered accepted by the committee. After the coming into force of the decision of the Committee, the contract parties recognize the certificates, etc. issued by the body. If the other contract party objects, the verification of the body's competence shall be undertaken jointly by the parties according to Art. 11 c) in conjunction with Art. 8 para. 2 of the MRA. The same procedure is used for cancelling the bodies. The notifying authorities are listed in the sector-specific appendixes of the MRA for Switzerland and the Member States of the EC respectively. Art. 8 para. 1 of the MRA arranges for the contract parties to contest the technical competence of a body in exceptional cases.

b) Implementation by the contract parties

Switzerland has regulated the requirements for the designation of conformity assessment bodies within the framework of multilateral agreements in the procedure of designation according to the AkkBV. The prerequisite for the designation is that the body fulfils the requirements of the respective agreement[81]. If the agreement for the evaluation of the expertise of the bodies refers to accreditation – as in Art. 6 para. 1 in conjunction with Appendix 2 of the Switzerland-EC MRA – the accreditation is given an assumption of conformity according to the AkkBV[82]. For cases in which the agreement contains no regulations on the requirements of the designation, the AkkBV stipulates minimal require-

79 More on the requirements and scope of the assumption of conformity in Appendix 2 B. 6 a) of the MRA.
80 Art. 7 para. 2 clause 2 MRA.
81 Art. 25 para. 1 of the AkkBV.
82 Art. 25 para. 2 of the AkkBV.

ments[83]. Applications for designation can be submitted to the responsible Designating Authority, which inspects the fulfilment of the requirement according to the respective agreement[84]. If a reference is made to an accreditation, the Designating Authority acts upon consultation of the SAS, which has issued the accreditation. If the result is positive, the SECO reports the body to the responsible authority, in this case the Committee in accordance with Art. 10 of the Switzerland-EC MRA. According to Art. 25 para. 4 of the AkkBV there is no entitlement to designation[85].

In the EC the applicants are examined by the respective Designating Authority whether they comply with the requirements of the agreement for designation. In Germany this is done by the responsible designation/accreditation body of the regulatory sphere[86]. In the other examined Member States the relevant rules according to national law for the respective sector apply for the involvement of the accreditation body in the designation decision. The Member State forwards the Commission (GD Enterprise) its decision, which – after completion if applicable – is passed on to the GD Trade; the latter provides for the authorization of the body by the responsible Committee of the MRA.

V. Surveillance of the conformity assessment bodies

The accredited bodies are monitored by the SAS, which has the right to access the premises of the conformity assessment bodies and information rights. This holds for the initial inspection of the bodies as well as for regular surveillance. Like in the case of the initial evaluation, representatives of the responsible authorities can be involved[87]. The suspension and revocation of the accreditation is arranged for in Art. 21 of the AkkBV. For bodies designated by the area-specific state authorities, the surveillance is generally incumbent on

83 Art. 11 para. 3 in conjunction with Appendix 5 of the AkkBV.
84 Art. 26 para. 1 of the AkkBV.
85 This provision has a trade policy background; as far as can be seen, it has yet to be used though.
86 For medical devices, for example, the designation is carried out by the Federal Ministry for Health after the accreditation by the ZLG, see Art. 15 para. 1 of the German MPG.
87 Art. 19 of the AkkbV in conjunction with Art. 12, 11 of the AkkBV.

these Designating Authorities; they act in coordination with the SAS when the designation is based on an accreditation[88].

C. The role of the accreditation body

Switzerland has opted for the creation of a single accreditation body which is responsible for the regulatory and non-regulatory sphere and based in the State Secretary for Economic Affairs. It is advised by the Swiss Federal Accreditation Committee AKKO, in which the parties involved in the accreditation are represented.

I. Legal status and tasks

The SAS was founded in 1991 and was originally incorporated as a department into the Federal Office for Metrology and Accreditation, METAS[89]. Since 1 April 2006 the SAS is based within the State Secretary for Economic Affairs (SECO)[90]. The SAS has currently accredited approx. 650 bodies, including over 350 calibration bodies, ca. 100 testing bodies and inspection bodies each, followed by the certification bodies in the areas of products, quality management systems and personnel[91]. According to figures from the SAS the number of initial accreditations has continually increased since 1992[92]. According to estimations, a majority of the accreditations are carried out for the non-regulatory sphere.

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88 Art. 21 para. 1 of the AkkBV.

89 SAS at URL: http://www.sas.ch/de/portraet/history.html (30.8.2005). The METAS reverts back to the Swiss Federal Office for Measuring, which changed its name to METAS on 1.1.2001, not least due to developments in accreditation. *SAS*, Annual Report (Jahresbericht) 2004 (Fn. 9), p. 4; now once again Federal Office for Metrology (METAS), see below Fn. 90.

90 The type of incorporation into the METAS led to concerns with regard to the impartiality of the accreditation body and the respective requirements of the ISO/IEC Standards 17011, which partially shed doubt on whether the SAS would remain in the MLA. Effective as of 1.1.2004 the accreditation commission was expanded and the status of the director enhanced, who now decides on the accreditation, not the director of the METAS. On 1.4.2006 the SAS as a unit was transferred from the METAS into the SECO. The former Federal Office for Metrology and Accreditation was renamed Federal Office for Metrology (METAS) in the course of these developments; see the decree on the modification of the Accreditation and Designation Decree (AkkBV) from 10.3.2006, AS 2006, 1089, Section I, Art. 5 para. 1; Section III no. 1.

91 *SAS*, Annual Report (Jahresbericht) 2004 (Fn. 9), p. 4.

92 *SAS*, Annual Report (Jahresbericht) 2004 (Fn. 9), p. 4.

II. National accreditation body for the regulatory and non-regulatory sphere

The Accreditation and Notification Decree (AkkBV) establishes the SAS within the State Secretary for the Economy, without formally granting it a monopoly status[93]. In factual terms, the SAS enjoys a unique status and is also supposed to provide for accreditations in the non-regulatory sphere. From the standpoint of the state, accreditation is regarded as a state task and as a service, which the state provides the conformity assessment bodies. Linking accreditation to a state agency is regarded as advantageous because the state can serve as an "anchor" and create credibility for the entire conformity assessment system[94]. It is also significant in this context that the accreditation in the regulatory sphere addresses state agencies, to which the competence and adequacy of the body can be successfully demonstrated by a state accreditation body. Along with that, synergy effects in a small market are attributed to a single accreditation body. As the Swiss market is very export oriented, particular significance is attached to the function of accreditation for the recognition of test results and certificates abroad[95].

