TECHNICAL BRIEFING

# EDCs CRITERIA
# Technical Briefing for Member States

HEAL
Promoting environmental policy that contributes to good health

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In its revised proposal from early November on the EDC Criteria, the Commission requires such a high burden of proof that harm to humans or the environment will almost certainly have to take place before a chemical can be identified as an EDC. This briefing lays out the main problems with the revised criteria proposal (which include some problems already existing and carried over from the June draft proposal).

## IDENTIFICATION CRITERIA

### When is something an endocrine disruptor? Is going from Known to Shown an improvement?

The June draft identification criteria limited the identification to substances '**known** to cause adverse effects' *[PPPR proposal Annex II, 3.6.5.2.2; BPR proposal Annex, Section 1 (1)]* without the accompanying words 'or presumed to cause'. We criticised this 'known' as an excessively restrictive condition. The recent November revision has taken away the wording 'known to cause' and now states 'that **shows** an adverse effect'. The terminology 'shows' deviates from

- the wording of option 2 in the EDCs Roadmap, agreed between DGs Environment & DG Sante, (*known **or presumed** to have caused endocrine-mediated adverse effects)*
- the wording used for the identification of CMR substances (*known and **presumed** effects*).

It is not evident that the wording 'shows' includes what was advocated and anticipated (in the Roadmap) through the wording 'known and presumed'. The deviations in wording render more uncertain which chemicals might fulfill the criteria, and what 'show' actually involves. Through these new wordings, the Commission are turning away from useful Member States' experience and EU practice of identifying other harmful chemicals.

***HEAL advocates: Ensure the wording 'shows' is changed.***

**Justification:** The criteria should be in line with the Commission's Better Regulation initiative that aims at consistency and **coherency across EU legislation**. There is an **equivalence** built into the legal text between EDCs and carcinogens, mutagens & reproductive toxicants (CMRs), which are also subject to cut off conditions in the Pesticides and the Biocides laws. So, it is important that there is not a higher identification requirements for EDCs than for CMRs.

## When is something an endocrine disruptor? Consequential conditionality

The three points below are still very difficult to fulfil because of the requirement to prove a *consequential* link between points (1) and (2).

> *Nov 2016 Proposal:*
> *(1) it shows an adverse effect …; AND*
> *(2) it has an endocrine mode of action, i.e., it alters the functions of the endocrine system; AND*
> *(3) the adverse effect relevant is a consequence of the endocrine mode of action*

While the WHO scientific definition of an EDC includes the wording 'consequentially causes', we maintain that in regulatory practice this sets a bar of proof that is unreasonably high, given that the studies which look into Mode of action or altered function tend not to deal with the adverse effects, particularly the adverse effects identified in the studies required from the industry applicants. In the Kortenkamp et al report of 2012, and the JRC report of 2013[1], a biologically plausible link between point 1 and 2 was considered appropriate for regulatory practice.

***HEAL advocates: Reject 'consequence' as the link between harm and altered function***

**Justification:** Requiring a consequential link between a mode of action and adverse effect, particularly between OECD protocol studies (adverse effect) and academic research (consequential link but usually to different adverse effects) is an impossibly high burden of proof. It would mean that DES could not be identified under these criteria, according to the Endocrine Society. See https://goo.gl/MNE4c7; http://goo.gl/u0LtIl; http://goo.gl/Xx6F8O

## When is something an endocrine disruptor that may harm?

The cutoffs that are enshrined in the EU Biocides and Pesticides laws are for substances that 'may cause adverse effects'. We insist that the wording 'may cause' includes two different levels of certainty about the adverse effects:

- the 'known and presumed' (equivalent to Cat 1 a & b in CMRs) and
- 'potential' edcs (equivalent to Cat 2 in CMRs).

