



PAN-EUROPE'S POSITION ON EDCS-ROADMAP

“Position on the roadmap published by the European Commission (COM)¹ to outline the options considered in the establishment of the criteria for Endocrine Disrupting Chemicals (EDCs)”

COMMENTS ON THE ROADMAP

The roadmap, as a regulatory tool, outlines the options considered by the COM to establish the criteria for the definition of EDCs in the context of ‘putting into force’ the Plant Protection Product Regulation PPPR (EC) 1107/2009 and Biocide Products Regulation BPR (EC) 528/2012.

THE “HORIZONTAL” APPROACH

EDCs are also included in other legislations (REACH, Water Framework Directive, Medical Devices, Cosmetics) and therefore the COM proposes a “horizontal” approach to apply the criteria in the wider legislation. The definition of EDCs must be universal; a chemical is an endocrine disruptor regardless of its purpose of use (as a pesticide, biocide, plastic components, personal care product or pharmaceutical). Thus, the COM must adopt common criteria to identify EDCs across legislations. However, applying a horizontal approach in the regulatory processes will jeopardize the effectiveness of PPP and BP regulations. PPPR and BPR are the only regulations that consider “hazard based” “cut-off” criteria for EDCs- that means **if a substance is an EDC, it will not get authorized for pesticide/biocide use**. There are some exceptions, with BPR embracing further risk and socio-economic considerations than PPPR, to allow the use of such substances, despite their EDC properties. REACH, WFD and Cosmetics however, do not have “cut-off” criteria. Thus, by applying a “horizontal” approach, as the roadmap implies, risk assessment and socioeconomic elements will be added in the decision-making of PPPR and probably additional such elements in BPR. This will undoubtedly water-down the PPPR legislation. As a result, such chemicals will be used on the crop fields and will end up in our food putting consumers’ health, especially babies and children, at risk.

¹ http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf



THE POLICY OPTIONS

The commission is considering 4 options to identify EDCs and 3 options for the regulatory decision making of these substances.

PAN-Europe highlights that what makes EDCs particular in comparison to other toxic substances is that **they are biologically active in very low concentrations**, comparable to the internal hormonal levels and that **their effects are mostly evident when exposure takes place during the early developmental stages, they may only become evident later in adult life and may also pass on to the next generations**. Adverse effects may also be observed in adults but both the nature of the effects and the dose of response may be different from juveniles. This demands changes in the international regulatory approach (Risk assessment) toward toxic substances that, to date, lack the tools to detect effects in the multi-functional endocrine system. Risk assessment of chemicals is still majorly based on short or long-term toxicity testing measured by a decrease in the “well being” of animals, such as a decrease in body and organ weight to identify a “no observed effect level” (NOEL) under which exposure may be considered safe. Such tests overlook the network of mechanisms that lead to toxicity. In relation to EDCs, there is an overall consensus within the scientific community whether a measurable NOEL (threshold) even exists during developmental stages, making the current decision-making on toxic substances inadequate for EDCs². Considering the lack of knowledge and specific tools to identify EDCs, a non-threshold precautionary approach should be applied for EDCs (similar to the one applied for carcinogenic compounds), which is also known as “hazard-based approach”.

The identification of EDCs; The criteria:

The identification of the correct criteria is crucial for the proper regulation of these substances and should be based on the current state of science of EDCs. All the options BUT option 3 will fail to protect human from exposure to these substances.

- **Option 1: No policy change (baseline). No criteria are specified. The interim criteria set in the BPR and the PPPR could continue to apply.**

“No specific criteria” means that EDCs will be identified using the current interim criteria³ that are not addressing specifically the effects arising from alterations in the

² Munn S., Goumenou, M., Report of the Endocrine Disrupters - Expert Advisory Group (ED EAG): Thresholds of Endocrine Disrupters and related uncertainties. Joint Research Center of the European Commission, Scientific and Policy reports 2013, <http://publications.jrc.ec.europa.eu/repository/handle/111111111/32062>

³ The commission decided (Annex II 3.6.5) that until the criteria to identify EDC are established, these substances will be temporarily identified within PPPR and BPR using the “interim criteria” addressed in CLP regulation (EC) No 1272/2008 for carcinogenic category 2 and toxic for reproduction category 2. In addition, substances such as those that are or have to be classified, in accordance with the provisions of



endocrine system. Substances with EDC properties that are not carcinogenic or toxic to reproduction may be left out (for example substances affecting the thyroid, brain function, behaviour or the energy metabolism that could trigger obesity and diabetes).

