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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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

Howard Chase

1.2. Your e-mail address for correspondence:*

hjchase@dow.com

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:*

Dow Europe - especially related to the Dow Microbial Control biocides business

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)*:

38235121060-73

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.iv. If private company, please specify size:*

- (○) Micro-entity (up to 10 employees)
- (○) Small company (11-50 employees)
- (○) Medium sized (51 - 250 employees)
- (●) Large company (more than 250 employees)

1.8. Your location:*

CH - Switzerland

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)**

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

If other, please specify.*

Contributed to the development and advancement of regulatory test guidelines relevant for the assessment of endocrine activity under the OECD via BIAC.

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)
- [ ] Plant Protection Products (Regulation 1107/2009)
- [x] Biocides (Regulation 528/2012)
- [x] Water Framework Directive (2000/60/EC)
- [x] Cosmetics (Regulation 1223/2009)
- [x] Chemicals Agents Directive (98/24/EC)
- [ ] Other
- [ ] Not involved

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

Dow is aware of the study commissioned by the European Biocides Product Forum (EBPF), an affiliate association of CEFIC.
Additionally, the Dow Microbial Control business does support 20 biocidal active substances under the Biocides Product Regulation (BPR) review programme. We have conducted an assessment of our active substances against the criteria.
Furthermore, as part of Dow's commitment to Responsible Care we perform detailed reviews of the hazard data of our products which we or others generate, and follow-up on any indication of hazard that needs further clarification. Finally, we actively inform relevant regulatory bodies on new relevant information that comes to our attention.

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

4,000 character(s) maximum

The results of the Cefic-EBPF commissioned study will be reported directly by this organization.

For the 20 biocidal active substances supported by Dow Microbial Control, 2 substances have been approved so far, and they do not meet the ED interim criteria. For another 5 active substances the assessment reports have been released and have either been reviewed by the Biocidal Product Committee (BPC) or will be reviewed by the BPC in 2015. None of these 5 substances meet the ED interim criteria.
For the remaining 13 active substances, the assessment reports have not yet been released. Based on our own evaluation of the data we don't expect them to meet the ED interim criteria.

Please provide the reference(s) if possible

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

Dow considers that the interim criteria included in the Biocidal Products Regulation 528/2012 are not suitable for the regulation of endocrine disruptors. Since they are not fully science based, they are not a reliable indicator of whether a substance should be regarded as an endocrine disruptor.
There will be active substances that have been or will be classified as C2 and R2, but where it is clear that this classification is not related to endocrine mediated adverse effects. This is not consistent with the requirements of the WHO/IPCS (2002) definition.

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

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

4,000 character(s) maximum

Dow is aware of the study commissioned by the European Biocides Product Forum (EBPF), an affiliate association of Cefic.
Additionally, the Dow Microbial Control business supports 20 biocidal active substances under the BPR review programme. We have conducted an assessment of our active substances against the criteria.
Furthermore, as part of Dow's commitment to Responsible Care we perform detailed reviews of the hazard data of our products which we or others generate, and follow-up on any indication of hazard that needs further clarification. Finally, we actively inform relevant regulatory bodies on new relevant information that comes to our attention.

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

4,000 character(s) maximum

The results of the Cefic-EBPF commissioned study will be reported directly by this organization.

For the 20 biocidal active substances supported by Dow Microbial Control, 2 substances have been approved so far, and they do not meet the WHO/IPCS definition of endocrine disruptors. For another 5 active substances the assessment reports have been released and either have been reviewed or will be reviewed by the BPC in 2015. None of these 5 substances meet the WHO/IPCS definition.
For the remaining 13 active substances, the assessment reports have not yet been released, but based on our evaluation of the data we don't expect them to meet the WHO/IPCS definition.

Please provide the reference(s) if possible:

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

Dow supports the CEFIC-EBPF position that the WHO/IPCS (2002) definition is a valid scientific definition that for regulatory purposes needs to be complemented with further elements of hazard characterisation, and that the determination of endocrine disrupting properties needs to be based on a robust "weight of evidence" approach. We believe that an assessment against the WHO/IPCS (2002) definition alone is not sufficient for the purposes of regulatory decision-making under the Biocidal Products Regulation 528/2012.

We do support the use of the WHO/IPCS (2002) definition in its original phrasing as a scientific starting point and as a basis for elaborating the criteria for the determination of "endocrine disrupting properties" as required under the Biocidal Products Regulation 528/2012. We also subscribe to the EFSA scientific opinion (*1) on the hazard assessment

of endocrine disruptors in which it has endorsed the WHO/IPCS (2002) definition of an ED implying that 'there must be reasonable evidence for a biologically plausible causal relationship between the endocrine activity and the induced adverse effect(s) seen in an intact organism or a (sub)population for a substance to be identified as an ED." The EFSA Scientific Committee concluded in its report that the WHO/IPCS (2002) definition of an ED and the WHO/IPCS (2009) definition of an adverse effect should be endorsed as working definitions for their scientific opinion.

