Case Id: a016fd50-f026-4e7b-a6ce-921a402e1c83

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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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

Susanne Smolka

1.2. Your e-mail address for correspondence:*

susanne.smolka@pan-germany.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:*

Pestizid Aktions Netzwerk e.V. (PAN Germany)

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.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:*

DE - Germany

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)
- [x] Plant Protection Products (Regulation 1107/2009)
- [x] 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. *

Veterinary Pharmaceuticals

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

PAN Germany would like to refer to PAN Europe´s assessment on endocrine disrupting pesticides in which all science available on endocrine disrupting pesticides has been evaluated, the regulatory dossiers of pesticides and peer-reviewed scientific literature, in total >800 documents and reports (Ref. PAN Europe ANNEX 1a and 1b).

PAN Germany compiled a list of biocides with endocrine-disrupting properties published in selected ED priority lists and ED survey studies. The investigation considered active substances notified for approval or already approved within the framework of the review program according to the BPR (see PAN Germany ANNEX “Biocides”, attached, and PAN Germany, 2014: (Ref: PAN Germany (2014): Endocrine disrupting biocides – Why highly hazardous biocides must be phased out”: http://www.pan-germany.org/download/biocides/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf).

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

4,000 character(s) maximum

5 pesticides will be covered by the first interim criterion C2+R2 (Chlorotoluron, Dimoxystrobin, Epoxiconazole, Profoxydim and Tepraloxydim), and 8 pesticides covered by the second interim criterion R2 + toxic to endocrine organs (Abamectin, Amitrole, Ioxynil, Mancozeb, Maneb, Metconazole, Myclobutanil, Tebuconazole; see PAN Europe's Summary Table and Graph). The first category of 5 pesticides (according to PPPR Annex II, 3.6.5 "shall be considered to have endocrine disrupting properties") might lead to an impact in the market, the second category (according to PPPR Annex II, 3.6.5 "may be considered to have endocrine disrupting properties") will unlikely create any impact since their regulation is uncertain (Ref. PAN Europe ANNEX 1a, 1b, Summary Table and Graph,).

No biocide has been classified as a C2+R2 substance. However, fenoxycarb and thiacloprid (both C2 substances in wood preservatives) can be considered toxic for reproduction and will fulfil the first interim criterion. Abamectin, cyproconazole and tebuconazole are classified as toxic for reproduction (R2) and could fulfil the second interim criterion R2 + toxic to endocrine organs. Comparable to the evaluation by PAN Europe on pesticides, the second category (according to Art. 5 (3), 528/2012/EC "may be considered to have endocrine disrupting properties") will unlikely create any impact since their regulation is uncertain. The three active substances have already been approved for ten years as biocides. The assessment reports indicate that insufficient data was provided to assess endocrine-disrupting effects. The potential ED-biocides carbendazim und boric acid fulfils the CMR exclusion criterion (see PAN Germany ANNEX "Biocides" and PAN Germany, 2014).

Please provide the reference(s) if possible

1. 7520b3c7-9867-467b-8349-0f6c1dd0afd7/ANNEX-Biocides_PAN-Germany_ED-Impact-Assessment.
2. 340eb19f-852c-4612-9718-7a5ab65a7747/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf
3. ff7943e2-d3a8-495e-ad80-131929730af1/IMPACT ASSESSMENT ANNEX 1b.xlsx
4. b114553c-23cf-45ae-914e-61709f57d9db/IMPACT ASSESSMENT ANNEX Ia.doc
5. f371c441-0d73-424f-9da3-6c9e2c875c77/IMPACT ASSESSMENT ANNEX II Alternatives.doc
6. 71da87c8-6a12-40ec-9606-71b373a78d35/Summary Diagram.pdf
7. 0ad937ab-9e9a-41c6-bf64-e16fa1d89415/Summary Table.pdf

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

PAN Europe did a survey on the most debated endocrine disrupting pesticides. Information of national institutes available on the internet was used followed by a peer review by a panel of international experts on alternatives (Ref. PAN Europe ANNEX II). Some of the pesticides from the interim criteria are included: e.g. Abamectin, Amitrole, Ioxynyl, Mancozeb, Myclobutanil and other azoles.

