# Position paper

**on European Commission's proposal for criteria to define Endocrine Disrupting Chemicals (EDCs) and Draft Delegated Act setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Biocidal Products Regulation (BPR) and Plant Protection Products Regulation (PPPR)**

July 28th 2016

WECF International has been acting for years as an international network of women's and environmental organizations, to advocate for the protection of human health from harmful exposure to chemical contaminants. For a decade, we have become concerned about the widespread exposure of populations to endocrine disrupting chemicals (EDCs), in everyday products and in our daily environment. We are much concerned about the approach to identify EDCs proposed by the European Commission in its communication of June 15th 2016, since it fails to provide a sufficient level of protection of populations and ecosystems from known and potential EDCs. As a member of the *EDC-Free Europe Coalition*, WECF would like to reassert that adequate criteria to identify EDCs are essential to allow EU regulations to properly address EDCs, and a key step towards the phase-out and substitution of known and potential EDCs. A number of scientific experts including members of the *Endocrine Society*, have expressed their concerns that the current European Commission's approach fails to protect human health from EDCs.

## 1) EDCs criteria shall provide a high level of protection of human health

### General principles governing EU law:

EDCs criteria must respect the key principles incorporated in the Treaty of Functioning of the European Union (TFUE) and Treaty of the European Union (TUE), which underpin all EU secondary law, in particular the following:

- "*In defining and implementing its policies and activities, the Union shall take into account requirements linked to the* […] *protection of human health*." (Article 9, TFUE)
- "*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*" (Article 168.1, TITLE XIV- Public Health, TFUE)

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**Biocidal Products Regulation provisions:**

Recital 4 of Biocidal Products Regulation (BPR) (EU) No 528/2012 states that: "*To ensure high level of protection for human health, animal health and the environment, this regulation should apply without prejudice to Union legislation on safety in the workplace and environmental and consumer protection.*"

As a consequence, the Commission's chosen criteria must take into consideration various elements, which make the high level of protection of human health consistent, including: the precautionary principle, the protection of the most vulnerable populations, the consideration of the latest scientific evidence available.

## 2) EDCs criteria shall be underpinned by a precautionary principle approach

**Provisions of the Treaty on Functioning of the European Union (TFUE):**

- Article 191 of the TFUE states that "*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay."*

**Provisions of the Biocidal Products Regulation (BPR):**

- Recital 3 states that "*This Regulation should be underpinned by the precautionary principle*"
- Article 1 states that "*The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment*."

Arguments developed below illustrate elements which may reinforce the use of the precautionary principle as part of EDCs scientific criteria.

## 3) EDCs criteria shall protect the most vulnerable populations, such as pregnant and nursing women, the unborn, infants and children

The protection of the most vulnerable populations is a key principle of EU health policies, and chemical policies. Many provisions of chemical regulations relate to this specific need to protect pregnant women, the unborn and children. This is especially relevant in the case of EDCs: during the last decades, scientists, researchers and health professionals have pointed out that early life, i.e. prenatal and perinatal periods of development are windows of particular sensitivity to chemical contaminations.

**Provisions of Biocidal Products Regulation:**

- Recital 3 states that: "*Particular attention should be paid to the protection of vulnerable groups, such as pregnant women and children*"

**Publications provide a range of scientific and medical evidence on the need to protect vulnerable groups from EDCs:**

- *Developmental origins of non-communicable disease: Implications for research and public health,* Robert Barouki, Peter D Gluckman, Philippe Grandjean, Mark Hanson and Jerrold J Heindel, Environmental Health 2012 12:42,
- *State of the science of Endocrine Disrupting Chemicals*, World Health Organization, United Nations Environment Programme, 2012
- *International Federation of Gynecology and Obstetrics opinion on reproductive health impacts of exposure to toxic environmental chemicals*, Gian Carlo Di Renzo, Jeanne A. Conry, Jennifer Blake, Mark S. DeFrancesco, Nathaniel DeNicola, James N. Martin Jr., Kelly A. McCue, David Richmond, Abid Shah, Patrice Sutton, Tracey J. Woodruff, Sheryl Ziemin van der Poel, Linda C. Giudice, International Journal of Gynecology and Obstetrics, December 2015, Volume 131, Issue 3, Pages 219–225.

**Proposed amendment** to draft delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012:
In Annex I, section A.1. (1): add the mention "*its progeny*"

- protecting early life (including the unborn) from EDCs exposure means protecting future generations, at risk from suffering from indirect exposures to EDCs, as shown by the historical case of DES (diethylstillbestrol),

- WHO/IPCS definition proposed in 2002 expressly mentions the progeny as a potential target of EDCs.

## 4) EDCs criteria shall cover known, presumed and suspected substances and mixtures

A high level of proof shall not be required to trigger classification as "EDCs". Indeed, as with other categories of toxics already regulated by EU legal acts, including CMR (carcinogenic, mutagenic and reprotoxic compounds) regulated by Regulation 1292/2008, there shall be a possibility to classify as EDCs, substances and compounds which are not know, but as well presumed and suspected EDCs.

