Case Id: 1ca3b2f5-fa0d-49ac-8cff-79239c62dfed

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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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

Elisabeth Ruffinengo

1.2. Your e-mail address for correspondence:*

elisabeth.ruffinengo@wecf.eu

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:*

WECF (Women in Europe for a Common Future)

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)*:

27402534747-67

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

1.7.b.vi(2): If other, please specify.*

environmental health and healthy environment

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

If other, please specify.*

use of scientific information on EDCs for awareness raising activities in the general public and the media

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)
- [ ] Water Framework Directive (2000/60/EC)
- [x] Cosmetics (Regulation 1223/2009)
- [ ] Chemicals Agents Directive (98/24/EC)
- [x] Other
- [ ] Not involved

If other, please specify.*

Toys safety directive

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

WECF is aware of the following study from the Swedish Chemical Inspectorate (KEMI).
In 2008 KEMI conducted an assessment, called “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)” (22th September 2008). The addendum contains a list of active substances identified in Sweden to meet the “cut-off” criteria in Annex II 3.6-3.7 adopted by the Council and may therefore not be approved.
This study has also been referenced in the EU Commission’s roadmap.
http://www.kemi.se/Documents/Bekampningsmedel/Docs_eng/SE_positionpapper_annenII_sep08.pdf

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

4,000 character(s) maximum

The table in the mentioned KEMI study identified 22 substances which may not be re-approved. 12 of them due to ED properties, 4 due to PBT/POP properties and 8 fall under the CMR cut-off. However, this list is based on data from before 2008 and would need to be carefully scrutinised. For example, some more pesticides may fall under the CMR cut-off than assumed at that stage. Moreover, a fully-fledged guidance on what “toxicity to endocrine organs’ means is still outstanding. Therefore it is basically impossible to make a reliable assessment of which substances would be identified with certainty under option 1.

Please provide the reference(s) if possible

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

- (●) Yes
- ( ) No

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

4,000 character(s) maximum

Many best practise examples and studies show that successful farming without or with less harmful pesticides is doable. We trust on the ability of the Commissions consultants to compile the vast literature on farming with non- and less chemical alternatives.

PAN Europe scrutinized the most discussed endocrine disrupting pesticides, like Abamectin, Amitrole, Ioxynyl, Mancozeb, Myclobutanil and other azoles. See PAN EU Report: Reducing pesticide use across the EU, 2013
http://www.pan-europe.info/Resources/Reports/PANE%20-%202013%20-%20Reducing%20pesticide%20use%20across%20the%20EU.pdf

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

4,000 character(s) maximum

see above

Please provide the reference(s) if possible

2.1.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- (•) Yes
- ( ) No

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

4,000 character(s) maximum

Many studies show that farming without or with less hazardous pesticides is successful. However, independent (not issued and paid by industry) assessment of the socio-economic cost taking EDC containing pesticides and biocides from the market, compared to the current state of regulation is still missing. Socio-economic assessment has to include not only economic aspects or focus on the potential losses for single companies, but also public health aspects, biodiversity and cost for health care and compensation, only to name a few. Examples show that these costs can be tremendous, like the case of DBCP (see Late lessons from early warnings, European Environment Agency, p. 203ff)

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

4,000 character(s) maximum

see above

Please provide the reference(s) if possible

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

4,000 character(s) maximum

WECF does not support option 1. This option prevents the EU setting comprehensive criteria for the identification of all endocrine disrupting chemicals (EDCs), in line with the specific nature, diversity and range of EDCs compared to other toxic categories. To protect human health and the environment, all EDCs need to be identified and regulated. Not only for the use in pesticides and biocides, but also for the use in all consumer products, which is regulated in e.g. the cosmetics directive, toys safety directive, textile regulation and many others. 58 per cent of all EDCs on the TEDX List are not used in pesticides and biocides. Therefore, applying option 1, means no sufficient protection from exposure to EDCs.
Option 1 is based on current interim criteria addressing only EDCs having carcinogenic and reprotoxic toxicity, not in line with recent research outcomes and has a too narrow scope misregarding potential effects of EDCs like epigenetics for example, as well as certain patterns of EDCs including low-dose effects, non-monotonic dose-responses, transgenerational effects, etc. They overlook all other EDCs affecting e.g. the metabolism and the thyroid system. They are not based on the state of the art of scientific evidence.

