



CHEMTrust

Protecting humans and wildlife
from harmful chemicals

Analysis

CHEM Trust's analysis of 'Scientific Principles For The Identification Of Endocrine Disrupting Chemicals – A Consensus Statement' June 2016

1 Introduction

Twenty three scientists, who had previously been portrayed as having differing opinions with regard to endocrine disruptors (EDs), came together in Berlin on 11-12th April 2016 at a meeting hosted by the German Federal Institute for Risk Assessment (BfR). The consensus reached at this meeting [1] is particularly pertinent, not least because the EU Health Commissioner, Vytenis Andriukaitis, has referred to it as providing a scientific common view to inform the pending EU decision on what the criteria to identify and ED should be.

The briefing is CHEM Trust's analysis of the consensus statement; the statement is available from the BfR's website:

- <http://www.bfr.bund.de/cm/349/scientific-principles-for-the-identification-of-endocrine-disrupting-chemicals-a-consensus-statement.pdf>

2 Main Points:

- The consensus statement acknowledged that there is a need “*to ensure continuation and enhancement of policies for the protection of human health and the environment from the effects of endocrine disruptors*” (para 5). Furthermore, it noted that “*Scientific knowledge ...is sufficient to warrant regulatory action*” (para 14).
- It is vital to note that the consensus statement concluded that “*The identification of a compound as an endocrine disruptor is a hazard identification procedure*” (para 20) and that “*potency is not relevant for the identification of a compound as an endocrine disruptor.*” (para 22). Therefore, this consensus statement well and truly underlined that it would be un-scientific to use some sort of potency filter to identify an ED, which is the approach favoured by industry because it would allow so-called ‘weak’ EDs to slip through the regulatory net. The scientists accepted the WHO definition of an endocrine disruptor (para 10) and noted that the identification of a chemical as an endocrine disruptor therefore has to rely just on “*evaluations of both adversity and mode of action together*” (para 21).
- In addition, the consensus statement highlighted that in order to identify endocrine disruptors there is a need, not only for the criteria for identification, but also for relevant test methods to be integrated into the regulatory frameworks. It also noted that, particularly to identify all endocrine disruptors that impact on human disease, there is a need to improve and design better test methods (paras 16 & 23).

3 Other important elements of consensus statement

- **The disrupting role of EDs during prenatal and postnatal development, and also possible effects due to exposure of adults.** “*We recognize that disruption of the programming role of hormones during prenatal and postnatal development can cause*

adverse effects that do not become evident until later in life” (para 12). Also “interference with the role of many hormones ...in adult life can also lead to adverse effects” (para 13)

- **Criteria for identification of EDs are possible without fully resolving controversies such as Non-Monotonic Dose-Response relationships (NMDRs) and low dose effects.** The consensus statement highlights that differing views on the importance of NMDRs and possible effects of EDs at very low doses will not be resolved in the near future, but noted that resolution of these issues is not a pre-requisite for the establishment of criteria to identify EDs. This is a crucial step forward and a clear signal to regulators. It is also underlined by the statement that these areas of uncertainty should not delay current efforts to regulate EDs (paras 17 & 18).
- **There is uncertainty and controversy about NMDRs and low dose effects (para 18), and there is a difficulty of distinguishing a true threshold from an apparent threshold**, which merely arises from the limits of detection of the experimental system (para 28).
 - This adds weight to CHEM Trust’s and other NGO’s argument that there is increased uncertainty in any quantitative or specific risk assessment of an ED. which requires a definite no observed effect level , thereby suggesting that it would be an error to try and regulate EDs on the basis of what might be an erroneous risk assessment (para 18).
- **Various pieces of EU chemicals regulation require different decision making approaches**, in that some require a generic risk assessment (a hazard based approach) while other regulations require a more risk based approach (para 19).
- **The consensus statement noted that assessment of the risks of an ED on human health and wildlife would further require consideration of dose-response relationships**, including potency, exposure, and risk characterisation, including susceptible sub-populations, severity and reversibility of effects. However, this is not at all saying that there was consensus that all EDs should be regulated on the basis of a quantitative risk assessment. All claims interpreting this in such a direction are plainly wrong and wishful thinking. Rather, the consensus is saying that IF a risk assessment was to be done (which is currently mostly not the case for EDs under EU laws) it would require consideration of all those elements (para 24). The scientists also agreed that “ *a chemical’s potency to induce an adverse effect is an important factor for consideration during the characterization of the hazards of endocrine disruptors*” (para 22), but again, the consensus statement is not saying that hazard characterisation is always required, as some claimed. Hazard characterisation is a step in risk assessment, and some pieces of EU legislation (see para 19) do not require a quantitative risk assessment approach to determine the risk management required. It is also important to note that agreeing what data would need to be considered for assessing the risks of a specific substance, does not preclude judging that because of the great uncertainty in some of the available data, such a quantitative risk assessment approach might not provide sufficient confidence of protection.
- **The identification and agreement of several important research needs (paras 25 – 31).**
- **“The importance of the ‘One substance – One toxicological assessment’ philosophy**,” which it suggested had “implications for data generation of both regulated and unregulated chemicals.” (para 24). The meaning of ‘One substance - One toxicological assessment’ is explained in the glossary, which states “A chemical that falls under several regulatory systems would have only one assessment, which would be accepted by all of the regulatory systems. This does not necessarily imply that the regulatory decision would be the same, which would depend on a number of considerations.” CHEM Trust would agree that the criteria for identification of a chemical as an ED should apply across all pieces of legislation, so that a substance judged to be