The 'may cause' two levels of certainty reflects a political agreement between Parliament and Council that cannot be narrowed in the elaboration of scientific identification criteria. Here it is worth noting that the full WHO definition of EDCs also covers 'full' and 'potential' EDCs.
In this November revised proposal, there is too little chance for chemicals at the second lower level of certainty to fulfil the 3 points of the identification.
Although the chapeau paragraph of the Pesticides Implementing Act point 3.6.5.2.2. now includes the words [a chemical] 'shall be considered as having ED properties that **may cause adverse**

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[1] State of the Art of the Assessment of Endocrine Disruptors, Authors: Andreas Kortenkamp et al, released February 2012. http://ec.europa.eu/environment/chemicals/endocrine/
"JRC Report on key scientific issues relevant to the identification of endocrine disrupting substances" Report of the Endocrine Disrupters Expert Advisory Group: "Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances" http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/endocrine_disrupters/jrc-report-scientific-issues-identification-endocrine-disrupting-substances/

**effects**', linguistically and logically this comes 'after' identification. It is within the identification that 'may cause' should be reflected, that is in the "following criteria" sub points 1, 2, and 3. But the criteria nowhere explicitly enable potential ED chemicals to be identified, as opposed to known and presumed EDCs. These distinctions between 'known and 'presumed' and 'potential' which are both within the word **may** would best be captured in categories to reflect the different levels of scientific evidence available. Categories would ensure that both levels of certainty on ED effects expressed in the legal wording are addressed and would, in our view, properly fulfil the spirit and intention of the law. The revised proposal include no categories.

***HEAL advocates: Ensure categories are used in order to capture both 'known and presumed' and 'potential/probable' EDCs***

**Justification 1:** The Nov 2016 wording **does not fulfil the legislative provisions**. The co legislators chose a level of certainty & proof about EDC identification (ID), expressed in legal text wording in both the PPPR and BPR for substances with endocrine disrupting properties "that **MAY** cause adverse effects" (PPPR, Annex II, 3.6.5; BPR, Chapter 2, Article 5 (1)d). The June 2015 proposed criteria wrongly narrow this by not explicitly providing for definite + potential EDCs via categories.

**Justification 2:** The criteria should be **consistent** with the approach used global to identify hazardous substances according to the GHS and the CLP regulation. The classification of CMRs according to the CLP Regulation covers `known and presumed effects' and is done with multiple categories.

## Criteria for more than just Active Substances

The November revised draft criteria have again been written for ACTIVE substances in pesticides and biocides. This is evident 1) from how the criteria have been separately laid out for humans and non-target organisms, ostensibly to reflect the structures of the Pesticides and Biocides laws and 2) by the unequal treatment of OECD protocol studies and other scientific studies, whilst referring to Commission Communications on Pesticides data requirements, and to Pesticides and Biocides guidances. See also the wording in the proposed Biocides Delegated act Annex Section A (1) & (2), Section B (1) & (2).

***HEAL advocates: The identification criteria must encompass/be applicable to ANY AND ALL substances, not just 'active substances' in biocides or pesticides***

**Justification 1:** The Pesticides law refers to all substances (active substances, safeners and synergists, inactive substances) which must not have endocrine disrupting properties (Article 23 (1b); Annex II, 3.6.5; 3.8.2).

**Justification 2:** In Article 19(4) of the Biocides law, a biocidal product FOR GENERAL USE must not have endocrine disrupting properties, hence the criteria must be applicable to any substances, not just active ones.

**Justification 3:** The newly adopted Medical Devices Regulation refers to the definition/criteria in the Biocides Products regulation, to identify endocrine disrupting substances used in medical devices; hence the criteria must be applicable to any substances, not just active ones in Pesticides or Biocides.

**Justification 4:** The 7th Environmental Action Programme commits the EU to horizontal criteria that can be applicable across multiple laws[2].

# CATEGORIES

## The November 2016 draft identification criteria only foresees 1 overly narrow category of EDCs *PPPR proposal,* Annex II, 3.6.5.2.2; *BPR proposal, Annex, Section A1 & B1.* (See also above Section on IDENTIFICATION When is something an endocrine disruptor that may harm?).

By using the word **may,** the legal texts of the BPR and PPR permit and envision more than one category, because may covers harm from *definite* EDCs (as per a parallel with CMRs in the Classification and Labelling: known and presumed, Category 1a and 1b) and possible harm from *potential/probable* EDCs (Category 2, suspected). The word **may** is best operationalised with the WHO full definition plus categories (Roadmap option 3), where substances are assigned to categories by expert judgement according to the totality of scientific evidence.

