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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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

Marko Susnik

1.2. Your e-mail address for correspondence:*

marko.susnik@wko.at

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:*

Wirtschaftskammer Österreich

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)*:

10405322962-08

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.viii. If other, please specify.*

Public body / chamber

1.8. Your location:*

AT - Austria

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
- [x] Use of scientific research for safety assessments
- [x] Use of scientific research for regulatory purposes
- [x] 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)* *

- [x] Classification and Labelling (Regulation 1272/2008)
- [x] REACH (Regulation 1907/2006)
- [x] 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)
- [x] Other
- [ ] Not involved

If other, please specify. *

you name it

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

The existing PPP and BP criteria lack of a scientific basis and can not supported. MoA of most carcinogenic and reprotoxic substances strongly differ from MoA of an endocrine disruptor. We do not consider this Approach to be suitable for regulatory actions, neither under PPPR / BPR nor for any other chemicals regulation.

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 WHO/IPCS definition is suitable as a working definition of endocrine disruptors. However, for the identification of a specific substance as endocrine disruptors and a sound risk characterisation more factors (e.g. lead toxicity, severity, and potency) need to be applied.

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

We do not support three categories for endocrine disruptors. That way a category III, which is in clear conflict with the WHO/IPCS definition, would be introduced. in our opinion a substances should be only considered as ab endocrine disruptor where the link between endocrine MoA and an adverse effect is present. Endocrine active substances do not have an adverse effect. Furthermore, category III could create a "black list" of substances with a high potential for misinterpretations and abuse. In particular the consumer is usually not able to distinct between the scientific rationale behind when a substance is a endocrine disruptor and when an endocrine active substance. Such a scheme - in particular a 3rd category - jeopardizes the regulatory intention to provide more information in a situation, where there is no legal requirement to establish a categorisation scheme for ED. However, also a category II of suspected endocrine disruptors has no scientific foundation and in our opinion is neither necessary nor informative. We consider one category of „Endocrine Disruptor of regulatory concern“ to e sufficient.

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

In our opinion following elements for hazard characterisation are important:

1) Severity of adverse effect describes the magnitude of an adverse effect and/or the nature of the adverse effect. Severe adverse effects contribute to a greater overall level of concern.

2) (Ir)reversibility: Reversibility or irreversibility contributes to the severity assessment. Reversibility implies that recovery of the individual or population can occur after exposure has stopped. Reversible adverse effects provide a lower overall level of concern.

3) Potency relates both to the dose at which adverse effects are induced and the duration required to cause those effects. A highly potent substance produces a large effect at low concentrations, while a substance of low potency leads to a small effect at high concentrations. Also, a potent substance may cause an adverse effect after a short exposure, whereas a less potent substance may require longer exposure. Potency measures the strength of a substance’s tendency to produce an adverse effect. It is a routine part of hazard characterisation, and is essential in discriminating between substances of high regulatory concern from those of lesser concern.

4) Lead toxic effect considers the dose response of all the toxicity effects of a substance. It is the adverse effect that occurs at the lowest dose. It describes the most sensitive toxicological endpoint (critical effect) and drives the risk assessment. Any risk management measures based on the lead toxic effect will be protective of all other adverse effects occurring at higher dose levels (including effects resulting from endocrine modes of action). For EDs, a substance should only be considered of regulatory concern when the endocrine mediated adverse effect is the lead toxic effect.

5) Specificity: For a substance to be considered to have endocrine disrupting properties, the adverse effect should occur as a consequence of a primary endocrine mode of action and not the result of a secondary consequence of another toxic effect.

6) Human and population relevance. The endocrine mediated adverse effects must be relevant to humans or non-target populations. Relevance to humans is assumed by default in the absence of scientific data demonstrating non relevance.

A proposal for the criteria for the identification has been elaborated by the German Association of the Chemical Industry, VCI, which we support.

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

Please provide the reference(s) if possible:

Contact

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