PAN-Europe's position

"Position on the roadmap published by COM[1] to outline the options considered in the establishment of the criteria for Endocrine Disrupting Chemicals (EDCs)"

Comments on Road Map

The main objective of the roadmap is to establish the criteria for identifying EDCs in the context of Plant Protection Product Regulation (PPPR) and Biocide Products Regulation (BPR) implementation. Since EDCs are referred in other legislations as well (REACh, Water framework directive, Medical devices, Cosmetics) the COM proposes a "horizontal" approach to apply the criteria in the wider legislation. PPPR and BPR are the only regulations that consider "hazard based cut-off criteria" for EDCs (if a substance is an EDC, it will not be authorized), however BPR has more exceptions (derogations/ risk and socio-economic considerations) to allow the use of biocides even though they have EDC properties and so does REACH and the other regulations. Thus, applying a "horizontal" approach as the roadmap implies, means that risk assessment and socioeconomic elements will be added in the decision-making, to PPPR and probably additional such elements to BPR, to allow the use of EDCs, which will jeopardise the effectiveness of the PPPR legislation and therefore our food from conventional farming will still contain considerable levels of EDC pesticide residues.

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 **their effects are mostly evident when exposure takes place during the early developmental stages and they may only appear when the organism reaches adulthood and may persist in the next generations**. Adverse effects may be observed in adults as well 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 (OECD) toward toxic substances that, to date, are incapable to detect effects in all the sections of the endocrine system and are still mainly based on "acute" toxicity testing (short-term) to identify a "no observed effect level" (NOEL) under which exposure may be considered safe. In relation to EDCs, there is a strong debate within the scientific community whether a measurable NOEL (threshold) exists during developmental stages, making the current

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

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decision-making on toxic substances inadequate for EDCs[2]. Thus, based on the precautionary principal, a non-threshold approach should be applied for EDCs.

The identification of EDCs, the criteria:

None of the options, as they are under the EU criteria to identify EDCs, will provide the correct identification of these substances (criteria).

- Option 1: No specific criteria means that EDCs will be identified using the current interim criteria[3] that are not addressing specifically effects arising from alterations in the endocrine system and therefore substances with EDC properties may be left out.
- Option 2: 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, having one category where only "clear evidence of endocrine-mediated adverse effects" are considered means that substances that alter the hormone levels but adverse effects are not fully understood yet or linked to the observed changes in the endocrine system will not be identified as EDCs.
- Option 3: Creating classes will allow space for regulative decision-making and will capture a wider range of substances that further investigation is needed. However, the proposed option 3 is too wide and substances falling into category 2 or 3 may not be regulated. PAN-Europe proposes two categories 1) EDCs and suspected EDCs and 2) potential EDCs (where the adverse effects are not understood yet and further research is necessary).
- Option 4: Potency should be dismissed from the criteria; potency is a risk assessment element used in the characterization rather the identification of a hazard.

The regulatory decision making approaches:

- Option A. 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. 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 Annex II, 3.6.5.[4] and BPR Article 5(1d2)[5].

[2] Munn S., Goumenou, M., Report of the Endocrine Disrupters - Expert Advisory Group (ED EAG): Thresholds of Endocrine Disprupters 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 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 Carc. 2 and Repr. 2.

[4] PPPR (EC) 1107/2009 Annex II 3.4.5: "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."

[5] BPR (EU) 528/2012 Article 5 (1d): "active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and

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- Option B proposes to apply "negligible risk" rather than "negligible exposure" for both biocides and pesticides. Both terms require the existence of a threshold value below which the exposure to these chemicals will be negligible and the risk will be zero. Expanding this derogation means that EDCs will be treated as chemicals with clear NOEL, which, as scientific evidence demonstrates, it is not the case. Thus, the regulation will fail to protect humans and wildlife from these trivial chemicals. Further, for the biocides, the regulation dictates that there shouldn't be a release into the environment, which is impossible to adapt to pesticides, since they are used in the open environment (this option its only for the benefit of the industry).
- Option C proposes to introduce further socio-economic considerations including risk-benefit analysis (amending the PPPR to include elements of BPR), 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.

The assessment of the impact of each option

EU criteria

- By following a horizontal approach on EDCs across all regulations it is inevitable the different sectors to 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 those that require the least modification of the other legislations.

Approaches to 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 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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third subparagraphs 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(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties"

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Conclusions

The both PPPR and BPR have been developed following the advice and hard work of experts. Suggesting to add risk assessment and socioeconomic elements to the PPPR and further such elements to the BPR reveals that the COM is unreliable and untrustworthy.

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