Competition between the accreditation bodies is viewed as disadvantageous, because it is associated with the need for an additional controlling authority, which does not bring about additional safety. However, the monopoly status of the accreditation body also leads to the difficulties typically associated with this. In order to alleviate these, particular emphasis allegedly must be placed on the incorporation of all involved parties, as is called for by the new ISO/IEC standard 17011[96]. Among other things, the sufficient organization and cooperation between the conformity assessment bodies is also regarded as desirable in this regard. As clients of the accreditation body, the conformity assessment bodies could evaluate its performance and, for example, gain a picture of the fee structure of the accreditation body by means of a corresponding representation. For some time now, the SAS has been

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93 See Art. 5 para. 1 of the AkkBV on the basis of Art. 10 of the THG, which stipulates, among other things, that the accreditation is conducted by a state agency.

94 The Dispatch on the THG states that the independence and credibility of the accreditation bodies play a decisive role; therefore accreditation bodies usually constitute state or state-controlled institutions; Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 607.

95 The SAS is explicitly committed to comply with and apply the international standards by the Accreditation and Designation Decree, Art. 5 para. 2, Art. 9 in conjunction with Appendix 1 of the AkkBV.

96 On the incorporation of the involved parties in the accreditation commission AKKO under C.IV.

conducting customer surveys among the accreditation bodies, in order to be able to evaluate its services and receive feedback on the utility of the accreditation in relation to the costs, among other things[97].

III. Organization and financing

The SAS operates with 30 employees and approx. 400 external assessors. Currently sector-specific committees exist for construction, chemicals, EMC, quality management in the health sector, informational safety, laboratory medicine, food and environment microbiology, legal medicine, transport and passenger transportation, environmental management systems as well as destructive and non-destructive materials testing[98]. Due to the financing through the proceeds from accreditation it reached a cost recovery level of 72 % in 2003, and 81 % in 2004[99].

IV. The Swiss Federal Accreditation Committee AKKO

The incorporation of the involved parties into the accreditation policy of the SAS is ensured by the Swiss Federal Accreditation Committee, AKKO[100]. The AKKO is appointed by the Swiss Federal Department of Economic Affairs (EVD)[101]. The AKKO is not an institution of the SAS, but is based as an independent consultation committee outside the structures of the SAS[102]. The number of members was raised from nine to eleven in order

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97 *SAS*, Annual Report (Jahresbericht) 2004 (Fn. 9), p. 23 et. seq.

98 SAS at URL: http://www.sas.ch/de/sektor/index.html (30.8.2005) with information on the composure and activities; short reports on the activities of the sector-specific committees can also be found in the annual reports of the SAS from 2003 and 2004 (Fn. 7, 9).

99 *SAS*, Annual Report (Jahresbericht) 2004 (Fn. 9), p. 4.

100 Information on the activities of AKKO is contained in the annual reports of the SAS from 2003, p. 8 et seqq. and 2004, p. 4 et seqq. (Fn. 7, 9); see also SAS at URL: http://www.sas.ch/de/kommission/info.html (30.8.2005).

101 Art. 6 para. 1 of the AkkBV. Until the modification of the AkkBV by the decree from 10.3.2006, AS 2006, 1089, the Swiss Federal Justice and Police Department (EPJD) in consultation with the Swiss Federal Department of Economic affairs (EVD) was responsible for appointing the AKKO.

102 The SAS indeed does administrate the secretariat of the commission, but the secretariat is exclusively subordinate to the instructions of the AKKO, as long as it is active for the commission; Art. 5 of the Decree on the Swiss Accreditation Commission, SR 941.291.4.

to better represent the interested parties[103]. Among the tasks of the AKKO is the consultation of the state agencies dealing with the accreditation as well as the SAS[104]. During the accreditation procedure the AKKO gives its opinion on every accreditation application, which is passed on to the SAS[105].

D. The activities of the conformity assessment bodies

The legal relationship between the conformity assessment bodies and their clients is based on private law. Cooperation or the exchange of information between the bodies only takes place to a limited extent.

I. Legal relationship between the conformity assessment bodies and their clients

The conformity assessment bodies of the private sector[106] conclude a private law contract with their clients on conformity assessment which also contains the authorization for the bodies to suspend and revoke the testing reports and certificates as well as corresponding information rights etc. Art. 35 Clause 1 of the AkkBV explicitly specifies that the Federal Government does not want to transfer any sovereign authority to the bodies with the accreditation or designation. The Dispatch on the THG states on this that the accreditation should instead constitute a kind of "proof of capability", which grants the bodies "the right to appear on the free market as a provider of services qualified by the state"[107]. The activities of the bodies are thus situated within the market, in contrast to a system of state organized inspections. The regulation must be viewed in relation with the regulation in Clause 2 of the provision, according to which the bodies remain responsible for their activities, in particular for the testing results they arrive at and the issued conformity certificates. This

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103 *SAS*, Annual Report (Jahresbericht) 2004 (Fn. 9), p. 4; a list of the members is available at URL: http://www.sas.ch/de/kommission/index.html (30.8.2005). With this, Switzerland is already reacting to the demands of ISO/IEC 17011, Section 4.3.2.

104 Art. 9 para. 2 of the AkkBV, Art. 2 of the Decree on the Swiss Federal Accreditation Commission, SR 941.291.4.

105 Art. 13 para. 2 clause 2, para. 3 of the AkkBV. In 2004 there were 160 such applications, *SAS*, Annual Report (Jahresbericht) 2004 (Fn. 9), p. 4.

106 In Switzerland numerous state bodies such as testing laboratories are accredited by agencies, for which questions of the legal relationship to their customers do not arise in this manner.

107 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 594.

has to do, above all, with liability law. As the bodies have not assumed any sovereign authority during the conformity assessment according to the guidelines of the THG, the results of their private activities are still subject to control by the market surveillance authorities[108].

II. Cooperation among the conformity assessment bodies

In Switzerland there is no extensive cooperation between the conformity assessment bodies. With regard to laboratories, which make up a large part of the accredited bodies in Switzerland, the national committee of *eurolab* was re-established after no active committee had existed for some time; it is currently based in the Swiss Association for Standardization. Otherwise, there appears to be no association of conformity assessment bodies. The SAS and the AKKO would certainly welcome greater cooperation among conformity assessment bodies. In practical terms, however, the difficultly also exists in Switzerland that cooperation between groups that exchange experiences is not only hampered by the competitive relationship between the bodies, but also is associated with substantial expenses, especially for the numerous small conformity assessment bodies.

E. The role of market surveillance in relation to conformity assessment

In Switzerland market surveillance is understood as an imperative instrument to assure the functional conditions for the free movement of goods. The implementation of market surveillance is incumbent on the area-specific authorities at the federal and cantonal level.

