



CHEMTrust

Protecting humans and wildlife
from harmful chemicals

Policy Briefing

Criteria for identifying endocrine disrupters: CHEM Trust's view on the proposed '4b' option from the German Federal Institute for Risk Assessment

Executive summary

The European Commission is currently investigating the potential impacts of different ways of setting criteria to identify Endocrine (or Hormone) Disrupting Chemicals (EDCs), and has proposed four options.

CHEM Trust is committed to working to achieve a science-based system for identifying hormone disrupting chemicals that ensures all such chemicals can be identified, thereby enabling a high level of protection of human health and the environment.

CHEM Trust supports the Commission's Option 3, which identifies EDCs based on their intrinsic hazard properties (that is their known toxic properties) and then puts chemicals into one of three categories based on the level of available evidence.

This briefing examines a proposal from the German Federal Institute for Risk Assessment (BfR), which it is calling '4b', which is supported by the chemical industry (CEFIC) and some other groups.

In our view the BfR proposal is fundamentally flawed, because:



It uses a potency- (and severity) based approach, which will not be protective of human health and the environment

- It suffers from the same crucial weakness as the Commission's Option 4 (based on potency), as a potency based approach will not identify all relevant EDCs, and introduces additional complex decision elements at the early identification stage



It mixes science and policy

- It mixes the scientific question of the most appropriate criteria for identifying chemicals with endocrine disrupting properties with the policy question of how these chemicals are to be regulated.



It is not in line with the advice from the EU EDC expert groups

- It goes against the advice from both the scientific committee of the European Food Safety Authority (EFSA) and the Endocrine Disrupters Expert Advisory Group chaired by the Joint Research Centre (JRC), who concluded that identification should be based on endocrine disruption (ED) activity and adverse effects, coupled with a plausible link between the two.



It is not in line with the relevant legislative text

- It is not in line with the democratically agreed current legal text because the BfR proposal fails to identify **all** chemicals with ED properties, and instead suggests a risk assessment for some weak and some likely EDCs, that is the "suspected EDCs"

In CHEM Trust's view the main impact of "option 4b" will be to result in fewer EDCs being affected by regulation. We consider that this will not provide adequate protection for human health and the environment.

Introduction

The European Commission, is currently investigating the potential impacts of different ways of setting criteria to identify Endocrine (or Hormone) Disrupting Chemicals (EDCs), and has proposed four options¹:

- Option 1: No policy change (baseline). No formal new criteria are specified, but the interim criteria set in the regulations on pesticides and biocides would continue to apply (although currently there has even been debate over how these should be interpreted).
- Option 2: WHO/IPCS definition to identify endocrine disruptors (hazard identification).
- Option 3: WHO/IPCS definition to identify endocrine disruptors and introduction of three categories based on the different strength of evidence for fulfilling the WHO/IPCS definition.
- Option 4: WHO/IPCS definition to identify endocrine disruptors and inclusion of potency as element of hazard characterization (hazard identification and characterisation).

CHEM Trust participated in the public consultation² on the impacts of these options³:

- We support Option 3, using three different categories to identify chemicals based on the current scientific knowledge on their endocrine disrupting properties. This approach allows the best use of available scientific evidence and is able to accommodate evolving research and new data. Furthermore, it is in line with the way carcinogens, mutagens and reproductive toxins are identified.
- We oppose Option 4, that is the proposal to have a system which would lead to the exclusion of many relevant EDCs based on an arbitrary and unscientific ‘potency’ filter. Not only would any such potency filter be arbitrary, but it would also only relate to what was currently known about the toxicity of that substance, based on inadequate testing for effects on the endocrine system and potential thresholds.
- We do not favour any changes to the existing EU pesticide and biocide laws, as we consider that they already give sufficient room for flexibility and exemptions.

The BfR proposal for an ‘Option 4b’

During the European Commission’s conference hosted in Brussels on 1st June 2015, the German BfR criticised option 4 as not science based and presented an extended option 4, a new “Option 4b”, as a way forward.⁴

The BfR presentation, and a later press release⁵, summarised their submission to the public consultation on defining criteria for identifying endocrine disruptors in the context of the pesticides regulation and the biocidal products regulation. The presentation and submission both refer to a paper by Marx-Stoelting *et al.* (2014).⁶

The authors considered after an evaluation of a ‘random’ sample of 22 substances (see section 3.2), that 20-40% of pesticide active substances might be identified as EDs if the criteria were solely hazard based (based on adversity and mode of action). When severity (which includes the effects graded as either severe or irreversible) and potency considerations were included as a filter to allow “weakly” potent substances to escape identification as EDCs – the 20-40 % of affected substances fell to just less than 5% (1 substance in this case). The BfR 4b option is based on this latter approach in that it includes not only hazard identification (mode of action and ability to cause adverse effects) but also hazard *characterisation* –i.e. severity of effects, reversibility, consistency and potency.

Why CHEM Trust opposes the 4b option proposed by BfR

1) A potency filter shouldn’t be included in the criteria for identification of EDCs

The Commission’s option 4 and BfR’s option 4b include potency based cut-offs as a filter mechanism to be included as part of the EDC criteria so that only ‘highly potent’ EDCs would be identified as EDCs

for regulatory purposes. However, setting such a filter at the identification stage would be arbitrary and have no scientific justification.