Currently, criteria proposed in section 1 of Annex of Commission's draft delegated regulation setting out criteria for the determination of EDCs pursuant to BPR, fail to address presumed or potential EDCs, which is contrary to the spirit, principles and provisions of BPR.

The draft delegated acts proposed by the Commission, by not addressing presumed or suspected EDCs, do not respect the scope and objectives of the BPR and PPPR. According to BPR, the Commission's mandate is only to draw up acts "*specifying scientific criteria for the determination of endocrine-disrupting properties*". Therefore, current Commission's proposal exceeds its mandate.

**Provisions of Biocidal Products Regulation:**

- Article 5(1)(d) of the BPR on exclusion criteria states that: "*active substances which, on the basis of the criteria specified pursuant to first paragraph of paragraph 3 […] are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are* identified in accordance with articles 57(1) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;"

**Scientific publications supporting a classification of EDCs in several categories:**

- *Scientific Issues Relevant to Setting Regulatory Criteria to Identify Endocrine Disrupting Substances in the European Union*, Rémy Slama, Jean-Pierre Bourguignon, Barbara Demeneix, Richard Ivell, Giancarlo Panzica, Andreas Kortenkamp, and Thomas Zoeller, Environmental Health Perspectives, DOI:10.1289/EHP217

**Proposed amendment** to draft delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012:
In section A. 1. (1): after "it is known", add: "it is presumed or suspected to…"

- To be coherent with the usual 3 categories used in the classification of chemicals classified for their hazardous properties under EU regulation,
- WHO/ICPS definition of EDCs released in 2002 defines a "potential ED", which shows the importance and relevance of addressing this category

## 5) EDCs criteria shall reflect a Systematic Review of Science approach

WECF would like to express its support to the recent Open Letter by a group of scientists and experts working on EDCs, sent to Commissioner Vytenis Andriukaitis on July 6th, which shares *a proposed framework for the systematic review and integrated assessment (SYRINA) of endocrine disruptors*, and which has been published in *Environmental Health*. In particular, we would like to underline and support the following:

- EDCs criteria shall ensure that data from animal studies are considered in evaluating potential harmful effects on human health, since evidence of harm in animal studies has been for long proven to be relevant for classification of other categories of toxic chemicals, substances and mixtures, including carcinogenic and reprotoxic substances. IARC, the International Agency for Research on Cancer, considers that "animal studies generally provide the best means of assessing particular risks to humans" (*Legally poisoned*, Carl F. Cranor, 2011, p. 70)
- Animal studies have the advantage to provide shorter latency periods, which allows to identify chemicals of concern earlier; The similarity in cellular and organ function across species is relatively strong among mammals, which allows reliable extrapolation (*Legally poisoned*, Carl F. Cranor, 2011, p. 65-66 )
- Relying to epidemiological studies only would mean a too high burden of proof and would require to wait many years before a substance can be classified as EDC, allowing it to contaminate humans and the environment during unacceptable periods of time,
- A systematic review approach, as presented by the authors of SYRINA proposal, would allow to use the best conducted studies, and therefore avoid to give more weight to studies conducted according to internationally agreed protocol, as currently envisaged by the Commission.

**Proposed amendment** to draft delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012: EDCs criteria should be revised and redrafted accordingly to reflect these concerns and considerations.

## 6) EDCs criteria shall encompass all characteristics which are specific to EDCs, compared to other categories of toxics

Despite similarities with other categories of toxic compounds, EDCs have certain own characteristics, which shall be specifically taken into account, and better integrated in proposed Commission's definition of EDCs criteria, such as (non-exhaustive):

- epigenetics effects
- transgenerational effects
- mixtures effects
- low-dose effects
- nonmonotonic dose responses

**Scientific publications providing evidence on the above:**

- *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, Vandenberg LN, Colborn T, Hayes TB, Heindel JJ, Jacobs DR Jr, Lee DH, Shioda T, Soto AM, vom Saal FS, Welshons WV, Zoeller RT, Myers JP, Endocr Rev. 2012 Jun;33(3):378-455

**Proposed amendment** to draft delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012: EDCs criteria should be revised and redrafted accordingly to reflect these concerns and considerations.

## 7) EDCs criteria applicable to PPPR should reinstall the notion of "negligible exposure" and not shift to a "negligible risk" approach

The Commission proposal goes beyond its mandate, since it does not respect article 3.6.5.1 of Annexe II of PPPR provisions, which are based on "negligible exposure" considerations to grant authorization of active PPP substances. By doing so, the Commission shifts from a hazard-based to a risk-based approach, and introduces a major change to the PPPR, going beyond its mandate.

This hazard-based approach would as well be consistent with the approach recommended for EDCs criteria, as expressed by several Member States, including a note by the French delegation shared during Biocides Competent Authorities meeting of My 2016 (agenda point 7.7).

**Proposed amendment** to draft delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 1107/2009: reinstall the notion of "negligible exposure" as originally stated in the PPPR.

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