

SAFE POSITION PAPER

On endocrine disruptors and the draft Commission Regulation (EU) amending Annex II to Regulation (EC) 1107/2009 and No 528/2012 by setting out scientific criteria for the determination of endocrine disrupting properties

ABOUT SAFE - SAFE FOOD ADVOCACY EUROPE

SAFE's mission is to improve the representation of ordinary citizens in the EU debate concerning the future of EU food regulation.

SAFE - Safe food advocacy Europe is a non-profit independent organisation based in Brussels whose main objective is to ensure consumers' health and concerns remain at the core of the European Union's food legislation.

SAFE members are consumer, food health, vegan and vegetarian associations and individual members such as independent research scientists, doctors and nutritionists spread across Europe. To date our membership collectively represents the voice of over 1.000.000 European consumers.

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

More information available on www.safefoodadvocacy.eu

CONTEXT

The multiplication in the past years of research results has pointed out endocrine disruptors' adverse effects on humans, wildlife and, more globally, the environment. EDs are primarily presents in food, industrial chemicals, plastics, cosmetic products, pesticides and biocides, interfering with our hormonal system. EDs have been linked to the development of various health problems, leading to serious diseases such as early puberty, fertility and heart problems, cancers and obesity, amongst others. Endocrine disrupting chemicals' ubiquity in our closed environment therefore stresses more and more the relevance of drafting clear and protective legislation on the matter.

Almost three years later than legally expected, the European Commission has proposed its definition of endocrine disruptors (EDs), along with a set of scientific

criteria for the determination of endocrine disrupting properties. On the 4th of July 2017, Member States representatives from the EU pesticides committee came to an agreement in the form of a draft aimed at amending Regulation (EC) No 1107/2009, concerning the placing of plant protection products on the market, and repealing Council Directives 79/111/EC and 91/414/EEC, as well as Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012, concerning the making available on the market and use of biocidal products.

The new draft raised strong criticisms from scientific experts: in a joint statement released the 11th of July¹, the Endocrine Society, the European Society of Endocrinology and the European Society for Paediatric Endocrinology called on the European parliament and the European Council to reject the Commission's draft regulation. From civil society's side, the EDC-free coalition, gathering 70 NGOs around the EU, expressed its concerns over the criteria set up by the EC.

SAFE'S POSITION

SAFE welcomes the declaration of the EC to consider as “appropriate” (cf. recital 2) the use of the WHO definition published in 2002 - widely recognized in the scientific community since then - describing EDs 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”. This has indeed for long been a request of SAFE, as well as several other NGOs, stated in our previous position paper of June 2016 on EDs.

Nevertheless, the actual definition of endocrine disrupting properties specified in the Annex of the draft regulation amending the Annex II to Regulation (EC) No 1107/2009 in point 3.6.5 and point 3.8.2. does not sufficiently protect European citizens' health for the four following reasons:

- No horizontal criteria

The EC adopted a silo approach restricted to plant protection products' regulation that does not entirely respond to one of the main feature of endocrine disruptors: their cross-sector impact. Indeed, EDs can be identified in an extensive variety of

¹ Endocrine Society, European Society of Endocrinology and European Society of Paediatric Endocrinology (11th July 2017), Joint Statement, can be found on twitter: <https://twitter.com/sfoucart/status/884793555931324416>

products - from food (e.g. coriander, dairy products, fish...), cosmetics, water, air and hygiene products, to children toys -. In order to better cover all the aspects of endocrine disrupting chemicals' detrimental effects, the EC should provide a comprehensive policy addressing ED property in its entirety.

- **A very high burden of proof**

A chemical would be considered to have disruptive properties only if it has been demonstrated that its “adverse effect is a consequence of the endocrine mode of action” (in Annex 1.3), which is very difficult to scientifically prove, or it may take a very long time to analyse the adverse effects of certain substances. Thus only very few substances would be considered as hormone disrupting chemicals.

- **Less protective risk-based approach**

The EC based the text on a risk-based approach which means that a certain level of risk is acceptable as long as the “adverse effects are not relevant to humans” (in Annex Paragraph 1) nor “at the (sub)population level for non-target organisms” (in Annex Paragraph 2). This way, adverse effects have to be first identified for a chemical compound with endocrine disruptive properties to be banned, while SAFE, in line with independent scientists and the European precautionary principle, supports the hazard-based approach that evaluates chemicals’ damaging potential prior to their authorisation.

- **Authorisation of disruptive effects on targeted organism**

The draft allows the use of a plant protection product with disruptive effect if its impact is circumscribed to targeted organisms that are not vertebrates. This exception represents a very important loophole in the definition allowing a legal exception for certain pesticides. Released on the 15th of July, the joint [statement](#) from the world’s leaders in endocrinology indeed highlighted that “the criteria contain arbitrary exemptions for chemicals specifically designed to disrupt target insect endocrine systems that have similarities to systems in wildlife and humans”.

CONCLUSION

SAFE believes that the draft is not entirely satisfactory, 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 definition actually allows 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.

Therefore, SAFE urges the European institutions to modify the draft regulation keeping in mind the following points:

- 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;
- Biocides and pesticides with endocrine disruptive chemicals that targets specific organisms should not be allowed;
- Elaborating a cross-sector policy that encompasses each aspect of the negative consequences of EDs.