Case Id: a236becf-bde3-4348-8711-e863551df551

Public Consultation on Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation

Fields marked with * are mandatory.

1. Information about you

All your answers to questions in sections 2, 3 and 4, are intended to be published on the web, together with some of your personal data (please read the specific privacy statement before answering the following questions). Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.

How would you like your contribution to appear?*

- (•) **Under the name supplied** (I consent to the publication of all the information in my contribution, and I declare that none of it is subject to copyright restrictions that would prevent publication)
- ( ) **Anonymously** (I consent to the publication of all the information in my contribution, except my name/the name of my organisation, and I declare that none of it is subject to copyright restrictions that would prevent publication)
- ( ) **I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account. In any case, the contribution will be subject to the rules on access to documents, Regulation (EC) No 1049/2001)

1.1. Your full name:*

Grazia Cioci

1.2. Your e-mail address for correspondence:*

grazia.cioci@hcwh.org

1.3. Your gender:*

( ) Male (•) Female

1.4. Your age:*

- ○ 15-24
- ○ 25-39
- ◉ 40-54
- ○ 55-64
- ○ 65+

1.5. Your level of education (highest degree obtained):*

- ○ Primary school
- ○ Secondary school
- ○ Technical college or similar
- ○ University
- ◉ Post/-University
- ○ Still in full time education

1.6. Your occupation:*

- ○ a. Self-employed
- ◉ b. Employee
- ○ c. Not in formal working arrangement
- ○ d. Other

1.6.b. If employee, please specify:*

- ○ Professional (employed doctor, lawyer, accountant, architect)
- ◉ General management, director or top management
- ○ Middle management
- ○ Civil servant
- ○ Office clerk
- ○ Other employee (salesman, nurse, etc...)
- ○ Manual worker
- ○ Other

1.7. I'm replying as a(n):*

- ○ a. Individual/citizen/consumer
- ◉ b. On behalf of an organization

1.7.b.1. If responding on behalf of a(n) organisation/association/authority/company/body, please provide the name:*

Health Care Without Harm Europe

1.7.b.2. Is your organisation listed in the EU transparency register?*

- ◉ a. Yes
- ○ b. No

- c. Do not know

1.7.b.2.a. Please specify identification number *(optional)*:

1.7.b. Please specify the organisation you represent:*

- i. Public authority
- ii. Academic/Research institution
- iii. Hospital / Health institution
- iv. Private company
- v. Agricultural producers (farmers)
- vi. Consumer / Non-Governmental Organisation
- vii. Industrial or trade association
- viii. Other

1.7.b.vi(1). If consumer/non-governmental organisation, please specify members:*

- International
- National
- Local

1.7.b.vi(2). If consumer/non-governmental organisation, please specify actions:*

- Environmental concerns
- Consumer concerns
- Worker concerns
- Human rights concerns
- Other

1.8. Your location:*

- AT - Austria
- BE - Belgium
- BG - Bulgaria
- CY - Cyprus
- CZ - Czech Republic
- DE - Germany
- DK - Denmark
- EE - Estonia
- EL - Greece
- ES - Spain
- FI - Finland

- FR - France
- HR - Croatia
- HU - Hungary
- IE - Ireland
- IT - Italy
- LT - Lithuania
- LU - Luxembourg
- LV - Latvia
- MT - Malta
- NL - Netherlands
- PL - Poland
- PT - Portugal
- RO - Romania
- SE - Sweden
- SI - Slovenia
- SK - Slovakia
- UK - United Kingdom
- NO - Norway
- CH - Switzerland
- IS - Iceland
- LI - Lichtenstein
- Other

1.9. Would you say you live in a ...?*

- (•) Metropolitan zone
- ( ) Other town/urban centre
- ( ) Rural zone
- ( ) Do not want to answer

1.10. Were you or your organisation involved in scientific issues in relation to endocrine disrupting chemicals in the last 3 years and in which way? *(more than one answer possible)**

- [ ] Direct experimental scientific research
- [x] Review of scientific research
- [ ] Use of scientific research for safety assessments
- [ ] Use of scientific research for regulatory purposes
- [x] Lobbying
- [x] Other
- [ ] Not involved

