Case Id: cb0a7136-c5ee-4515-a5c7-1956ba3586ec

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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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

Dr. Gerd Maack

1.2. Your e-mail address for correspondence:*

gerd.maack@uba.de

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:*

Umweltbundesamt (UBA), Deutschland; [Federal Environment Agency, 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.2.a. Please specify identification number *(optional)*:

85428576646-51

1.7.b. Please specify the organisation you represent:*

- (●) i. Public authority
- ( ) ii. Academic/Research institution
- ( ) iii. Hospital / Health institution
- ( ) iv. Private company
- ( ) v. Agricultural producers (farmers)
- ( ) vi. Consumer / Non-Governmental Organisation
- ( ) vii. Industrial or trade association
- ( ) viii. Other

1.7.b.i. If public authority, please specify:*

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

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

- (●) National
- ( ) Regional

1.8. Your location:*

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)*:*

- [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
- [ ] Lobbying
- [x] Other
- [ ] Not involved

If other, please specify.*

Use of scientific research for guidance development in the regulatory contextReview of scientific research in the context of the EU COM ED advisory group

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.*

As the national authority for the environment UBA provides advice to the national government and is thus involved in nearly all EU legislations concerning the environment. Despite the chemical legislations listed above UBA is responsible for the implementation of several EU legislations

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

We would like to highlight that Option 1 does not reflect the originally intended regulatory measures of the pesticide (1107/2009/EC) and biocide regulation (528/2012/EC) in that the interim criteria do only apply to human health. The endocrine exclusion criteria for non-target wildlife organism of both regulations are thus not implemented if Option 1 would be followed. Since ar hazard-based regulation of “environmental endocrine disruptors” is requested by both regulations, Option 1 is not supported by UBA.

UBA is aware of a couple of studies conducted or commissioned by scientific, regulatory and industrial bodies trying to estimate the expected agronomical and socio-economic consequences of banning pesticide active ingredients in accordance with the (interim) exclusion criteria established under 1107/2009/EC. Examples include (non-exhaustive list):

- Interpretation in Sweden of the impact of the “cut-off” criteria adopted in the common position of the Council concerning the Regulation of placing plant protection products on the market (document 11119/08)

- European Parliament Report; The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products (2008)

- PSD/CRD Summary Impact assessment (2009)

- Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by

HSE, CRD; WRc (2013)

- Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances; Report to Chemicals Regulation Directorate (2013)

- Potential Trade Effects on World Agricultural Exporters of European Union Regulations on Endocrine Disruptor. Dtbassociates (2014)

- Evaluation of the benefits provided by and of the effect of losing the azole class of compounds on durum and common wheat production in Italy. ECPA (2012)

- Evaluation of the benefits provided by the azole class of compounds. ECPA (2011)

- Evaluation of the agronomic impact of losing azole fungicides in the production of oilseed rape. ECPA (2012)

- Restricted availability of azole-based fungicides: impacts on EU farmers and crop agriculture; IAB (2011)

- The assessment of the economic importance of azoles in European agriculture: Wheat case study (ECPA 2012)

- Potential impact of draft proposal for endocrine disruption criteria. ECPA, (2013)

- The Cost of Inaction : A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health. Nordic Council of Ministers, Nordic Council of Ministers Secretariat (2014)

In the view of UBA all these studies have only restricted significance for an overall impact analysis since either (i) the procedure of identification of the ED (candidate) substances (to which the exclusion criteria are assumed to apply) is not transparent/consistent/all-encompassing or only provisional and/or (ii) the agronomical / socio-economic impact assessment is lacking a robust methodological and statistical basis, i.e. qualifying the results as only very rough estimates (“screening”). This is especially problematic with regard to studies conducted / commissioned by industry which clearly has an inherent conflict of interest. Furthermore, there is an obvious imbalance in the available socio-economic studies: with the vast majority only addressing the agronomical / societal costs of the implementation of the ED exclusion criteria, the economic benefits generated by the avoidance of environmental and health costs being clearly rarely considered.