PAN Germany provides a list of potential alternatives including non-chemical alternatives and preventative measures for the most relevant biocidal product types. However, it must be considered that experience and knowledge of those comparative assessments is still weak for biocides. The review program for biocides that have been on the market before May 2000 is still running until 2014. As a result, the state of knowledge about effectiveness and risks of both – specific biocides and its alternatives – differs considerably for various active substances and types of uses. Therefore the assessment of substitutability is qualitative rather than quantitative in nature (see PAN Germany ANNEX “Biocides”).

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

4,000 character(s) maximum

For the pesticides evaluated by PAN Europe non-synthetic alternatives are available, generally as a system of alternatives, and almost in all cases (a range of) synthetic alternatives are available and the peer review panel didn't expect substantial yield losses if these alternatives are used (PAN Europe ANNEX II, attached). For example, for the use of Abamectin to control mites in strawberries, some non-synthetic alternatives are: Heat treatment of plants, Biological control with a range of Amblyseius spp. (predatory mites) and Hymenopteran parasites, all with very good results. Some synthetic alternatives are Spinosad, Bifenazate, Hexythiazox.

Regarding biocides several active substances have been notified or approved for each kind of the 22 product types of biocidal use. It is probable that chemical biocidal alternatives will be available for all product types considered. Also a range of non-chemical alternatives and prevention measures are available for many product types.
For example, for the use of fenoxycarb and thiacloprid as wood preservative some non-chemical alternatives are: prevention measures: use of rubinia or oak heardwood, application of constructive preventative measures, the use of heat (technical) drying wood, wood treatment with furfuryl alcohol or acetylation; control measures: hot-air technique (“Blue Angel label”), high frequency technology or microwave technology and last but not least chemical alternatives: 22 potential biocidal alternatives with no indications of ED properties (approved or notified) at the moment.

Please provide the reference(s) if possible

1. 9999b5d9-1cee-416c-8d5a-0e5abdb12bbb/ANNEX-Biocides_PAN-Germany_ED-Impact-Assessmen
2. cf3a02e4-2c28-49cf-a7ed-d36d268cac60/IMPACT ASSESSMENT ANNEX 1b.xlsx
3. b28d3cc0-4d15-4c47-ae03-968b01ea8a47/IMPACT ASSESSMENT ANNEX Ia.doc
4. 5674369f-31c0-42b5-8f9b-6a323f47ee96/IMPACT ASSESSMENT ANNEX II Alternatives.doc

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

We would like to refer to PAN Europe´s evaluation reveals that only lobby reports are published by pesticide industry and farmers organizations, looking at their own potential costs in a worse case scenario; an independent assessment is still lacking. Some of the pesticides for the interim criteria are included in these lobby reports. On top of this it will be impossible to calculate the benefits of the endocrine policy in monetary terms (Ref. PAN Europe ANNEX III and IV)

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

4,000 character(s) maximum

The outcome of PAN Europes shows exaggerated claims on costs for industry and farmers, based on flawed assumptions and false data; they generally ignore the availability of alternatives and they all ignore the current costs and future benefits of banning EDCs for society, for human health, the environment and biodiversity (see for an assessment of these reports PAN Europe ANNEX III and IV, attached).

Concerning biocides there are considerable gaps in existing data that make it difficult to assess the actual socio-economic impacts either for industry on the one hand or for the society on the other hand. Overall, data on marketing and application of biocidal products (such as wood preservatives) and biocidal treated articles (such as treated wood, treated furnitures, construction materials etc.) are neither available for the public in general nor for single active substance. The BPR do not require that such data has to be collected regularly and systematically. This is also the case for monitoring data regarding impacts on the environment and human health. PAN Germany considers that it is crucial to improve data availability and transparency. External costs, such as for water suppliers or for the public health sector must be take into consideration in socio-economic impact assessments (Ref: PAN Germany (2014): Endocrine disrupting biocides – Why highly hazardous biocides must be phased out": http://www.pan-germany.org/download/biocides/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf

Please provide the reference(s) if possible

1. **3be28f94-68b4-4c06-b255-fb74fd431e55/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf**
2. **37da48d7-0440-4ef0-a441-4932009b24cc/IMPACT ASSESSMENT ANNEX III.doc.docx**
3. **e6c06f11-f11f-482e-b313-eb4186564468/IMPACT ASSESSMENT ANNEX IV.doc**

