



Submission to European Commission Consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection product regulation and the biocidal products regulation.

Link to consultation:

- http://ec.europa.eu/dgs/health_consumer/dgs_consultations/food/consultation_20150116_endocrine-disruptors_en.htm

NB: We have omitted the initial part of the consultation, which focuses on the individual filling in the consultation form

Part 2

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):*

We are aware of the following 2008 study from the Swedish Chemical Inspectorate (KEMI), "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)." The addendum of this study 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 which 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_positionpaper_annenII_sep08.pdf

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

The table identified 23 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 time. 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.

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

- Yes

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

There are many general studies highlighting the possibility to use less pesticides. These studies focus on more traditional approaches to pest management, including Integrated Pest Management (IPM). IPM is a system that uses current, comprehensive information on the life cycles of pests and their interaction with the environment. This information, in combination with available pest control methods, is used to manage pest damage by the most economical means, and with the least possible hazard to people, property, and the environment. We feel sure that the Commission’s consultants should be able to pull together the vast literature on farming with less chemical pesticide input.

However, as a start e.g. there are the following studies and information sources worth taking into account:

F. Jacquet et al: An economic analysis of the possibility of reducing pesticides in French field crops, *Ecol. Econ.* 2011, DOI: 10.1016/j.ecolecon.2011.04.003

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>

Also for example – a recent review (Ponisio LC, M'Gonigle LK, Mace KC, Palomino J, de Valpine P, Kremen C (2014). Diversification practices reduce organic to conventional yield gap, *Royal Society Proceedings B*, DOI: 10.1098/rspb.2014.1396) highlighted that previous reviews have been biased in favour of high input agriculture, and that organic yields are only about 19.2% lower than conventional ones, a smaller difference than in previous estimates. Moreover, this lower yield could be reduced to just eight per cent if the pesticide-free crops were rotated more frequently. Furthermore, in some crops - especially leguminous plants such as beans, peas and lentils - there were no significant differences in yields. These conclusions were reached after the researchers conducted a meta-analysis of 115 studies, a dataset three times greater than previously published work comparing organic and conventional agriculture.

However, CHEM Trust is not suggesting that in the short term organic farming should be the only way forward, but rather highlighting that pesticide reduction and use of least harmful pesticides is urgently needed in order to reduce the negative impacts on biodiversity and health.

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

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

Many of the pesticides identified will also be those identified under section 2.2 – so please see answers in section 2.2 regarding the socio economic impacts of option 2.

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

CHEM Trust does not favour option 1 because the EU needs comprehensive criteria for identification of all endocrine disrupting chemicals (EDCs) - not only for pesticides and biocides - but also for the regulation of other uses falling under other EU laws, e.g. cosmetics, food packaging etc.. Moreover, the interim criteria do not address all impacts on thyroid hormones and metabolism.

However, if option 1 was to be pursued, it would be important to use the latest science in the field of endocrinology in order to capture the full scope of the interim criterion “toxic to the endocrine organ”. This is also relevant to the decisions on upcoming pesticide and biocide re-evaluations which will have to be taken before the final criteria are decided.

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

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

As mentioned in the Commission roadmap several impact assessments on the cut-off criteria have been carried out by many different organisations, both during and after the negotiations on the PPPR. These include, but are not limited to, impact assessments done by or for

- UK Government departments and agencies,
- the pesticide industry,
- the European Parliament's Committee on the Environment, Public Health and Food Safety. (Ref to contract: IP/A/ENVI/FWC/2007-057/C1/SC2) .

We feel sure that the Commission's consultants will be well able to collate these studies. However, it should be noted that some of them may not be so useful for the current impact assessment because the criteria used for identification may not be clear or may not be relevant as agreed criteria were and are not available.

