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

CONSULTATION RESPONSE

Executive summary

Following previous positions and advocacy by the AmCham EU Environment Committee on the issue of Endocrine Disruption, this paper provides the proposed AmCham EU input for the European Commission Public Consultation on defining criteria for identifying Endocrine Disruptors. Answers are provided to the Commission questionnaire relating to the four proposed options for identifying ED's. The questions on the options are repetitive and hence AmCham EUs responses are also repeated where relevant. The essential point of AmCham EU's input is that the WHO definition is an appropriate starting point for identifying EDs, but needs to be supplemented by full hazard characterization (Option 4 Plus), and then risk assessment should be carried out prior to determining appropriate risk management options. The deadline for submission to the public consultation is January 15, 2015.

* * *

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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19 December 2014

1. Information about you

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 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**I ask for confidential treatment of my contribution and do not give consent for publication** (the contribution will not be published and its content may not be taken into account.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:*

Julie Linde Kjeldsen

1.2. Your e-mail address for correspondence:*

jlk@amchameu.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.a. If self-employed, please specify:*
☐Farmer, forester, fisherman
☐Owner of a retail or service outlet, craftsman
☐Professional (lawyer, medical practitioner, accountant, architect)
☐Manager of a company
☐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

1.6.c. If not in formal working arrangement, please specify:*
☐Looking after the home
☐Student (full time)
☐Retired
☐Seeking a job
☐Other

1.7. I'm replying as a(n):*
☐a. Individual/citizen/consumer
☒b. On behalf of an organization

1.7.a.If replying as an individual/citizen/consumer, please specify if your reply is based on your knowledge acquired in your working environment (e.g. private company, NGO, public institution, research) or on general interest:*

☐ i. General interest

☐ ii. Working environment

1.7.a.ii. If you selected working environment, please specify:*

☐ Academic/scientist with main publication area within endocrine disruption or endocrinology

☐ Academic/scientist with main publication area within (eco)toxicology

☐ Other academic/scientist

☐ Public health/medical sector

☐ National authority (responsible for human or environmental health), e.g. government or agencies.

☐ National authorities (other)

☐ Local/regional authority (responsible for human or environmental health)

☐ Local/regional authorities (other)

☐ European Institution/Agency

☐ International Institution/Agency

☐ Chemical Industry

☐ Other private companies/Enterprises /SMEs

☐ Industry or trade association

☐ Non-governmental organisation (NGO)

☐ Consumer association

☐ Other

If other, please specify.*

1.7.b.1. If responding on behalf of a(n) organisation/association/authority/company/body, please provide the name:*

American Chamber of Commerce to the European Union

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):

5265780509-97

1.7.b. Please specify the organisation you represent:*
☐i. Public authority
☐ii. Academic/Research institution
☐iii. Hospital / Health institution
☐iv. Private company
☐v. Agricultural producers (farmers)
☐vi. Consumer / Non-Governmental Organisation
☒vii. Industrial or trade association
☐viii. Other

1.7.b.i. If public authority, please specify:*
☐(1) International institution
☐(2) EU Agency
☐(3) Government authority

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

1.7.b.ii. If Academic/Research institution, please specify:*
☐Public Research
☐Private Research
☐University (including teaching)
☐Other

1.7.b.iii. If hospital/health institution, please specify:*
☐Public

☐Private
☐University (including teaching)
☐Other

1.7.b.iv. If private company, please specify size:*
☐Micro-entity (up to 10 employees)
☐Small company (11-50 employees)
☐Medium sized (51 - 250 employees)
☐Large company (more than 250 employees)

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.*

1.7.b.vii. If industrial or trade association, please specify:*
☒International
☐National

1.7.b.viii. If other, please specify.*

1.8. Your location:*

Belgium

If other, please specify.*

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

☒Metropolitan Zone ☐Other town/urban centre ☐Rural zone ☐Do not want to answer

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

☐Direct experimental scientific research

☐Review of scientific research

☐Use of scientific research for safety assessments

☐Use of scientific research for regulatory purposes

☒Lobbying

☒Other

☐Not involved

If other, please specify.*

Provision of regulatory and scientific information to EU institutions and Member States