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

4,000 character(s) maximum

PAN Germany does not support option 1.
"No-specific criteria" means that EDs will be identified according to the current interim criteria (when testing confirms that they are carcinogenic category 2 and toxic for reproduction category 2 OR reproduction category 2 and which have toxic effects on the endocrine organs). The option would not comply with Article 5.1.d and 5.3 in the BPR (EU) No 528/2012 nor is it in compliance with 1107/2009 (Plant Protection Products Regulation, PPPR), since these two regulations clearly state that scientifically based criteria should be set.
Furthermore, to continue the implementation of this option only directly applies to human health effects. Whereas, the environment is only indirectly addressed via REACH article 57(f) and article 59.
In addition, the interim criteria do not address specifically the effects arising from alterations in the endocrine system. Substances with ED-properties that are not carcinogenic or toxic to reproduction may be left out (for example substances affecting the thyroid, brain function, behaviour or the energy metabolism that could trigger obesity and diabetes).
Moreover, a guidance on what "toxicity to endocrine organs' means is still outstanding. Finally, the interim criteria are not adequate to detect EDs.

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

See 2.1.1

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

4,000 character(s) maximum

The use of this very strict definition, requiring a full proven endocrine mechanism of action, will lead to likely no pesticide identified as an endocrine disruptor for regulatory purposes (apart from the interim-criteria if they stay in place). The reason is that regulatory studies do not require the mechanism to be elucidated; and independent studies -which more likely have mechanistic information- are not taken into account in the regulatory process. In this case no further assessment is needed because no pesticides will be identified under this Option (Ref. PAN Europe ANNEX 1a, 1b and Summary Graph).

This evaluation by PAN Europe can also be applied to biocides; 13 pesticides with ED properties are also used as biocides (see PAN Germany ANNEX "Biocides").

Please provide the reference(s) if possible:

1. 8ec86dc2-411c-4de9-953c-1c7171183bd1/ANNEX-Biocides_PAN-Germany_ED-Impact-Assessment
2. 1a9b985e-da51-41a6-bcd0-d3fa5650f9a5/IMPACT ASSESSMENT ANNEX 1b.xlsx
3. 8f631653-0025-4e25-84b0-f6e78d0b7277/IMPACT ASSESSMENT ANNEX la.doc
4. 674d55b5-8278-4f07-ae83-c5c87e885354/Summary Diagram.pdf
5. f88a920e-deac-414e-9a1e-46942fd1883e/Summary Table.pdf

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

PAN Germany does not support option 2.
This option uses the first part of the WHO/IPCS definition on endocrine disruptors: “Endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.” And it totally neglects the second part of the WHO/IPCS definition: “a potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub) populations”.

The PPP and BP Regulations require that “substances having endocrine disrupting properties which may cause adverse effects will not be approved for the respective use”, adding this extra element “may cause” of precaution in the legislation. The regulations aim to ban both identified endocrine disruptors and suspected endocrine disruptors because they recognize that in both cases these chemicals are a threat towards human and wildlife (also concluded in the WHO report “State of the science of endocrine disrupting chemicals”, 2012).
The WHO/IPCS reports of 2002 and 2012 are the result of the work of experts from the international scientific community of endocrine disruption research. The definition is divided into two parts to reflect the current scientific knowledge of the endocrine system and endocrine disruption. We know very little about the endocrine system of humans and other mammals, particularly during early developmental stages and even less for other vertebrate and invertebrate species. Thus, by focusing only on the first part of the WHO definition and having one category where only “clear evidence of endocrine-mediated adverse effects” are considered means that substances that alter the hormone levels but for which the adverse effects are to date not fully understood or for which the mechanism of action is still under investigation will not be identified as EDCs. This is the case for many pesticides and biocides.

Further, regulatory assessment of pesticides and biocides does not require any mechanistic information on the effects of active substances and thus regulatory dossiers do not provide such information. Therefore, since the commission uses data only from the industry’s dossiers, no pesticides and biocides will be recognized as EDCs under this option due to the lack of information on the mechanism of action of these chemicals. 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

See 2.1.1

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

4,000 character(s) maximum

If the pesticide Regulation 1107/2009 is followed (may-cause adverse effects) together with the State-of-the-Science on endocrine disruptors, 50 will be identified as having endocrine disrupting properties and 31 pesticides will qualify as endocrine disruptors that may cause adverse effects for regulatory purposes (Columns E & F; Annex 1b). 13 of these pesticides are also used as biocides (Summary Table). If the academic studies are disregarded (which is the current Commission practice) only 20 pesticides will qualify (Column G). If the draft endocrine criteria developed by DG ENV are used -defined in the roadmap under 2 b) and 2 d)- only 7 pesticides will remain in place (Column L) and qualify as an ED pesticide for regulation. These pesticides are: Amitrole, Mancozeb, Maneb, Metconazole, Propyzamide, Tralkoxydim and Thiophanate-methyl (these 7 pesticides are not used as biocides). The rest of the pesticides with ED-properties identified in Column B will likely qualify for 'endocrine active substances' (Ref. PAN Europe ANNEX 1a, 1b, Summary Table and Diagram).

