

Why the proposed EDC criteria are legally unacceptable

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Endocrine Disruptors - expert discussion on the Commission proposal

European Parliament

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Contents

- Introduction to ClientEarth
- Does the EU care about endocrine disruptors?
- Hazard based criteria – risk based regulation
- Legal assessment of the criteria
- Assessment of change in risk management approach

Introduction to ClientEarth

- ClientEarth is a non-profit environmental law organisation
- We use law, science and policy to tackle key environmental challenges
- We work on climate change, energy, environmental justice, biodiversity, forests and human health

The EU cares about endocrine disruptors

- Water Framework Directive (2000)
- REACH (2007)
- Cosmetics (2009)
- Plant Protection Products (pesticides) (2009)
- Biocides (2011)
- 7th Environment Action Programme (2013)
- Medical devices (2016)

Hazard based vs risk based

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products

{SWD(2016) 211 final}

{SWD(2016) 212 final}

Regulation by "hazard" or "risk"

The regulation of chemical substances can be approached in two different ways: based on hazard or based on risk. A hazard-based approach regulates substances on the basis of their intrinsic properties, without taking account of the exposure to the substance. A risk-based approach factors in the exposure. A common analogy used is from the animal kingdom: a lion is intrinsically a hazard, but a lion safely constrained in a zoo is not a risk, since there is no exposure. In the area of chemical safety, there are several pieces of EU legislation that apply a hazard-based approach to toxicological safety, while others follow a risk-based approach.^{26 27}

EU regulation always risk based

EVALUATION AND FITNESS CHECK (FC) ROADMAP

Fitness check on the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries

GROW/D.2 & ENV/A.3

**DATE OF THIS
ROADMAP**

18/05/2016

Depending on the nature and dimension of hazards and the exposure situations involved, risk management measures are taken directly based on the identified hazard classification using generic risk considerations justifying a direct risk management consequence, or based on a specific risk assessment.

Direct mechanisms applying measures to classified substances based on generic risk considerations without further specific assessment of the risk may be justified by specific considerations, such as the characteristics of the hazard, the vulnerability of certain parts of the population (e.g. children), non-controllable or widespread exposure.

Examples of risk management and communication measures based on generic risk considerations include coverage of industrial sites by the Seveso Directive, labelling requirements under CLP, EU Ecolabel eligibility under the Ecolabel Regulation and cut-off criteria under the Plant Protection Products Regulation.

High level of protection

- Both the Biocides and Pesticides Regulations:
 - Aim at ensuring a high level of protection for human health and the environment;
 - Are underpinned by the precautionary principle.
- Article 191(2) Lisbon Treaty:
 - Union policy on the environment shall aim at a high level of protection [...] It shall be based on the precautionary principle and on the principles that preventive action should be taken [...]

The European Commission Proposals and Legal Requirements Concerning the Determination of Scientific Criteria to Identify Endocrine Disruptive Properties of Active Substances

sofia

Julian Schenten and Martin Führ

Sonderforschungsgruppe
Institutionenanalyse

With the co-operation of *Vito Buonsante*

Legal opinion on behalf of



Main findings [Criteria]

- The scientific criteria need to be based solely on hazard identification (no exposure considerations)
- The same approval mechanism for ED as for substances that meet the CMR classification criteria
- The approval mechanisms for active substances are applicable both to substances known and presumed to have endocrine disruptive properties
- The scientific criteria, too, need to reflect the precautionary principle

Hazard based criteria

The scientific criteria set out by the drafts are in all likelihood* based on scientific considerations exclusively. In particular, they are based on hazard identification.

* See Point 2.(3)(a)(iii) of COM proposal

Equivalent level of concern to CMRs

- The Biocides and Pesticides Regulations provide for the same regulatory mechanism for EDCs as it does for CMR classified or classifiable according to CLP.
- It can be followed that in order to ensure a high level of protection the co-legislators attribute to ED an equivalent level of concern as they attribute to CMR substances.

Known and presumed

- Limiting the identification to “known” and not to “presumed” EDCs is contrary to the objectives and the systematic context of the biocides and the pesticides;
- Therefore the criteria exceed the objectives, content and scope of the powers mandated to the Commission by the basic acts.

Approval mechanism for pesticides

The derogation mechanism based on negligible exposure would be substituted by a mechanism based on a specific risk assessment which would allow non-negligible exposure as long as the risk assessment concludes that the identified risk is sufficiently low

Original text

„An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.“⁹⁶

Commission proposal

“An active substance, safener or synergist shall only be approved if, on the basis of the assessment of the available evidence carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, it is not identified as having endocrine disrupting properties with respect to humans according to the criteria specified in point 3.6.5.2, unless the risk to humans from exposure to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible, in particular where the product is used in closed systems or in other conditions which aim at excluding contact with humans, and where maximum residue levels of the active substance, safener or synergist concerned in or on food and feed can, taking account of the latest opinion of the Authority with respect to that active substance, synergist, safener, be set in accordance with Regulation (EC) No 396/2005, which ensure a high level of consumer protection.”⁹⁷

Legal basis

- The change is based on Art. 78(1)(a) PPR which allows changes of non-essential elements taking into account current technical and scientific knowledge.
- Changes in risk management are not a technical decision, but a political one and affect an essential element of the Regulation

Conclusions

- The Commission proposal exceeds its powers as it changes essential elements of the regulation
- The Commission ignores the fact that the legislator places an equivalent level of concern to CMR for ED substances
- The proposal fails to protect human health and the environment and is not precautionary

Thank you

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