If other, please specify.*

Communications on scientific evidence

1.11. Were you or your organization directly involved in/affected by the EU legislation mentioned below in the past 3 years? *(more than one answer possible)**

- [ ] Classification and Labelling (Regulation 1272/2008)
- [x] REACH (Regulation 1907/2006)
- [ ] Plant Protection Products (Regulation 1107/2009)
- [ ] Biocides (Regulation 528/2012)
- [x] Water Framework Directive (2000/60/EC)
- [ ] Cosmetics (Regulation 1223/2009)
- [ ] Chemicals Agents Directive (98/24/EC)
- [x] Other
- [ ] Not involved

If other, please specify.*

Medical Device Regulation Proposal

1.12. In what context have you been made aware of the discussions about endocrine disrupting chemicals?*

- ( ) Media for the general public
- (•) Scientific publications
- ( ) As part of my profession
- ( ) Schools, universities, etc.

2. Options for criteria for determination of endocrine disrupting properties

The roadmap defines 4 different options for the establishment of criteria for determination of endocrine disrupting properties.

2.1. Questions regarding option 1 *(No policy change (baseline). The interim criteria set in the plant protection products and biocidal products regulations continue to apply. No other criteria are specified).*

2.1.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 1?*

- ( ) Yes
- (•) No

2.1.2. Are you aware of any assessment(s) of substitutability of the identified substances?*

- ○ Yes
- ◉ No

2.1.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- ○ Yes
- ◉ No

2.1.4. Please, provide us with any other comments you may have regarding option 1:

4,000 character(s) maximum

HCWH Europe does not support option 1 because the EU needs comprehensive criteria for identification of all endocrine disrupting chemicals (EDCs). The interim criteria apply only to pesticides and biocides, but regulation of other uses falling under other EU law, i.e. medical devices, cosmetics, food packaging, children toys, etc., should also take place.
Therefore, criteria for a scientific identification of EDCs are needed for other EU laws, and any other uses as well, which option 1 will not deliver.
Moreover, the current interim criteria will only identify EDCs that are carcinogenic and reprotoxic and not the ones that affect the brain or the metabolism, contributing to mental disorders, diabetes or obesity.

2.2. Questions regarding option 2 *(WHO/IPCS definition to identify endocrine disruptors (hazard identification)*

2.2.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 2?*

- ○ Yes
- ◉ No

2.2.2. Are you aware of any assessment(s) of substitutability of the identified substances?*

- ○ Yes
- ◉ No

2.2.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- ○ Yes
- ◉ No

2.2.4. Please, provide us with any other comments you may have regarding option 2.

4,000 character(s) maximum

HCWH Europe does not support option 2 as an acceptable option as we do not believe it provides the best systematic, science-based approach to the EDCs criteria. Dropping the WHO/IPCS definition for "potential EDCs" and keeping only the definition for "confirmed EDCs" would not take into consideration the full state of the science and knowledge on EDC's adverse effects and would exclude all chemicals that need to be further investigated to determine whether they are EDCs or not.

It should also be kept in mind that the pesticides and biocides EU laws say "may have adverse effects" aiming at phasing out both known and potential EDCs. Therefore we need a definition that is not only for confirmed EDCs but also for chemicals for which adverse effects are suspected but not proven. Moreover, the "may have adverse effects" phrase allows for a lower level of proof that the endocrine disrupting properties are responsible for those adverse effects. In this way potential EDCs can still be tracked until more evidence can confirm their endocrine disrupting properties and change their 'potential' status into the 'confirmed' one. The aim should be to establish a plausible link between and adverse effect or a predictor of an adverse effect and an Endocrine Disruptor (ED) mode of action.
The world's leading scientific report on the "State of the science of EDCs 2012" from the WHO and United Nations Environment Programme (UNEP) highlights that endocrine disrupting chemicals are a global threat to human health and ecosystems. Therefore, we must be able to distinguish between confirmed and potential disruptors.