***HEAL advocates: The criteria should contain the following categories:***

**Category 1A – Known and presumed from human evidence/data**
**Category 1B – Known and presumed from animal evidence/data**
**Category 2 – Suspected from human or animal evidence/data**
**Category 3 – Endocrine active properties indicated from other data (in vitro, in silico)**

***HEAL advocates: The EDC cut offs be applied to Category 1A and 1B, AND Category 2***

**Justification:** PPPR cut-off criteria refers to ED substances that 'MAY cause adverse effects', hence not only Cat 1a & 1b should be affected, but also Category 2 EDCs.

**Justification:** The criteria must be consistent with the globally accepted approach for identification of hazardous substances according to the GHS and the CLP regulation.

**Justification:** The criteria should also be in line with the Commission's Better Regulation initiative that aims at consistency and coherency across legislation. Note, in the PPPR and BPR, for CMRs both categorisation as 1a or 1b triggers the same regulatory restrictions.

[2] Article 50. The Union will further develop and implement approaches to address combination effects of chemicals and safety concerns related to endocrine disruptors in all relevant Union legislation. In particular, the Union will develop harmonised hazard-based criteria for the identification of endocrine disruptors.

**Justification:** The Cosmetics Regulation has Category 2 bans for CMRs, of which some are carcinogens or reproductive toxicants because of their Endocrine Disrupting properties. This highlights the need for a Category 2 for EDCs, which may have other adverse effects than C and R, effects that have not yet be adequately captured in the C or R classification (such as neurodevelopmental toxicity, immunotoxicity, metabolic toxicity).

# WEIGHT OF EVIDENCE

The November 2016 draft identification criteria set out at length the methods for reviewing and integrating the evidence (PPPR proposal Annex II, 3.6.5.2.3; BPR proposal Annex Section A point 2, Section B point 2).

Whilst striving for transparent and rigorous elaboration and conclusions of why a substance fulfils the criteria is very important, we note that there are some difficulties. Internationally agreed standards for systematic review or weight of evidence procedures do not yet exist. Nor within the EU are harmonised guidance documents from both ECHA and EFSA yet available. Also, systematic review is a highly labour and data intensive undertaking. Therefore it is not clear why the Commission has chosen to lay out these weight of evidence points within the official criteria, when they subsequently get published in the official journal.

The most striking problems in this section are

1) that the internationally agreed testing protocol studies are **not** subject to the 'systematic review methodology' to be applied to the other relevant scientific data. Either all data should be subject to systematic review or none.
2) the other relevant scientific data are to be **selected** via systematic review methodology, using guidance where:
    a. first it is unclear whether the guidances to be followed pertain to the **review methodology** or to the **selection** of the other data
    b. second, and more importantly, in contradiction to the fact that **here** {Pesticides point 3.6.5.2.3, point (1) b} **it should be science other than the internationally agreed study protocols,** the guidances listed in the Commission Communications for Regulations 283/2013, and 284/2013 specifically for endocrine disrupting properties, refer to internationally agreed study protocol studies. This is circular and flawed.

***HEAL advocates: Accept only text that ensures that OECD/GLP protocol studies are treated equally to, and do not have precedence over other data (PPPR proposal 3.6.5.2.3, point 1b; BPR proposal Section A 2 (1) a & b; Section B 2 (1) a & b); ideally get text with a simple clear separation between the protocol studies and the other scientific data.***

***HEAL advocates: Insist on clarity and relevance in references to the guidance documents.***

# DEROGATION

For endocrine disrupting pesticides, the PPPR proposal changes the derogation conditions from 'negligible exposure' to 'negligible risk from exposure'.

The following paragraph has been edited with highlights and other colours to illustrate what the European Commission has changed between the original legal text and the revised version that was published on 8 November 2016. All parts highlighted in blue illustrate important elements of the new proposal, without which the text does not stand by itself. All parts highlighted in red illustrate are new elements that the European Commission has inserted into the original legal text. The words struck out are words that the European Commission has deleted from the original text, as part of their proposed revised phrasing of the legal text.