an ED under one law should also be judged to be an ED under all other laws. We also agree that the regulatory management outcome of this assessment does not have to be the same, in that the regulatory consequences may depend on the use to which that ED chemical is put. It also should not preclude regulating on the basis of the identification only as an ED, if that is what the law prescribes.

- We however strongly disagree with any erroneous interpretation of this ‘one substance – one assessment’ that tries to suggest that the ‘one assessment’ should be a specific (or quantitative) risk assessment. There is good reason for basing risk management measures on generic risk assessment considerations whenever the type of usage makes exposure inevitable, as in the case of pesticides and biocides (see also CHEM Trust’s briefing on ‘Hazard versus risk in the EDC debate [2]’). This common sense approach has been implemented in EU laws, for example in the laws on Toys and Pesticides.

4 Attempts to muddy the discussion

As an addendum to this critique it is clear that some scientists are again trying to muddy the clarity that has been achieved by this consensus statement, by releasing a press release claiming that “*Well-known Scientists Ready to Stem the Onslaught of Pseudoscience in the EU*” [3].

This statement states that if the EU regulates man-made chemicals that are EDs, then the EU should also regulate chocolate and sugar, which trigger insulin release, which confuses normal hormonal responses with hormone disruption. They also suggest that foods such as broccoli, which are rich in phytoestrogens, would need to be regulated, which is not the case.

For more information on CHEM Trust’s response to these arguments, see these questions in our EDC FAQ

- Industry claims chocolate could be banned as well, is it true?
<http://www.chemtrust.org.uk/industry-claims-chocolate-could-be-banned-as-an-edc-is-it-true/>
- Can man-made EDCs have any serious impact on health given that our bodies are used to dealing with naturally occurring phytoestrogens from food?
<http://www.chemtrust.org.uk/can-man-made-edcs-have-any-serious-impact-on-health-given-that-our-bodies-are-used-to-dealing-with-naturally-occurring-phytoestrogens-from-food/>

The full EDC FAQ is here:

- <http://www.chemtrust.org.uk/hormone-disrupting-chemicals-edcs-faq/>

5 For more information

For a broader CHEM Trust perspective on the EDC criteria process please see:

- <http://www.chemtrust.org.uk/criteria-to-identify-edcs/>

For all our blogs on the EDC criteria issue, see:

- <http://www.chemtrust.org.uk/tag/edc-criteria/>

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6 References

- 1 “*Scientific principles for the identification of endocrine disrupting chemicals – a consensus statement. Outcome of an international expert meeting organized by the German Federal Institute for Risk Assessment (BfR)*”, May 2016
<http://www.bfr.bund.de/cm/349/scientific-principles-for-the-identification-of-endocrine-disrupting-chemicals-a-consensus-statement.pdf>
- 2 “*HAZARD VERSUS RISK within the context of the current debate on endocrine disrupting chemicals (EDCs) management in the EU*”, CHEM Trust, November 2013
<http://www.chemtrust.org.uk/wp-content/uploads/Hazard-v-Risk-a-CHEM-Trust-position-paper-Nov-2013.pdf>
- 3 “*Well-known Scientists Ready to Stem the Onslaught of Pseudoscience in the EU*”, PR Newswire, May 11th 2016, <http://www.prnewswire.co.uk/news-releases/well-known-scientists-ready-to-stem-the-onslaught-of-pseudoscience-in-the-eu-578980091.html>