Moreover, CHEM Trust would like to point out that some of these studies are fatally flawed because:-

- Double counting has been used, in that many of the substances will anyway have to be phased out under the CMR cut-off criteria (using current or future classification).
- We would question some of the underlying assumptions projecting yield losses, which also are often untransparent in many cases.
- Many of the studies imply a comparison of yield drop from intensive agriculture with high use of pesticides as compared to yields without the use of EDCs. However, this is wrong because the comparison should not be with

high input intensive agriculture but rather one following IPM as now specifically required under the EU's Sustainable Use Directive (http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/index_en.htm).

- Many of the studies do not acknowledge that derogation for use of an EDC pesticide is allowed for another 5 years if necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods. This should give industry time to innovate and develop safer options. It should be noted that this innovation will not happen if the legislation is weakened.

Additionally, in answer to the question as to whether we are aware of an assessment of substances identified as endocrine disruptors according to option 2, a couple of other assessments are worth mentioning:

- i) under the EU (REACH) law on chemicals, four alkylphenols have been identified as EDCs, using the WHO/IPCS definition (see ECHA background documents)
- ii) the International Chemical Secretariat ChemSec listed 32 chemicals solely based on their endocrine disrupting properties on the SIN list: www.sinlist.org

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

- Yes

see 2.1.2

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

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

See note under 2.2.1. which highlights that the assessments of the impacts on agriculture have flaws. It is also noteworthy that those impact assessments done by the pesticide industry itself or by countries where there is a large pesticide industry tend to ignore the benefits of reducing pesticide use.

Moreover, past experience should tell the Commission that assessments of the impacts done by, or on behalf of the industry concerned, may be grossly inflated.

We are aware of studies which highlight the benefit of phasing out EDCs, some of which may be identified under options 2 and 3. CHEM Trust considers that it is crucial that all the studies which cost the health benefits should be part of the socio-economic impact assessment.

Some examples are mentioned below:

- 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>

- The Norden Study estimated the cost of male reproductive health problems from yearly exposure to EDCs: Assuming that EDs constitute 2, 20 or 40% the total costs for the selected health effects are 3.6, 36.1 or 72.3 million Euros/year of exposure in the Nordic countries, this corresponds to 59, 592 and 1,184 million Euros/year at EU-level.
- 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
 - The HEAL study estimated that if EDCs 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.
- 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>
 - This study from New York University found that removing BPA from food uses in the US might prevent 6,236 cases of childhood obesity and 22,350 cases of newly incident coronary heart disease per year, with potential annual economic benefits of \$1.74 billion (sensitivity analysis: \$889 million–\$13.8 billion per year).

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

CHEM Trust does not support option 2 as we do not believe it provides the best systematic, science-based approach to the EDC criteria. It lacks the possibility to differentiate between different levels of evidence, which is very much needed to deal with the different kinds and amounts of data available for respective substances. Dropping the WHO/IPCS definition for “potential EDC” would lead to a lack of transparency and ignore a lot of existing research and knowledge (see also our points for option 3).

It also needs to be kept in mind that the EU laws re pesticides and biocides say “may have adverse effects”. This needs to be considered when applying the WHO/IPCS definition. The “**may** have adverse effects” allows a lower level of proof that the substance causes adverse effects. It requires regulation of chemicals where adverse effects are suspected but not proven. Moreover, it allows a lower level of proof that the ED properties are responsible for those adverse effects. The aim should be to establish a plausible link between an adverse effect or a predictor of an adverse effect and an ED mode of action. Ensuring the correct interpretation of the wording of EU law is vital, because if too high a level of proof is stipulated it would delay or prevent being able to conclude a substance is an ED.

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

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

Under the EU Community Strategy on EDCs the Commission services developed a priority list of substances to be investigated further for their possible endocrine disrupting properties. It has been officially noted that this “database containing the information that was used to establish this priority list”.. “has proven useful in providing regulators and researchers with a considerable amount of information on potential endocrine disruptors” and “has been used by a number of stakeholders for prioritization” (SEC(2011) 1001 final). An overview of this work can still be downloaded here:

http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm

It is important that this work should not be lost, particularly in view of its value and the time and resources invested both by paid consultants and by scientists brought in by the Commission.