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

TEDX, The Endocrine Disruption Exchange, developed in 2009 the Critical Windows of Development (CWD) website tool that identifies primary scientific literature on physiological effects in laboratory animals exposed (in vivo) to low concentrations of EDCs prenatally or during early postnatal development. To date, the following chemicals have been entered into the CWD: bisphenol A, phthalates, dioxin (TCDD), chlorpyrifos, perfluorooctanoic acid (PFOA), and perfluorooctanesulfonic acid (PFOS). The results of the complete literature search entered into a database, available on the TEDX website.

PAN Europe evaluated all science available on endocrine disrupting pesticides, the regulatory dossiers of endocrine disrupting pesticides and peer-reviewed scientific literature, in total >800 documents and reports.

The ChemSec SIN List includes endocrine disruptors. Ist methodology involved rigorous literature reviews, and had a build in 'conservative' bias, hence only those chemicals where the evidence is sufficiently strong are featured in this list.
http://www.chemsec.org/images/stories/2014/Full_SIN_Methodology_October_2014.pdf

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

4,000 character(s) maximum

see above

Please provide the reference(s) if possible:

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

- (●) Yes
- ( ) No

If yes, please describe the 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

see above

Please provide the reference(s) if possible:

2.2.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- (●) Yes
- ( ) No

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

4,000 character(s) maximum

see note under 2.1.3.

We would like to highlight again, that assessments done by the pesticide industry, related industry associations, and countries with large chemical and pesticide industry often do not or rarely reflect the benefits of reducing pesticides use, and overestimate the benefits of pesticide and/or chemicals use, as well as replacing them by non-chemical and non-toxic alternatives.
WECF is aware of studies showing the socio-economic benefits of regulating EDCs, pesticides and other hazardous chemicals. Some examples:
- The cost of inaction – A socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health, Nordic Council report, November 2014, http://norden.diva-portal.org/smash/get/diva2:763442/FULLTEXT04.pdf
- Health costs in the EU – How much is related to EDCs, Health and Environment Alliance (HEAL), June 2014, http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf
- Cost of Inaction on the Sound Management of Chemicals, United Nations Environment Programme, 2013, http://www.unep.org/chemicalsandwaste/UNEPsWork/Mainstreaming/CostsofInactionInitiative/tabid/56397/Default.aspx
- L. Trasande: Further Limiting Bisphenol A in Food Uses Could Provide Health and Economic Benefits, Health Affairs; January 2014, http://content.healthaffairs.org/content/early/2014/01/16/hlthaff.2013.0686.abstract?sid=a35dbd53-44fe-4cbf-9ca4-147f0c58826f

Finally, to perform "socio-economic" impacts assessment would mean emphasizing in the scope of such assessments many different factors, including mid-term and long-term positive and negative consequences of regulation of hazardous chemicals: the very complexity of assessing and expressing in figures elements of different nature like (non exhaustive): jobs gains and losses linked to the regulation, impact on the innovation i.e. development of less toxic alternatives, costs/gains related to the absence and/or necessity to dispose of generated toxic waste, polluter pays principle implementation to affect the costs to the adequate and stakeholder most responsible of the generation of toxics, etc. The report Global Chemical Outlook released by UNEP in 2012 gives an overview of the variety of aspects which need to be covered when assessing socio-economic impact as well as global impact. We recommend that their approach is adequately taken into account in the next steps of the Commission’s work and activities.

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

4,000 character(s) maximum

see above

Please provide the reference(s) if possible

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

4,000 character(s) maximum

For WECF option 2 is unacceptable. It drops 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”. It would only refer to the first part. However, the PPR and BP Regulations require that “substances having endocrine disrupting properties which may cause adverse effects will not be approved for the respective use”. The legal text introduces specifically precaution by saying “may cause adverse effects”. Both regulations aim to ban both endocrine disruptors and potential endocrine disruptors because they recognize that in both cases these chemicals are a threat to human health and wildlife (also concluded in the WHO report “State of the science of endocrine disrupting chemicals” 2012). The regulation must enable a distinction between definite and potential disruptors. All potential ones should be tracked until more evidence can confirm or eliminate their “potential” status.

The limited availability of validated test methods used to identify EDCs at present, and the lack of government approved scientific tools results in a very limited number of EDCs being identified as such. This would lead to a high number of unregulated endocrine disrupting substances, because they would not be covered by any regulation.

WECF does not wish the inclusion in the definition of the elements "secondary consequences of toxic effects" as well as "specific endocrine-mediated mode of action". The notion of "secondary consequences of toxic effects" excludes from the scope of the definition those compounds which are a secondary consequences of toxic effects. This could result in certain compounds being regulated under legal regimes of other categories, despite their endocrine effects, and therefore not according to the adequate application of endocrinology: why the same effect should be treated differently if it is a secondary or primary effect?

