Case Id: d3306df1-5248-4674-bbea-f9d8adb7407b

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 Please note that answers to questions 1.2 to 1.6, as well as 1.8 to 1.10 will not be published.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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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

Lisette van Vliet

1.2. Your e-mail address for correspondence:*

lisette@env-health.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:*

Health and Environment Alliance (HEAL)

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)*:

00723343929-96

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.*

Health from environmental conditions, or 'Environmental health'.

1.8. Your location:*

BE - Belgium

1.9. Would you say you live in a ...?*

- ◉ Metropolitan zone
- ○ Other town/urban centre
- ○ Rural zone
- ○ Do not want to answer

1.10. Were you or your organisation involved in scientific issues in relation to endocrine disrupting chemicals in the last 3 years and in which way? *(more than one answer possible)* *

- [ ] Direct experimental scientific research
- [ ] Review of scientific research
- [ ] Use of scientific research for safety assessments
- [x] Use of scientific research for regulatory purposes
- [ ] Lobbying
- [x] Other
- [ ] Not involved

If other, please specify. *

Advocacy for public interest (as distinct from lobbying for commercial interests)

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)
- [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)
- [ ] Chemicals Agents Directive (98/24/EC)
- [x] Other
- [ ] Not involved

If other, please specify. *

Food Contact Materials, Medical Devices, ROHS, Toy Safety,

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

The 2008 KEMI study on the Council's position on 'cut off' criteria Kemi 2008. It is a preliminary assessment of active substances, identifying EDs, CMRs and PBTs/vPvBs/POPs- see the Study for the details of the methodology and qualifiers.
"Interpretation of criteria for CMR ED & PBT in PPP", 22 Sept 2008, Kemi

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 KEMI study found 15 EDCs, depending on how and whether their methodology is interpreted to conform to the option 1 criteria (Carcinogenic category 2 + Toxic to reproduction category 2; or Toxic to reproduction category 2 + toxic to endocrine organ) . Because the term 'toxic to endocrine organ' has not been formally defined or elaborated in technical guidance documents, it is difficult to know how it can / should be interpreted.
"Interpretation of criteria for CMR ED & PBT in PPP", 22 Sept 2008, Kemi

http://www.kemi.se/Documents/Bekampningsmedel/Docs_eng/SE_positionpapper_annenII_sep08.pdf

See also the TEDX assessments under 2.2.1, and 2.3.1 - some of the chemicals identified on the TEDX list of potential Endocrine Disruptors and in the 'Critical Windows of Development' project would be identified under the interim criteria due to their carcinogenic and reproductive toxic properties.

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

There are numerous studies looking at the viability of reduced pesticide use, including Integrated Pest Management, which – it is important to note – is already required of EU farmers for crop protection as of January 2014 according to Directive 2009/128, Annex III.(Framework for Community Action to achieve Sustainable Use of Pesticides).

Again, because there is no agreed definition of or guidelines on what qualifies as 'toxic to an endocrine organ', some of these assessments may be judged as conforming to the option 1 criteria identification, depending on the interpretation brought to bear on the term 'toxic to an endocrine organ', and some not.
See for example,

PAN Europe, 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

PAN Europe, "NAP Best Practice: Meeting the challenge, protecting health, environment & biodiversity. Sustainable use of pesticides: Implementing a National Action Plan http://www.pan-europe.info/Resources/Reports/NAP_best_practice.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

Again, because there is no agreed definition of what qualifies as 'toxic to an endocrine organ', the assessment conducted by HEAL may be judged as wholly or only partly conforming to the option 1 criteria identification, depending on the interpretation brought to bear on the term 'toxic to an endocrine organ'. See 2.2.3

HEALTH COSTS in the European Union: How much is related to EDCs?
HEAL, 2014
http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf

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

4,000 character(s) maximum

see 2.2.3

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

HEAL does not agree with option 1 for several reasons.
1. Contrary to law:
The legislators' intention was clearly for these criteria to be temporary, and not permanent, as they specifically used the term INTERIM; therefore option 1 goes against the spirit and letter of the Plant Protection Products Regulation (EC) 1107/2009 (or PPPR), and the Biocides Product Regulation (EU) 528/2012 (or BPR).
2. Scientifically lacking:
It is unclear whether one of the interim criteria (toxic to reproduction category 2 AND toxic to an endocrine organ) would catch those EDCs which

are not carcinogenic or toxic to reproduction, but which are neurological or metabolic disruptors. Such EDCs can contribute to maldevelopment or malfunctioning of the brain or nervous system, diabetes or obesity or other metabolic disorders. Until 'toxic to the endocrine organ' is defined and agreed, it is uncertain whether these criteria will catch the neurological or metabolic disruptors, and hence are not scientifically satisfactory.
It is clear that the interim criteria (carcinogenic category 2 and toxic to reproduction category 2) would not catch the neurological or metabolic disruptors.
The Commission Roadmap of June 2014 on Defining Criteria for identifying EDCs stated "there is general consensus on the WHO/IPCS (2002) definition of an endocrine disruptor". The interim criteria are not close to equivalent to this definition.

3. Inadequate protection of public health
The interim criteria do not apply to EDCs in any other sectors than pesticides and biocides (for example food contact materials which could be a major source of the public's exposure). To protect public health, and reduce the exposure of all EU residents to EDCs, we need criteria that identify EDCs across all sectors, in line with the EU's 7th EAP which says in Art 54 (d) "by 2020: […] the combination effects of chemicals and safety concerns related to endocrine disruptors are effectively addressed in all relevant Union legislation, and risks for the environment and health, in particular in relation to children, associated with the use of hazardous substances, including chemicals in products, are assessed and minimized". Therefore, horizontal criteria for a scientific identification of EDCs across all sectors are needed to tackle the ubiquitous public and environmental exposure
4. Regulatory impracticality

So long as the Commission is undertaking the establishment of criteria to identify endocrine disruptors, it is both good policy and administration to establish criteria that will be consistent across different regulatory sectors. The interim criteria for the BPR and PPR may not capture all the same EDCs as those identified via REACH Article 57f; nor are the interim criteria likely to suffice for other legislation where future clauses on EDC identification would not restrict themselves to such a limited definition, particularly in light of the general consensus on the WHO / IPCS definition.
Toxic to endocrine organ has not yet been defined in law or elaborated in guidelines, so it is disputable whether the effort, resources and time required to do this is effective compared to establishing permanent EDC criteria, and the associated technical guidance documents, minimum test requirements, etc.

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

There are various studies including:

TEDX list of chemicals under their Critical Windows of Development project;

KEMI 2008 (see 2.1.1);

the ChemSec SIN List which includes endocrine disruptors. The ChemSec SIN List 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. See http://www.chemsec.org/images/stories/2014/Full_SIN_Methodology_October_2014.pdf

http://endocrinedisruption.org/prenatal-origins-of-endocrine-disruption/critical-windows-of-development/overview.

www.sinlist.org

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

4,000 character(s) maximum

The ChemSec SIN List has up to 73 individual substances which are listed for their endocrine disrupting properties. Depending on how one interprets the evidence for these substances, some number of these substances would meet these option 2 criteria (e.g., a substance that is category 1 on the EU Commission EDC database would meet option 2 criteria). In addition, some substances which would meet the WHO definition are listed under other categories on the SIN List (eg DEHP is listed as a Reproductive Toxicant). See www.sinlist.org

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, and submission from Pesticide Action Network Europe and national PAN organisations.

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

1. As noted in 2.1.3, HEAL's assessment partly relates to the substances identified by this criteria option.
See HEAL report, Health Costs in the European Union: How much is related to EDCs?
http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf

2.See Milieu Ltd, The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products, report for European Parliament, 2008. This study was before the final 'cut off' criteria for CMRs and EDCs had been

agreed.
http://www.europarl.europa.eu/RegData/etudes/etudes/join/2008/408559/IPOL-JOIN_ET%282008%29408559_EN.pdf

3 See Norden 2014, The Cost of Inaction: A Socioeconomic analysis of costs linked to effects of endocrine disrupting substances on male reproductive health
http://www.norden.org/en/news-and-events/news/endocrine-disruptors-cost-the-eu-billions-every-year

The HEAL Report identified six endocrine related diseases, based on a review of the scientific literature: Breast and Prostate Cancer, Diabetes and Obesity, ADHD and Autism, and Infertility (as a proxy for male and female reproductive health problems).