1.11. Were you or your organization directly involved in/affected by the EU legislation mentioned below in the past 3 years? (more than one answer possible)*

☒Classification and Labelling (Regulation 1272/2008)

☒REACH (Regulation 1907/2006)

☒Plant Protection Products (Regulation 1107/2009)

☒Biocides (Regulation 528/2012)

☒Water Framework Directive (2000/60/EC)

☒Cosmetics (Regulation 1223/2009)

☒Chemicals Agents Directive (98/24/EC)

☒Other

☐Not involved

If other, please specify*

RoHS, waste, packaging directives, medical devices legislation, etc.

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 status quo includes:

- Interim criteria for biocides and pesticides: category 2 for carcinogenicity and toxicity for reproduction (C2+R2) and category 2 for toxicity for reproduction (R2) associated with toxicity to endocrine organs
- Case by case for substances under REACH article 57(f): substances of equivalent concern with endocrine disrupting properties are evaluated for possible inclusion on the candidate list.

- Under REACH, substance evaluation (CORAP), substances which are suspected endocrine disruptors are evaluated by Member States on a case-by-case basis.

For pesticides, the Commission maintains a database of approved (or non-approved) active substances, which provides established classifications:
http://ec.europa.eu/sanco_pesticides/public/?event=homepage
The European Chemicals Agency website provides the official classification of substances (not limited to pesticides):
http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

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

4,000 character(s) maximum

A list of biocides and pesticides meeting interim ED criteria has not been compiled. The list of substances already classified as R2 or C2+R2 can easily be drawn up from the SANCO or ECHA databases. However, in order to obtain a reliable inventory of substances meeting interim criteria (biocides or pesticides), substances meeting classification criteria but not yet officially classified would have to be added to substances already classified.
Interim criteria will identify a number of substances which are not endocrine disruptors based on the scientific data.
The same outcome would apply if these interim criteria would apply more broadly. This would result in an unjustified stigmatization and deselection of substances.

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

See below

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

4,000 character(s) maximum

For Pesticides: studies on the benefits of azole fungicides show that the family as a whole is the backbone of disease control in a number of key crops, e.g. wheat. No other fungicide family can replace azole fungicides sustainably without developing disease resistance. Therefore substitution should be very carefully considered as a risk management option.
For Substances regulated under REACH: Annex XIV substances for which Authorisation is sought are first assessed for possible risk and adequate control before substitution is considered as a risk management

option. Substances identified as endocrine disruptors with thresholds can be assessed using risk assessment approaches. If found to be safe, Authorisation is granted and substitution is not necessary. Substitution should not be an automatic consideration for endocrine disruptors.
For Phthalates: the low molecular weight phthalates which are classified for reproductive effects (and often cited as endocrine disruptors) have been recommended for authorisation based on risk control and for some uses on socio-economic grounds by the ECHA RAC and SEAC. While Authorisation is time limited and REACH still proposes substitution, for uses where adequate control and safe use have been demonstrated the benefits of substitution are highly questionable.

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

See below

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

4,000 character(s) maximum

It is important to note that the Chemical Industry and downstream users throughout the supply chain continuously assess the socio-economic impact of substitution. They continuously assess trade-offs between performance, health, safety, environmental impact and economic consequences for manufacturers, suppliers and customers. The whole process relies on thorough risk assessments. Because the resulting product represents the best balance between all requirements, component substances often cannot be easily substituted, and this is particularly the case for high volume commodity chemicals which take decades and major capital investment to develop the products and bring them to full commercialization.

Regarding pesticides: a number of studies assess the socio-economic benefits of the azole fungicides or costs of complete phase-out. The main consequences/impact would be that the EU would lose its self-sufficiency in wheat production and no longer be a net exporter. That scenario would lead to disruption in global grain supply and increased price volatility.