According to the PAN Germany´s investigation about 10% of the notified or approved biocides (27 active substances) will be identified as having endocrine disrupting properties (see PAN Germany Annex “Biocides” and PAN Germany, 2014).
Under the EU Community Strategy on EDCs the Commission services developed a priority list of substances to be investigated further for their possible endocrine disrupting properties. It has been officially noted that this “database containing the information that was used to establish this priority list”.. “has proven useful in providing regulators and researchers with a considerable amount of information on potential endocrine disruptors” and “has been used by a number of stakeholders for prioritization” (SEC(2011) 1001 final). An overview of this work can still be downloaded here:
http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm
According to this EU priority list eight of the identified biocides are classified as Category 1, and eight as Category 2 substances.

In addition, the biocides tebuconazole and triclosan are classified as endocrine disrupter in category 1 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).

Please provide the reference(s) if possible:

1. df3cba1b-f947-4424-a153-6034a77fc805/ANNEX-Biocides_PAN-Germany_ED-Impact-Assessment.p
2. a6b3cc0a-27c4-45e6-b613-3ff853f054c7/IMPACT ASSESSMENT ANNEX 1b.xlsx
3. b92569ce-9597-48f0-bc78-f08b5e0fbfc6/IMPACT ASSESSMENT ANNEX Ia.doc
4. 3a3488f3-c1d5-443b-a060-ce8b69f4d872/Summary Diagram.pdf
5. 9894cde2-cead-4ac7-a2fe-a9a3c9de9ef0/Summary Table.pdf

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

- (●) Yes
- ( ) No

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

4,000 character(s) maximum

See 2.1.2

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

4,000 character(s) maximum

For all pesticides studied non-synthetic alternatives are available, generally as a system of alternatives, and almost in all cases (a range of) synthetic alternatives are available (Ref. PAN Europe ANNEX II); the peer review panel didn't expect substantial yield losses if these alternatives are used. For example, the use of mancozeb against “late blight” of potatoes can be substituted by selecting resistant varieties (Carolus, Bionica, Sarpo Mira, Vitabella), by planting distance and early harvesting. If the farmers wish to continue using pesticides, there are chemical alternatives such as Cyazofamid, fluazinam (preventive), and potassium phosphite among others. No significant costs and yield losses are expected from the substitution of mancozeb.

Regarding biocides several active substances have been notified or approved for each kind of the 22 product types of biocidal use. It is therefore probable that chemical biocidal alternatives will be available for all product types considered. Also a range of non-chemical alternatives and prevention measures are available for many product types. (see PAN Germany Annex “Biocides”).

Please provide the reference(s) if possible:

1. 1f290a80-005c-4206-b84e-7b8902fa4d88/ANNEX-Biocides_PAN-Germany_ED-Impact-Assessment.p
2. ed952dfa-c920-4836-ba51-1193850e0392/IMPACT ASSESSMENT ANNEX II Alternatives.doc

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 the methodology(ies):*

4,000 character(s) maximum

PAN Europe research reveals that only lobby reports are available from pesticide industry and farmers organisations, looking at their own potential costs in a worse case scenario (Ref. PAN Europe Annex III); an independent assessment is still lacking. Some of the pesticides considered potential endocrine disruptors are included in these lobby reports. On top of this it will be impossible to calculate the benefits of the endocrine policy in monetary terms (Ref. PAN Europe ANNEX IV) and the impact should be assessed in another way (Ref. PAN Europe proposal, Annex IV).

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

4,000 character(s) maximum

Concerning PAN Europe´s evaluation on pesticides: The outcome is exaggerated claims on costs for industry and farmers based on flawed assumptions and false data; they generally ignore the availability of alternatives and they all ignore the costs for society, for human health, the environment and biodiversity (see for an assessment of these reports PAN Europe ANNEX III, and ANNEX IV on proposed solutions).

