# ANEC response to the European Commission Consultation on Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation

## Introduction

EU-legislation on biocidal products (Biocidal Products Regulation (EU) No 528/2012 – "BPR") and plant protection products (Plant Protection Product Regulation (EC) No 1107/2009 – "PPPR") requires the Commission to "specify scientific criteria for the determination of endocrine-disrupting properties" of chemical substances. Pending adoption of these criteria, interim criteria for identifying endocrine disrupting chemicals apply.

In this context, the Commission is carrying out an impact assessment according to its standard procedures. More information about the context of this initiative is published in the roadmap: "Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation". The roadmap provides background to this dossier, sets out the scope of the impact assessment, and presents the policy options that are being assessed in the impact assessment.

ANEC gives preference to policy option 3 proposed in the roadmap, which introduces categorisation with known endocrine disruptors as category I (WHO/IPCS definition), suspected disruptors as category II and endocrine active substances as category III.

We report in this document the answers ANEC gave to the online European Commission 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 with the relevant consultation questions.

## Consultation question 2. Options for criteria for determination of endocrine disrupting properties

The roadmap defines 4 different options for the establishment of criteria for determination of endocrine disrupting properties.

**2.1. Questions regarding option 1 (No policy change (baseline). The interim criteria set in the plant protection products and biocidal products regulations continue to apply. No other criteria are specified).**

2.1.1. Have you conducted or are you aware of an assessment of substances which would be identified as endocrine disruptors according to option 1?

☐ Yes

☑ No

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

☐ Yes

☑ No

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

☐ Yes

☑ No

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

*ANEC Response:*

Option 1 is inadequate for several reasons:

1) the interim "criteria" are just provisional and questionable, it remains unclear what "endocrine disrupting properties" means, they are limited in scope (cancer, reproductive toxicity) for good reasons the Commission was requested to provide scientific criteria by both Regulations;

2) scientific criteria for the identification of EDCs are needed also for other legislation, particularly to establish regulatory provisions for EDCs in consumer products such as toys, child use and care articles, medical devices, cosmetics, food contact materials and so forth.

Option 1 ignores consumer protection.

**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

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

☐ Yes

☑ No

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

☐ Yes

☑ No

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

*ANEC Response:*

Option 2 is not supported by ANEC as the WHO/IPCS definition is in conflict with EU legislation (PPPR and BPR refer to chemicals which "may" cause adverse effects) and will most likely disregard potential hormone disrupting chemicals. In view of the state-of-the-art (difficulties to prove a causal relationship between exposure to EDCs and adverse effects, uncertainties associated with the assessment of EDCs) a precautionary approach is needed. Hence it is necessary to go beyond the WHO/IPSC definition.

**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

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

☐ Yes

☑ No

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

☑ Yes

☐ No

If yes, please describe the methodology(ies):

*ANEC Response:*

The Health and Environment Alliance (HEAL) published the report "Health costs in the EU - How much is related to EDC" in June 2014. The report compiles a cost calculation for a list of diseases that are related to the human endocrine system.

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 outcome(s) of the assessment(s):

*ANEC Response:*

The HEAL study estimates the total costs in the EU for the selected diseases such as fertility problems, cancer of breast, prostate and testes to 636 - 637.1 billion € per year. However, this could be a gross

underestimate as figures were not available for all endocrine-related health problems.

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

*ANEC Response:*

Option 3 broadening the WHO/ICPCS definition (used as first category - confirmed EDCs) by adding two additional categories (suspected and potential EDCs) is the only option which can be supported by ANEC. This approach is in line with current classifications (CMR cat. 1A, 1B and 2) defined in EU legislation which have shown their usefulness in practice. Thus, rulemaking could make use of these three EDC categories in the same way as it is done for CMRs (e.g. to eliminate one, two or all categories of EDCs from products depending on the user group and exposure patterns). Of course, the corresponding criteria for assigning a chemical to a certain category need to be defined as well. The categorisation system including the corresponding criteria will have to be used in all relevant legislation (REACH, CLP, product legislation).

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

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

☐ Yes
☑ No

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

☐ Yes
☑ No

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

☐ Yes
☑ No

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

*ANEC Response:*

ANEC strongly opposes option 4 with the addition of "potency" as a cut-off as this would be even a step backwards compared to the restrictive WHO/IPCS definition. Proposals to deal with endocrine disrupters on the basis of potency-based cut-off values are scientifically highly questionable and controversial. To quote Kortenkamp (from "State of the art assessment of endocrine disruptors", 2012): "Such values are largely arbitrary and not scientifically justifiable". There is nothing to add!

**Consultation question 3. Options for approaches to regulatory decision making**

The roadmap defines 3 different options for approaches to regulatory decision making. Option A (no changes of the existing provisions in BPR and PPPR), Option B (introduction of further elements of risk assessment) where necessary and desirable to reduce potential socio-economic impacts, and Option C (introduction of further socio-economic considerations) where necessary and desirable to prevent adverse socio-economic impacts.

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

☐ Yes
☑ No

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

☐ Yes
☑ No

## 4. Other information

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

*ANEC Response:*

With regard to the options for regulatory decision making as outlined in chapter 3, ANEC can only support option A: No changes of existing provisions in BPR and PPPR. Both alternatives would not only constitute a step backwards but also undermine democratically agreed legislation in the EU.

We also challenge the inherent bias in this consultation ignoring the benefits of stricter regulation of EDCs.

# About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 33 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.

***Raising standards for consumers***

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