Please provide the reference(s) if possible

i. EPPO workshop - http://archives.eppo.int/MEETINGS/2010_conferences/septoria/Triazole_Workshop_Conclusions.pdf

ii. Agronomic and economic impact assessment for possible human health and ecotoxicology criteria for endocrine disrupting substances; Report to Chemicals Regulation Directorate; June 2013 - http://randd.defra.gov.uk/Document.aspx?Document=11346_PS2818finalreportfull.pdf
iii. Evaluation of the benefits provided by and of the effect of losing the azole class of compounds on durum and common wheat production in Italy; Horta, September 2012; http://www.ecpa.eu/article/agriculture-today/assessment-economic-importance-azoles-european-agriculture-wheat-case-stud?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+ECPA+%28ECPA%29
iv. Evaluation of the benefits provided by the azole class of compounds, ADAS; September 2011 - http://www.ecpa.eu/files/attachments/Microsoft%20Word%20-%20ADAS-ECPA%20report%201%20-%20Azoles%20-%2030%20Sep%2011.pdf
v. Evaluation of the agronomic impact of losing azole fungicides in the production of oilseed rape; ADAS, September 2012 – http://www.ecpa.eu/files/attachments/22205_Azoles%20in%20OSR%20ADAS-JKI%20.pdf
vi. Restricted availability of azole-based fungicides: impacts on EU farmers and crop agriculture; IAB; April 2011 - http://www.agribusiness.de/images/stories/pdf/iab_nr_27_triazole.pdf
vii. Overview of the potential impact the withdrawal of azoles – Teagasc; http://www.asktheeu.org/en/request/795/response/2817/attach/6/4th%20Annex.pdf
viii. The assessment of the economic importance of azoles in European agriculture: Wheat case study; Nomisma; June 2012 - http://www.ecpa.eu/files/attachments/Nomisma%20-%20Economic%20importance%20of%20azoles%20in%20Europe%2006.2012.pdf
ix. Potential impact of draft proposal for endocrine disruption criteria, ECPA, April 2013 http://www.ecpa.eu/files/attachments/22658_Agri%20impact%20of%20ED%20criteria%20-%20Update%20Nov%202013.doc

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

4,000 character(s) maximum

In summary, AmCham EU does not support the interim criteria included in the plant protection products and biocidal products regulations since they are not robust science-based criteria for the identification of endocrine disruptors. AmCham EU would also note that risk assessments should be conducted before deciding on risk management options such as substitution. In many cases risk control should be sufficient to allow continued safe use of substances, thereby ensuring minimal health and environmental impacts, while allowing society to continue to have the benefits which the substances bring, and contributing to job creation, growth and competitiveness.

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 themethodology(ies):*

4,000 character(s) maximum

In 2013 the UK HSE evaluated 98 pesticide active substances for potential endocrine disruption using the WHO/IPCS definition.
In the 2000s DG Environment commissioned a study on 500+ chemicals which were evaluated for their potential endocrine activity (latest report: DHI, 2007). It is important to note that the Commission consultant's approach did not follow the WHO/IPCS definition.
Danish EPA prepared annex XV dossiers for four low molecular weight phthalates (DEHP, DIBP, DBP, BBP) for inclusion in the candidate list as endocrine disruptors.

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

4,000 character(s) maximum

14-40% of crop protection active substances were identified as meeting or potentially meeting the definition in the UK HSE study. AmCham EU believes, based on our knowledge, that these would equally apply to other chemicals.
The DHI report suggests that about a third of all substances assessed showed endocrine activity in vivo or in vitro in at least one study.
The Danish EPA dossiers identified four phthalates as endocrine disruptors for health and the environment without fulfilling the requirements of the WHO definition because they do not demonstrate ,to any reasonable degree, a causal relationship between the proposed endocrine mechanism of action and the adverse reproductive effects in rodent studies; they simply assume a relationship between a potential mechanism and adverse effects. In addition, the dossiers identified concerns for wildlife, endangered species and top predators without any robust scientific evaluation and justification.