I. Market surveillance to complement the conformity assessment system

In the Dispatch on the Law on Technical Trade Obstacles (THG) market surveillance is described as a necessary supplement to the conformity assessment system. The Dispatch states that in order to develop in a sustainable manner, the greatest possible free movement of goods within the framework of substantiated state guidelines also requires that its rules

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[108] The Dispatch on the THG indicates this, Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 594.

are complied with. If globalized markets and the increased self-administrative of the market participants led to the violation of minimal state standards for health protection, for example, the looming result would be an insufficient level of protection or more restrictive trade rules. For this very reason the efficient and credible control and enforcement of product standards is imperative[109].

II. Organization of market surveillance

During the introduction of the THG a decision was made to leave the regulation of the structures and the organization of market surveillance and above all their financing up to the sector-specific legislation. One reason was that as a horizontal regulation, the THG seemed to be unable to satisfy the different needs and possibilities of the various areas[110]. Accordingly, market surveillance is incumbent on the responsible authorities according to the area-specific laws. In product safety law a large share of the products are covered by the Law on the Safety of Technical Facilities and Devices (*Gesetz über die Sicherheit von technischen Einrichtungen und Geräten* - STEG), which applies to e.g. machines, gas appliances, personal protective equipment, lifts or pressure equipment[111]. Electrical equipment and electro-magnetic compatibility are also an important area, which means that the areas of responsibility do not become too fragmented. However, in Switzerland, as well, the financing of market surveillance is also problematic.

As a horizontal legal provision, the THG stipulates the authorities which are supposed to be granted to the respective agencies[112]. The provision applies in subsidiary manner in conjunction with the area-specific laws and is supposed to ensure that the agencies have the sufficient powers, which might be lacking in the area-specific laws. The Dispatch on the THG clarifies that the control measures mentioned in Art. 19 para. 1 of the THG can only be applied randomly and may not take over the functions of an actual admission to the

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109 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 611.
110 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 611.
111 *Gesetz über die Sicherheit von technischen Einrichtungen und Geräten* (STEG) from 19 March 1976, SR 819.1.
112 Art. 19 of the THG.

market[113]. Art. 20 of the THG concretizes the principle of proportionality for exerting control; in view of the general orientation of the law – the prevention of technical trade obstacles – the provision shall set certain limits to market surveillance[114].

With regard to international cooperation in market surveillance, Switzerland participates in the development of the ICSMS databank.

113 Dispatch on a Federal Law on Technical Trade Obstacles (THG) from 15 February 1995 (Fn. 14), p. 612.

114 The Dispatch on the THG states that the provision should subject the activities of the market surveillance agencies to "certain basic rules for the free movement of goods", Dispatch on a Federal Law on Technical Trade Obstacles / Botschaft zu einem Bundesgesetz über die technischen Handelshemmnisse (THG) from 15 February 1995, 95.013 (Fn. 14), p. 611.

Sixth Section: Conformity Assessment in the United Kingdom

The following section shall provide an overview of the structure of conformity assessment in the United Kingdom. The main focus of the analysis will be placed on the regulatory sphere. After a short overview of the relevance of conformity assessment, its application in the regulatory sphere will be discussed; particular attention will be given to the role of accreditation in the process of approving and monitoring conformity assessment bodies by state authorities. Furthermore, the organization and status of the accreditation body UKAS will be described, followed by several remarks on the activities of the conformity assessment bodies. The section is concluded with a brief overview of the organization and orientation of market surveillance in the United Kingdom.

A. Overview of the relevance of conformity assessment

In the United Kingdom there is no comprehensive legal regulation on conformity assessment, for example in the form of a law on conformity assessment or accreditation. The scope of activity of conformity assessment bodies in the regulatory spheres is determined by the respective laws. Besides the great political and economic relevance of conformity assessment, the benefits of its private sector basis are particularly emphasized.

I. Relevance of conformity assessment

In the United Kingdom conformity assessment indeed has a special tradition in the field of certification of quality management systems[1]. The first standards for the third-party certification of quality management systems were already developed at the beginning of the 1970s for the electrical industry[2]. Nowadays, like in the other examined countries, all forms of conformity assessment are of comparable significance.

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1 *Joerges/Falke/Micklitz/Brüggemeyer*, Sicherheit von Konsumgütern, p. 124 et. seq.

2 The series of standards ISO 9000 originally was based on the British standard BS 5750, which was developed in the 1970s by the British Standards Institute BSI. For the history of the certification according to the series of standards ISO 9000, *Ensthaler*, Zertifizierung, Akkreditierung und Normung, p. 65, see as well *Wikipedia* article “ISO 9000” at URL: http://en.wikipedia.org/wiki/ISO_9000 (12.8.2005); BSI at

The conformity assessment policy views conformity assessment from a strong economic perspective[3]. Conformity assessment is viewed as a means of providing purchasers with confidence in products or services they use, help businesses to be competitive, create market advantages and facilitate trade, both at the national as well as international level. It creates the necessary link to standardization, which is viewed from a strong economic perspective and is promoted as such[4]. As a result, conformity assessment is an indispensable part of the national infrastructure for the economy, technology and standardization[5].

II. Integration into a flexible regulation strategy

Similar to standardization, conformity assessment also is suited as a part of a regulatory strategy, which refrains from strict guidelines to the greatest possible extent and focuses on the notion of *co-regulation*. It is deemed important that the conformity assessment in the regulatory sphere does not pose an additional burden to business, but instead promotes its economic standing[6]. To this extent, the New Approach with its emphasis on standards, self-certification and third-party certification fits well into the national regulatory strategy[7].

URL, http://www.bsi-global.com/HigherEducation/Quality+Management/History_9000.xalter (17.8.2005); on the development of the quality management systems from the systems for the military procurement scheme, see Zollondz, Grundlagen Qualitätsmanagement, 2002, p. 246 et. seq.The DTI contributes to the further development of the standard ISO 9000:2000 through the standardization activities of the BSI, see *DTI* at URL: http://www.dti.gov.uk/strd/certify.html (11.8.2005).

3 For the essentials of the conformity assessment policy in the United Kingdon, see the paper published by the Department of Trade and Industry (DTI) "Conformity Assessment Policy in the United Kingdom", May 2005, URN 05/1241, available online at URL: http://www.dti.gov.uk/strd/capp0505.pdf (26.7.2005).

