

ENDOCRINE DISRUPTING CHEMICALS ARE BEST IDENTIFIED WITHOUT THE USE OF POTENCY CUT-OFFS

Finally, after delays of more than three years, it looks as if the EU Commission will propose criteria for endocrine-disrupting chemicals in 2016. The responsible Commissioner, Health Commissioner Vytenis Andriukaitis has repeatedly stated that the Commission's ambition is to deliver draft criteria "before summer". These draft criteria are then to be further scrutinized within the Commission.

At ChemSec we hope that the Commission will present functional, science-based criteria, fulfilling its aim to protect human health and the environment. In this paper we explain why including potency cut-offs cannot be part of such criteria:

- Potency cut-offs are impossible in practise
- Relevant EDCs can, and are already, being identified without potency cut-offs
- Progressive companies need protective criteria
- Truly scientific criteria are independent of socioeconomic considerations

► POTENCY CUT-OFFS ARE IMPOSSIBLE IN PRACTICE

Potency is a measure of how much of a substance that is required to cause a certain effect. The idea is that when knowing this, it is possible to establish a cut-off, or a safety threshold. It should then be safe to use the substance as long as this cut-off is not reached. However, endocrine disruption cannot be measured in a single test as it is not a single effect, or endpoint. There are numerous possible modes of action and effects; there are differences between species and organisms. Making direct comparisons and determination of relative potency is therefore impossible. A more holistic, weight of evidence approach is needed in order to identify EDCs.

The underlying problem with potency based criteria stems from the innate ability of EDCs to interfere with the hormone system. Such interactions are often non-linear. Effects observed at low doses may not occur at higher doses and the timing of the exposure is crucial. Exposure during foetal development may result in effects not discovered until months, years or even decades later.

One of the most well known examples in humans is the treatment of certain pregnant women with the synthetic oestrogen DES between the years 1940 and 1970. The treatment has now been linked to increased cancer rates and other health problems in the adult children. It is suspected that also the grandchildren may develop diseases due to this previous exposure.

Unpredictable dose-effect relations, low-dose effects and the critical timing of exposure make it in practice impossible to identify a true safety threshold, a potency cut-off.

The scientific complexity and uncertainties associated with EDCs poses a challenge and necessitates a reliable and workable way to deal with them. It has been suggested that potency cut-off values should be used only "until the uncertainties have been resolved". However, we consider this to be a paradoxical approach as this is exactly the opposite of a precautionary approach. Use of the precautionary principle would logically exclude the use of potency cut-offs for EDC identification.

By comparison other types of chemicals e.g. carcinogenic, mutagenic or toxic to reproduction (CMRs) are already identified without the use of a potency cut-off. EDCs should be treated in the same way and not by the introduction of potency.

"Unpredictable dose-effect relations, low-dose effects and the critical timing of exposure make it in practice impossible to identify a true safety threshold, a potency cut-off."



► RELEVANT EDCS CAN, AND ARE ALREADY, BEING IDENTIFIED WITHOUT POTENCY CUT-OFFS

Endocrine disrupting chemicals are targeted under REACH as being substances of very high concern (SVHCs). A handful EDCs have already been identified as being SVHCs and placed on the Candidate List using a weight of evidence approach.

For the SIN List, ChemSec has used a similar weight-of-evidence approach to identify 32 substances as being of

high concern based on their ED properties only. Companies in public procurement and financial investors are already targeting these SIN List EDCs for phase-out. The criteria to be established by the Commission must be designed to capture these 32 well-investigated compounds.

► PROGRESSIVE COMPANIES NEED PROTECTIVE CRITERIA

Many responsible companies have already phased-out a number of EDCs and are prepared for stricter regulation. They consider the risk of such substances being used in their products as detrimental to their reputation among consumers

and also in direct opposition to their long-term ambitions. Having protective scientific EDC criteria would facilitate their internal work, enhance communication through the supply chain and contribute to a more level playing field for them.

► TRULY SCIENTIFIC CRITERIA ARE INDEPENDENT OF SOCIOECONOMIC CONSIDERATIONS

The task for the Commission is to establish scientific criteria for identification of endocrine disrupting chemicals. However, the Commission still stands firm that a socioeconomic impact assessment should be used to guide the criteria development. How this impact assessment is performed and how the results of it will weigh into the draft criteria is unclear.

The view of ChemSec is that the scientific criteria should solely be used to identify EDCs, without being mixed together with

economic considerations. If required, in a separate and subsequent step, socioeconomic consequences can be considered on a case-by-case basis: there are legal tools to handle this.

We find it unacceptable, confusing and ambiguous to mix science and policy considerations. Indeed, the Pesticides regulation, Biocides regulation and REACH all include provisions for the continued use of identified hazardous chemicals if the consequences of a ban are disproportionately negative.

We hereby urge the Commission to acknowledge existing science and to address remaining uncertainties with precaution by not including potency cut-offs in the EDC criteria. It is time that responsible companies receive clear and unambiguous legal support for their efforts and that the citizens of the EU gain a better protection against endocrine disrupting chemicals.