The total cost of six endocrine related diseases (from all causes) across the EU were calculated, based on literature searches of published costs. The principal costs estimates were adjusted for inflation and reported at price levels existing in 2012. Total cost estimates for the EU28 countries for each disease / health problem were generated by scaling up, on the basis of population size, from the estimates derived from the documented cost studies. The costs include indirect costs where these were available (for 4 of 8 diseases/ conditions). Indirect economic costs include lost productivity resulting from absenteeism and premature retirement, the lost productivity or leisure time spent by family and friends in care, and the costs of rehabilitation and retraining or additional educational resources devoted to the individual, as well as subsequent losses in their own productivity (e.g. as affected children enter the workforce).

For each health effect, a table presents a summary of the incidence and economic evidence gathered. Health care costs are presented for the EU28. These have been derived by scaling existing country-level and regional-level cost data up to the EU28 level on the basis of population and serve to allow for an initial comparison of the size of the cost burden between individual health effects. Clearly, scaling on the basis of population is a simplifying process that abstracts from the realities of local and national differences in a) treatment costs, and b) varying incidence rates between countries.

On the basis of previous published work on attributable fraction of two diseases from one application of one (widely accepted) EDC, (see Trasande, 2014, Further Limiting Bisphenol A In Food Uses Could Provide Health And Economic Benefits, Health Aff January 2014 10.1377/hlthaff.2013.0686
http://content.healthaffairs.org/content/early/2014/01/16/hlthaff.2013.0686.abstract?sid=a35dbd53-44fe-4cbf-9ca4-147f0c58826f), HEAL posited with multiple chemicals and diseases and interconnections between diseases, that an attributable fraction of 2-5% would be a more realistic proportion of diseases related to EDCs exposure.

The Norden Study calculated direct and indirect tangible costs and some intangible costs for male reproductive health problems in the Nordic countries, including some discounting and preference rates, using 3 estimates of etiological fractions (2%, 20% and 40%); and extrapolated these to the EU 28. (The Nordic countries are Denmark, Finland, Iceland, Norway and Sweden)

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

4,000 character(s) maximum

For HEAL report:
HEAL's report found that if EDCs (some of which would be identified according to option 2)
contribute to only 2-5% of the total health costs from endocrine-related chronic diseases, EU policy change such as the phasing out of these hazardous substances and promoting safer alternatives could save Europeans up to €31 billion each year in health costs and lost productivity.

The cost for Breast Cancer is estimated at 16 billion euros.
The cost for Prostate Cancer is estimated at 9 billion euros.
The cost for Cryptorchidism & Hypospadias is estimated at up to 1.3 billion euros.
The cost for Attention Deficit Hyperactivity disorder is estimated at 0.7 billion euros (this cost is certainly an underestimate because it only includes minimum medical costs, not special schooling costs)
The cost for Autism is estimated at 226 billion euros.
The cost for Obesity is estimated at 81 billion euros.
The cost for Diabetes is estimated at 300 billion euros.

The report also found that the 13-31 billion potential savings each year could be an underestimate because future costs are likely to be even higher than today's.
The Milieu study found that the Initial economic analysis indicates potential benefits are significant, that the cut-off criteria are intended to provide additional health protection for all EU citizens, but will have the most direct benefit on the farmers and agricultural workers who have the highest risk of pesticide exposures and associated health problems, due to their occupational and environmental situations.
The study also found that due to the gravity of the potential health impacts and the high costs to society from low-level chronic damage to children from neurotoxicants, many experts have recommended adopting a precautionary approach to limiting children's exposure to such chemicals. (Here it is important to underline that some EDCs are considered to be able to disrupt neurological functions, including those that disturb normal thyroid functioning).
The Norden Study estimated that the cost of male reproductive health problems from yearly exposure to EDCs (at 20% etiological fraction) to be 1) 36 million euros in the Nordic countries; 2) 592 million euros for the EU 28 (discounted socio economic costs); 3) 1,267 million euros for the EU 28 (undiscounted socio economic costs). Testicular cancer in the EU 28 ranges between 25 and 499 million euros per year of exposure.