4 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 4. Here a reference is made to the National Strategic Standardisation Framework (NSSF), which is supplemented by the conformity assessment policy. For a summary of the NSSF, see the strategy paper at URL: http://www.nssf.info/resources/documents/NSSF_Strategy.pdf (11.8.2005) and in general at URL: http://www.nssf.info (11.8.2005).

5 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 1, 4.

6 See, for example, the emphasis placed on the economic benefits of conformity assessment and the simultaneous warning about potential obstacles to trade and innovation in: *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 1, 2, 4.

7 Before the introduction of the directives on product safety law based on the New Approach, there was apparently no comprehensive system of caveats to the authorization of products or other obligatory security inspections in the United Kingdom. English laws on consumer goods protection traditionally focused on voluntary compliance with Safety Regulations, which was only secured by penal sanctions. One clause, according to which only safe products could be put on the market, existed since 1974 for the area of occupational health and safety in the Health and Safety at Work Act; in the Consumer Protection Act of 1987, it was introduced to the consumer goods segment. With regard to the laws on consumer goods safety, it has been demonstrated that consumer protection policy approaches were also strongly linked

It is emphasized that the conformity assessment to support state regulations should fall back as much as possible on the infrastructure which was developed in the non-regulatory sphere[8]. The conformity assessment bodies are basically supposed to offer their services on the basis of mutual competition and on the free market[9]. The positioning of conformity assessment in the private sector and the contracts as a basis of the legal relationships – e.g. between the conformity assessment bodies and their clients or between the accreditation body and the conformity assessment bodies – is regarded as a strong point of the system, which should be maintained.

B. The application of conformity assessment in the regulatory sphere

Conformity assessment is primarily used in areas affected by the New Approach directives, but also is applied to the national, non-harmonized sphere. The respective ministries are responsible for the approval and designation of conformity assessment bodies; however, they generally rely on the evaluation by the national accreditation body UKAS.

I. Designation and notification by the ministries

In the scope of the directives based on the New Approach, the Member States are responsible for the evaluation of the conformity assessment bodies and the notification. A majority of the areas affected by the New Approach directives fall within the responsibility of the Department of Trade and Industry (DTI), which also assumes a leading role in the coordination of the conformity assessment policy[10]. Within in the DTI, the Standards and

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with deregulation strategies aimed at reducing unnecessary burdens and costs for the British economy. See *Joerges/Falke/Micklitz/Brüggemeyer*, Sicherheit von Konsumgütern, p. 106 et seqq., in particular p. 115, 115 et seqq.

8 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 2.

9 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 2.

10 In a document on evaluating conformity assessment bodies in the regulatory sphere, the accreditation body UKAS lists the responsible ministries, see. *UKAS*, Assessment of approved and notified bodies (P 16), Edition 9, May 2004, Appendix (p. 3 et seq.) available online at URL: http://www.ukas.com/Library/downloads/publications/P16.pdf (27.7.2005). The Department for Transport, the Health and Safety Executive, the Strategic Rail Authority or even the Office of the Deputy Prime Minister are responsible.

Technical Regulations Directorate (STRD) is responsible[11]. The accredited bodies have no right to designation and notification, even if they can prove that they have fulfilled the Essential Requirements of the directives[12]. The view prevails that this coincides with the Commission's guide for the implementation of directives based on the New Approach, according to which designation is at the discretion of the Member States and they are not obligated to designate all accredited bodies according to Community Law[13]. However, in practice, a limitation of the number of conformity assessment bodies has not occurred.

II. Role of accreditation in the competence evaluation by the state

In the United Kingdom the competence and independence of the conformity assessment bodies in the regulatory sphere are primarily evaluated and monitored by the national accreditation body, UKAS. In doing so, it draws on *Guidelines* elaborated with the responsible ministries, which further specify the demands to the conformity assessment bodies.

1. Evaluation of conformity assessment bodies by UKAS

The DTI and the majority of the other concerned ministries mandate UKAS to evaluate the competence and independence of conformity assessment bodies[14]. After the evaluation of a

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11 Further information on the responsibilities of the STRD at URL: http://www.dti.gov.uk/strd/index.html (27.7.2005).

12 *DTI*, The Lifts Directive - Guidelines on the Appointment of Notified Bodies to undertake inspection and certification for the purposes of the Conformity Assessment Procedures in the UK Regulations, April 1997, URN 97/717, Item 1.11 (p. 3), the document is available online at URL: http://www.dti.gov.uk/strd/liftab.pdf (27.7.2005), quoted in the following as *DTI*, Lifts Guidelines.; *DTI*, The Pressure Equipment Regulations 1999 - Guidelines on the Appointment of Notified Bodies, August 1999, URN 99/1051, Item 2.1 (p. 3); The document is available online at URL: http://www.dti.gov.uk/strd/pedcabgd.pdf (27.7.2005), quoted in the following as *DTI*, Pressure Equipment Guidelines; with regard to the operational compatibility of the Trans-European high-speed railway system, see the Guidelines of the Strategic Rail Authority (SRA), *SRA*, Guidelines for the Assessment and Appointment of Bodies Applying for Notified Status, Version 4.41 from 4.12.2003, p. 6; the document is available online at URL: http://www.sra.gov.uk/technical/guidelines (28.7.2005), quoted in the following as *SRA*, Guidelines.

13 *European Commission*, Guide to the implementation of directives based on the New Approach and Global Approach, 2000.

14 DTI, Assessment of Applicants for Appointment as Notified Bodies; Monitoring of Notified Bodies; and Surveillance/Assessment of Manufacturers by Notified Bodies: Some Principles, December 1998, p. 1; available online URL: http://www.dti.gov.uk/strd/nbprin.pdf (27.7.2005); quoted in the following as, *DTI*, Assessment of Notified Bodies; in comparison with the other ministries, see the overview in: *UKAS*, Assessment of approved and notified bodies (Fn. 10), Appendix (p. 3 et seq.); with regard to the

conformity assessment body, UKAS gives a recommendation on the basis of which the responsible ministry decides on the designation and notification[15]. However, not all ministries rely on UKAS for the evaluation of the competence and independence of the accreditation bodies. The Department of Health, Medicines and Healthcare which is responsible for medical devices has transferred this task to a subordinate agency, the Medicines and Healthcare products Regulatory Agency (MHRA)[16].

2. Criteria for the designation of conformity assessment bodies

For the evaluation of the conformity assessment bodies by UKAS, the DTI and other ministries in cooperation with UKAS have developed directive-specific *Guidelines*, which UKAS uses as a basis for the evaluation of conformity assessment bodies seeking notification[17]. The starting point is that, according to the directives based on the New Approach, accreditation on the basis of the series of standards EN 45000 and ISO 17000 constitutes the presumption for the fulfilment of the Essential Requirements of the directive, but is not obligatory[18]. Hence, an accreditation by UKAS according to the standards of the series EN 45000 is explicitly recommended, but is not a binding requirement for designation and notification[19]. However, existing accreditations are taken into consideration[20].

