

Open letter: draft regulation on endocrine-active chemicals

Daniel R. Dietrich

Dear Prof. Glover,

We, the undersigned, are writing to draw your attention to imminent decisions by the European commission to set a regulatory framework for so-called endocrine-disrupting chemicals. We are concerned that the approach proposed could rewrite well-accepted scientific and regulatory principles in the areas of toxicology and ecotoxicology without adequate scientific evidence justifying such a departure from existing practices.

First of all, we want to emphasize that “endocrine disruption” is not a toxicological endpoint, but one of many mechanisms which may cause adverse effects. In addition, we recognize that such a policy initiative is highly technical and complex and requires an understanding of the modes of action for endocrine disruption and their significance. It also implies the in-depth involvement not only of toxicological disciplines but also of environmental sciences and thus requires scientific input from experts in this area. The undersigned are concerned that the commission’s scientific committees have so far not been consulted by the commission when drafting such regulations. What is even more disturbing is that where a scientific advisory body such as EFSA has been consulted, critical elements of this body’s opinion are ignored. For example, in assessment of chemicals with endocrine activity, EFSA supported a substance-specific risk assessment approach integrating exposure and adverse effects instead of developing horizontal criteria for defining whether a substance is an “endocrine disruptor”. Development of horizontal lists ignores the long-standing principle that an assessment of a substance should be based

on data obtained from toxicity testing on this specific substance and derived information on potency.

If the commission will adopt a policy stating that it is impossible to define a safe limit or threshold for a substance classified as endocrine disruptor, this would reverse current scientific and regulatory practices and, more importantly, ignore broadly developed and accepted scientific development and accepted knowledge regarding thresholds of adversity. Moreover, the latter approach may not only apply to potential EDCs but rather would apply to all chemical substances and thus nullify decades of experience and repeatable observations in exposure–response relationships in pharmacology and toxicology and well-established and widely proven procedures in hazard and risk assessment.

It also appears that the commission will propose that identification of an *in vitro* effect without a causal relationship to adversity in an intact organism may be sufficient to classify a substance as an “endocrine disruptor”. This would not only represent a rewriting of the rules and accepted practices of toxicology, which rely on well-defined adverse effects observed in adequately performed studies, but also would be contrary to all accumulated physiological understanding.

This leaves us concerned that there is neither a scientific basis nor broad support by scientists established in risk assessment behind the approach of setting horizontal criteria and the lists of confirmed and suspected “endocrine disruptors”.

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¹ This letter has also been provided by Prof. Daniel R. Dietrich. An identical version has been published in *Chemico Biological Interactions*, *ALTEX*, *Toxicology*, *Toxicology in Vitro*, *Toxicology Letters*, *Regulatory Pharmacology and Toxicology*, *Frontiers in Predictive Toxicology*, *Toxins*, *European Journal of Pharmacology*, *Food and Chemical Toxicology*, *Toxicology Research*, *Toxicol*, and *Human and Experimental Toxicology*.

We have noted your important interventions on the need for scientific evidence to be at the heart of EU policy and are therefore writing to urge your review of the emerging policy to ensure that the opinion of relevant scientific committees and member states authorities are taken into account.

The following individuals are supporting this initiative:

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