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

HEAL does not agree with option 2 for several reasons:

1. Contrary to law
The PPPR and BPR clearly intend to ban both confirmed and suspected EDCs because the legal texts intend and make specific mention of endocrine disruptors which 'may cause adverse effects'. Therefore the criteria used to identify chemicals meeting that definition must go beyond capturing those chemicals that are definite EDCs but also catch potential EDCs (as per the full WHO definition for endocrine disruptors and potential endocrine disruptors). Otherwise to properly implement the PPPR and BPR by including those substances that 'may cause adverse effects', the EU 'confirmed' regulatory category deployed for these laws using this option would actually have to include both confirmed and potential EDCs – which would engender endless confusion and be at odds with the WHO terminology.

2. Scientifically lacking
Option 2 artificially shortens the World Health Organisation definition – by omitting the accompanying World Health Organization (WHO) definition for "potential endocrine disrupter".

Only using the definition for confirmed EDCs blocks systematic and effective consideration of the state of the science, and its translation into an EU regulatory classification. Different levels of evidence and different quality of evidence between substances cannot be sufficiently distinguished with this approach.

Given that the vast majority of the validated test methods are limited to parts of the hormone system (Estrogen, Androgen, Thyroid, Steroidogenesis), it is important to use those innovative academics studies which are capturing other aspects of the endocrine disruption via other endpoints.

3. Inadequate protection of public health

This truncated, 'confirmed-only' definition would either 'disappear' or potentially wrongly 'exonerate' all chemicals that may be EDCs, but for which the current studies do no look at the correct endpoints and only provide initial indications of potential ED properties. These chemicals need to be further investigated, to determine on the basis of more 'fit for purpose' evidence, whether they are EDCs or not.

The WHO/UNEP report on EDCs from 2012, the most authoritative global report to date, highlights that endocrine disrupting chemicals are a global threat to human health and ecosystems. Therefore, we must be able to identify potential disruptors, and ensure that any studies/results

subsequently generated contributes to clarifying their status – whether confirming their ED properties or downgrading their 'potential' status to a lower category.

4.Regulatory impracticality
This black or white approach exerts pressure on assessors to 'downgrade' or 'upgrade' their interpretation of the evidence, which will mean that very few substances will obtain an solidly-agreed 'classification'.
Some assessors will feel under pressure to identify a chemical is an EDC on a precautionary basis if they are concerned about its potential ED properties, others will object to 'precautionary identification'.

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

1. 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

2. The ChemSec SIN List (see 2.2.1)

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

4,000 character(s) maximum

3. The TEDX list of potential endocrine disruptors has nearly 1000 potential endocrine disruptors.

Please provide the reference(s) if possible:

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

- (●) Yes
- ( ) No

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

4,000 character(s) maximum

See 2.1.2 and 2.2.2

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:

2.3.3.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

See 2.2.3.
HEALTH COSTS in the European Union: How much is related to EDCs?
HEAL, 2014
http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf

HEAL identified six endocrine related diseases, based on a review of the scientific literature: Breast and Prostate Cancer, Diabetes and Obesity, ADHD and Autism, and Infertility (as a proxy for male and female reproductive health problems).

The total cost of six endocrine related diseases (from all causes) across the EU were calculated, based on literature searches of published costs. The principal costs estimates were adjusted for inflation and reported at price levels existing in 2012. Total cost estimates for the EU28 countries for each disease / health problem were generated by scaling up, on the basis of population size, from the estimates derived from the documented cost studies. The costs include indirect costs where these were available (for 4 of 8 diseases/ conditions). Indirect economic costs include lost productivity resulting from absenteeism and premature retirement, the lost productivity or leisure time spent by family and friends in care, and the costs of rehabilitation and retraining or additional educational resources devoted to the individual, as well as subsequent losses in their own productivity (e.g. as affected children enter the workforce).

For each health effect, a table presents a summary of the incidence and economic evidence gathered. Health care costs are presented for the EU28. These have been derived by scaling existing country-level and regional-level cost data up to the EU28 level on the basis of population and serve to allow for an initial comparison of the size of the cost burden between individual health effects. Clearly, scaling on the basis of population is a simplifying process that abstracts from the realities of local and national differences in a) treatment costs, and b) varying incidence rates between countries.

