SAFE POSITION PAPER

On endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products

About SAFE – *Safe Food Advocacy Europe*

SAFE is a non-profit European independent organisation based in Brussels, in charge of improving the representation of ordinary citizens in the EU debate concerning the future of EU food legislation.

SAFE members are consumer associations, vegan and vegetarian associations spread across different EU countries. To date our membership collectively represents the voice of approximately 8,000,000 European consumers.

The core mission of SAFE is to influence the future of European food legislation in favour of European consumers' interest through policy advocacy and outreach.

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Context

Almost three years later than legally expected, the European Commission proposed its definition of endocrine disruptors (EDs), along with a set of scientific criteria for the determination of endocrine disrupting properties. It came in the form of two drafts aimed at amending legislation on plant protection products (EC 1107/2009) on the one hand, and legislation on biocidal products (EU 528/2012), as well as a Communication and an Impact Assessment.

The multiplication in the past years of research results pointing at EDs' responsibility in the development of various diseases and health problems amongst humans had indeed been stressing more and more the relevance of drafting clear and protective legislation on the matter. Furthermore, the publication in 2002 by the WHO of its own definition – widely recognised within the scientific community since then – should have even more prompted EU legislators to act fast, and thus make the EU the first regulatory system in the world to set scientific criteria in its legislation.

Yet, SAFE deems the current result to be controversial, as it potentially threatens the EU's precautionary principle, and thus citizens' health, whereas the latter should however be the prime focus of this legislation. SAFE indeed argues that, first, the proposed amendments and definitions actually allow for too much room for exceptions and, second, they increase the burden of proof so heavily that it would become very hard for a given substance to meet the criteria set up by the European Commission.

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Here below there is a lists of the main concerns:

- **A statement calling for clearer and stricter rules regarding exemptions to the hazard-based approach, in order to uphold the EU's precautionary principle**

Currently, while the rule regarding market authorisation for substances is to use a hazard-based approach (looking at their intrinsic dangerousness), the legislation gives way for exemptions. In the case of the biocidal products legislation, exceptions are allowed on the base of "negligible risk", while in that of plant protection products there are two possibilities to avoid exclusion from the market: either based on "negligible exposure", or based on a serious danger to a plant's health.

In its Communication, the Commission asserts the rules for exceptions in the case of plant protection products should change and match those of biocidal products, and thus switch towards a risk-based approach. The Commission claims this idea to be supported by the European Food Safety Authority, and adds that "[s]cientific and technical knowledge has been evolving and suggests that endocrine disruptors in this area could be assessed based on risk, like most other substances".

SAFE is critical of such a change, for numerous reasons. First, the study of "risk" and "exposure" is a very complicated one, as a substance's impact on health can vary greatly from one individual to another depending on their intrinsic characteristics as well as the length and mode of exposure; allowing exceptions to be made on the ground of such uncertain and difficult studies thus jeopardises consumers' health, as well as the precautionary principle.

Second, the Commission's claim that "scientific and technical knowledge has been evolving" and therefore points towards a risk-based approach for exceptions is not supported by any data or evidence which could support it, while it appears nonetheless to be the core of the Commission's decision. SAFE thus urge the Commission to provide more date supporting this claim, or else avoid bending this rule.

Finally, allowing a substance to remain in the market if the exposure risk is negligible and if its use is necessary to a certain plant's health should not constitute a base for further exceptions, unless commercial cultivation of that plant is proved to be essential to health or the environment.

- **A statement calling for a wider definition of EDs, which preserves the application of the precautionary principle**

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The qualification of EDs needs to take into account the effects on "human health" as well as on animal and environment

Point 1.1 of the Annex of both draft legislations presents EDs as active substances which are "known to cause an adverse effect relevant for human health", have "an endocrine mode of action" and whose connection between both elements is proved.[1]

By adopting this definition, the commission has decided to get rid of a major part of the current surveys. Indeed, the reference to "human health" induces that we should wait to observe the effects of the substance on human and no more take into account the adverse effects on animals and the environment.

SAFE calls for keeping the definition of the World Health Organization (WHO) proposed in 2002[2] to define those disruptors as "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."

The difference between the two definitions has important consequences on the outcome of the qualification. The new definition implies that a substance that provokes an adverse effect on an organ or an animal's function will not be necessary classified as an ED.

Surveys on fauna and flora would no more be taken into consideration as to the current proposition. This new restriction will complicate the task of scientists and extend considerably the time required to prove a substance is dangerous and should be withdrawn from the market. In those conditions, the precautionary principle would completely be put aside, as a given substance would have to be proven dangerous before actions could be taken against it and not the other way around.

However, a lot of EDs have been qualified as such using evidence from animal experience and the new definition suggested by the European Commission called into question all these researches conducted on flora and fauna.

For instance, it was observed that administration of methoxychlor, a pesticide with potential estrogenic effects, in female rats during pregnancy and lactation periods, led to vaginal opening and appearance of puberty at a very early age in their female offspring.[3]

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[1] Annex to the Commission's delegated regulation

[2] State of the Science of Endocrine Disrupting Chemical (WHO, 2002)

[3] Gray LE Jr, Ostby J, Ferrell J, Rehnberg G, Linder R, Cooper R, Goldman J, Slott V, Laskey J. A dose-response analysis of methoxychlor-induced alterations of reproductive development and function in the rat. Fundam Appl Toxicol. 1989;12:92–108.