The Guidelines provide the detail underpinning the minimum criteria for appointment given in the regulations or directives and relate the conformity assessment activitiy to the

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operational compatibility of the Trans-European railway system, see Guidelines of the Strategic Rail Authority, *SRA*, Guidelines (Fn. 12). p. 4.

15 *UKAS*, Assessment of approved and notified bodies (Fn. 10), Item 4 paragraph 3 (p. 2); *DTI*, Lifts Guidelines (Fn. 12), Item 2.7 (p. 4); with regard to pressure devices, see *DTI*, Pressure Equipment Guidelines (Fn. 12), Item 2.1 (p. 3).

16 The MHRA is a state authority and has the status of an executive agency of the Department of Health. The MHRA is also responsible for the designation and notification of the accreditation bodies, MHRA Guidance Note 6 – Requirements for UK notified bodies – introduction, p. 1; the document is almost identical with MEDDEV 2.10/2 and available online at URL: http://www.mhra.gov.uk, see How we regulate/Devices/Notified Bodies (12.3.2005). For more on the MHRA see also *MHRA* at URL: http://www.mhra.gov.uk/aboutmhra/aboutmhra.htm (27.7.2005).

17 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 1. The guidelines of the DTI are available online at URL: http://www.dti.gov.uk/strd/strdpubs.html#gen (27.7.2005).

18 DTI, Assessment of Notified Bodies (Fn. 44), p. 1; available online at URL: http://www.dti.gov.uk/strd/nbprin.pdf (27.7.2005); quoted in the following as *DTI*, Assessment of Notified Bodies.

19 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 1, 2.

20 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 1; *UKAS*, Assessment of approved and notified bodies (Fn. 10), Item 4 para. 2 (p. 2).

relevant EN45000/ISO17000 series standards, to the essential health and safety requirements and to product standards where they exist. The Guidelines make it clear that accreditation is not mandatory but still use the EN 45000/ISO17000 series standards as the basis for assessment. UKAS is required to assess against the requirements of the guidelines and provide a view on the status of applicants against the requirements of the guidelines or equivalent and make a recommendation to the competent authority on the applicant's overall competence in respect of the specified conformity assessment duties and proposed technical scope of work. To comply with regulations, and in contrast with accreditation, the technical scope of work against which a regulatory appointment is made is often defined in general terms.

In terms of their requirements, the *Guidelines* partially exceed the criteria of the standards; doing so they partially refer to requirements which are laid down in some Directives. For example, the Notified Bodies are required to have thorough knowledge of the directives and the applicable implementation provisions[21]. Furthermore, the conformity assessment bodies are also supposed to be able to evaluate the products directly on the basis of the Essential Requirements of the directive, when no harmonized product standards exist[22]. The *Guidelines* also stipulate in part that the willingness to participate in national or international exchanges of experiences is a prerequisite for approval or designation and notification[23]. Whether the accreditation bodies actually participate, can be checked by UKAS; however, to limit expenses, it is indeed common for not all accreditation bodies to participate, but instead sometimes represent each other at the meetings. The regulations on passing on information from the conformity assessment bodies to state authorities vary; as a rule, conformity assessment bodies are only obligated to maintain the documents on the inspection and certification and make them available on request[24].

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21 *DTI*, Lifts Guidelines (Fn. 12), Item 2.6 (p. 4); *DTI*, Pressure Equipment Guidelines (Fn. 12), Item 3.2 (p. 3).

22 *DTI*, Lifts Guidelines (Fn. 12), Item 2.6 (p. 3);

23 *DTI*, Lifts Guidelines (Fn. 12), Item 2.8 (p. 4).

24 See, for example, the regulations in *DTI*, Lifts Guidelines (Fn. 12), Item 7.1 (p. 13); *DTI*, Pressure Equipment Guidelines (Fn. 12), Item 6.6 (p. 8).

3. Monitoring the conformity assessment bodies

When the ministries responsible for evaluating the conformity assessment bodies fall back on UKAS, the bodies are generally also monitored by UKAS[25]. The surveillance is should generally be consistent with the standard measures applicable for an accreditation by UKAS, i.e. a surveillance at least annually and a re-assessment every four years; for newly accredited bodies an additional inspection after the first six months[26]. Additional surveillance may be carried out at more frequent intervals if justified by the circumstances. The DTI explicitly provides for *witnessed assessments* by UKAS[27].

The designation decision can contain further specifications on monitoring the bodies[28]. If a conformity assessment body is accredited by UKAS, the loss of the accreditation can lead to the revocation of the designation, when the ministry is instructed by UKAS that the minimum criteria of the directive are no longer complied with[29].

C. The Role of the Accreditation Body

The United Kingdom Accreditation Service - UKAS, works on the basis of a *Memorandum of Understanding*, which the Department of Trade and Industry concluded with UKAS on behalf of the government[30]. UKAS is active in the regulatory and non-regulatory sphere and holds a virtual monopoly.

I. Status of UKAS

1. Foundation and legal form

In the United Kingdom, the view consistently prevailed that accreditation is in the interest

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25 For the DTI, see *DTI*, Assessment of Notified Bodies (Fn. 44), p. 2; for the SRA.
26 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 3; *SRA*, Guidelines (Fn. 12), p. 4.
27 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 3.
28 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 3; see also *SRA*, Guidelines (Fn. 12), p. 19.
29 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 3; *SRA*, Guidelines (Fn. 12), p. 4; *UKAS*, Assessment of approved and notified bodies (Fn. 10), Item 4 para. 4 (p. 3 et seq.).
30 More details under C I 3. The text of the memorandum is available at URL: http://www.ukas.com/Library/downloads/About_UKAS/MOU.pdf (3.8.2005).

of the public, because it increases the trust of the market in the quality of conformity assessment. Accreditation is regarded as a service of general economic interest[31]. Accordingly, the government initially maintained its own accreditation system from 1984 through 1995[32]. In 1995 a decision was made to establish a unified accreditation body, which was not supposed to be affiliated with the state authorities, but still have close ties with the government. UKAS is a non-profit distributing company, limited by guarantee[33].

2. Areas of activity

UKAS is active as the national accreditation body of the United Kingdom in the regulatory and non-regulatory sphere. The areas of activity for which UKAS is recognized as the national accreditation body are ultimately specified in the Memorandum of Understanding[34]. UKAS carries out no further accreditations, not even in the non-regulatory sphere.