On the basis of previous published work on attributable fraction of two diseases from one application of one (widely accepted) EDC, (see Trasande, 2014, Further Limiting Bisphenol A In Food Uses Could Provide Health And Economic Benefits, Health Aff January 2014 10.1377/hlthaff.2013.0686 http://content.healthaffairs.org/content/early/2014/01/16/hlthaff.2013.0686.abstract?sid=a35dbd53-44fe-4cbf-9ca4-147f0c58826f), HEAL posited with multiple chemicals and diseases and interconnections between diseases, that an attributable fraction of 2-5% would be a more realistic proportion of diseases related to EDCs exposure.

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

4,000 character(s) maximum

HEAL's report found that if EDCs [some of which would be identified according to option 1]
contribute to only 2-5% of the total health costs from endocrine-related chronic diseases, EU policy change such as the phasing out of these hazardous substances and promoting safer alternatives could save Europeans up to €31 billion each year in health costs and lost productivity.

The cost for Breast Cancer is estimated at 16 billion euros.
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The cost for Autism is estimated at 226 billion euros.
The cost for Obesity is estimated at 81 billion euros.
The cost for Diabetes is estimated at 300 billion euros.

The report also found that the 13-31 billion potential savings each year could be an underestimate because future costs are likely to be even higher than today's because:
• Current exposure may not appear as cancer or diabetes until decades later.
• Certain EDC-related conditions imply future health risks. For example, a
baby boy born with a genital defect known as hypospadia has a higher risk of becoming infertile or developing testicular cancer later in life.
•Trans-generational, or epigenetic, effects may occur. This means that future generations may be affected by damage caused by EDC exposure in the current generation

Health Costs in the European Union: How much is related to EDCs? HEAL 2014
http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf

See also Norden and Milieu Report discussed in 2.2.3.

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

HEAL believes Option 3 best captures & enables the optimal use of the existing state of the art science in a way that will best serve protection of public health.

1. Compliant with law

This option fulfils the spirit and the letter of the PPPR + BPR. It also follows the recommendation of European Parliament in its own initiative report of March 2013 on Endocrine Disrupting Chemicals.

2. Scientifically optimal and accurate

This set of 3 categories is very transparent about the different levels of scientific evidence available which was used to categorise the substances, + about the comparative ranking between the substances. This option can be used to properly rank a given chemical according to the data situation. This option allows assessors to make a fair assessment of data, & ensures they are not forced, simply because there is only one category, to 'bump up' or 'push back' a given substance from the Option 2 confirmed or [nothing] category.

Under this option, endocrine disruptors will be not be identified as such where information demonstrates that the effects are clearly not relevant for humans & not relevant at the population level for animal species in the environment. HEAL views this as appropriate only if there is explicit information that clearly proves irrelevance for humans / animal populations – such that doubts about human relevance would not be sufficient to disqualify a chemical. In other words, it should always be assumed to be relevant for humans unless the evidence explicitly & positively points to the contrary (and is derived from peer-reviewed, openly published sources).

Please see "A path forward in the debate over health impacts of endocrine disrupting chemicals," Environmental Health 2014, 13:118 doi:10.1186/1476-069X-13-118
http://www.ehjournal.net/content/pdf/1476-069X-13-118.pdf

3. Better enables protection of public health

This option better enables the protection of public health intended by the PPPR & BPR, by allowing those substances for which adverse effects are proven, + those for which adverse effects are still probable but not fully proven, to be categorised as such and dealt with by the provisions of those laws. HEAL views the correct interpretation of those laws as including both category 1 and 2 EDCs in the cut off criteria (in the terminology of the Roadmap, this equates to Endocrine Disruptors and Suspected Endocrine Disruptors).

Humanity faces rising levels of hormone related illnesses, so what the European Commission must do is to establish a system that leads to reducing our exposures to hormone disruptors, to help prevent these illnesses. Using categories is a sophisticated, powerful & necessary part of such as system.

4. Practical regulation

This option, once EDCs have been categorised according to the 3 rankings, generally allows for an effective & efficient use of resources by enabling regulatory action to focus first on those substances that are confirmed (and as appropriate, those that are potential); second on ensuring further research for those that are potential (and further precautionary reduction measures if appropriate).
This option enables better analysis when examining the costs & benefits of different possible regulatory actions as part of impact assessments, and when considering new policy measures.
This option specifically facilitates the implementation of criteria in BPR & PPPR because these 2 laws differ in their provisions.
It also facilitates regulation of these chemicals according to the different clauses in the various laws governing their sectoral / product uses (food contact materials, pesticides, cosmetics, etc.).
This option is coherent with current approaches to rank other chemicals in EU CLP/GHS, e.g. how cancer causing chemicals are classified.
It gives industries advance notification to generate/ gather more information on the substances, to help re-categorise the chemical up or out; and help downstream users.