Concerning biocides: There are considerable gaps in existing data that make it difficult to assess the socio-economic impacts either for industry on the one hand and for the society on the other hand. Overall, data on marketing and application of biocidal products (such as wood preservatives) and biocidal treated articles (such as treated wood, treated furniture, construction materials etc.) are not available for the public neither in general nor for single active substances. The BPR do not require that such data has to be collected regularly and systematically. This is also the case for monitoring data on impacts of the environment and human health. PAN Germany considers it as is crucial that data availability and transparency must be improved. External costs, such as for water suppliers or for the public health sector must be take into consideration in socio-economic impact assessments (see PAN Germany (2014): Endocrine disrupting biocides – Why highly hazardous biocides must be phased out". (Ref: PAN Germany (2014)

Please provide the reference(s) if possible:

1. **af528f9a-2e97-43c8-b89c-0e464294dc00/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf**
2. **25cd0283-f980-461b-b515-590fcd2d1930/IMPACT ASSESSMENT ANNEX III.doc.docx**
3. **8fdbe3f7-4ef1-4b4f-aa22-18fac5cb7d30/IMPACT ASSESSMENT ANNEX IV.doc**

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

4,000 character(s) maximum

PAN Germany supports option 3.
Creating classes is the best option as it will capture a wider range of substances with EDC properties (following the State-of-the-Science on EDCs) and will allow space for regulative decision-making based on human and environmental exposure to EDCs. It will also detect the gaps of knowledge for specific substances that could be EDCs, which can act as an “early-warning” for the manufactures and industry to disregard or gradually replace such chemicals.

We consider 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 legally binding obligation of the PPPR and PBR (“that may cause”). Therefore the Option 3 should include elements of the whole WHO definition.

However there are also two "dangerous" elements: -human relevance and that the effects should occur in the absence of other toxic effects- that have been misinterpreted and abused so far by the industry and regulators to maintain their products on the market. According to the mandate of the PPPR and BPR, active substances that have endocrine disrupting properties that may cause adverse effects should be banned. Following the current scientific knowledge on endocrine disruptors the causality between mechanism of action and adverse effect is difficult to prove- changes in the endocrine system and adverse effects have been observed but the link between them has not been found. Thus if applied correctly, most pesticides and biocides with ED properties would fall under "suspected EDCs" (that may cause adverse effects) and the rest under “endocrine active substances” (where there are indications of endocrine disruption but adverse effects and mode of action are not understood yet and further research is necessary). The Pesticide and Biocide Regulations therefore should ban all chemicals falling under the categories Endocrine Disruptors (Cat. 1) and Suspected Endocrine Disruptors (Cat. 2).
In reality however, regulators disregard studies from independent scientific literature, misinterpret studies as irrelevant to humans and don’t recognize endocrine disrupting properties in the presence of other toxic effects. PAN Europe evaluated that - taken this into account - only 7 pesticides would fall under Cat. 2 and the rest (24 pesticides) would end up in the third category proposed by the commission and will not be regulated.

Cat. 3 provides a crucial trigger for generating more information. In some cases this will lead to insight that an initial concern may not be justified; whereas in other cases the further data may confirm the concern. For the regulation of pesticides and biocides, the third category would have to be linked to mandatory requirements that further data has to be generated and provided for the decision-making in the renewal process of the approval for active substances.

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

We would like to refer to PAN Europe´s evaluation of all science available on endocrine disrupting pesticides, the regulatory dossiers of endocrine disrupting pesticides and peer-reviewed scientific literature (Ref. PAN Europe ANNEX 1a and 1b). PAN Europe assumed that potency is applied to Option 3, as with Option 2 no pesticides would be identified as endocrine disruptors due to the lack of data on the mechanism of action and the exclusion of independent literature for the evaluation. As threshold for potency they used the default value proposed by UK-CRD of LOAEL (lowest observed adverse effect level) 10 mg/Kg for oral exposure. This value derives from the “Specific Target Organ Toxicity following repeated exposure”, category I, as described in the Globally Harmonized System of classification and labeling of chemicals (GHS) for potent hazardous chemicals. Pesticides with observed effects on the endocrine system above this level are dismissed because they are considered less potent.

