



**CHEM**Trust

Protecting humans and wildlife  
from harmful chemicals

# Consultation Response

## **CHEM Trust feedback to the Commission proposal on scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009**

**July 2016**

[https://ec.europa.eu/info/law/better-regulation/initiatives/ares20163071834\\_en](https://ec.europa.eu/info/law/better-regulation/initiatives/ares20163071834_en)

CHEM Trust`s main point is that the current wording of the Commission proposal requires such a high burden of proof, that there will almost certainly have to be harm to humans or the environment before a chemical can be identified as EDC. While the WHO definition has been used as a basis, the draft text includes additional elements, so it is not the same as the original option 2 in the Commission Roadmap. The Commission`s decision not to include potency in the definition is positive, but the required level of evidence is so high that it will, in most cases, prevent action on ED chemicals.

We note with concern that the Regulatory Scrutiny Board stated that DG Santé`s multi-criteria analysis was biased towards identifying fewer chemicals, when the aim of the legislation is to provide a high level of protection to human health and the environment.

### **Issue 1: Ensure EDCs can be identified**

The proposal includes a very demanding wording for identification of EDCs, calling for evidence to show that it is *‘known to cause an adverse effect relevant to human health/non-target organisms’*. In reality it is usually very hard to demonstrate that a chemical has harmed humans without harming a large number of people. In CHEM Trust`s view the most effective – and scientifically realistic – way to identify EDCs [is through a three category approach](#), which equals the approach for Carcinogens,

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Mutagens and Reproductive toxins. The classification of CMRs as 1A and 1B according to the CLP Regulation requires `known and presumed effects` and this triggers many downstream regulatory consequences. Why should EDCs be treated differently? In CHEM Trust's view there is also no legal basis to change the regulatory text from "**may cause**" to "**cause**".

### **Issue 2: Ensure all relevant data will be looked at**

Revise the text to ensure that GLP studies do not necessarily have precedence over other data, as e.g. old 2 gen studies are not adequate to capture antiandrogens and other ED endpoints. We also caution against the legal requirement for systematic review, in the absence of internationally agreed standards for systematic review procedures. This brings in significant legal uncertainty. As regards the text for non-target organisms we particularly support the comments and suggestions made by the German Environment Agency (UBA) [in their response](#).

### **Issue 3: Ensure derogation is only based on tightly defined negligible exposure, as in the current wording of the Pesticides Regulation**

The Commission has proposed to weaken the pesticides legislation by proposing to change the safety standard of 'negligible exposure' into 'negligible risk', [which will mean more exposure of the environment and people to pesticides](#), even if they have been identified as EDCs. This alters the agreement made between Council, EP and Commission in the co-decision procedure. Furthermore, the Commission goes beyond their task of identifying criteria and instead reintroduces new specific risk assessments in the derogation. The Commission has justified this on the basis of an EFSA opinion which suggested that EDCs could be subject to risk assessment, but in CHEM Trust's view this is potentially illegal as such an EFSA opinion is not an adequate legal basis for such an important and significant change in the agreed political text.

### **Issue 4: Ensure safety standard of pesticide laws is not weakened.**

- Reinstatement of the text of the derogation which says `excluding contacts with humans` and reject change to `which aim to exclude contact with humans`
- Reinstatement of the reference to default residue values and reject change to MRLs
- Reinstatement of the review of the scientific literature

In conclusion, this proposal will have wide ranging implications for all EU chemicals laws and as it stands, would allow continued uncontrolled exposure to these chemicals of high concern. Therefore CHEM Trust calls on the EU institutions to change this proposal in order to live up to the legally agreed high protection for wildlife and people.