3. Unique status of UKAS on the basis of the Memorandum of Understanding

UKAS holds a virtual monopoly both in the regulatory as well as non-regulatory sphere. In the Memorandum of Understanding, the Secretary of State for Trade and Industry acknowledges UKAS as the only national accreditation body for the evaluation and accreditation of conformity assessment bodies[35]. UKAS is not rewarded a legally guaranteed monopoly[36], but the government is obligated to not establish or promote any other accredi-

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31 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn.24), p. 3.

32 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 4 et. seq.The accreditation of inspection and calibration laboratories was carried out by the National Measurement Accreditation Service (NAMAS), a department of the National Physical Laboratory, which in turn was subordinate to the DTI. The National Accreditation Council for Certification Bodies (NACCB), which in formal terms was a committee of the BSI, was responsible for the accreditation of certification bodies. An accreditation body for inspection agencies did not exist. UKAS emerged from NAMAS and NACCB at the initiative of DTI.

33 *UKAS* at URL: http://www.ukas.com/about_UKAS/default.asp (3.8.2005).

34 Memorandum of Understanding (Fn. 30), Art. 1 in conjunction with Appendix 1.

35 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 3; Memorandum of Understanding (Fn. 30), Art. 1.

36 See the Memorandum of Understanding (Fn. 30), Art. 15: The Memorandum of Understanding is not binding. In the non-regulatory sphere, the activities of other accreditation bodies are thus generally possible. Besides UKAS, other agencies who offer accreditation are active in the United Kingdom. However, the scope of their activities is very small in comparison to UKAS.

tation bodies than UKAS[37]. It additionally pledges to encourage the conformity assessment bodies to make use of the accreditation by UKAS[38]. In the regulatory sphere, the Secretary of State is supposed to ensure that the government, as a rule, arranges for the use of such conformity assessment bodies, which are accredited by UKAS[39]. The DTI encourages UK Businesses, Government and local authorities requiring third party conformity assessment services to source such services, where they exist, from conformity assessment bodies accredited by UKAS or an equivalent accreditation body (e.g. a member of the European or international multilateral arrangements)[40]. With the support of the DTI, UKAS has carried out an *Accreditation Awareness Campaign*, which is to make both businesses as well as state authorities aware of the advantages of an accreditation by UKAS[41].

From the standpoint of British conformity assessment policy, another advantage of a uniform national accreditation body is that it enables a unified interpretation and application of the standards and that UKAS can function as a centre of expertise. One benefit of this is that the accreditation for the regulatory and non-regulatory sphere is from one source. The concentration of activities within one accreditation body yields further benefits for the areas in which an accreditation would otherwise not be cost-effective. As for international ties, the existence of only one accreditation body makes the accreditation more recognizable and allows for the United Kingdom to be recognized in international committees by only one accreditation body. Finally, this organizational form agrees with that of other European countries[42].

In the United Kingdom, the view prevails that there should be no competition between the accreditation bodies, neither at the national nor at the international level[43]. However, it is also recognized that if competition is absent, other mechanisms are necessary to guarantee that UKAS conducts its activities as well as possible. The connection to the government

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37 Memorandum of Understanding (Fn. 30), Art. 1.
38 Memorandum of Understanding (Fn. 30), Art. 2 para. 1; *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 3.
39 Memorandum of Understanding (Fn. 30), Art. 2 para. 1.
40 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 3.
41 More on *UKAS* at URL: http://www.ukas.com/information_centre/accreditation_awareness_campaign.asp (3.8.2005).
42 For a broader overview, see *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 5.
43 *DTI*, Conformity Assessment Policy in the United Kingdom (Fn. 24), p. 2.

through MoU, the status as a *non-profit-distributing company*, the membership structure of UKAS, committees such as the Policy Advisory Committee or the international *peer review* are cited here. In the MoU, UKAS is obligated to subject itself to an audit on a regular basis which examines the compliance of the accreditation activities with the internationally harmonized demands and the MoU[44]. Furthermore, in 2004 DTI mandated an independent consulting firm to conduct a probe on the activities of UKAS (*efficiency review*). The probe was primarily concerned with customer satisfaction[45]. Since spring 2005, UKAS has been conducting its own inquiries on customer satisfaction[46].

II. Organization of the accreditation body

As a private firm in the form of a non-profit-distributing company, limited by guarantee, UKAS has members who represent the interested parties. Among the 15 current members are representatives of national and local authorities, representatives of the associations of certification bodies, inspection bodies and laboratories, industry, and small and medium-sized enterprises, among others[47].

UKAS is managed by a Board of Directors. As regards the general orientation of activities, the Board is advised by the Policy Advisory Committee. The committee consists of representatives of the parties interested in the accreditation and convenes at least three times per year[48]. In technical terms, the Board is supported by different Technical Advisory Committees. Assessors, conformity assessment bodies, clients of the conformity assessment bodies as well as professionals from industry and governmental agencies are represented in these committees at the invitation of UKAS. UKAS may seek the advice of the Technical Advisory Committees on technical matters or during the selection of assessors as well[49].

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44 Memorandum of Understanding (Fn. 30), Art. 10 clause 2.

45 A summary of the results is available at URL: http://www.dti.gov.uk/strd/ukaser.pdf (8.8.2005).

46 A summary of the results of the first survey in April 2005 is available at URL http://www.ukas.com/news/2005/CSI_Survey.asp (8.8.2005).

47 A list of members is available online at URL: http://www.ukas.com/about_UKAS/structure.asp (3.8.2005).

48 More on the composition and mode of operation of the Policy Advisory Committee UKAS at URL: http://www.ukas.com/about_UKAS/PolicyAdvisoryCommittee.asp (3.8.2005).

49 More on the Technical Adisory Commitees UKAS at URL: http://www.ukas.com/about_UKAS/committees.asp (3.8.2005).

UKAS is basically supposed to finance its activities on its own. Support from the DTI sometimes comes into question, when UKAS is supposed to develop new services, which help support regulatory strategies[50].

III. Legal relationship between UKAS and the conformity assessment bodies

UKAS concludes a contract based on private law with the accredited bodies[51]. The contract includes, among other things, the authorization to conduct regular surveillance measures and to limit, suspend or revoke the accreditation[52]. The accredited bodies can appeal to UKAS against decisions on the issue, limitation and revocation of the accreditation[53], as well as against a decision on a recommendation as a Notified Body. If the appeal submitted in writing within one month is not remedied, a *review panel* is appointed, which can consist of members of UKAS or the Policy Advisory Committee. In some cases, a representative of the DTI can also be a member[54].