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

In the context of the REACH legislation, several suspected endocrine disruptors were analysed in order to verify if they should be considered as substances of very high concern according to Art 57f of the REACH legislation due to their endocrine disrupting properties. The assessment included an in depth substance specific analysis of all available information with a focus on fish.
The assessment was mainly based on the OECD guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption (OECD, 2012). Information provided in this document was supplemented by information from other guidance documents (e.g. OECD 123 Guidance document on the diagnosis of endocrine related histopathology in fish gonads (OECD, 2010)) and information from literature (e.g. (IPCS, 2002; Kendall et al., 1998; Knacker et al., 2010; OECD, 2004)).
A substance was considered as an endocrine disruptor if, in line with the OECD guidance document 2012, a causal link between an endocrine mode of action and the adverse effects observed was likely. In order to do so two different types of effects were considered and analysed separately:
- Indicators of an endocrine mode of action and
- Effects on apical endpoints that are considered to provide evidence that a substance results in adverse effects owing to its endocrine mode of action.

Substances were considered Endocrine Disruptors if either apical effects occurred that are clearly endocrine mediated and fit to the assumed endocrine mode of action (e.g. female biased sex ratio for an estrogen mode of action) or if in an overall weight of evidence approach clear indicators of an endocrine mode of action are available and the observed adverse effects fit to the mode of action. See e.g the annex XV dossier for 4-tert-octylphenol

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

4,000 character(s) maximum

An in depth analysis of two substances verified the endocrine disrupting properties. An Annex XV dossier under REACH was submitted and the substances were unanimous adopted as substances of very high concern by the responsible REACH committee.

• http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance/190/search/octylphenol/term

• IPCS: Global assessment of the state-of-the-science of endocrine disruptors. Damstra, Terri; Barlow, Sue; Bergman, Aake; Kavlock, Robert; Van der Kraak, Glen. 2002, WHO/PCS/EDC/02.2, WHO.

• Kendall, R. J.; Dickerson, R. L.; Suk, W. A.; Giesy, J. P.: Principles and Processes for Evaluating Endocrine Disruption in Wildlife. 1998, 1-419. Society of Environmental Toxicology & Chemistry. SETAC Technical Publications.

• Knacker, T.; Boettcher, M.; Frische, T.; Rufli, H.; Stolzenberg, H.-C.; Teigeler, M.; Zok, S.; Braunbeck, T.; Schäfers, C.: Environmental Effect Assessment for Sexual Endocrine-Disrupting Chemicals: Fish Testing Strategy. Integrated Environmental Assessment and Management 2010, 6; 1-10.

• OECD 2004: Detailed review paper on fish csreening assays for the detection of endocrine active substances. ENV/JM/MONO(2004)18; 1-170. OECD Series on Testing and Assassment No. 47.

• OECD 2010: Guidance document on the diagnosis of endocrine-related histopathology in fish gonads. ENV/JM/MONO(2010)14; 1-114. Series on Testing and Assessment No. 123.

• OECD 2012: Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption. ENV/JM/MONO(2012)22. OECD Series on Testing and Assassment No. 150.

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

In general the UBA supports the use of the WHO/IPCS definition to identify endocrine disruptors. The definition is scientifically based and widely accepted. Our analysis shows, that a very high level of information is needed to identify substances as Endocrine Disruptors if the WHO/IPCS definition is applied. However we support a further categorization as described in option 3 (see answer to 2.3.4)
The criticism on available "impact assessment studies" raised already for Option1 does apply here also.
In the view of UBA all these studies have only restricted significance for an overall impact analysis since either (i) the procedure of identification of the ED (candidate) substances (to which the exclusion criteria are assumed to apply) is not transparent/consistent/all-encompassing or only provisional and/or (ii) the agronomical / socio-economic impact assessment is lacking a robust methodological and statistical basis, i.e. qualifying the results as only very rough estimates ("screening"). This is especially proble¬matic with regard to studies conducted / commissioned by industry which clearly has an inherent conflict of interest. Furthermore, there is an obvious imbalance in the available socio-economic studies: with the vast majority only addressing the agronomical / societal costs of the implementation of the ED exclusion criteria, the economic benefits generated by the avoidance of environmental and health costs being clearly rarely considered.

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

As a case study, the line and weight of evidence of available in-vitro and in-vivo data on the endocrine disrupting potential in fish of 10 EBI fungicides (ergosterol biosysnthesis inhibitors, i.e. azoles and imdiazoles) in wildlife was - in a clearly provisional manner (since no agreed ED criteria / Weight-of-evidence-rules for decision making are available yet) - assessed.

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

4,000 character(s) maximum

For 3 out of the 10 active substance the ED criterion of 1107/2009/EC was judged as fulfilled, while for the remaining substances the final judgement was either “inconclusive” (4 substances) or “not fulfilled” (3 substances).

- Frische, T., Kotschik, P. (2011). Where to cut-off? Endocrine hazard profiles of EBI fungicides. SETAC Europe 21st Annual Meeting, Milano/Italy, 15-19.05.2011 (a PDF-version of the poster can be provided upon request).