Please provide the reference(s) if possible:

Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD; © WRc plc 2013 - http://randd.defra.gov.uk/Document.aspx?Document=11345_PS2812finalreportfull.pdf

i. Study in enhancing the endocrine disruptor priority list with a focus on low production volume chemicals – ENV.D.4/ETU/2005/0028r - DHI, May 2077 – http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#report3

ii. Danish Environmental Protection Agency (EPA). 2014a. Annex XV report. Proposal for Identification of a Substance of Very High Concern on the Basis of the Criteria Set out in REACH Article 57. Benzyl Butyl Phthalate (BBP): http://echa.europa.eu/documents/10162/09b7985b-bdbd-4594-874a-ab73ee1a8d70

iii. Danish EPA. 2014b. Annex XV report. Proposal for Identification of a Substance of Very High Concern on the Basis of the Criteria Set out in REACH Article 57. Dibutyl phthalate (DBP): http://echa.europa.eu/documents/10162/d3796777-6d15-4d7a-8ee8-e8eda0aff18f

iv. Danish Environmental Protection Agency, Denmark. 2014c. Annex XV report. Proposal for Identification of a Substance of Very High Concern on the Basis of the Criteria Set out in REACH Article 57. Bis (2-ethylhexyl)phthalate(DEHP): http://echa.europa.eu/documents/10162/04233311-4be2-4a41-8c1b-8e6d0c6fe260

v. Danish Environmental Protection Agency, Denmark. 2014d. Annex XV report. Proposal for Identification of a Substance of Very High Concern on the Basis of the Criteria Set out in REACH Article 57. Diisobutyl phthalate (DIBP): http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/substances-of-very-high-concern-identification/-/substance/6717/search/+/term

2.2.2. 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

Same as 2.1:
For Pesticides: studies on the benefits of azole fungicides show that the family as a whole is the backbone of disease control in a number of key crops, e.g. wheat. No other fungicide family can replace azole fungicides sustainably without developing disease resistance. Therefore substitution should be very carefully considered as a risk management option.
For Substances regulated under REACH: Annex IV substances for which Authorisation is sought are first assessed for possible risk and adequate control before substitution is considered as a risk management option. Substances identified as endocrine disruptors with thresholds can be assessed using risk assessment approaches. If found to be safe, substitution is not necessary. Substitution should not be an automatic consideration for endocrine disruptors.
For Phthalates: the low molecular weight phthalates which are classified for reproductive effects (and often cited as endocrine disruptors) have been recommended for authorisation based on risk control and for some uses on socio-economic grounds by the ECHA RAC and SEAC. While Authorisation is time limited and REACH still proposes substitution, for uses where adequate control and safe use have been demonstrated the benefits of substitution are highly questionable.

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

4,000 character(s) maximum

Same as 2.1:
It is important to note that the Chemical Industry and downstream users throughout the supply chain continuously assess the socio-economic impact of substitution. They continuously assess trade-offs between performance, health, safety, environmental impact and economic consequences for manufacturers, suppliers and customers. The whole process relies on thorough risk assessments. Because the resulting product represents the best balance between all requirements, component substances often cannot be easily substituted, and this is particularly the case for high volume commodity chemicals which take decades and major capital investment to develop the products and bring them to full commercialization.

Regarding pesticides: a number of studies assess the socio-economic benefits of the azole fungicides or costs of complete phase-out. The main consequences/impact would be that the EU would lose its self-sufficiency in wheat production and no longer be a net exporter. That scenario would lead to disruption in global grain supply and increased price volatility.