D. The activities of the conformity assessment bodies

The legal relationship between the conformity assessment bodies and their clients is based on private law in the United Kingdom as well. The conformity assessment bodies which compete with each other have created associations in several areas, which primarily serve to represent their common interests towards industry and political institutions, but to a certain extent also provide a contribution towards the harmonization of conformity assessment.

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50 Memorandum of Understanding (Fn. 30), Art. 2 para. 3.

51 A sample of the contract text is available online at URL: http://www.ukas.com/Library/downloads/forms/ukas%20agreement.pdf (8.8.2005).

52 Sections 1.5 and 1.6 of the UKAS Agreement (Fn. 51). Data on the number of limited or revoked accreditations are available at URL: http://www.ukas.com/about_accreditation/sanctions.asp (8.5.2005).

53 Section 7.1.of the UKAS Agreement (Fn. 51).

54 *UKAS* at URL: http://www.ukas.com/about_accreditation/appeal_process.asp (8.8.2005).

I. Legal relationship between the conformity assessment bodies and their clients

The activities of the conformity assessment bodies are regarded altogether as being competition-oriented and based in the private sector, even if they are conducted for the regulatory sphere[55]. The conformity assessment bodies conclude a private law contract on the conformity assessment with their clients. The possibility of limiting or revoking certificates, etc. results exclusively from this contract and is not stipulated by law. The same holds for rights to information and access in the course of the surveillance procedure. In the regulatory sphere, the *Guidelines*, which serve as the basis of the approval, partially allow all manufacturers of the respective products general access to the service of the Notified Body; the bodies are supposed to work in a non-discriminatory manner[56].

II. Cooperation among conformity assessment bodies

At the suggestion of the DTI, approximately 15 to 20 certification bodies formed the Association of British Certification Bodies (ABCB)[57]. Membership is open to all accredited certification bodies[58]. The association has set the objective of representing its members in national and international committees, in particular towards UKAS and the government as well, but above all to advocate the creation of an environment which allows for efficient and at the same time profitable certification activities[59]. ABCB is a member of UKAS and a founding member of the European Federation of Associations of Certification Bodies (EFAC)[60]. The association enables the exchange of information between its members and also promotes to a certain extent the consistent application of the standards. This is mainly effected through its membership of IAF. These are not its main tasks, though; there is, for instance, no organized exchange of experiences with technical matters, on the interpretation and application of the standards, etc. The main focus of the activities lies instead on

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55 For example, any liability on behalf of the state for the consequences of faulty decisions by the conformity assessment bodies is ruled out, see *DTI*, Lifts Guidelines (Fn. 12), Item 1.6 (p. 2); *DTI*, Pressure Equipment Guidelines (Fn. 12), Item 3.17 (p. 6).

56 *DTI*, Lifts Guidelines (Fn. 12), Item 3.7 (p.6).

57 *ABCB* at URL: http://www.abcb.demon.co.uk/background.htm (11.8.2005).

58 More on the *ABCB* at URL: http://www.abcb.demon.co.uk/Members%20of%20the%20Association.htm (11.8.2005).

59 *ABCB* at URL: http://www.abcb.demon.co.uk/background.htm (11.8.2005).

60 More on the members of UKAS in C II.

the representation of the common interests of the bodies which otherwise compete with each other.

Numerous inspection agencies are organized in the Safety Assessment Federation, or SAFed. SAFed represents (third-party) inspection bodies, which offer services in the area of work health and safety, thus in particular the inspection and certification of equipment, work supplies and machines within the scope of applicability of the Health and Safety at Work Act[61]. Since the members of SAFed primarily also carry out inspection activities regulated by law, the organization has set the objective to work closely with the responsible authorities[62]. An additional goal of SAFed is to put the benefits of the inspection services to better use through the exchange of professional knowledge[63]. SAFed works with different Technical Committees, which were established for special areas such as pressure equipment or machines, lifts and cranes[64]. The association has an additional Technical Committee to accompany the conformity assessment, which observes the development of interpretation guidelines on the aids for the ISO 17020 standard, for example[65]. The full members of SAFed are accredited by UKAS according to the standard ISO 17020[66] and SAFed is, like ABCB, a member of UKAS. Measurement and testing laboratories are represented by the British Measurement and Testing Association (BMTA). This Association is also a member of UKAS and promotes the interests of its members both nationally and internationally[67].

E. The role of market surveillance in relation to conformity assessment

A basic principle of the product safety policies of the United Kingdom is that the legislation sets the objectives to be achieved, but leaves the selection of the means to achieve

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61 *SAFed* at URL: http://www.safed.co.uk/About_Us/index.htm (11.8.2005).

62 See the Mission Statement by SAFed at URL: http://www.safed.co.uk/About_Us/Mission.htm (11.8.2005).

63 See the Mission Statement by SAFed at URL: http://www.safed.co.uk/About_Us/Mission.htm (11.8.2005).

64 See the overview by SAFed at URL: http://www.safed.co.uk/Committee/index.htm (11.8.2005).

65 *SAFed*, URL: http://www.safed.co.uk/Committee/Assessment.htm (11.8.2005).

66 A list of the members is available at URL: http://www.safed.co.uk/Members/index.htm (11.8.2005). Non-accredited bodies can become associated members. For the membership structure, see *SAFed* at URL: http://www.safed.co.uk/Joining/Types.htm (11.8.2005).

67 More at URL: http://www.bmta.co.uk/ (11.8.2005).

these objectives up to the enterprises to the greatest possible extent. Particular emphasis is placed on flexible regulatory strategies and cooperation between firms and agencies; this also holds for the area of market surveillance[68].

I. Organization of market surveillance

In the United Kingdom the authority to monitor products on the market primarily results from consumer protection laws as well as work health and safety laws[69]. Thus the Trading Standards Departments of the local *weights and measures authorities* und the *Health and Safety Executive* (HSE) are primarily responsible for market surveillance.

1. Products for private use

The Trading Standards Departments are sections of the Weights and Measures Authorities, which are local agencies essentially responsible for guaranteeing a fair market for consumers and consumer services[70]. They are entrusted with the task of monitoring numerous products for private use which fall under the directives based on the New Approach[71]. They are financed by the local authorities[72]. In the year 2002 the government developed the National Performance Framework for Tradings Standards. The program is intended to improve the quality of surveillance by means of instruments such as set performance standards and goals or peer reviews among the agencies[73]. Altogether, this is supposed to guarantee effective surveillance across the country. In order to promote a consistent approach among the more than 200 local agencies, a central service was established, the Local Au-

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68 See *DTI*, Market Surveillance in the UK – UK Policy on enforcement of European Product Safety regulations, November 2003 (URN 03/1577), Item 3; The document is available online at URL: http://www.dti.gov.uk/strd/marketsurveill.pdf (2.8.2005); quoted in the following as *DTI*, Market Surveillance in the UK.

