Case Id: ed4370c1-60df-4175-bac6-29fff0c94644

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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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:*

Lisa Anfält

1.2. Your e-mail address for correspondence:*

lisa.anfalt@kemi.se

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:*

Swedish Chemicals Agency (KEMI)

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

- ○ a. Yes
- ◉ b. No
- ○ c. Do not know

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.i. If public authority, please specify:*

- ( ) (1) International institution
- ( ) (2) EU Agency
- (●) (3) Government authority

1.7.b.i.(3). If government authority, please specify:*

- (●) National
- ( ) Regional

1.8. Your location:*

SE - Sweden

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

If other, please specify.*

Information/Dissemination

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)* *

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

If other, please specify.*

Acts: Environmental code (1998:808); Products Safety Act (2004:451); Act (2011:579) on Toy Safety. Ordinances: Environmental Enforcement Ordinance (2011:13); Ordinance (2007:19) on PCB; Biocidal Products Ordinance (2000:338); Plant Protection Ordinance (2006:1010); Chemical Products (Handling, Import, and Export Prohibitions) Ordinance (1998:944); Ordinance (2008:245) on chemical products and biotechnical organisms; Ordinance (2004:469) on Product Safety; Ordinance (2011:703) on Toy Safety; Ordinance (2012:861) on hazardous substances in electrical and electronic equipment. Regulations: Swedish Chemicals Agency´s Classification and labelling regulations (KIFS 2005:7); Swedish Chemicals Agency´s Chemical products and biotechnical organisms regulations (KIFS2008:2); Swedish Chemicals Agency´s Pesticides regulations (KIFS 2008:3). EU-regulations: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH); Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP); Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC (POPs); Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents; Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products. EU-directives/Implemented in Swedish legislation: Council Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations; Directive 2004/42/CE of the European Parliament and of the Council on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC. The directives are implemented in Swedish legislation under the Environmental Code, in particular in the Swedish Chemicals Agency´s regulations (KIFS 2008:2); Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2). The directive is implemented in Swedish legislation with Ordinance (2012:861) on hazardous substances in electrical and electronic equipment; Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. The directive is implemented in Swedish legislation under the Environmental Code and in the Swedish Chemicals Agency´s Classification and labelling regulations (KIFS 2005:7); Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. The directive is implemented in Swedish legislation under the Environmental Code and in the Swedish Chemicals Agency´s Classification and labelling regulations (KIFS 2005:7) and Swedish Chemicals Agency´s Chemical products and biotechnical organisms regulations (KIFS 2008:2); Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys. The directive is implemented in Swedish legislation under the Act (2011:579) on Toy Safety and the Ordinance (2011:703) on Toy Safety.

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

If yes, please describe the methodology(ies):*

4,000 character(s) maximum

In 2008, the Swedish Chemicals Agency conducted a preliminary assessment of the impact on the number of approved active substances by applying the interim criteria. For further information, see attachment (Pdf-file: “Interpretation of criteria for CMR ED & PBT in PPP 22 Sept 2008”).

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

4,000 character(s) maximum

A total of 271 substances were evaluated and of these 15 were identified as having endocrine disrupting properties. Of these 13 are still approved within the EU.

Please provide the reference(s) if possible

1. 4a1cd8ed-f148-49ab-ace2-9dfc2b7b31b2/Interpretation of criteria for CMR ED & PBT in PPP 22 Sept 2008...Scan.pdf

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

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The Swedish Chemicals Agency does not support option 1.
To adopt this action would not comply with Article 5.1.d and 5.3 in
REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL of 22 May 2012 concerning the making available on the market and
use of biocidal products. Nor is it in compliance with 1107/2009 (Plant
Protection Products Regulation), since these two regulations clearly
state that scientifically based criteria should be set. Furthermore, to
continue to implement this option only applies directly to human health
effects. Whereas, the environment is only indirectly addressed via REACH
article 57(f) and article 59.
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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

