



PAN Europe's briefing on:

Commission's EDC (Endocrine Disrupting Chemicals) criteria proposal in line with the requirements of the Plant Protection Products Regulation 1107/2009

On the 4th of July 2017, at the Standing Committee of Plants, Animals, Food and Feed (SC PAFF) Member States voted in favour of European Commission's proposal of scientific criteria to identify endocrine disruptors (EDs) in the field of Plant Protection Products (PPP), drafted by Health and Food Safety Directorate-General (DG Sante).

The voted criteria proposal has been criticised by the Endocrine Society, the European Society for Endocrinology, and the European Society for Paediatric Endocrinology, who also sent a letter to European Ministers to alarm them that *"the criteria, as currently constructed, will likely fail to identify EDs that are currently causing human harm, and will not secure a high level of health and environment protection as required per the Treaty on the European Union (EU)"* and to urge them to take action. They also criticize the arbitrary exemptions for chemicals specifically designed to disrupt target insect endocrine systems¹.

PAN Europe emphasizes that **the Commission has failed to fulfil its role** to provide a set of scientific criteria to determine the endocrine disrupting properties of pesticide active substances that guarantee **a high level of protection for humans, animals, the environment and its ecosystems** from the harmful effects of these chemicals, in line with the provisions of the European Regulation (PPP Reg. 1107/2009), which is underpinned by the precautionary principle. This is particularly relevant for the protection of the vulnerable groups of the European population, i.e. pregnant women, babies and children. Furthermore, **the Commission went beyond its legal mandate** and included an exception for non-target organisms within the scientific criteria, which allows the use of pesticides that are designed to be endocrine disruptors for non-vertebrates and therefore cancels out the provisions of the EU law.

The Commission modified the proposal five times for a qualified majority of Member States to vote in favour of the proposal, some of which stated that their decision is political rather

¹ Press Release, Endocrine Society, June 16th 2017. [Endocrine experts united in disappointment with European Commission's proposed criteria on EDCs](#)



than scientific. In fact, several Member States criticised the proposal for lacking scientific clarity and are expecting this issue to be resolved by ECHA/EFSA/JRC who are already preparing a guidance document on how the criteria will be implemented. However, this lack of scientific clarity of the criteria will inevitably result in debates and even in legal prosecutions by the industry, which has a commercial interest on pesticide active substances that are indeed endocrine disruptors, against the Commission. Still, recognising that the criteria are not in line with the principles of endocrinology, Denmark and Sweden voted against the proposal and declared their regret that the Commission did not listen to their major concern: *“that the criteria proposed require an unprecedented high level of evidence to identify endocrine disruptors compared to other problematic substances, such as CMR-substances and do not properly reflect today’s scientific knowledge on endocrine disruptors... In total, the criteria fail to meet the level of protection foreseen by the co-legislators.”*

We are calling **the European Parliament to exercise its power under Regulatory Procedure with Scrutiny and block the Commission’s proposal** as it:

- Exceeds the Commission's implementing powers
 - The Commission has included a derogation that was not requested and contradicts the provisions of the PPPR 1107/2009
- Is not compatible with the aim or content of the Pesticide Regulation 1107/2009
 - The Commission presented a set of criteria that are not in line with the principles of endocrinology and therefore cannot be considered scientific
 - The criteria will fail to provide a high level of protection for humans and non-target organisms in line with the provisions of the law
 - The criteria do not implement the precautionary principle as they set a very high burden of proof to identify a pesticide substance as an endocrine disruptor

We would also like to bring to your attention to the request of the Endocrine Society, who also urges the Parliament to take action².

² Press Release, Endocrine Society, July 7th 2017. [Society urges EU Parliament to be transparent around EDC criteria.](#)



Background:

On the 15th of June 2016, two and a half years past its deadline, the Health Directory (DG SANTE) of the European Commission (COM) published two draft legal acts -one under the Pesticides (PPP) Regulation 1107/2009 and one under the Biocides Regulation 528/2012- which set the criteria to identify Endocrine Disrupting Chemicals (EDCs). To ensure homogeneity in European Law, these criteria must be horizontal and will be applied in other European Regulations on Chemicals (e.g. Cosmetics, REACH, Medical Devices, Water Framework Directive). The first draft legal act was strongly criticised by some Member States, Scientists, Stakeholders and Members of the Parliament. This is because the criteria draft had great scientific inconsistencies and did not comply with EU law, but also because the COM went beyond its mandate and removed the “cut-off” element from the pesticides criteria, by introducing a derogation to allow the use of such chemicals in the field. The “cut-off” criteria for hazardous substances (mutagenic, carcinogenic, toxic to reproduction and EDCs) in PPP Regulation was set to refuse their admission for assessment. This decision was a mutual agreement among European Parliament, Council and the Commission and therefore, COM does not have the power to change the rules by its own. After all, the Regulation aims to provide a high level of protection for humans, animals, the environment and its ecosystems.