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 methodology(ies):*

4,000 character(s) maximum

Same as 2.1:
It is important to note that the Chemical Industry and downstream users throughout the supply chain continuously assess the socio-economic impact of substitution. They continuously assess trade-offs between performance, health, safety, environmental impact and economic consequences for manufacturers, suppliers and customers. The whole process relies on thorough risk assessments. Because the resulting product represents the best balance between all requirements, component substances often cannot be easily substituted, and this is particularly the case for high volume commodity chemicals which take decades and major capital investment to develop the products and bring them to full commercialization.

Regarding pesticides: a number of studies assess the socio-economic benefits of the azole fungicides or costs of complete phase-out. The main consequences/impact would be that the EU would lose its self-sufficiency in wheat production and no longer be a net exporter. That scenario would lead to disruption in global grain supply and increased price volatility.

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

4,000 character(s) maximum

Same as 2.1:
It is important to note that the Chemical Industry and downstream users throughout the supply chain continuously assess the socio-economic impact of substitution. They continuously assess trade-offs between performance, health, safety, environmental impact and economic consequences for manufacturers, suppliers and customers. The whole process relies on thorough risk assessments. Because the resulting product represents the best balance between all requirements, component substances often cannot be easily substituted, and this is particularly the case for high volume commodity chemicals which take decades and major capital investment to develop the products and bring them to full commercialization.

Regarding pesticides: a number of studies assess the socio-economic benefits of the azole fungicides or costs of complete phase-out. The main consequences/impact would be that the EU would lose its self-sufficiency in wheat production and no longer be a net exporter. That scenario would lead to disruption in global grain supply and increased price volatility.

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

AmCham EU supports the use of the WHO definition as the starting point for the identification of endocrine disruptors; however the definition is insufficient on its own and should be supplemented by full endocrine related adverse effects characterization using a robust weight of the evidence evaluation process, taking into account causality, human and/or environmental relevance. The use of the IPCS Mode of Action / Human Relevance Framework and the OECD Conceptual Framework for Assessing and Testing (potential) Endocrine Disrupters should be utilized to conduct a weight of evidence assessment of substances by relevant experts.

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 methodology(ies):*

4,000 character(s) maximum

See below

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

4,000 character(s) maximum

See below

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 methodology(ies):*

4,000 character(s) maximum

See below

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

4,000 character(s) maximum

See below

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 methodology(ies):*

4,000 character(s) maximum

See below

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

4,000 character(s) maximum

See below

Please provide the reference(s) if possible:

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

4,000 character(s) maximum

AmCham EU opposes the use of categories since they are not required by any legislation, have no scientific basis and would lead to the stigmatization (black-lists) of substances assigned to them.
The analogy to CMR categories is flawed because endocrine disruption is a mode of action to be causally linked to adverse effects. There is no practical value in regulating those effects twice, via both CMR and endocrine regulation, particularly if threshold information is available.
Categories are likely to lead to additional and unnecessary animal testing to further assess and characterize substances in the second and third categories.
Under REACH EDs identified under article 57f go to the candidate list and 'suspected EDs' would be further evaluated under substance evaluation, therefore there is no need for categories for these substances.

2.4. Questions regarding option 4 *(WHO/IPCS definition to identify endocrine disruptors and inclusion of potency as element of hazard characterisation (hazard identification and characterisation)*

2.4.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 4?*

☒Yes

☐No

If yes, please describe the methodology(ies), including the potency thresholds that applied:*

4,000 character(s) maximum

In 2013 the UK Health and Safety Executive evaluated 98 pesticide active substances for potential endocrine disruption using the WHO/IPCS definition.The HSE also evaluated the effect of potency by using the STOT RE1 threshold as trigger (effects observed below the trigger indicated potency).

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

4,000 character(s) maximum

5-9% of substances evaluated in the HSE study were or could be considered as meeting the WHO definition using STOT RE1 as the threshold for significant potency (against 14-40% if potency is not taken into account).