2.3. Questions regarding option 3 *(WHO/IPCS definition to identify endocrine disruptors and introduction of additional categories based on the different strength of evidence for fulfilling the WHO/IPCS definition)*

2.3.1. Have you conducted or are you aware of an assessment of substances which, in addition to those identified according to option 2, would be identified as suspected endocrine disruptors or endocrine active substances (Categories II or III) according to option 3?*

- ○ Yes
- ◉ No

2.3.2. Are you aware of any assessment(s) of substitutability of the identified substances?*

- ○ Yes
- ◉ No

2.3.3.Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- Yes
- (•) No

Please, provide us with any other comments you may have regarding option 3.

4,000 character(s) maximum

HCWH Europe strongly supports option 3, defining a comprehensive, crosscutting system that ranks EDCs in 3 categories: confirmed, suspected and potential EDCs. Option 3 offers the possibility of categorising according to different levels of evidence available depending on the data situation. However, instead of calling the third category "endocrine active compounds" we would keep the WHO/IPCS definition of a potential endocrine disrupting chemical. This category of "potential EDC's" is coherent with current approaches to rank other chemicals, such as the classification of carcinogenic and reprotoxic chemicals. It also facilitates regulating EDCs according to the different laws governing their various uses (food contact materials, pesticides, cosmetics, medical devices, etc.).
The first two categories (confirmed and suspected) should determine regulation. The third category (potential) is important to gather more information on the potentially harmful properties of the chemical. This additional information will help to either remove chemicals from this category or upgrade them.
When placing chemicals in the different categories, it will be crucial not to raise the bar of proof too high. Waiting for complete knowledge means risking taking action too late to prevent illness and save lives (as it happened with asbestos and lead).

2.4. Questions regarding option 4 *(WHO/IPCS definition to identify endocrine disruptors and inclusion of potency as element of hazard characterisation (hazard identification and characterisation)*

2.4.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 4?*

- (•) Yes
- No

If yes, please describe the methodology(ies), including the potency thresholds that applied:*

4,000 character(s) maximum

The Danish EPA report "Establishment of Criteria for Endocrine Disruptors and Options for Regulation" of 17th May 2011 (J.nr. MST-621-00011) evaluated the c

onsequences of using a potency cut off as suggested in the German Federal Institute for Risk Assessment (BfR) and the UK's Chemicals Regulation Directorate (CRD) Joint Position Paper entitled "Regulatory Definition of an Endocrine Disrupter in Relation to Potential Threat to Human Health".

If yes, please describe the outcome(s) of the assessment(s):*

4,000 character(s) maximum

The Danish analysis suggested that relatively few EDCs would be considered EDCs for regulatory purposes if the proposed potency cut off was used.

Please provide the reference(s) if possible:

2.4.2. Are you aware of any assessment(s) of substitutability of the identified substances?*

- ○ Yes
- ◉ No

2.4.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- ○ Yes
- ◉ No

2.4.4. Please, provide us with any other comments you may have regarding option 4.

4,000 character(s) maximum

HCWH Europe does not support option 4 which would take into consideration the potency factor. The proposal to use the 'potency' of a chemical to determine regulation is indeed scientifically flawed as potency is not a characteristic of a chemical like its molecular structure or weight. Potency depends on the timing of exposure (particularly if it is prenatal or early in life) and what endpoint is measured. So any given chemical could have many different potencies, depending on when exposure occurs and how effects are measured.
Moreover, potency is not used to identify chemicals that are carcinogenic or toxic for reproduction; therefore, it would make no scientific sense to use it for identifying whether a chemical is a hormone disruptor or not.

EDCs vary in how strongly they affect different parts of the body and different hormone systems, so relying on selective tests for potency may wrongly leave some chemicals unidentified. In addition, animals in our ecosystems are also exposed to EDCs, but potency may vary dramatically between different species.

Windows of exposure to EDCs are also extremely important. During most vulnerable periods, such as development in the womb and early age, even extremely smal

l amounts of EDCs may contribute to serious health effects, particularly later in life.
Finally, both humans and wildlife are exposed to many EDCs from different sources at the same time and over time, and science has shown that EDCs can act together, leading to harmful cocktail effects. Not identifying 'low potency' EDCs would hamper any attempts to address health risks arising from cumulative exposure to these EDCs. For all these reasons HCWH Europe believes that using potency will not appropriately protect people and wildlife and therefore rejects option 4, as being inadequate as identification criteria.