Knowledge on potency is dependent on:

- a) the type of test system and observed effect;
- b) the organism/species used in the test system;
- c) the observed life-stage (pregnancy, late life);
- d) the specific mode of action in question

For example, studies have shown that BPA is a very weak estrogen in some test systems, but it is reported to be equipotent with oestradiol (E2) with respect to the induction of insulin in mice⁷. If current toxicity tests examine endpoints that may be insensitive measures of hormone disruption, chemicals may be wrongly assigned as weakly potent. Therefore, comparing relative potencies of chemicals can be very misleading.

A potency based cut-off would also mean that weak EDCs with very high exposures could slip through the regulatory net. Even a weak EDC can interfere prenatally with hormones which are crucial for the long term development of the child⁸. We must also consider the reality of multiple exposures, and known combination effects which have been demonstrated in laboratory experiments.

Furthermore, it is worth noting that potency considerations are currently not applied in the *identification* decision on carcinogens and reproductive toxins (e.g. phthalates) according to the Classification and Labelling Regulation, so equally this should not be applied in the identification of EDCs.

2) It mixes the scientific question of the most appropriate criteria for identifying chemicals with endocrine disrupting properties, with the policy question of how these chemicals are to be regulated.

BfR suggest 3 categories: Cat 1: endocrine disrupters, Cat 2: suspected endocrine disrupters and Cat 3: endocrine active substances.

This is confusing as the category names are the same ones that the Commission uses in their roadmap Option 3 for ED identification, but the context is completely different. While the Commission roadmap proposes these 3 categories for the hazard based identification of EDs based on adversity and mode of action, the BfR inserts a *risk-based management* approach for all suspected EDs in category 2 (see slide 3 of the presentation), something not foreseen in the legislation.

At the same time BfR opposes the Option 3 (3 categories) of the Commission roadmap, as “scientifically not sufficient” (slide 6 of their presentation), without further explanation.

3) It goes against the advice from EFSA and the JRC ED expert advisory group, and the “State of the Art” report

Both EFSA and the JRC expert group proposed identification based on ED activity and adverse effects, coupled by a plausible link. In CHEM Trust’s view all the elements of hazard characterisation (potency, irreversibility of effects etc.), can play a role. However, such considerations should come in only AFTER the identification of an endocrine disrupter and be used for subsequent prioritisation.

Our viewpoint echoes that of the JRC Endocrine Disrupters Expert Advisory Group.⁹ The Executive Summary of their report states “*Factors such as potency, severity, irreversibility and lead toxicity were considered not part of the identification but rather inform on characterization of the hazard of EDs.*”

In addition, the Scientific Committee of the European Food Safety Authority (EFSA) also concluded in the summary of their 2013 opinion: “*that an ED is defined by three criteria: the presence of i) an adverse effect in an intact organism or a (sub)population; ii) an endocrine activity; and iii) a plausible causal relationship between the two*”¹⁰ **Therefore, it can be seen that expert scientific bodies agree on how to identify EDCs and that such identification should not include potency or severity, nor any other element of hazard characterisation.**

In their presentation during the 1st of June conference, BfR suggested their approach was in line with the report “State of the Art on Endocrine Disrupters”¹¹. However, the State of the Art report recommends against the use of potency based trigger values in identifying EDCs of regulatory concern (see section 7.2.3). Furthermore, it is clearly enunciated that identification should be based on the hazard properties, *i.e.* the mode of action and the ability to cause adverse effects (see section 7.2.2). In contrast, the BfR proposal inserts additional characteristics into the identification criteria which would act as filters, being used to differentiate between EDs and chemicals which would not be regulated as EDs.

Thus, the BfR proposal goes against the EU expert advice received. Their proposal to make a certain potency and a certain severity of effects a **prerequisite** for the identification of EDCs, ***in addition*** to an ED mode of action and adversity of effect would mean that several EDCs would **not be identified despite having an ED mode of action leading to known/detectable adverse effects**.

4) It is not in line with the democratically agreed legal text

The current legal situation is that both the pesticide (PPPR) and biocide (BPR) laws require EDCs to be identified based on intrinsic ED properties:

According to PPPR: *An active substance(...) shall only be approved, if (...) 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 (...) is negligible (...).*

It is noteworthy that the law says “which may cause an adverse effect”. In our view this makes it clear that it should cover both known EDs (cat1) and suspected EDs (cat2). Moreover, the wording in the legislation means a full elucidation of a causal link is not required, which is why the JRC report and EFSA opinion speak of “a plausible link”. The BfR proposal is not in line with the democratically agreed current legal text because it fails to identify **all** chemicals with ED properties, and instead suggests a risk assessment for some weak and some likely EDCs, that is the “suspected EDs”

Proposing a “risk-based management approach” for all “suspected EDCs” of category 2 (see BfR’s slide 3) is therefore not appropriate. It is a subversion of the legislation, which clearly requires a hazard based identification.

Conclusions

The BfR ‘4b’ proposal may at first sight look like a reasonable way of identifying those EDs of regulatory concern, but we have identified several flaws and misleading aspects. If this proposal was to be adopted, the main outcome would be a reduction in the number of pesticides and biocides that would be identified as EDCs. Thus, important substances may escape the regulatory requirements for EDCs in the pesticides and biocides regulations for the wrong reasons. It would thereby reduce the protection of human health and the environment.

Concerns have been expressed about the removal of substances from the market, however, it is important to note that the pesticide law allows derogations for a continued use of a particular pesticide: In urgent cases there can be an exemption to avert serious danger to plant health under article 4.7. The Biocidal Products regulation foresees an even broader range of exemptions.

Ultimately, this BfR proposal is a slight modification and re-branding of the Commission’s option 4, and suffers from the same problems. The potency approach is not sufficiently protective, and it surreptitiously contradicts the existing laws on pesticides and biocides.

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