- **Option 2: WHO/IPCS definition to identify endocrine disruptors (hazard identification):**

This option uses the first part of the WHO/IPCS definition on endocrine disruptors: **“Endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.”**

And it totally neglects the second part of the WHO/IPCS definition: **“a potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub) populations”.**

The PPR and BP Regulations require that “substances having endocrine disrupting properties which **may cause adverse effects** will not be approved for the respective use”, adding this extra element “*may cause*” of precaution in the legislation. The regulations aim to ban both endocrine disruptors and potential endocrine disruptors because they recognize that in both cases these chemicals are a threat towards human and wildlife (also concluded in the WHO report “State of the science of endocrine disrupting chemicals” 2012).

The WHO/IPCS reports of 2002 and 2012 are the result of the work of experts from the international scientific community of endocrine disruption research. The definition is divided into two parts to reflect the current scientific knowledge of the endocrine system and endocrine disruption. We know very little about the endocrine system of humans and other mammals, particularly during early developmental stages and even less for other vertebrate and invertebrate species. Thus, by focusing only on the first part of the WHO definition and having one category where only “clear evidence of endocrine-mediated adverse effects” are considered means that substances that alter the hormone levels but the adverse effects are not fully understood yet or the mechanism of action is still under investigated will not be identified as EDCs.

- **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: endocrine disruptors, suspected endocrine disruptors, endocrine active substances.**

Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties (this is only applied for Pesticides and not for Biocides).

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Creating classes is the best option as it will capture a wider range of substances with EDC properties and will allow space for regulative decision-making based on human and environmental exposure to EDCs. It will also detect the gaps of knowledge for specific substances that could be EDCs, which can act as an “early-warning” for the manufactures and industry to disregard or gradually replace such chemicals.

However, extra caution is needed in the regulation of these three options as substances falling into category 2 or 3 may not be regulated due to lack of understanding of the adverse effects. For regulatory purposes, PAN-Europe proposes two categories 1) EDCs and potential EDCs and 2) Indicated EDCs (where there are indications of endocrine disruption but adverse effects and mode of action are not understood yet and further research is necessary).

- **Option 4: WHO/IPCS definition to identify endocrine disruptors and inclusion of potency as element of hazard characterization (hazard identification and characterisation).**

Potency doesn't belong in the criteria; it is a risk assessment element used in the characterization rather the identification of a hazard. Nevertheless, at the current stage of knowledge, potency is irrelevant for the definition of EDCs. Potency describes the strength of a chemical to give a specific effect. Endocrine disruption is not a specific endpoint (effect) but a network of mechanisms that lead to deferential endocrine-related diseases (deformities and cancer of the reproductive organs, cognitive dysfunction, obesity, diabetes). Strong and weak triggers on specific sites may equally result in the development of disease and therefore potency cannot be used as an indicator to characterize the severity of the adverse effect. For example, a chemical that weakly imitates the function of the female hormones may strongly inhibit the neuronal signals in the brain leading to mental disorders. Further, potency will vary not only in different sites of the endocrine system but also among old and young individuals and across different species.

The regulatory decision-making approaches:

- **Option A: No policy change (Baseline). The provisions in the BPR and the PPPR on regulatory consequences are not changed.**

Both the PPPR and BPR legislations are very clear in the regulatory decisions that have to be taken (hazard-based cut-off criteria approach) and therefore no amendment is required, apart from defining the criteria. Thus, if a substance has EDCs properties that **may cause** adverse effects it will not be approved, unless it falls under the



specific exceptions as explained in PPPR Article 4(7)⁴ Annex II, 3.6.5.⁵ and 3.8.2.⁶, and in BPR Article 5(2)⁷.