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The danger of Bisphenol A (BPA) was also first noticed with animal studies. In rats prenatally exposed to BPA, scientists have observed an increase in estrogen feedback as well as development of precocious puberty via inhibition of tyrosine hydroxylase activity in rostral preoptic periventricular neurons.[4]

According to the Commission's definition, those surveys, beyond many others, would not help to qualify a substance as endocrine disruptors.

Evidential requirements are consequently too high to identify a substance as endocrine disruptors.

➢ ***The risk of random appreciation of the "relevancy" of a scientific survey***

The Commission has adopted one more condition: adverse effects must be "relevant" for human health to lead to the banning of a substance. By using the term "relevant" the Commission brings another obstacle in the pursuit of identification of EDs. Indeed, some effects noticed on animal species are never been observed at human level and therefore will not be considered as "relevant" by the Commission.

Moreover, numerous conditions are listed to approve a survey and the term "relevant" is once more used at point 2.1 of the Annex. Those conditions come to add to the various obstacles that have already been set up by the Commission. Especially, the term "relevant" will allow evaluators to enjoy broad discretion considering the term's vagueness.

Beyond the fact that the burden of proof has shifted onto consumers, SAFE considers that, in those terms, overall conditions to get a sufficient weight of evidence would proof a succession of difficulties and would not prevent people from the menace that constitutes EDs.

In summary, assessors will have to overcome two difficulties: first, the requirements to prove a particular ED has clear effects on human health; second, once the impact is observed on human health, it would have to be deemed "relevant" by the officials. This combination of factors completely negates the EU's precautionary principle.

While SAFE agrees requirements should be set out to ensure the seriousness of scientific surveys used to assess whether a substance is an ED or not, SAFE nonetheless insists that the European Commission should 1° go back to the WHO's 2002 definition and 2° precise the meaning of the term "relevant".

A statement calling for the introducing of category-based system

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[4] Rubin BS, Lenkowski JR, Schaeberle CM, Vandenberg LN, Ronsheim PM, Soto AM. Evidence of altered brain sexual differentiation in mice exposed perinatally to low, environmentally relevant levels of bisphenol A. Endocrinology. 2006;147:3681–3691

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The Commission has not taken up the option of categories whereas the impact assessment[5] considers this possibility. Indeed, option 3 goes further than the WHO's definition by introducing additional categories based on the strength of evidence. Three categories are suggested: the first one is the definition adopted by the Commission; the second category gathers suspected EDs; finally, the third category would regroup "endocrine active substances", i.e. "substances for which there is some in vitro or in vivo evidence indicating an interference with the endocrine system (endocrine activity) but without evidence of an adverse effect in intact organisms".

In its communication[6], the Commission repels the idea by stating it “considers that establishing different categories of what may be an endocrine disruptors does not help to define what is an endocrine disruptors in the context of biocides and pesticides”.

SAFE considers that the subtle difference underlined here between “what may be” an ED and “what is” an ED is not a pertinent argument. Complexity prevails in endocrine disruptors’ identification and a strict definition without graduation cannot lead to efficient legislation. Furthermore, the logic behind the Commission’s statement threatens once again the EU's precautionary principle.

SAFE deems that the definition adopted by the Commission is too much static to consider all adverse effects of EDs. A category-based system provides nuances in the qualification of an endocrine disruptor and thus restores the place of the precautionary principle.

SAFE maintains the Commission should adopt categories in order to take account of substances for which doubts persist and where the evidence is not yet sufficiently strong. The current text does not allow for substances for which there are strong presumptions of hazard to be put aside from the market.

Categories would at least permit to offset the necessity of adverse effects’ proof on human health. During the period of the establishment of the proof, the substance could be identified as a suspected ED, and subsequently the precautionary principle could be preserved.

Summary

SAFE considers the Commission's proposed amendments to the biocide legislation (EU 528/2012) and to the plant protection products legislation (EC1107/2009) to

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[5] Impact Assessment defining criteria for identifying endocrine disruptors in the context of the plant protection products regulation and biocidal products regulation (Commission, 15 June 2016)

[6] Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products (Commission, 15 June 2016)

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fundamentally threaten the EU's precautionary principle as well as citizens' health, noticeably by significantly increasing the burden of proof. Indeed:

- By allowing new ban exceptions through a shift from a hazard-based approach towards a risk-based one, the risk is to create more loopholes for exceptions and make the exceptions the norm.
- By choosing to take only into account studies that tend to prove adverts effects of a substance solely on *human* health, the legislator deliberately choses to ignore a vast array of studies on animal and plant health, while the reason for this decision remain uncertain.
- The vagueness of some terms used in the legislative drafts to describe what constitutes "relevant" evidence as to determine whether a given substance is an ED leaves too much room for interpretation, and could likely increase even more the burden of proof

In light of these concerns, SAFE makes the following claims to the European Commission:

- The EU's definition of EDs should match the 2002 WHO's definition.
- The legislation should clearly define what is expected as a "relevant" evidence.
- The EU should adopt a category-based system to classify EDs, in the same way it does for carcinogenic substances, and which would embrace the precautionary principle.
- The hazard-based banning system should remain the norm; legislation should not allow for too many exceptions.

If these recommendations were taken into account, the EU would then not only become the first regulatory system in the world to set scientific criteria for EDs in its legislation, but also set a worthwhile precedent.

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