Furthermore, Option 2 foresees that the available evidence needs to support a strong presumption that an alteration of the endocrine system is the basis for the observed effect. We agree with this wording. Option 2 also suggests that the data needs to provide clear evidence of endocrine-mediated adverse effects. We also agree with this wording.

However, the WHO/IPCS (2002) definition on its own is not sufficient for the purposes of regulation and regulatory decision-making on individual active substances. The determination of endocrine disrupting properties should not be based on mere "strength of evidence" but based on a robust "weight of evidence" approach, taking into account data on "potency", "severity", "(ir)reversibility" and "lead toxicity", "specificity" and "human and population relevance". Furthermore, the "route of exposure" should also be considered as only adverse effects induced via the relevant exposure route(s) shall be employed.
Therefore, Dow supports the adoption of the alternative industry proposal (*2) for criteria for identifying endocrine disruptors of regulatory concern – as included in the Cefic submission to the Commission's public consultation under 2.4.4. – under the Biocidal products Regulation 528/2012.

(*1) EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132. [84 pp.] doi: 10.2903/j.efsa.2013.3132
2*
http://www.cefic.org/Documents/PolicyCentre/Endocrine/Elaboration-of-ED-Criteria-with-Full-Hazard-Characterisation-Nov2014.pdf

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

Dow is aware of the study commissioned by the European Biocides Product Forum (EBPF), an affiliate association of Cefic.
Additionally, the Dow Microbial Control business supports 20 biocidal active substances under the BPR review programme. We have conducted an assessment of our active substances against the criteria.
Furthermore, as part of Dow's commitment to Responsible Care we perform detailed reviews of the hazard data of our products which we or others generate, and follow-up on any indication of hazard that needs further clarification. Finally, we actively inform relevant regulatory bodies on new relevant information that comes to our attention.

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

4,000 character(s) maximum

The results of the Cefic-EBPF commissioned study will be reported directly by this organization.

For the 20 active biocidal substances supported by Dow Microbial Control, 2 have been approved so far, and they don't meet the criteria under option 3. For another 5 active substances the assessment reports have been released and either have been reviewed or will be reviewed by the BPC in 2015. None of these 5 substances meet the option 3 ED criteria.
For the remaining 13 active substances, the assessment reports have not yet been released, but based on our evaluation of the data we don't expect them to meet the option 3 ED criteria.

Please provide the reference(s) if possible:

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

Dow supports the CEFIC-EBPF position that a categorisation system for endocrine disrupting substances is not relevant for the following reason:
1) Establishing categories for ED substances is not required under the Commission's legal obligations relating to endocrine disruption. Under the Biocidal Products Regulation 528/2012, the Commission is required to specify "…scientific criteria for the determination of endocrine disrupting properties". This requires establishing a single set of criteria to determine whether or not a substance has endocrine disrupting properties.

2) Categorisation of ED does not have a scientific basis, even if designed by analogy with the existing CMR classification system. Whereas CMR represent well-defined adverse effects which are suitable to categorisation, endocrine disruption is not an adverse effect in itself - it rather artificially groups under the same terminology multiple modes of action leading to adverse effects of variable nature, severity and concern (i.e. manifested as carcinogenic, reproductive, developmental or other effects which are already considered in regulatory decision making). What is and should be regulated are adverse effects themselves, not the underlying modes of action that cause them.

3) Categorisation will inevitably lead to the creation of "black lists" that will be highly vulnerable to misinterpretation, misuse and unwarranted additional primary or secondary regulation, in Europe and globally. Substances not considered as "Category I endocrine disruptors" under the proposed scheme will still be labelled as "suspected endocrine disruptors" or "endocrine active substance", despite the fact that they will have been fully evaluated for their human health and environmental safety under the Biocidal Products Regulation 528/2012.

4) The option of categories could bring with it further consequences to consider. For example, if a substance was to be placed in either category II or III ("suspected endocrine disruptor" or "endocrine active substance" respectively), it would require additional vertebrate animal testing for clarifying proper categorization - thus sacrificing large numbers of animals to provide data. Data that goes beyond what is necessary to robustly assess the hazard of the substance.