Secondly, step e) iv) of option 2 seems inadequate, since including identifying mode of action is only one element in the identification of EDCs, which may already delay the identification itself, due to the complexity of the issue – i.e. when one effect is obvious but when no mode of action can be determined. Making the differentiation of "specific endocrine-mediated mode of action " from "non-specific secondary consequences of other toxic effects" one step of the identification procedure would mean long delays in the implementation of the regulation of EDCs, incompatible with the urgency and necessity to regulate this category of toxic compounds, recognized widely by the scientific community as well as EU institutions and its member states.

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

WECF is aware of the TEDX list of potential endocrine disruptors. Full description of methodology can be found at http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/overview
The ChemSec SIN List (see 2.2.1)
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. An overview of this work can still be downloaded here: http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm
Outcome: The TEDX list of potential endocrine disruptors has nearly 1000 potential endocrine disruptors. The ChemSec SIN (Subtitute It Now) List includes a certain number of endocrine disruptors identified according to the REACH category. There is now a need to take forward this work with EDC criteria that include a more rigorous 1, 2, and 3 category. Adopting such an approach with 3 categories, would provide an important incentive for further information to be brought forward to inform regulatory decision making.
On “secondary consequences of toxic effects”: WECF does not wish the inclusion in the definition of the elements "secondary consequences of toxic effects" as well as "specific endocrine-mediated mode of action". The notion of "secondary consequences of toxic effects" excludes from the scope of the definition those compounds which are a secondary consequences of toxic effects. This could result in certain compounds being regulated under legal regimes of other categories, despite their endocrine effects, and therefore not according to the adequate application of endocrinology: why the same effect should be treated differently if it is a secondary or primary effect?
On “specific or non-specific mode of action” : step e) iv) of option 2 seems inadequate, since including identifying mode of action is only one element in the identification of EDCs, which may already delay the identification itself, due to the complexity of the issue - i.e. when

one effect is obvious but when no mode of action can be determined. Making the differentiation of "specific endocrine-mediated mode of action " from "non-specific secondary consequences of other toxic effects" one step of the identification procedure would mean long delays in the implementation of the regulation of EDCs, incompatible with the urgency and necessity to regulate this category of toxic compounds, recognized widely by the scientific community as well as EU institutions and its member states. Option 3 also includes two elements, which we see as highly critical: human relevance and that the effects should occur in the absence of other toxic effects. These two elements are difficult to apply and have opened the door for misinterpretation. The legal text of the PPPR and BPR does not require such elements. Moreover, it is legitimate to question these two criteria.
On “human relevance” : Regarding the criterion of “human relevance”, WECF recommends the chapter “Experimental animal studies” of Legally poisoned (2011) by Carl F. Cranor. This chapter points out several elements like the commonality of biological function across species, or the fact that IARC (International Agency for Research on Cancer), regarding carcinogenicity – a field where extensive research has been performed and which is more advanced that endocrine disruptors regarding regulation – points out that “animal studies generally provide the best means of assessing particular risks to humans”. As well, Carl F. Cranor mentions a study by J.L. Schardein and K.A. Keller comparing the concordance of fifty-one human developmental toxicants and animal data for the same substances, which concludes that on the 165 substances reviewed, “the match to the human was rat 98 percent, mouse 91%, hamster 85 percent, monkey 82 percent, rabbit 77 percent”. The authors conclude on good predictive value in animal studies for humans.

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

4,000 character(s) maximum

see above

Please provide the reference(s) if possible:

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

- ○ Yes
- ◉ No

2.3.3.Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- ○ Yes
- ◉ No

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

4,000 character(s) maximum

Of all four options provided by the EU Commission, WECF thinks that option 3 is the best. We welcome the addition of three categories (confirmed, suspected, and potential EDC). This provides transparent, comprehensive and crosscutting system, reflecting the different levels of evidence available depending on the data situation.
Such a system will steer further research to fill knowledge gaps, and motivate industry to substitute or phase out EDCs. It will capture a wide range of substances, and therefore increase the level of protection for human health and the environment. It is coherent with other approaches to classify chemicals and can be applied in different regulations and laws.
However, applying such a system is only effective if the bar of proof is not too high and the criteria for assessing endocrine effects are applied in a strictly scientific way. As in option 2 it is crucial to implement the legal text, which says “may cause adverse effects”. Ignoring this element, means undermining the democratic system, and is not acceptable at all. Implementation of this phrase means that it is sufficient to demonstrate a plausible link between the likely adverse effects or predictors of adverse effects and an endocrine mode of action.
The first two categories should be used for regulation, whereas category I should be treated equally as category II until it is clear if these substances fall in category I or III. Category III should keep the name “potential EDs” instead of “endocrine active compounds”.