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

4,000 character(s) maximum

According to PAN Europe´s assessment, the use of the potency criterion will reduce the number of identified ED pesticides for regulatory purposes from 7 to 4 (see PAN Europe Annex Ib, Column M) if option 3 and Regulation 1107/2009 is the basis of decision-making. These pesticides are Amitrole, Mancozeb, Maneb and Tralkoxydim (Ref. PAN Europe ANNEX 1a, 1b, Summary Table and Diagram,). This is because the documented effects on the endocrine system for 3 out of 7 pesticides occur above the threshold level of 10 mg/kg. If potency is applied, most ED-pesticides would be mislabeled as non-endocrine disruptors because they would be considered of “low” potency. If option 2 is the basis for Option 4, potency doesn't matter because in option 2 there will be no ED pesticides identified, no banning and no impact.

In addition, 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 consequences 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”. This 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:

1. **9da411ec-99c4-42da-96e0-18c080a801d2/IMPACT ASSESSMENT ANNEX Ia.doc**
2. **edb6437d-edb5-4797-80ea-dbfd9a9b1ec0/Summary Diagram.pdf**
3. **ae5bad04-f95c-4c91-81f6-72af6e80b827/Summary Table.pdf**

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

- (●) Yes
- ( ) No

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

4,000 character(s) maximum

See 2.1.2

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

4,000 character(s) maximum

For all pesticides studied non-synthetic alternatives are available, generally as a system of alternatives, and almost in all cases (a range of) synthetic alternatives are available, see PAN Europe ANNEX II; the peer review panel didn't expect substantial yield losses if these alternatives are used.

Regarding biocides several active substances have been notified or approved for each kind of the 22 product types of biocidal use. It is probable that chemical biocidal alternatives will be available for all product types considered. Also a range of non-chemical alternatives and prevention measures are available for many product types (see PAN Germany Annex “Biocides”).

Please provide the reference(s) if possible:

1. 8366ab02-184e-4b80-a4da-78a02c4ee959/ANNEX-Biocides_PAN-Germany_ED-Impact-Assessment
2. cc01afa2-9b8c-4003-808f-b828cf42536f/IMPACT ASSESSMENT ANNEX II Alternatives.doc

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 the methodology(ies):*

4,000 character(s) maximum

According to PAN Europe´s investigation, only lobby reports are published by pesticide industry and farmers organizations, looking at their own potential costs in a worse case scenario; an independent assessment is still lacking (Ref. PAN-Europe ANNEX III). Some of the pesticides assessed in option 4. On top of this it will be impossible to calculate the benefits of the endocrine policy in monetary terms (Ref. PAN Europe ANNEX IV).

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

4,000 character(s) maximum

The outcome of PAN Europe´s investigation presents exaggerated claims on costs for industry and farmers, based on flawed assumptions and false data; the reports generally ignore the availability of alternatives and they all ignore the costs for society, for human health, the environment and biodiversity (see for an assessment of these reports PAN Europe ANNEX III).

Concerning biocides there are considerable gaps in existing data that make it difficult to assess the actual socio-economic impacts either for industry on the one hand or for the society on the other hand. Overall, data on marketing and application of biocidal products (such as wood preservatives) and biocidal treated articles (such as treated wood, treated furniture, construction materials etc.) are neither available for the public in general nor for single active substance. The BPR do not require that such data has to be collected regularly and systematically. This is also the case for monitoring data regarding impacts on the environment and human health. PAN Germany considers that it is crucial to improve data availability and transparency. External costs and benefits, such as for water suppliers or for the public health sector must be take into consideration in socio-economic impact assessments
(Ref: PAN Germany (2014): Endocrine disrupting biocides – Why highly hazardous biocides must be phased out”: http://www.pan-germany.org/download/biocides/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf

Please provide the reference(s) if possible:

1. **ff1abfa0-5f70-442c-ae8c-2dc6e4215934/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf**
2. **634f5fec-da86-45ab-bfc4-7e7cd4fd71bd/IMPACT ASSESSMENT ANNEX III.doc.docx**
3. **c77b6cbb-01ff-4f5c-89bc-d9898c4ba17d/IMPACT ASSESSMENT ANNEX IV.doc**

