# PAN Europe's position on:

**Commission's legal act (fourth update) on the draft EDC (Endocrine Disrupting Chemicals) criteria proposal presented on 21th of December Standing Committee on Plans, Animals, Food and Feed (SCoPAFF), section phytopharmaceuticals.**

**Key points:**

Below we provide our criticism on key points of the current draft criteria proposal, highlighting why should Member States oppose the Commission's proposals:

**<u>Amending scientific criteria. Points 3.6.5 and 3.8.2 of Annex II</u>**

- [1] 3.6.5. In the identification criteria for endocrine disruption:
  - In point (2) "it has an endocrine mode of action" should be deleted and leave "it alters the function(s) of the endocrine system". According to WHO, an endocrine disruptor "alters the function of the endocrine system", which is substantially different than an endocrine mode of action.
  - In point (3) "the adverse effect is a consequence of the endocrine mode of action" should be deleted completely or at least changed 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). We are still investigating the endocrine mode of action that leads to the adverse effects of very known endocrine disruptors, like PCBs and tributyltin (TBT, used as biocides in boat paints). It is absurd to ask a certain link between endocrine mode of action and the observed adverse effect. This element can be easily misused during risk assessment procedure, result in endless debates and end up dismissing known EDCs due to data gaps on the mechanism of action that gives rise to the adverse effect.
- [2] 3.8.2. In the identification criteria for endocrine disruption: (2) and (3) as with previous (humans)

- Subpoints
  - (4) With this addition, the COM creates a new derogation and permits the use of pesticides that their mode of action to control a target pest is through the endocrine system, even though it is an endocrine disruptor to non-target organisms of the same taxonomic phylum. This means for example that an insecticide made to kill pests of the arthropod phylum through the endocrine system can still be used even though it is toxic to pollinators. This subpoint cancels out the aim of the criteria to regulate pesticides that cause endocrine disruption to non-target organisms and protect the environment and its ecosystems, which was the initial mutual agreement among European Parliament, Council and the Commission. Here we need to highlight that most documented cases of endocrine disruption in wildlife have been due to pesticide exposure, and aim of the Europe Law was to prevent this from reoccurring in the future.

**Amending first paragraph points 3.6.5 and 3.8.2 of Annex II**

This amended has not been presented for discussion in the February SCoPAFF meeting and it is important to understand the underlying reasons as it could change drastically the effectiveness of the scientific criteria.

❖ 3.6.5 first paragraph
- The COM went beyond its mandate and 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 fasten up the authorization process, remove certain hazardous pesticides from the market and provide a high level of protection for 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 no-observed adverse effects level (this is much higher than 'negligible' exposure), which is exactly what the law mandates for every other pesticide. Further, the residues in food (including imported food from countries that 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 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: the pesticides used to produce our food should lead to ZERO health risk.

- The same text (negligible exposure) has changed for non-target organisms as well (3.8.2) 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".

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**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 applied in other European Regulations on Chemicals (e.g. Cosmetics, REACH, Medical Devices, Water Framework Directive). The draft legal act has been strongly criticised by some Member States, Scientists, Stakeholders and Members of the Parliament. This is because the criteria reveal great scientific inconsistencies and fail to comply with the EU law, but also because the COM went beyond its mandate and modified significantly the legal text. It introduced a derogation to permit the use of EDCs in the field and essentially removed the "cut-off" element from the pesticides criteria. The "cut-off" criteria for hazardous substances (mutagenic, carcinogenic, toxic to reproduction and EDCs) in PPP Regulation, was set to fasten up the procedure of

pesticide risk assessment while increasing the level of protection for humans, animals and the environment. 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.

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 (SCoPAFF/section phytopharmaceuticals) on 18th of November. Although there were some improvements in comparison with the previous draft, the changes were characterised as "cosmetic" in the sense that the burden of proof remained too high to identify a chemical as an EDC and the "cut-off" element to remove EDC pesticides from use, is still not respected. Furthermore, the text as it is, is vague as it fails to give clear definitions. This leaves room for legal misinterpretation that will be easily misused by the chemical industry, and its lawyers, to allow the use of hazardous chemicals in the field. As a result, the European law will fail to protect humans (especially our most vulnerable, newborn babies and babies in the womb), animals, the environment and its ecosystems from exposure to EDCs.

Following the feedback by Member States, the COM updated once again the criteria (for the 3rd time) but this time split the annex in two part (one for the change in the derogation and another for the criteria), hoping that in the next Standing Committee of December 21st a qualified majority of the Member States will vote in favour for at least one of the documents. This time, not only the COM didn't do any substantial changes but it also added a further exception to allow pesticides that regulate moulting and/or growth of harmful organisms via their endocrine system to be used, even if they are endocrine disruptors for non-target organisms and they cause adverse effects. Once again the COM did not have a qualified majority and the voting was postponed.

Now, once more, the COM has called the Member States to discuss and to possibly deliver an opinion on the 4th-time updated criteria proposal at the Standing Committee of PAFF at 28th of February. This time the COM only presented the scientific criteria leaving it unclear whether it has dropped the amended derogation on negligible risk or it has something else in mind.

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**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.