Dow believes that substances should only be considered as endocrine

disruptors when there are clear adverse effects unambiguously caused by a well identified and empirically described endocrine mode of action. These adverse effects must be relevant to humans, not to be secondary to other toxic effects, and occur at exposure levels indicative of significant potency. Based on these considerations, only one category (confirmed endocrine disruptors of regulatory concern) is the logical consequence. The classification of a substance as an endocrine disrupter could be based on the available data package and – if necessary – additional testing to clarify the uncertainties. By default, all chemicals that do not meet these criteria are not EDs of regulatory concern and are subject to the existing regulatory framework based on the risk assessment principle offered by the Biocidal Products Regulation 528/2012.

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

Dow is aware of the study commissioned by the European Biocides Product Forum (EBPF), an affiliate association of Cefic.
Additionally, the Dow Microbial Control business supports 20 biocidal active substances under the BPR review programme. We have conducted an assessment of our active substances against the criteria.
Furthermore, as part of Dow's commitment to Responsible Care we perform detailed reviews of the hazard data of our products which we or others generate, and follow-up on any indication of hazard that needs further clarification. Finally, we actively inform relevant regulatory bodies on new relevant information that comes to our attention.

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

4,000 character(s) maximum

The results of the Cefic-EBPF commissioned study will be reported directly by this organization.

For the 20 biocidal active substances supported by Dow Microbial Control, 2 have been approved so far, and they don't meet the option 4 ED criteria. For another 5 active substances the assessment reports have been released and either have been reviewed or will be reviewed by the BPC in 2015. None of these 5 substances meet the option 4 ED criteria. For the remaining 13 active substances, the assessment reports have not yet been released, but based on our evaluation of the data we don't expect them to meet the option 4 ED criteria.

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

Dow Microbial Control supports Cefic-EBPF position that that all elements of hazard characterisation need to be considered, severity of effect, (ir)reversibility of effect, potency and lead toxicity These should not be limited to potency alone as currently described in option 4.
The additional hazard characterisation elements are essential to ensure that all relevant scientific information on the hazard of a substance is considered in regulatory decisions within the hazard based exclusion criteria included in Article 5 of the Biocidal Products Regulation 528/2012. Taking full account of the data on these additional elements is a routine part of chemicals evaluation and is critical to be able to distinguish between those substances that may be of high and of low regulatory concern.
Without fully taking account of all hazard characterisation elements, substances which pose little or no concern for human health or the

environment could be considered to have endocrine disrupting properties and unnecessarily be excluded under the Biocidal Products Regulation 528/2012 which would result in loss of essential biocidal products.

In summary, in reviewing the four proposed policy options for the ED criteria, and in the current absence of a risk assessment framework, we do not favour any of the four suggested options. Instead, we support the development of a single set of criteria for the determination of endocrine disrupting properties, which use the WHO-IPCS definition as a basis, but which also incorporate all the hazard characterisation elements (severity, (ir)reversibility, potency and lead toxicity). We also believe that all relevant scientific information should be evaluated using a structured weight of evidence approach considering both the quality and consistency of data. This approach should provide a solid basis for regulatory decision making and ensure that the final ED criteria are sufficiently discriminative to separate out those substances that are of high regulatory concern from those that are not.

Dow Microbial Control supports Cefic-EBPF proposal that the Commission consider an additional policy option when weighing all possible options in the establishment of ED criteria. This 5th option full risk assessment, taking into account all the available information of sufficiently good quality on the mode of action, hazard, exposure and adverse effects, using a structured weight of evidence approach. This is the conclusion reached by EFSA who have stated that “endocrine disruptors can be treated like most other substances of potential concern for human health and the environment, that is subject to risk assessment, considering both the hazard and exposure”(*1). Therefore Cefic has developed a concept (*2) of criteria for identifying substances requiring specific regulatory action for ED to be considered as option 5.

1* EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132. [84 pp.] doi: 10.2903/j.efsa.2013.3132

2* http://www.cefic.org/Documents/PolicyCentre/Endocrine/Elaboration-of-ED-Criteria-with-Full-Hazard-Characterisation-Nov2014.pdf

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

Dow Microbial Control recognises that risk-benefit and socio-economic considerations as options for regulatory decision-making as described in options B and C in the roadmap document are incorporated into the Biocidal Products Regulation 528/2012 when it concerns the approval of active substances.

However, for any other toxicological effect, Dow Microbial Control believes that decision-making for approval or non approval of an active substance should be based on science and on a well documented and transparent full risk-assessment, and should consider the possibility of implementing relevant risk mitigation measures.

Please provide the reference(s) if possible:

1. 4fbb1a82-abb5-449d-8d12-842e89410aab/Elaboration of ED Criteria with Full Hazard Characterisation 9 Jan 2015.pdf

Contact

✉ EC-consultation-endocrine-disruptors@ec.europa.eu