| **Side by side comparison between original legal text and revised November 2016 proposal** | | |
|---|---|---|
| ***Original legal text (Bold = main parts of sentence)*** | | ***November 2016 proposal (Red text = new insertions)*** |
| Annex II 3.6.5 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. | | Annex II 3.6.5.2 An active substance, safener or synergist shall only be approved if, on the basis of the ~~assessment of Community or internationally agreed test guidelines~~ *available evidence carried out in accordance with the data requirements for the active substances, safeners or synergists and* ~~or~~ other available data and information, ~~including a review of the scientific literature, reviewed by the Authority,~~ it is not considered*, in accordance with the criteria specified in point 3.6.5.2.2,* to have endocrine disrupting properties that may cause adverse effect in humans, unless the risk to humans from exposure ~~of humans~~ to that active substance, safener or synergist in a plant protection product, under realistic worst case proposed conditions of use, is negligible, ~~that is,~~ 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~~s~~ levels of the active substance, safener or synergist concerned on food and feed ~~do not exceed the default value~~ can, taking account of the latest opinion of the Authority with respect to that active substance, synergist, safener, be set in accordance with ~~point (b) of Article 18(1) of~~ Regulation (EC) No 396/2005, which ensure a high level of consumer protection. |

***HEAL advocates: Reject the text changes in the derogation (return to original language):***

***'Negligible Risk';***
***'which aim to exclude contact with humans';***
***'where maximum residue levels … can … be set'.***

***If Negligible Risk is desired, it should be in a separate legal proposal that undergoes a full, open, democratic co-decision process between Parliament and Council.***

**Justification:** The specification of **exposure** (elaborated as 'a closed system or excluding contact with humans') was a deliberate policy choice of the co-legislators. There is and can be no scientific justification (of current knowledge on EDCs), for changing a political choice from exposure to risk.

**Justification:** The EP legal service has judged this change to the derogation illegal, because it changes 'essential elements' of the Regulation, which cannot be altered in an implementing act (PRAC /Commitology). The EP ENVI Chair has formally conveyed this legal service view to Health Commissioner Andriukaitis.

**Justification:** Another legal opinion, commissioned by Client Earth, from Professor Martin Fuehr, University of Darmstadt in Germany, also found the derogation illegal for the same reasons.

**Justification:** The article 78(1) which the Commission is citing as justification to change the Derogation in PPPR Annex II does not apply to 'essential elements' of the act, because those address the basic balance the co-legislators have agreed between safeguarding the competitiveness of European Community agriculture and a high level of protection of human and animal/environmental health.

**Justification:** The Commission has provided no evidence and no clear examples to demonstrate that the move to 'negligible risk' will offer MORE protection to humans/environment than the 'negligible exposure' approach does.

# FINAL CONCLUSION

The revised Commission proposal of early November 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. This is unacceptable, and is clearly not what the Parliament and Council intended when the Pesticides and Biocides laws were agreed. Moreover, these criteria will have significant implications for identification of EDCs in the future, in all other EU laws dealing with chemicals. Equally importantly the quality of these identification criteria will affect the levels of ambition of legal provisions to address EDCs and reduce public exposure when EU laws are revised in the future.

***PCBs**, chemicals that were banned in the 1970s and now recognised as more harmful than was understood at the time they were banned, or the infamous chemical **DES would not qualify as endocrine disruptors under these criteria**[3]. The November proposed criteria will allow continued wide exposure to these harmful chemicals.*

Therefore, HEAL calls upon you to insist on major changes to the November 2016 proposal, in order to live up to the legally agreed high protection for human health and the environment. We urge you to **only adopt** a criteria text proposal that uses a reasonable burden of proof for identification, has multiple categories, doesn't arbitrarily discriminate between academic and OECD protocol studies, and retains 'negligible exposure' as the basis for derogations of pesticides to the EDC ban.

*An overview of all HEAL recommendations can be found on the overleaf of this briefing.*

***Lisette van Vliet***
***Senior Policy Officer, Chemicals and Health***
Health and Environment Alliance (HEAL)
E-mail: lisette@env-health.org

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**Health and Environment Alliance (HEAL)**
28, Boulevard Charlemagne
B-1000 Brussels – Belgium
Tel.: +32 2 234 36 40
E-mail: info@env-health.org
Website: www.env-health.org

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[3] According to presentations made by the Endocrine Society at events in the European Parliament and elsewhere.

# HEAL Recommendations

## IDENTIFICATION CRITERIA

### When is something an endocrine disruptor? From Known to Shown an improvement?

- ***HEAL advocates: Ensure the wording 'shows' is changed.***

### When is something an endocrine disruptor? Consequential conditionality

- ***HEAL advocates: Reject 'consequence' as the link between harm and altered function.***

### When is something an endocrine disruptor that may harm?

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