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

4,000 character(s) maximum

PAN Germany strongly disagree with option 4
The level of evidence required to fulfil the exclusion criteria according to PPPR and BPR have to correspond to the intentions of the legal provisions ("that may cause"). We consider the concept of potency to be highly inappropriate in the context, given that the designation of "endocrine disruptor" according to the EU legislation is -and should be - purely hazard based. Potency is a risk assessment element used in the characterization rather than in the identification of a hazard.
Beside the legal issues, the selection of a threshold for potency for EDCs is against the current scientific knowledge (JRC, 2013) that suggests that such thresholds may be impossible to define in the case of exposure during the early developmental stages of life.
Thus thresholds and safe limits cannot be assumed for EDs. Overall, potency is irrelevant for the definition of EDs. Potency describes the strength of a chemical to give a specific effect and is used by the industry during the assessment of chemicals to dismiss "less potent" effects in the presence of "more potent" effects. Endocrine disruption is not a specific endpoint (effect) but a network of mechanisms that lead to deferential endocrine-related diseases (deformities and cancer of the reproductive organs, cognitive dysfunction, obesity, diabetes). Strong and weak triggers on specific sites may equally result in the development of disease and therefore potency cannot be used as an indicator to characterize the severity of the adverse effect. For example, a chemical that weakly imitates the function of the female hormones may strongly inhibit the neuronal signals in the brain leading to mental disorders. Further, potency will vary not only in different sites of the endocrine system but also among old and young individuals and across different species.
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".

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

We would like to refer to PAN Europe´s evaluation of all science available on endocrine disrupting pesticides, the regulatory dossiers of endocrine disrupting pesticides and peer-reviewed scientific literature, together with the regulatory approaches proposed in Options A-C (Ref. PAN Europe ANNEX 1a and 1b).

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

4,000 character(s) maximum

Option A: PAN Germany supports this option, because the option is taking into account the recent and ongoing implementation of the PPPR and BPR and avoids further delay in the implementation of these legislations.

According to PAN Europe´s evaluation for pesticides, Option A seems to only concern the interim-criteria, 5 “shall” be considered as an endocrine; 8 “may” be considered as an endocrine.

Option B: PAN Germany does not support this option.
Option B is the return to traditional risk assessment and safe thresholds; this option will lead according to PAN Europe´s evaluation to no single ban (Ref. PAN Europe ANNEX Ia and Ib, Column N) and no impact;

Regarding biocides: Additional risk-based elements would weaken Art. 19 (4) which restricts the market availability of biocides with endocrine-disrupting properties and other highly hazardous properties for the general public. This provision in the BPR is especially important because biocide products are freely available on the market and there are no requirements stipulating that qualified sales representatives must advise consumers. The use of biocidal products is often incorrect, overdosed or unnecessary and shows high risks for poisoning and accidents especially by untrained non-professionals (in households, children, etc.). For similar reasons the FAO has already recommended in 2006 – with view to pesticide users and their families in the south – a stepwise phase-out of highly hazardous pesticides (see PAN Germany, 2014).

Option C: PAN Germany does not support this option.
Option C is impossible to implement if a science-based approach will be followed. Particularly, it will not be possible to calculate the benefits to society of banning ED-pesticides in monetary terms, due to inherent and practical problems. Implementation of Option C will mean arbitrary political decisions and an abandonment of Regulation 1107/2009. Furthermore, following the implementation of the other options, Option C is unnecessary since the number of banned pesticides will be zero (based on Options 2 and B) or close to zero (Options 3 & 4). The discussion on this element is futile.

Concerning biocides, socioeconomic elements are already implemented in the derogation provision (Art. 5(2), BPR). PAN Germany doesn´t support this derogation in the BPR because of the reasons mentioned above and has therefore recommended the deletion of this provision during the revision negotiations of the new biocide legislation. We are concerned about the lack of concrete guidelines and definitions which would put the derogation phrase into concrete terms. As a consequence transparency of the decision making process (about criteria setting, data weighting, plausibility assessment, etc.) is unsufficient. Because of these shortcomings the Art 5(3) BPR should not be used as a positive example for the regulation of EDs or other highly hazardous substances in other legal frameworks (PAN Germany, 2014).

Please provide the reference(s) if possible:

1. fe5ac3a0-400d-45bd-aca5-4d4e3adc0462/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf
2. a0353dea-a844-4066-9b17-c03a96baf99d/IMPACT ASSESSMENT ANNEX 1b.xlsx
3. 9b347880-59a9-488d-9441-5b87a7311e29/IMPACT ASSESSMENT ANNEX Ia.doc

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

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

4,000 character(s) maximum

We would like to refer to PAN Europe analyses on the currently available reports (industry, farmers and independent literature), Ref. PAN Europe ANNEX III and IV).