3. Options for approaches to regulatory decision making

The roadmap defines 3 different options for approaches to regulatory decision making. Option A (no changes of the existing provisions in BPR and PPPR), Option B (introduction of further elements of risk assessment) where necessary and desirable to reduce potential socio-economic impacts, and Option C (introduction of further socio-economic considerations) where necessary and desirable to prevent adverse socio-economic impacts.

3.1. Have you conducted or are you aware of an assessment applying any of the 3 different options for regulatory approaches to decision making (option A-C) to substances identified as endocrine disruptors by any of the options for defining criteria (option 1-4)?*

- ○ Yes
- ◉ No

3.2. Have you conducted or are you aware of an assessment of the socio-economic impact of the 3 different options for regulatory approaches to decision making (option A-C) for substances identified as endocrine disruptors by any of the options for defining criteria (option 1-4)?*

- ○ Yes
- ◉ No

4. Other information

4.1. Please provide any other data or information that could help the Commission to conduct its impact assessment.

4,000 character(s) maximum

As regards the 3 options for regulatory decision making, HCWH Europe supports option A, no change in law, as best protecting health and well-being of the en

vironment and humans. HCWH Europe does not support options B or C, which will both lead to delays in removing harmful chemicals. Options B and C are unacceptable because they would undermine the democratically agreed rules in the EU pesticides law adopted by the elected European parliamentarians and national governments in 2009.The EU pesticides and biocidal laws already contain provisions for exemptions so that no changes are necessary or useful.

Furthermore, HCWH Europe believes that micro and macro-economic, social, political and environmental benefits of reducing our exposure to EDCs should be included in impact assessments. The following reports and studies made an attempt to cost the benefits of stricter controls for EDCs and reduced human exposure. These should be integrated in the Commission's impact assessment:

- The cost of inaction – A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, Nordic Council report, November 2014
- Health costs in the EU - How much is related to EDCs, Health and Environment Alliance (HEAL), June 2014
- L. Trasande: Further Limiting Bisphenol A in Food Uses Could Provide Health and Economic Benefits, Health Affairs, January 2014

However, HCWH Europe also believes that socio-economic impacts should not be the primary drivers of decision-making on the scientific identification of EDCs. Regulatory decisions should be based primarily on the health of citizens and the environment. The use of risk assessment elements should be avoided because "safe" exposure concentrations have not been able to be determined consistently or accurately with respect to EDCs.
Scientists have repeatedly voiced concerns about EDCs because it is likely that they are contributing to the dramatic increases of serious diseases and health disorders, such as reproductive and fertility problems, breast, prostate and testicular cancers, effects on brain development and nervous system problems, and obesity and diabetes.
Recent biomonitoring studies from across Europe have shown that people in the general population are typically contaminated with several chemicals, coming into contact with consumer products, food, medical devices, etc. Special care should be taken to reduce exposures before and during pregnancy, in early childhood, and during puberty.
Wildlife is also suffering from exposure to hormone disrupters and impaired reproduction and development linked to EDCs has been reported in many species, including fish, birds, otters and even polar bears.

The following studies highlight the levels of certain EDCs found in urine and hair of children and their mothers:
- EU biomonitoring project: http://www.eu-hbm.info/democophes
- M. Casas et al: Exposure to brominated flame retardants, perfluorinate

d compounds, phthalates and phenols in European birth cohorts, International J ournal of Hygiene and Environmental Health 216 (2013) 230-242.
• O. Leino et al: Pollutant concentrations in placenta. Food and Chemica l Toxicology 54 (2013), 59-69.

The following studies have reported EDCs in the urine of neonates under treatm ent in hospitals:
• Rose et al., 2012, Anaesthesia 67: 514-520
• Calafat et al., 2004, Pediatrics 113: e429–e434
• Duty et al., 2013, Pediatrics 131: 483-489

HCWH Europe would also like to draw attention to the fact that this consultati on ignores important questions for citizens, society and companies interested in replacing EDCs with safer alternatives. For example, what will be the benef its of stricter controls for EDCs? How much will we save in terms of reduced h ealthcare costs? What are the business opportunities for innovative and safer alternatives? These are important questions that HCWH Europe believes should b e addressed.

Please provide the reference(s) if possible:

Contact

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