Please provide the reference(s) if possible:

i. Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by HSE, CRD; © WRc plc 2013 - http://randd.defra.gov.uk/Document.aspx?Document=11345_PS2812finalreportfull.pdf

2.4.2. 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

See 2.1

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

4,000 character(s) maximum

See 2.1

Please provide the reference(s) if possible:

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

☒Yes

☐No

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

4,000 character(s) maximum

See 2.1 for pesticides

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

4,000 character(s) maximum

See 2.1 for pesticides

Please provide the reference(s) if possible:

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

4,000 character(s) maximum

AmCham EU believes that the proposed hazard characterization should not be limited to potency, consistent with sound scientific principles and good toxicological practice hazard characterization is much broader. It should also include severity, reversibility, lead toxicity, specificity, human and population relevance. In addition a robust weight of evidence evaluation process, using the IPCS Mode of Action/Human Relevance Framework and the OECD Conceptual Framework for Assessing and Testing (potential) Endocrine Disruptors should be applied by qualified experts. Once a substance is identified as an ED, risk assessment should be applied before risk management options are decided upon.

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

See Section 4.

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

4,000 character(s) maximum

See Section 4.

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

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

4,000 character(s) maximum

See Section 4.

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

4,000 character(s) maximum

See Section 4.

Please provide the reference(s) if possible:

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

While AmCham EU could consider Options B and C as improvements versus current PPPR and BPR legislation, we believe that the soundest way to regulate any substance, including EDs, is via risk assessment. For PPPR and BPR risk assessment is preferred over regulating by derogation. The same point applies to substances regulated under REACH, meaning that authorisation should not be temporary, or short-term, where adequate control has been demonstrated.

The US EPA has had in place an Endocrine Disruptors Screening Program (EDSP) since 1998 following the recommendations of the Endocrine Disruptors Science and Technical Advisory Committee (EDSTAC). The EDSP involves a tiered screening process for pesticides and many other chemicals including everyday food and drink components such as caffeine. A large number of substances have been identified to go through the tiered screening process, with many substances having gone through Tier I, followed by prioritization for Tier II. The EPA though has stated that it "...does not consider endocrine disruption to be an adverse effect per se, but rather to be a mode or mechanism of action potentially leading to other outcomes, for example carcinogenic, reproductive, or developmental effects, routinely considered in reaching regulatory decisions. Evidence of endocrine disruption alone can influence priority setting for further testing and the assessment of the results of this testing could lead to regulatory action if adverse effects are shown to occur. The current Agency position is consistent with a broad definition of endocrine disruption that must of necessity entail research questions, but also recognizes that regulatory decision-making is generally based on adverse effects using legislatively mandated risk-based criteria." As part of the EDSP test methods are being developed and validated and shared within OECD as appropriate.
This approach is consistent with a robust scientific approach and it will be important for the EU to take into account the approach of trading partners such as the US in order to avoid unjustified impacts on trade including for example on the import of food containing pesticide residues. If the EU does not take a robust scientific approach this may result in pesticides and other substances be proposed for regulation as EDs in the EU but not in the US with the associated implications for trade.

It is important to note that, should the ED cut-off for pesticides be extended to import tolerances (maximum legal concentrations in food or feed items imported into the EU), this would result in massive trade disruption with food trading partners, by severely limiting such imports or making them impossible. The total value of food/feed imported by the EU from countries protecting the corresponding crops with potential ED active substances is in excess of € 60B.

It is important that a robust scientific approach is taken to the identification of endocrine disruptors with risk control based on thresholds when demonstrated. If such an approach is not taken then many imported articles e.g. electrical and electronic equipment, could be impacted if they contain residues of substances which are identified in the EU as endocrine disruptors and for which hazard based substitution may be proposed. This could lead to trade disputes and barriers including when there is no threat to health or the environment based on risk assessment.

Please provide the reference(s) if possible:

Potential Trade Effects on World Agricultural Exporters of European Union Regulations on Endocrine Disruptors - http://www.dtbassociates.com/docs/EUregsEndocrineDisruptorsTradeEffects2-2014.pdf