

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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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- I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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

Filip Cnudde

1.2. Your e-mail address for correspondence:*

FCnudde@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 AgroSciences Europe, subsidiary of Dow Europe GmbH, Switzerland

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 (Dow Europe)

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:*

BE - Belgium

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
- Other
- Not involved

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)
- REACH (Regulation 1907/2006)
- Plant Protection Products (Regulation 1107/2009)
- Biocides (Regulation 528/2012)
- Water Framework Directive (2000/60/EC)
- Cosmetics (Regulation 1223/2009)
- 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 AgroSciences is aware of several sources of information which should be considered as an input into the impact assessment on EDs. These have been submitted by the European Crop Protection Association (ECPA). Furthermore Dow AgroSciences has conducted an assessment of our active substances against the interim criteria.

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

4,000 character(s) maximum

Based on our assessment we don't expect our active substances 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

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

4,000 character(s) maximum

Dow AgroSciences is aware of the studies that have been submitted as input by the European Crop Protection Association.

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

4,000 character(s) maximum

Dow AgroSciences is aware of the studies that have been submitted as input by the European Crop Protection Association.

Please provide the reference(s) if possible

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

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

4,000 character(s) maximum

Dow AgroSciences is aware of the studies that have been submitted as input by the European Crop Protection Association.

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

4,000 character(s) maximum

Dow AgroSciences is aware of the studies that have been submitted as input by the European Crop Protection Association.

Please provide the reference(s) if possible

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

4,000 character(s) maximum

The recourse to interim criteria is not a good model for law-making as it potentially affects substances which are no longer considered as EDs by the final criteria, and may create an unequal playing field by targeting substances in a different timeframe.

The interim criteria have been established on an arbitrary basis using certain elements of the EU classification system without assessing if the effects that determine the classification are caused by an endocrine mode of action. Therefore substances can be targeted without meeting the intended protection goals. The interim criteria are not science based and are therefore not suitable for the regulation of endocrine disruptors.

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 methodology(ies):*

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

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

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

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

Please provide the reference(s) if possible:

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

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

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

Please provide the reference(s) if possible

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

4,000 character(s) maximum

For Dow AgroSciences the use of the WHO/IPCS definition is a step in the right direction for establishing science based criteria for the determination of "endocrine disrupting properties" under Regulation 1107/2009. However, the missing further elements of hazard characterisation (severity, (ir)reversibility, potency and lead toxicity) need to be included to make this option adequate for regulatory decision making on pesticide substances. Furthermore, the "route of exposure" should also be considered as only adverse effects induced via the relevant exposure route(s) shall be employed. Regulating ED chemicals should be based on risk assessment and management taking into account socioeconomic factors.

We believe that an assessment against the WHO/IPCS (2002) definition alone is not sufficient for the purposes of regulatory decision-making under Regulation 1107/2009.

We would like to draw attention to the fact that without consideration of potency a large number of low potency natural substances such as common food ingredients (e.g. caffeine or phytoestrogens in vegetables) would be covered by this definition.

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 methodology(ies):*

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

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

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

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

Please provide the reference(s) if possible:

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

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

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

Please provide the reference(s) if possible:

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

4,000 character(s) maximum

Dow AgroSciences does not support the creation of categories for endocrine disruptors as an option for determining and ultimately regulating endocrine disruptors for the following reasons:

1. Not required: Regulation 1107/2009 requires the Commission to establish specific scientific criteria. This does not require a set of categories, but a single set of criteria, which will show, if a substance has endocrine disrupting properties.

2. No scientific basis: Categorisation of endocrine disruptors has no scientific basis and thus contravenes the specific conditions set in the legislation. Endocrine disruption per se is not an adverse effect. Adverse effects that should be regulated, not the modes of action that cause these effects.

3. Black Lists: Categorisation will inevitably lead to the creation of "black lists", as substances not considered endocrine disruptors will still be labelled as "suspected endocrine disruptors". Such "black lists" are highly likely to be misinterpreted, misused and lead to additional regulation beyond Europe.

4. More animal testing: This option 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.

5. Under Regulation 1107/2009 active substances need to undergo a regular renewal. The creation of several lists of suspected endocrine disruptors would lead to a significant extra workstream of additional evaluations in between, leading to uncertainty on the market and putting extra pressure on available resources for regulators and industry.

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

See ECPA response

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

4,000 character(s) maximum

See ECPA response

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

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

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

Please provide the reference(s) if possible:

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

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

4,000 character(s) maximum

See ECPA response

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

4,000 character(s) maximum

See ECPA response

Please provide the reference(s) if possible:

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

4,000 character(s) maximum

Option 4 requires that the potency of a substance be considered as part of the endocrine disruptor criteria and thus recognises that potency is a key factor in determining, if a substance induces adverse effects at relevant concentrations. However, in addition to potency all elements of hazard characterisation should be included into the endocrine disruptor criteria, i.e. severity and (ir)reversibility of effect and lead toxicity.

These elements are essential to ensure that all relevant scientific information on the hazard of a substance is considered in regulatory decisions. Taking full account of the related data is a routine part of the evaluation of chemicals and avoids negative regulatory actions for substances of low or no regulatory concern.

In summary, in the current absence of a risk assessment framework, Dow AgroSciences does not favour any of the four suggested options. We call for the development of a single set of criteria for determination of endocrine disrupting properties, which is based on the WHO/IPCS definition and also incorporates all the hazard characterisation elements.

However, beyond our comments above we suggest that a full risk assessment approach should be considered as an additional and preferred policy option.

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 AgroSciences supports a full risk assessment option. Decision-making of 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.

Using cut-offs based simply on hazard fails to take account of all relevant scientific information and does not provide a suitable basis for regulatory decision making.

We recommend that priority is given to ensuring the development of sound regulatory criteria and then make arrangements for returning to a comprehensive risk assessment framework consistent with the approach taken by other global regions.

Failure to return to risk assessment and regulating endocrine disruptors purely on the basis of hazard cut-offs is likely to result in serious impact on the trade in agricultural commodities and produce. It is today still unclear, in situations when active substances are removed from the European list of approved active substances, if it will still be possible to maintain import tolerances (and request new import tolerances) of those active substances on crops being imported from third countries. Therefore we support the development of regulatory policies on potential endocrine disruptors that minimize the potential trade impact.

Please provide the reference(s) if possible:

Contact

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