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

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.

CHEM Trust considers that implementing criteria with a potency cut off would make a mockery of the science, as it mixes science with policy rather than judging substances solely on the basis of the science as to whether or not they have ED properties that may cause adverse effects. It also leaves the public unprotected because even weakly potent EDCs may act together to cause effects in the population at large. Please also see this joint CHEM Trust and HEAL briefing: http://www.chemtrust.org.uk/wp-content/uploads/Criteria-Briefing-CTHEAL-FINAL.pdf

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

4,000 character(s) maximum

see above

Please provide the reference(s) if possible:

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

- ○ Yes
- ◉ No

2.4.3. Are you aware of any assessment(s) of the socio-economic impact if the identified substances were regulated without further risk assessment?*

- ○ Yes
- ◉ No

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

4,000 character(s) maximum

WECF supports CHEM Trust opinion not to support option 4. Potency can be used among other elements to prioritise and decide which chemicals to tackle first, but there should be no role for consideration of potency in the identification step of an endocrine disrupter. Therefore, CHEM Trust strongly advises the Commission against a potency-based cut-off value as part of the decision criteria for ED identification.

A potency cut-off is difficult to justify and is not based on science (for example, the STOT RE values were set arbitrarily). It should also be kept in mind that potency is not a simple thing to measure, such as a boiling point. Potency is dependent on a) the type of test system and which effect is being monitored, b) the organism/species used in the test system; and c) the observed life-stage (pregnancy, late life). That means the timing of exposure can be more decisive for the adverse impact, rather than its potency in any one particular study.

Comparing relative potencies of chemicals can be very misleading. Studies have shown that BPA is a very weak estrogen in some test systems, but it is reported to be equipotent with oestradiol (E2) with respect to the induction of insulin in mice (see Paloma Alonso-Magdalena, Sumiko Morimoto, Cristina Ripoll, Esther Fuentes, and Angel Nadal: The Estrogenic Effect of Bisphenol A Disrupts Pancreatic β-Cell Function In Vivo and Induces Insulin Resistance, Environ Health Perspect 114:106-112 (2006). doi:10.1289/ehp.8451 available via http://dx.doi.org/). This illustrates that a cut-off (or filter) at a certain potency level will always be arbitrary and may overlook harmful EDs because of the limited range of tests that are necessarily carried out.

There are other reasons which argue against identifying only highly potent EDs as ED, among them the following:

- Regulating only highly potent EDs could lead weakly potent EDs unaddressed even when exposure in the general population is very high.
- Moreover, given that many weak EDs can act together (combination effects), an approach to regulate only a few highly potent ones is likely to be unprotective of the public at large. The general population is exposed to many substances from many different sources such as food, water and indoor air, which makes up a cocktail of exposure.

In addition, it should be noted that the current identification of CMRs is not based on potency, and there are no grounds for taking an approach for identifying EDCs which is not consistent with this. Similarly, there is no potency element in the WHO/IPCS definition of EDCs.

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

WECF regrets that no room was provided to express concerns on the Commission's approaches if not related to “socio-economic” impacts understood in a very way. This questionnaire is not in a suitable format for getting input from the public or even from involved stakeholders, as the questions are of a highly technical nature and the framing of some questions results in impossibility to express certain key considerations. The consultation is clearly focused on gathering information on likely costs to producers of existing pesticides and biocides, and other categories of products rather than looking at the costs and benefits for society as a whole. The Commission should make a real effort to consult the public at large, whether regarding the format of the consultation or even the contents and period during which one can take part. The questionnaire is also too narrow and limits the consultation to just the biocides and pesticides perspective, rather than also including industrial chemicals used in products in the home. Given that the EU Commission’s roadmap clearly illustrated the need for horizontal criteria to ensure consistent policy making across various pieces of EU legislation, this is inappropriate. The questions completely ignore the (health, environment and societal) benefits of reducing exposure to endocrine disrupters. There are likely to be significant differences under the options proposed. We hereby are

calling on the Commission to make an extra effort to fully explore the potential benefits, particularly for human health, but also in relation to the stimulation of innovation to deliver a safer and more sustainable chemical industry. A full study of all the potential benefits of regulation is needed, and this should be included in any impact assessment. If criteria that embrace all EDCs are finally agreed, without changes to the laws relating to pesticide and biocides, then the potential savings on public health costs are likely to be very high. As CHEM Trust, WECF believes there should be no legal changes to the democratically established laws.The EU has introduced specific legislative obligations aimed at phasing out endocrine disruptors. 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. Re Option C, - which is to include a change the pesticides law to include socio-economic considerations - we note that SEAs required elsewhere in EU legislation e.g. REACH authorization) have typically focused largely on the costs to the industry producing the existing chemical rather than on what the impact would be on society as a whole, including public health and potential innovators of safer alternatives.