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

4,000 character(s) maximum

The outcome presents exaggerated claims on the costs for industry and farmers, based on flawed assumptions and false data; the reports generally ignore the availability of alternatives and they all ignore the costs for society, for human health, the environment and biodiversity (see for an assessment of these reports PAN Europe ANNEX III).

It is impossible to calculate the socio-economic impact of the ban of pesticides in monetary terms. This has to do with inherent problems (how to put a market price of a human persons life? How to not discount future generations?), and the fact that exposure and harm in society cannot be linked due to the lack of monitoring and the many thousands of risks that cause harm. Regulation 1107/2009 requires "no harmful effects" and the options described should be used to select the option with the lowest risk of harmful effects for humans, following the mission of Regulation 1107/2009 to not allow harmful effects.

Concerning biocides, socioeconomic elements are already implemented in the derogation provision (Art. 5(2), BPR). PAN Germany doesn´t support this derogation in the BPR because of the reasons mentioned above and has therefore recommended the deletion of this provision during the revision negotiations of the new biocide legislation. We are concerned about the lack of concrete guidelines and definitions which would put the derogation phrase into concrete terms. As a consequence transparency of the decision making process (about criteria setting, data weighting, plausibility assessment, etc.) is unsufficient. Because of these shortcomings the Art 5(3) BPR should not be used as a positive example for the regulation of EDs or other highly hazardous substances in other legal frameworks (PAN Germany, 2013).

Please provide the reference(s) if possible:

1. 4e36de8e-d32f-401a-ac6f-8ded7aaf378e/ED-Biocides_backgroundpaper_PAN-Germany_F.pdf
2. 7571eb5e-f2c7-4250-9a54-d4367570496e/IMPACT ASSESSMENT ANNEX III.doc.docx
3. 9b1c4a86-9a07-4f51-840a-f307eeaf6b5e/IMPACT ASSESSMENT ANNEX IV.doc

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

The consultation is clearly focused on gathering information on likely costs to producers of existing pesticides and biocides rather than looking at the costs and benefits for society as a whole. When conducting an impact assessment, we want to emphasize that the socio-economic impact of ED substances on the human health and the environment has also to be taken into account. A full study of all the potential benefits of regulation is needed, and this should be included in any impact assessment.

The EU has introduced specific legislative obligations in the PPPR and BPR aimed at phasing out endocrine disruptors. There are sufficient provisions for derogation from the exclusion decisions in both legislations PPPR and PBR.
In PAN Germany´s view, there should be no legal changes to the democratically established laws. Essential elements such as the cut-off criteria cannot be changed via delegated acts but would require involvement of EU Parliament and 28 Member States. We find it very concerning that the Commission even consults on these options and wonder if this risks a breach of their mandate as there is not really a legal basis for proposing changes to the law.

Additional references:

“Food burden”: PAN Europe (2012): Disrupting food: http://www.disruptingfood.info/en/. The report provides a list of ED pesticide residues, identified in European food monitoring.
“Body burden”: European Biomonitoring project: http://www.eu-hbm.info/democophes and citations). Studies examined levels of certain chemicals in urine and hair, found several EDCs in children and their mothers.
German Commission on Human Biomonitoring: defined reference values for Pyrethroids (used as biocides and pesticides). This illustrates the ubiquitous background exposure to these potential EDs (http://www.umweltbundesamt.de/sites/default/files/medien/1/dokumente/tabelle-ref-werte-biozide_2009_0.pdf).
„Effects“: PAN Germany (2013): Endokrine Wirkung von Pestiziden auf Landarbeiter, insbesondere auf Beschäftigte in Gewächshauskulturen und Gärtnereien.
http://www.pan-germany.org/download/pan_studie_endokrine_pestizide_1303.pdf. The report compiled scientific studies about endocrine effects on reproduction and fertility focussing on agricultural workers e.g. in glass houses and provides a list of suspected ED pesticides.
"health cost calculations":
Norden (2014): The cost of inaction - A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health. Nordic Council report: http://norden.diva-portal.org/smash/get/diva2:763442/FULLTEXT04.pdf
HEAL (2014): Health costs in the EU - How much is related to EDCs. Health and Environment Alliance: http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf

Please provide the reference(s) if possible:

Contact

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