The Swedish Chemicals Agency (KEMI) does not support option 2. KEMI considers that the WHO/IPCS definition is an acceptable working definition to designate a substance as an endocrine disruptor. However, the level of evidence required to fulfil this criteria have to correspond to the intentions of the EU legislations ("that may cause"). Thus, we consider that option 2 will lead to practical difficulties, as it is impossible for most substances to unequivocally prove a causal relationship between hormonal changes and adverse health effects in an experimental study. As a consequence, we consider that the "yes-no" option to be too restrictive and rigid system which only relies on identifying clear positive endocrine disruptors. Such an approach would possibly work if the available validated test methods were not limited only to parts of the hormonal system (i.e. the estrogenic, androgenic, thyroid and parts of the steroidogenesis of the endocrine system (EATS) for mammals, fish and possibly amphibians). At present we do not have the scientific tools to categorically assess chemicals regarding their endocrine properties for all relevant endpoints at an adequate level of certainty.

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

If yes, please describe the the methodology(ies):*

4,000 character(s) maximum

Evaluation of a suggested set of criteria with 3 levels of similar to option 3 has been performed by Denmark.
Evaluation of plant protection products comparing several suggested systems for categorisation has been performed by France.
Ref: - Evaluation of 22 SIN List 2.0 substances according to the Danish proposal on criteria for endocrine disruptors (Danish Centre on endocrine disruptors, May 2012).
http://mst.dk/media/mst/67169/SIN%20report%20and%20Annex.pdf
Ref: - Evaluation of tebuconazole, triclosan, methylparaben and ethylparaben according to the Danish proposal for criteria for endocrine disruptors (Danish Centre on endocrine disruptors, May 2012).
http://mst.dk/media/mst/9106715/chemicalsreportandannex.pdf
Ref: - Opinion of the French Agency for Food, Environment and Occupational Health & Safety on a request for scientific and technical support regarding the European strategy for endocrine disruptors (Request no. 2011-SA-0237).
https://www.anses.fr/sites/default/files/documents/DPR2011sa0237EN.pdf

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

4,000 character(s) maximum

Twenty-two SIN-list 2.0 chemicals were evaluated of which 7 were pesticides; in another study 4 additional pesticides are evaluated according to the Danish/suggested criteria. Of these 11 pesticides, 8 were placed in category 1, and 3 in category 2.
The French evaluation showede that there are some active substances that will probably be identified as endocrine disruptors.

Please provide the reference(s) if possible:

1. 829db386-c5b4-48b1-9574-257166f2d9ec/Danish_Evaluation of tebuconazole ....pdf_2012.pdf
2. 505ff707-ba34-47bb-b9d6-34d2af8b2264/Danish_SIN report and Annex_2012.pdf
3. 95075270-724a-4084-82a2-6f35666232a8/French_Opinion of French Agency ...pdf_2011.pdf

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

The Swedish Chemicals Agency (KEMI) supports option 3.
KEMI considers that the WHO/IPCS definition is an acceptable working definition to designate a substance as an endocrine disruptor. However, the level of evidence required to fulfil this criteria have to correspond to the intentions of the EU legislations ("that may cause"). Thus, we consider option 3 at present to be the best approach to utilise information from the currently available test methods. Given that the tests available today only cover parts of the endocrine system (EATS) and sufficient tests are not available to cover the whole life cycle for all relevant taxa (e.g. evaluation of early exposure and late effects). Generally, one of the advantages of having several categories is that such an approach is less restrictive and provides a greater degree of transparency, increased awareness, and ability to further prioritise chemicals with possible endocrine properties for further testing, assessment and management.
Specifically, this option provides several advantages:
Category 1 – substances with adequate information can be identified as endocrine disruptors.
Category 2 – substances with some but not enough information can be clearly identified and subsequently on a case-by-case or group basis be prioritised/selected for further work and testing.
Category 3 – is desirable as it enables traceability of substances that may have endocrine disrupting properties, but where data is lacking or inadequate to properly evaluate them and designate them to category 2. This set of substances will be a signal to researchers and product developers to consider with interest and due prudence.
Furthermore, we consider it desirable to have a single set of harmonised criteria across all EU legislations to ensure legal clarity and avoid ambiguity, i.e. also REACH and the Cosmetics regulation have to be considered ("for which there is evidence of probable").