Following the criticism, the COM revised the legal act and presented a second draft of the criteria proposal which was discussed in the Standing Committee (of Plant, Animal , Food and Feed known as SCoPAFF/section phytopharmaceuticals) on 18th of November. Although there were some improvements in comparison to the previous draft, the changes were characterised as “cosmetic”, in the sense that the burden of proof remained still too high to identify a chemical as an EDC, and the “cut-off” element to remove EDC pesticides from use was still not respected. Furthermore, the text remained vague as it was lacking clear definitions and was leaving room for legal misinterpretation that could be easily misused by the chemical industry, and its lawyers, to allow the use of hazardous chemicals in the field. Once again, this would result for the European law to fail to protect its people (especially our most vulnerable, new-born babies and babies in the womb), animals, the environment and its ecosystems from exposure to EDCs.

In a third attempt, following the feedback by Member States, the Commission updated the criteria once again, and this time split the annex in two parts, hoping that in the next Standing Committee of December 21st a qualified majority of the Member States would vote in favour of at least one of the documents. The Commission also informed the Member States that European Chemical Agency (ECHA) and European Food Safety Authority (EFSA) were asked to prepare a guidance document on how the criteria will be implemented. However, not only did the Commission not carry out any substantial changes in the proposal, but it also added a



further exception to allow pesticides that are endocrine disruptors to non-target organisms to be used, even if adverse effects are present.

In a fourth attempt, the COM once more called the Member States to discuss, and to possibly deliver an opinion on, the updated criteria proposal at the Standing Committee of PAFF at 28th of February. This time the COM only presented the scientific criteria hoping for Member States to reach a consensus, however, once again this didn't happen.

In a last attempt, the Commission updated for one more time the criteria proposal, specifying that the exception in the definition for non-target organisms is only for non-vertebrates, and reassuring member states that the negligible risk derogation will be discussed again in a later stage. As a result, on July 4th 2017 a qualified majority of Member States (21) voted in favour of the Commission's proposal.

Specific comments:

Criteria for the determination of pesticides with endocrine disrupting properties:

- We welcome the clarification (recital 4) that the criteria aim to identify both known and presumed endocrine disrupting substances.
- We are concerned that point 3.6.5. (3) has been kept in the criteria, which asks that the substance-induced adverse effect (assumably observed in experimental animals) is a consequence of the (defined) endocrine mode of action. Such a high level of proof is not required for any other hazardous substance. We understand that the aim of the PPPR 1107/2009, **which is underpinned by the precautionary principle**, is to protect people and the environment from the harmful effects of pesticides, whether the mode of action is known or not. The investigation of the mode of action of different EDCs is a very complex task that belongs to the field of research and not to the industry-contracted laboratories that should follow clear and easy-to-use protocols. Finally, the OECD Conceptual Framework for endocrine disruptors and the Guidance Document No. 150 provide a list of test guidelines that are designed or have been modified to assess effects of endocrine disrupting chemicals that are relevant for humans and environmental ecosystems. Why is the mode of action requested when the experiment has been designed to detect endocrine-related adverse effects caused by chemical exposure? We worry that this 'mode of action' element can easily be misused during the risk assessment of a substance, that it will result in endless debates, and that the industry sector may even take the Commission to court for not providing sufficient evidence to prove there is a clear link between mode of action and adverse effect and authorities will end up approving harmful EDCs due to data gaps on our understanding about their mode of action. We propose to delete sub point 3.6.5. (3) completely or at least change it substantially to remove the certain link between mode of action and adverse effect (change to e.g. it is plausible that adverse effects are endocrine mediated).