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 2011 report (Criteria for Endocrine Disruptors and Options for Regulation) analysed the use a potency identification approach in this report, alongside other analyses and considerations.
http://mst.dk/media/mst/9106718/danskeforslag.pdf

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

4,000 character(s) maximum

The Danish EPA noted that OECD test validation work showed that strong and moderate EDs were detected [in this test], whereas other EDs showing effects during sensitive developmental periods were not detected. Given the indications that for EDs it is the time of exposure during
pregnancy and/or early life-stages that matters (exposure during critical time windows) rather than the dose, they concluded against using potency as part of the identification criteria. They stated that the use of potency for identification of EDs could result in a situation with lower protection of human health and environment as potent EDs with only very limited exposure would be categorised as EDs whereas moderate or weak EDs with extensive exposure would not be identified as EDs (page 55).

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

HEAL does not agree with option 4 in the IDENTIFICATION of EDCs for several reasons.
See HEAL and CHEMTrust's joint paper:
http://www.env-health.org/IMG/pdf/36-_heal_ct_edc_criteria_briefing_paper.pdf

1. Contrary to existing EU law and policy
The EU's 7th Environmental Action Programme Article 50 states "In particular, the Union will develop harmonised hazard-based criteria for the identification of endocrine disruptors." Option 4 is not truly hazard based for the reasons noted below.

2. Scientifically flawed

This proposal is scientifically flawed & is contrary to the policy advice the Commission received in reports by the Joint Research Centre (JRC) + the European Food Safety Agency (EFSA). See e.g. JRC p17 which says that from a scientific point of view potency considerations are not part of the identification of an ED and page 42-43 of EFSA – there is no scientific basis to include severity, irreversibility, critical effect or potency in the Identification of EDCs.
“Scientific Opinion on the hazard assessment of endocrine disruptors” . EFSA Journal 2013;11(3):3132 [84 pp
http://www.efsa.europa.eu/fr/efsajournal/pub/3132.htm
“Key Scientific issues relevant to the identification and characterisation of endocrine disrupting substances” JRC 2013
https://ec.europa.eu/jrc/sites/default/files/lbna25919enn.pdf

Potency is not used to identify chemicals which cause cancer (C) or are toxic to reproduction (R); some of these C or R chemicals are so classified because they exert these toxic effects via an Endocrine [disrupting] mode of action. Therefore it is scientifically illogical to use potency in identifying whether a chemical is an endocrine disruptor or not.
The potency of a chemical that can be measured depends on what the endpoint is that is being observed & during what phase the exposure is occurring (prenatal versus adult middle age, for example). EDCs vary in how strongly they affect different parts of the body & different hormone systems, so relying on certain tests for potency may wrongly leave some chemicals unidentified. For example, an EDC may be weak in disrupting female hormonal signalling but strong in disrupting some aspect of brain development.
In addition, because effects are not adequately examined over a range of low doses and the effects (endpoints) examined may not represent the ones most sensitive to that chemical, even quite potent chemicals are likely to be missed.

In addition, during the most vulnerable periods, such as growth and development in the womb, even extremely small amounts of ‘weak’ EDCs may contribute to ill health, particularly later in life.
Moreover, people and wildlife are exposed to many EDCs from different sources at the same time and over time, and science has shown that EDCs can act together, leading to harmful cocktail effects. It is not the potency that creates the health risk from these substances. See Kortenkamp, Faust & Backhaus, 2009
http://ec.europa.eu/environment/chemicals/effects/pdf/report_mixture_toxicity.pdf

2. Insufficient public health protection
This option would result in only some but not all EDCs being identified – only those which act in highly potent ways on those taxa used in the tests considered. Potency may vary dramatically between different species – so using potency cannot reliably protect people and wildlife. If people are highly exposed to many ‘weak’ EDCs the (problematic combination or cumulative) exposure would not be ‘caught’ under option

4.

3. Regulatory Impracticality
This option would be inconsistent with the Globally Harmonised System of Classification and Labelling which the EU follows, because hazard characterisation does not normally include potency, and because it is not separate from exposure assessment.