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

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

The Swedish Chemicals Agency (KEMI) does not support option 4
KEMI considers that the WHO/IPCS definition is an acceptable working definition to designate a substance as an endocrine disruptor. However, the level of evidence required to fulfil this criteria have to correspond to the intentions of the EU legislations ("that may cause"). Thus, we consider the concept of potency to be highly inappropriate in the context of defining an endocrine disruptor, given that the designation of "endocrine disruptor" is, and should be purely hazard based.
The problem of considering potency is discussed in the "State of the Art of endocrine disruptors" (Kortenkamp et al. 2012) and was highlighted: "Scientifically, it is impossible to draw a borderline for potency in isolation, without considering exposure. As such, solely potency-based trigger values will always be arbitrary.".
Furthermore, potency should not be considered because it cannot account for: different mechanisms of action, critical windows of susceptibility, non-linear dose response curves, low-dose-response curves, additive effects by mixtures of low doses of EDCs, non-threshold mechanisms, effects on the population and vulnerable sub-groups.
Problems will also arise because of variability in data sets and study designs, e.g. mixtures of old and new studies (with and without relevant endpoints), and different sensitivities in the tests (statistical power).

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

If yes, please describe the methodology(ies)*

4,000 character(s) maximum

Comment:
Option A. The Swedish Chemicals Agency supports this option. Taking into account the recent and ongoing implementation of the PPPR and BPR option A is the only valid alternative.
Option B. The Swedish Chemicals Agency does not support this option. This option will only cause prolonged discussions, time delays, increased confusion, incongruence and waste of already invested resources.
Option C. The Swedish Chemicals Agency does not support this option. This option further undermines the hazard and risk assessment processes. If required, additional socioeconomic assessments should be considered in other legislations.
We consider that there are good reasons to be extra careful concerning the use of pesticides, as they are designed to be toxic and are often used directly in the open environment, leading to increased risk for exposure of non-target organisms. Furthermore, plant protection products are intentionally used on human and animal foods

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

4,000 character(s) maximum

See previous field.

Please provide the reference(s) if possible:

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

When making criteria decisions we urge the Commission to take into account the recommendations made by the Endocrine disruptors expert advisory group that during 2012-2013 worked under the lead of DG JRC on the issue of how to identify endocrine disruptors.
When conducting an impact assessment, we want to emphasise that the socio-economic impact of ED substances on the human health and the environment has also to be taken into account. The Nordic Council recently published a report "The Cost of Inaction - A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health", which provides important considerations in this sense. Furthermore, HEAL has published a report "Health costs in the EU - how much is related to EDCs?" which shows that there are substantial cost related to endocrine disrupting substances and human health.
Ref: - Key scientific issues and characterisation of endocrine disrupting substances (Munn and Goumenou 2013) (http://www.efsa.europa.eu/en/events/documents/130320a-p07.pdf).
Ref: - Thresholds for endocrine disruptors and related uncertainties (Munn and Goumenou 2013) (http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/32062/1/lb-na-26-068-en-n.pdf).
Ref: - The Cost of Inaction - A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health" (http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A763442&dswid=-2821).

Ref: - HEAL report "Health costs in the EU - how much is related to EDCs?" (http://env-health.org/resources/press-releases/article/eur31-billion-per-year-in-eu).

Please provide the reference(s) if possible:

1. **af9b3521-c917-4710-a61c-588f815d0ab7/HEAL_Health costs in the EU_2014.pdf**
2. **d2a2a8c9-9341-47cd-8b25-b1a57d6ccf04/JRC_Key scientific ..... 20 March 2013.pdf**
3. **ebeb77c4-c494-4880-9f56-12e5f2a520f0/JRC_Thresholds for Endocrine ... 2013.pdf**
4. **20a4cb1d-3a30-49dc-b8ad-3472404fb47e/Norden_The Cost of Inaction_2014.pdf**

Contact

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