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.

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

- x Yes

See 2.1.2

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?

- x Yes

See response to 2.2.3

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

CHEM Trust is in favour of option 3. As previously stated in our briefings we support a comprehensive, cross-cutting system with 3 categories (see detailed position and analysis: “CHEM Trust’s Contribution to the Ongoing Debate on Criteria for EDCs”, <http://www.chemtrust.org.uk/wp-content/uploads/CHEM-Trust-Position-on-EDC-Criteria-Sept11.pdf>) and “Proposal for regulation of EDCs under REACH and PPPR” <http://www.chemtrust.org.uk/wp-content/uploads/CHEM-Trust-WWF-EDC-Classification-Paper-Dec-2010.pdf>).

Option 3 is the most transparent option and offers the possibility of categorizing according to different levels of evidence available depending on the data situation.

Instead of calling the third category “endocrine active compounds” we would prefer keeping the WHO/IPCS definition of a potential endocrine disrupter. This category of “potential ED’s is important, for listing substances active in vitro, but where that in-vitro data is considered inadequate to extrapolate to in vivo effects. It also provides a crucial trigger for generating more information. In some cases this will lead to the clarification that an initial concern may not be justified; whereas in other cases the further data may confirm the concern.

In accordance with our comments for option 2 we would like to stress that it will be crucial to respect the legal text which says “may cause adverse effects”. We can’t wait for complete knowledge of all steps in the mechanism of action. The aim should be to demonstrate a plausible link between the likely adverse effects or predictors of adverse effects and an endocrine mode of action.

In addition, we note the following:

- Work done by the JRC ED expert group in assessing substances suspected of being EDCs, based on different available evidence.
- The Danish Centre for endocrine disruptors evaluated 22 SIN list chemicals and proposed respective categories based on the available scientific information (the study can be accessed here: <http://mst.dk/media/mst/67169/SIN%20report%20and%20Annex.pdf>)
- The French Agency ANSES evaluated a range of chemicals and the resulting categories according to different proposals (see table 3, page 22 and 23 of the following document): <https://www.anses.fr/sites/default/files/documents/DPR2011sa0237EN.pdf>

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

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

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>

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

- Yes

see 2.1.2

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

See response to 2.2.3

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

CHEM Trust does not 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.

Part 3

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

Part 4

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

The Commission should make a real effort to consult the public at large. This consultation is only focused on the likely costs to producers of existing pesticides and biocides rather than looking at the costs and benefits for society as a whole. The questions completely ignore the health, environment and societal benefits of reducing exposure to endocrine disruptors, which are likely to be significantly different under the options proposed. We hereby are calling on the Commission 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. 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.

In CHEM Trust's view, 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 are very concerned that the Commission even consults on these options and wonder if this is a breach of their mandate as there is not really a legal basis for proposing changes to the law.

Re Option B, a change of the legal text from negligible exposure to negligible risk is not acceptable because a single substance risk assessment would not prevent effects due to combination effects from exposure to mixtures, including EDCs used in applications other than pesticides.

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 (according to article 4.7).

Moreover, the new EDC criteria will only apply when a substance comes up for review and re-authorisation under the PPPR and BPR. The WHO/UNEP report from 2012 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. In conclusion therefore, the Commission's impact assessment needs to address the benefits of phasing out EDCs. Even if EDCs only contribute a small proportion to the total incidence of the diseases to which they have been linked, the potential health cost savings and benefits for the public are enormous. CHEM Trust therefore considers that this impact assessment should focus on the benefits to public health and innovation rather than this narrow focus of short term costs to the pesticide industry.

Just for clarification: CHEM Trust is an environment and health charity with staff and advisers based in the UK and elsewhere in the EU. We do not offer membership but all our materials are made freely available to the public on our website (www.chemtrust.org.uk).