This option would present the difficulty of selecting which taxa in which tests the potency threshold should be based on.

This option is inconsistent with how hazardous chemicals are identifie

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

HEAL conducted an internal analysis, in collaboration with other NGOs, on the implications of the different regulatory options. We evaluated the options according to their ability to ensure the intended purposes of the PPPR and BPR provisions on EDCs - to phase out use of EDC active ingredients in order to improve public health and environmental sustainability in balance with the regulatory possibilities for maintaining use of these EDCs where still necessary.

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

4,000 character(s) maximum

HEAL found that regulatory option A (adhering to the existing provisions of the Pesticides and Biocides regulations which prohibit EDCs) is the best way forward
HEAL opposes the EU Commission's proposed regulatory options B and C. These are unacceptable because they would undermine the democratically agreed rules in the EU pesticides law adopted by the elected European parliamentarians and national governments in 2009, and the Biocides law in 2011.
The EU pesticides and biocides laws already contain provisions for exemptions if certain ED pesticides and biocides are found to absolutely necessary.

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

The best most practical solution is definitive regulatory action & comprehensive implementation of EU laws, including improving existing laws, & formulating new ones to systematically reduce all our exposures. Criteria which clearly identify all EDCs without a potency filter will allow the EU to more effectively address the health + environmental threats posed by EDCs.

The leading scientists on endocrine disruption have made clear that enough evidence now exists to justify acting to protect human health + the environment. They have repeatedly voiced their concerns because it is likely that EDCs are contributing to the increasing rates of chronic diseases: infertility, hormonal cancers, learning disabilities + other neurodevelopmental & neurodegenerative disorders, obesity & diabetes.

Those studies of pollution in people (human biomonitoring) have shown

that the general population is typically contaminated with several synthetic chemicals, possibly even hundreds of substances would be found in anyone if they were all to be measured. See e.g.: http://www.eu-hbm.info/democophes

People generally are unwittingly & involuntarily exposed to EDCs on a daily basis from consumer products, air, water, food + indoor environments. It is therefore urgent that exposures should be immediately reduced especially for women before & during pregnancy, for infants, young children, and people during puberty.

HEAL advocates that the EU:

Swiftly establish official European methods for identifying & classifying EDCs (into 3 categories) across all uses/sectors
Overhaul all relevant, existing EU laws to reduce exposure to EDCs
Set out a timetable by which EDCs must be identified, the id tests mandatory, and safer alternatives phased in (including non-chemical ones).
Reform risk assessment process to ensure the characteristics of EDCs are fully reflected in final assessments and risk management decisions
Promote safer alternatives & thereby stimulate safer, greener innovation
Include the phasing out of EDCs in national plans to tackle chronic diseases and other disease prevention efforts
Educate health professionals, medical experts & health affected groups so they can better undertake exposure reduction, clinical research, + participate in policy making.

HEAL believes that strong regulation to protect public health and the environment from EDCs will stimulate safer more environmentally sustainable innovation across all sectors. This will help European industry to provide meaningful safe jobs & superior, safe products, help the EU & the world to move to more sustainable production & consumption, including in agriculture.

HEAL also regrets the format of this public consultation, which it deems overly technical, ill-advisedly slanted towards data from other 'impact assessments' and alienating to the public, in stark contradiction to the enormous importance of this topic for public health. We note particularly that this consultation is oriented overwhelmingly towards the pesticides and biocides laws, in contrast to the Roadmap for defining EDC Criteria, which notes that because EDs are referred to in numerous laws, these criteria should be developed to enable their horizontal application in different legal settings (p.4).

We call upon the Commission, and in particular DG Health and Consumers, and the Health Commissioner to ensure that 1, the most scientifically accurate, rigorous ID criteria are taken, and 2, that the Impact Assessment fully analyse & reflect the benefits from ID Option 3 with regulatory Option A – the health, societal, & environmental benefits of

reduced exposure to EDCs, comparing costs of inaction and lack of innovation in the industries. Because of the inherent difficulties involved in costing such long term benefits Impact Assessment is limited, particularly in quantitative terms. Careful consideration of qualitative evidence must be made, especially for combination & cumulative exposures.

Please provide the reference(s) if possible:

Contact

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