- **Option B: Introduction of further elements of risk assessment into sectorial legislation**

This option proposes to apply “negligible risk” rather than “negligible exposure” for both biocides and pesticides. This change in words is crucial, as a negligible risk does not mean that the exposure is negligible, rather, the probability of adverse effects occurring from exposure is low (exposure doesn’t need to be negligible). In both terms, “negligible” requires the existence of a threshold value below which the exposure to these chemicals will be negligible and the risk will be zero. Expanding this exception means that EDCs will be treated as chemicals with clear NOEL (No observed effect level), which, as scientific evidence demonstrates, is not the case for these chemicals, when organisms are under development. If the regulations assume that EDCs have a safe limit of exposure, they will fail to protect humans and wildlife from these peculiar chemicals. Further, for the biocides, the regulation dictates that there shouldn’t be a release into the environment, which is impossible to adapt to

⁴ PPPR (EC) 1107/2009 Article 4 (7): “By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.”

⁵ PPPR (EC) 1107/2009 Annex II 3.6.5: “An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.”

⁶ PPPR (EC) 1107/2009 Annex II 3.8.2: “An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.”

⁷ BPR (EU) 528/2012 Article 5 (2): Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:

- (a) the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;
- (b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or
- (c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.”



pesticides, since they are used in the open environment (this option is only for the benefit of the industry).

- **Option C: Introduction of further socio-economic considerations, including risk-benefit analysis, into sectorial legislation.**

This option proposes to introduce further socio-economic considerations including risk-benefit analysis (amending the PPPR to include elements of BPR, or further such elements to both), where an EDC may be “essential” to prevent adverse socio-economic impacts. BPR refers to the social impact that banning an active substance may have due to the spread of life-threatening pests, germs or bacteria. *Social impact is measured in economic terms.* From a human health perspective, it is absurd to apply this derogation to PPPR, since in this case pesticides are used to protect plants and not humans. The withdrawal of a “plant protection product” from market and use is not life threatening in any case. If this derogation is applied, it means that the economic loss from withdrawing a pesticide from the market will be a reason to refuse its withdrawal even though adverse health effects have been demonstrated.

THE ASSESSMENT OF THE IMPACT OF EACH OPTION

EU criteria

- By following a horizontal approach to regulate EDCs across all legislations, the different sectors will inevitably be affected in a different way. The main objective of PPPR and BPR is to remove these hazardous substances from pesticides and biocides that come in contact with humans and the environment regardless of the impact on the other legislations. **The most favourable criteria are the ones that will capture all substances with EDC properties** and not those that require the least modification of the other legislations.

Approaches to the regulatory decision-making

- In relation to option A (no policy change in regulatory consequences), the fact that the differences in regulatory approaches will persist is not a reason to change the PPPR. If a harmonization is required then REACH, Cosmetics and Medical Devices Regulation should change to adapt to a hazard based cut-off criteria approach in relation to EDCs, where necessary.
- In option B the impacts are evaluated in terms of the market, i.e. impacts on the availability of substances on the market will be less than option A. Whether there is an impact on the market or not it is irrelevant to the protection of human health and wildlife.
- In option C the impact on the availability of a substance on the market is even less because further socio-economic parameters are introduced. Once again the impact on the market is irrelevant to the protection of human health.

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CONCLUSIONS

Both PPPR and BPR have been developed following the advice and hard work of experts and have been approved by the European Parliament and the European Council. The only step left is to identify the criteria to identify EDCs and proceed to the regulation of these substances. Several scientific panels (WHO, JRC, Endocrine Society) have provided scientific evidence that these chemicals should not be treated like the classic toxic compounds but further regulatory action is needed to protect human and environmental health. The suggestion of selecting only the partial definition of EDCs, adding potency, neglecting scientific evidence of “no threshold”, adding risk assessment and socioeconomic elements to the PPPR and further such elements to the BPR shows that the COM is acting against the scientific proof and will fail to fulfil its commitment to protect human health and the environment against these chemicals. This makes the COM unreliable and untrustworthy to the European citizens.

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