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

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

4,000 character(s) maximum

Yes, there have been several (industry-sponsered) studies (listed under 2.1.4) estimating the socio-economic impact if several (or the entire EBI group) would be regulated by a hazard-based management (i.e. non-authorization):

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

4,000 character(s) maximum

UBA is aware of a couple of studies conducted or commissioned by scientific, regulatory and industrial bodies trying to estimate the expected agronomical and socio-economic consequences of banning pesticide active ingredients in accordance with the (interim) exclusion criteria established under 1107/2009/EC. Examples include (non-exhaustive list):

- Interpretation in Sweden of the impact of the “cut-off”

criteria adopted in the common position of the Council concerning the Regulation of placing plant protection products on the market (document 11119/08)

- European Parliament Report; The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products (2008)

- PSD/CRD Summary Impact assessment (2009)

- Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD; WRc (2013)

- Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances; Report to Chemicals Regulation Directorate (2013)

- Potential Trade Effects on World Agricultural Exporters of European Union Regulations on Endocrine Disruptor. Dtbassociates (2014)

- Evaluation of the benefits provided by and of the effect of losing the azole class of compounds on durum and common wheat production in Italy. ECPA (2012)

- Evaluation of the benefits provided by the azole class of compounds. ECPA (2011)

- Evaluation of the agronomic impact of losing azole fungicides in the production of oilseed rape. ECPA (2012)

- Restricted availability of azole-based fungicides: impacts on EU farmers and crop agriculture; IAB (2011)

- The assessment of the economic importance of azoles in European agriculture: Wheat case study (ECPA 2012)

- Potential impact of draft proposal for endocrine disruption criteria. ECPA, (2013)

- The Cost of Inaction : A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health. Nordic Council of Ministers, Nordic Council of Ministers Secretariat (2014)

In the view of UBA all these studies have only restricted significance for an overall impact analysis since either (i) the procedure of identification of the ED (candidate) substances (to which the exclusion criteria are assumed to apply) is not transparent/consistent/all-encompassing or only provisional and/or (ii)

the agronomical / socio-economic impact assessment is lacking a robust methodological and statistical basis, i.e. qualifying the results as only very rough estimates ("screening"). This is especially problematic with regard to studies conducted / commissioned by industry which clearly has an inherent conflict of interest. Furthermore, there is an obvious imbalance in the available socio-economic studies: with the vast majority only addressing the agronomical / societal costs of the implementation of the ED exclusion criteria, the economic benefits generated by the avoidance of environmental and health costs being clearly rarely considered.

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

For the environment Option 3 is logical in respect to the general exclusion criteria: There will be always a list of candidate substances, for which an ED suspicion is raised or for which no final conclusion on whether the WHO/IPCS definition does apply or not, can - in view of the available information - finally be answered. Therefore, an adoption of respective categories based on a clearly described set of (sub-)criteria in combination with a mechanism for a regular revision of the listed substances by an acknowledged regulatory authority is generally supported by UBA. This mechanism should trigger the generation of data for substances falling under the respective categories and should finally enable regulators to either include the substances of concern in the list of EDs according to the WHO/IPCS definition or to reject the ED concern for certain chemicals and to remove them from the category lists. Hence, together with the criteria for listing suspected ED substances under certain categories, criteria for the priorisation of further action (data generation, regular review e.g.) on certain substances in these categories need to be established.

Regarding option 3 from the REACH perspective please see answer to question 2.2.1. Although no clear categorization was applied, substances which did not fullfill the WHO/IPCS criteria but showed some evidence of endocrine disruption or endocrine activity were considered separately and submitted as potential candidates for substance evaluation (see http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table)

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

An exercise was conducted at the BfR considering different sets of criteria for human health.
The authors concluded that for human health this option (hazard identification plus additional elements of hazard characterisation) scored high on sensitivity for hazard identification, while it enabled prioritisation of substances to be regarded as of lower or higher concern. In addition, reproducibility was comparable to the option based on hazard identification only. Applicability of this option in terms of facilitating decision making was, however, regarded as better due to the integration of elements of hazard characterization.
Nevertheless for environmental aspects only Option 3 is suitable.