Of course there may be instances where a known EDC pesticide is really needed to protect a crop. However, there is already provision for this, because under the existing pesticide law, it can be the subject of a derogation and used for another 5 years with appropriate justification (according to article 4.7). Moreover, the new EDC criteria will only apply when a substances comes up for review and re-authorisation under the PPPR and BPR. The WHO/UNEP report summarized the state of the science and highlights the rising levels of hormone related illnesses, so the European Commission must establish a system leading to reduced exposures. Chemicals that act as EDs in mammalian systems are clearly undesirable. They should be replaced in the long run such that industry in all sectors develop and use safer substances and technologies. The Commission’s impact assessment needs to address benefits of EDC phase-outs for health and the environment.

Please provide the reference(s) if possible:

1. 39f5b2a0-1057-44d0-aab0-7928b6baccb8/WECF EDCs consultation 2015 - Point 4.1 attachment.pdf

Contact

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WECF complementary elements to point 4.1 of European Commission Consultation on endocrine disruptors – January 2015

Complementary remarks to Aspect II: Approaches to regulatory decision-making

Since no room was provided to express concerns on these approaches if not related to "socio-economic" impacts understood in a very narrow scope, WECF would like to underline the following:

The terminology used in the Commission roadmap is problematic It has to be remained that Endocrine disrupters is first of all a health and environment issue. The very reason why the EU should today regulate EDCs is because of their adverse effects on human health and the environment. As such, WECF considers that a terminology like "management measures", "risk-benefit analysis", "desired", "stigmatised" is not appropriate when considering EDCs.

On Option A : Option A seems inadequate, since a new category of toxic compounds/substances, once existing, must necessarily imply regulatory changes, not only in 2 sectorial legislations, but far beyond.

On Option B : Option B and C both have in common to adopt the prerequisite conception that if any harmonization may occur between PPPR and BPR, it is necessarily in the sense of an amendment of the PPPR to reflect certain provisions of the BPR. Why not open the door for an "Option D" which would allow an amendment of the BPR to reflect the more health and environment protective regime of the PPPR? Is that not "desired"?

Options B and C state that current PPPR has "adverse socio-economic impacts" – not defined in the Commission paper- which are not desirable - again whose stakeholders' "desire" does it reflect ? - whereas no analysis or impact assessment has been made which would allow for such conclusions. How could it be possible to conclude even before an impact assessment has been made?

Option B seeks to undermine the use of the "hazard-based approach" by inserting "risk-based approach", first of all in the Plant Protection Products regulation, but not only. This option, even before having performed any impact assessment, already concludes on two elements which have not been investigated. First option B seems to conclude on the inadequacy of the "hazard-based approach" as well as justification/legitimation of "negligible risk" – this notion is even not defined yet under the BPR–whereas the new biocidal products regulation is just being implemented and one cannot prevail over its consequences. The mention of "management measures" is a surprisingly new terminology, since the BPR deals exactly with "exclusion criteria" in its article 5, not "management measures" in the sense that the measures of market exclusion are based on hazard classifications and dedicated to prevent impacts on human health and the environment.

On Option C: Similar remarks can be done on option C. WECF is especially surprised by the following sentence: "…to allow the placing on the market of products in situations where an Endocrine Disruptor is essential to prevent adverse socio-economic impacts.". Shall we understand that the Commission consider that an ED - a

substance that is classified as ED under any of the categories chosen in a near future has or is suspected to have adverse health effects – may be placed on the market for the benefit of a number of economic operators? WECF recommends the Commission to carefully reconsider these regulatory options, to better reflect concerns on EU citizens's health and impacts on the environment related to EDCs. As well, is key principles may be mentioned, proportionality principle is indeed important, but we recommend that the precautionary principle, which is equally important in a context of environmental health.

Remarks on Part D – initial assessment of impacts

WECF wishes to point out that no element at all in the paragraphs "preliminary impact for the different options – Aspect I EU criteria to identify ED and aspect II – Approaches to regulatory decision making" reflects considerations of impacts – positive or negative – for exposure of populations, animals and the environment to EDCs. It seems this part D narrowly focuses on "impacts on different economic sectors", searching to quantify how many substances/products would stay or have to be phased out from the market. We do strongly hope the impact assessment will allow to investigate impacts far beyond these too narrow considerations.