- The derogation for non-target organisms (3.8.2 last paragraph) seems to be incorrectly placed within the criteria to identify chemicals with endocrine disrupting properties. This is an exception and not an element to determine which pesticides have endocrine properties, therefore should not form part of the criteria. Further, this exception was not in the PPPR 1107/2009 mandate of the European Commission and hence should go through the legislative procedure before it is included in any part of the regulation. Lastly, it is very disappointing to see that endocrine disruptors for non-vertebrates will be approved since 95% of the animal kingdom are invertebrates and play a key role to maintain the balance of ecosystems and the population of species.
- Testing of all pesticides in line with GD 150 (OECD) for endocrine disrupting properties should start immediately.
- The criteria have to be horizontal and should be fit to apply across all EU regulations on chemicals according to the EU political commitments of the Seventh Environment Action Program and the European Council³. The criteria as they are unfit for other regulations.

Amending first paragraph points 3.6.5 and 3.8.2 of Annex II from negligible exposure to negligible risk (the European Commission confirmed that it will present it to Member States on a later stage for discussion)

This amendment has not been presented for discussion yet in the SCoPAFF meeting. But it is important to understand that this amendment in the derogation of the regulatory text from ‘negligible exposure’ to ‘negligible risk’ is extremely important as it will drastically change the effectiveness of the scientific criteria to protect human and environmental health from exposure to EDCs.

- Annex II 3.6.5 first paragraph: The COM has gone beyond its mandate as it changed the current derogation in the annex text from “negligible exposure” (i.e. closed systems or conditions excluding contact with humans, residue levels below the default value of 0.01 mg/kg), which also appears in the case of carcinogens and mutagens, to “negligible risk” [*in particular* when the product is used in closed systems or conditions *that aim at* excluding contact with humans, and respect the Maximum Residues Limits (MRLs)]. First of all, the definition of negligible risk – i.e. *in particular* - **is unacceptably vague** in the new text, as it leaves room for misinterpretation. This change in the text is actually major. It contradicts the aim of the cut-off criteria to speed up the authorization process, remove certain hazardous pesticides from the market and provide a high level of protection for

³ The Council “NOTES the Commission Communication accompanying its proposal for scientific criteria to identify Endocrine Disruptors; CALLS UPON the Commission to comply with the relevant 7th EAP provisions 19 when further developing those criteria in order to better protect humans and the environment from endocrine disruptors; and INVITES the Commission to subsequently update as appropriate the 1999 EU endocrine disruptors strategy”, Council Conclusions of 19 December 2016, 15673/16.



human, animal and environmental health. With this element, the COM gives the green light for applicants to establish a safe-exposure level for EDCs, based on models that consider the use of mitigation measures and high-tech equipment, which doesn't correspond to real-life situations. As a result, such pesticides will still be used in the field as long as exposure levels are below the non-observed adverse effects level (this is much higher than 'negligible' exposure), which is exactly what the law mandates for every other pesticide. Further, residues in food (including imported food from countries where such pesticides are not regulated) are to be compared with MRLs, as with any other pesticide that is authorised for use. This can be 100 or 1000 times more than the previously agreed default value. Here we need to highlight that there is **no scientific consensus** that exposure to EDCs during pregnancy or early development can be considered safe. The new proposal will leave our most vulnerable unprotected. The COM should leave the text as it was, "negligible exposure", which means exposure to the chemical is so low that it cannot be measured or detected and therefore its risk is absolute ZERO. This is what consumers, farmers, countryside residents and bystanders expect from European Law: that pesticides used to produce our food should lead to ZERO health risk.

- Annex II, paragraph 3.8.2: The same text (negligible exposure) has changed for non-target organisms as well but in this case "negligible risk" is not explained. The COM will be in a difficult situation to define how exposure of non-target organisms to ED pesticides could have a negligible risk. As with the previous point, the COM should leave the text as it was: "negligible exposure"

Pesticide Action Network (PAN) was founded in 1982 and is a network of over 600 non-governmental organisations, institutions and individuals in over 60 countries worldwide working to minimise the negative effects and replace the use of harmful pesticides with ecologically sound alternatives. Its projects and campaigns are coordinated by five autonomous Regional Centres. PAN Europe is the regional centre in Europe. It was founded in 1987 and brings together consumer, public health, and environmental organisations, trades unions, women's groups and farmer associations from across Europe.