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

With regard to pesticides and biocides, UBA clearly favors approaches for regulatory decision making, which, after the identification of a substance as Endocrine Disruptor according to WHO/IPCS, allows a subsequent assessment.
This assessment should focus on the overall environmental burden, which should not increase by replacing an Endocrine Disruptor by an environmental even more harmful, but eventually not endocrine, substance.
Therefore Option A is not adequate.
However neither Option B nor Option C fulfils the criteria needed for this assessment. Both options are hampered today already by the fact that the methodological basis for conducting an adaequate socio-economic analyses in such a regulatory context is only in premature state, particularly for environmental impacts and even more costs (see SEA-exercise under REACh). Respective methodological developments aiming at scientifically robust and widely agreed approaches are thus a precondition for the implementation.

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

4,000 character(s) maximum

With regard to pesticides and biocides, UBA clearly favors approaches for regulatory decision making, which, after the identification of a substance as Endocrine Disruptor according to WHO/IPCS, allows a subsequent assessment.
This assessment should focus on the overall environmental burden, which should not increase by replacing an Endocrine Disruptor by an environmental even more harmful, but eventually not endocrine, substance.
Therefore Option A is not adequate.
However neither Option B nor Option C fulfils the criteria needed for this assessment. Both options are hampered today already by the fact that the methodological basis for conducting an adaequate socio-economic analyses in such a regulatory context is only in premature state, particularly for environmental impacts and even more costs (see SEA-exercise under REACh). Respective methodological developments aiming at scientifically robust and widely agreed approaches are thus a precondition for the implementation.

Please provide the reference(s) if possible:

3.2. Have you conducted or are you aware of an assessment of the socio-economic impact of the 3 different options for regulatory approaches to decision making (option A-C) for substances identified as endocrine disruptors by any of the options for defining criteria (option 1-4)?*

- ○ Yes
- ◉ No

4. Other information

4.1. Please provide any other data or information that could help the Commission to conduct its impact assessment.

4,000 character(s) maximum

UBA wants to point out that the statements above are inline with the German position on Endocrine Disruption. This DE Position Paper on Endocrine Disruption, submitted in May 2013 is still the German position.
The paper states that for management purposes, substances with effects on the endocrine system should be allocated to one of the following three groups:

- Group 1: Endocrine disruptors
- Group 2: Endocrine effective substances
- Group 3: Suspected endocrine effective substances

The identification of a substance as Endocrine Disruptor should be based on the WHO/IPCS (2002) definition in general.

Considering the complexity of the matter, it appears generally inappropriate to base grouping on the outcome of individual tests. Rather, weight of evidence considerations and expert judgement should be used case-by-case to decide on the grouping.

The allocation of a substance into any of the groups mentioned should consider differences regarding the assessment for human health and the environment:

- Provided substances have undergone comprehensive evaluation, current testing and assessment methodologies are generally suitable to derive dose/concentration levels which can be considered safe. While absolute certainty regarding safe dose/concentration levels for substances are generally not achievable, there is no convincing evidence to assume that levels of uncertainty are generally different regarding endocrine disrupters as compared to other toxic substances. Based on considerations on potency in combination with specificity, severity, reversibility and consistency of effect it is possible to allocate substances falling under the WHO/IPCS definition to group 1 or 2 or even dispense such substances from grouping.

• For the environmental assessment the situation is different. First, as also pointed out by the Scientific Committee of EFSA, for major taxa there exists no adequate testing methods and strategies to derive safe dose/concentration level. Second, standard testing methods normally only monitor very severe adverse effects. Third, interspecies variation appears to be higher for substances with effects on the endocrine system as for other toxic substances. As a consequence, substances meeting the WHO/IPCS definition should be allocated to group 1 in general.

Potentially useful background information:

• Frische, T., Bachmann, J, Frein, D., Juffernholz, T., Kehrer, A., Klein, A., Maack, G., Stock, F., Stolzenberg, H.-C., Thierbach, C., Walter-Rohde, S. (2013). Identification, assessment and mana-gement of “endocrine disruptors” in wildlife in the EU substance legislation – Discussion paper from the German Federal Environment Agency (UBA). Toxicology Letters. Online 15 March 2013 http://authors.elsevier.com/sd/article/S0378427413001021

• Stolzenberg, H.C., Frische, T., Dellario, V., Timm, G., Gourmelon, A., Iguchi, T., Ingerslev, F., Roberts, M. (2013). The regulatory need for tests to detect EDCs and assess their hazards to wildlife. In: Matthiessen, P. (Ed.): Endocrine Disrupters – Hazard Testing and Assessment Methods.

• Germany. DE Position Paper on Endocrine Disruptors. 24Th of May 2013

Please provide the reference(s) if possible:

Contact

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