69 Consumer Protection Act 1987 and (for Great Britain) Health and Safety at Work etc. Act 1974, *DTI*, Market Surveillance in the UK (Fn. 68), Item 2.

70 An overview of the laws enforced by these agencies is available at URL: http://www.tradingstandards.gov.uk/consumers/clegis.cfm (25.8.2005) under the category “Legislation”.

71 *DTI*, Market Surveillance in the UK (Fn. 68), Item 19.

72 *DTI*, Fact Sheet, Role of Tradings Standards in the UK, available online at URL: http://www.dti.gov.uk/ccp/topics1/facts/tradingstandards.htm (2.8.2005).

73 *DTI*, Market Surveillance in the UK (Fn. 68), Item 5. Further information at URL: http://www.tradingstandards.ws/ (2.8.2005).

thorities Coordinators Regulatory Service – LACORS[74]. LACORS provides a platform for coordinating activities between different local authorities and promotes the exchange of information.

The *Home Authority Principle* plays an important role for market surveillance by the Trading Standards Departments. *The Home Authority Principle* is a mechanism for coordination between local authorities which deal with companies with outlets in more than one area of local authority and/or distribute goods and services beyond the boundaries of one area of local authority. For the surveillance of products and services, this principle is not concerned with the location where they are present on the market, rather the headquarters of the manufacturing firm. The principle stipulates that the agency, in whose jurisdiction the head offices of a company are located, should act as a focus for communication and liaison, on the one hand for the firm itself, on the other hand for other local agencies as well, which are confronted with the products or services of the company. This is supposed to enable the responsible authority to reach agreements with the company, which apply to the entire firm.[75] Other authorities are first supposed to seek advice from the responsible *Home Authority*, before taking a decision to pursue formal action[76]. The *Home Authority Principle* puts the notion of cooperation with the firms into practice. It also allows the authorities to acquire technical expertise in certain areas. Finally, it supports cooperation between the authorities and thus contributes to improving the effectiveness of the surveillance on the whole.

2. Products used for commercial or industrial purposes

The surveillance of products used for industrial or commercial purposes is to a great extent incumbent upon the Health and Safety Executive (HSE), partially in cooperation with local

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74 *DTI*, Market Surveillance in the UK (Fn. 68), Item 5. Further information on LACORS at URL: http://www.lacots.com/pages/trade/about.asp (2.8.2005).

75 See *LACORS*, An introduction to the Home Authority Principle and how it operates, p. 1; available online at URL: http://www.lacors.gov.uk/tempBE/Download1.pdf (2.8.2005); *DTI*, Market Surveillance in the UK (Fn. 68), Item 5. Besides the Home Authority, the Originating Authority also exists, which is responsible for goods or services produced in its field of responsibility; see *LACORS*, An introduction to the Home Authority Principle and how it operates, p. 2.

76 *LACORS*, Home Authority Principle – Standards, p. 6. available online URL: http://www.lacors.gov.uk/tempBE/Download2a.pdf.

authorities[77]. The HSE employs more than 4000 people[78]. It tries to work closely with the more than 400 local agencies and, to do so, has created a committee, which promotes the exchange of information[79]. Similar to the *Home Authority Principle*, regional branches of the HSE are primarily responsible for certain firms with regard to work health and safety (*Lead Authority Partnership Scheme*)[80].

II. Instruments used

The United Kingdom aims to focus market surveillance measures on those products which have a particularly high risk potential. To this end, regional coordination groups exist among the Trading Standards Departments in which technical questions and adequate approaches are discussed[81]. The Trading Standards Departments have a national databank, TS Interlink, through which information can be exchanged[82]. Concerning industrial products, the HSE also closely cooperates with the *trade associations.* The comparative analysis of accident data is regarded as an indicator for the effectiveness of the monitoring measures[83].

III. Assignment of tasks, competences, and responsibilities between conformity assessment and market surveillance

In the United Kingdom emphasis is placed on the fact that market surveillance is the task of state agencies. In contrast to the conformity assessment, market surveillance is under-

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77 More in *HSE*, Health and safety system in Great Britain, 2002, p. 4 ff; the document is available online at URL: http://www.hse.gov.uk/pubns/ohsingb.pdf (2.8.2005). Since the Health and Safety at Work etc. Act only applies to Great Britain, Northern Ireland is not part of the field of responsibility of the HSE; Here the Health and Safety Executive for Northern Ireland has similar responsibilities, *DTI*, Market Surveillance in the UK (Fn. 68), Item 2.

78 *HSE*, Health and safety system in Great Britain, 2002, p. 4; the document is available online at URL: http://www.hse.gov.uk/pubns/ohsingb.pdf.

79 Further details from HSE at URL: http://www.hse.gov.uk/lau/hela/index.htm (2.8.2005).

80 *DTI*, Market Surveillance in the UK (Fn. 68), Item 6. Further details from HSE at URL: http://www.hse.gov.uk/lau/laps/index.htm (2.8.2005).

81 *DTI*, Market Surveillance in the UK (Fn. 68), Item 20.

82 *DTI*, Market Surveillance in the UK (Fn. 68), Item 20.

83 See *DTI*, Market Surveillance in the UK (Fn. 68), Item 23. The collection of data on household and leisure accidents supported by DTI (HASS and LASS Systems) was discontinued in 2003 though, see URL: http://www.hassandlass.org.uk/query/HassLassFAQ.htm (12.8.2005).

stood as the measures taken after the introduction of a product on the market. Market surveillance thus serves to oversee products and manufacturers, but indirectly conformity assessments and Notified Bodies as well. As a rule, Notified Bodies are not supposed to carry out market surveillance measures[84]. However, the difficulty also exists here that the responsible authorities do not always have the required inspection capacity. They thus are supposed to be able to fall back on inspection laboratories and/or Notified Bodies[85]. One should bear in mind here that they were not involved in the market entry, wherever possible. However, the agency always remains responsible for the decision on whether the product agrees with the legal requirements[86].

84 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 4; *DTI*, Market Surveillance in the UK (Fn. 68), Item 7.
85 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 4; *DTI*, Market Surveillance in the UK (Fn. 68), Item 7.
86 *DTI*, Assessment of Notified Bodies (Fn. 44), p. 4; *DTI*, Market Surveillance in the UK (Fn. 68), Item 7.

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