



European Commission's Fitness Check roadmap on Endocrine Disruptors¹ - PAN Europe's feedback

Background

Exposure to endocrine disrupting chemicals (EDCs) is an issue of concern, particularly for our children and future generations. Exposure to such chemicals during early life developmental stages, even at low environmental doses, may result in permanent physiological alterations and lead to dysfunction and disease later in life. In humans, the rise of endocrine-related cancers, metabolic disorders such as obesity and diabetes, cognition deficits and learning disabilities, reproductive problems and infertility have been linked to exposure to EDCs. In Europe, these diseases create an enormous cost of more than €157 billion to society². Surely, political actions to identify and eliminate EDCs from our lives, are urgent at the very least.

EDCs have been in the Commission's agenda since 1999, with the adoption of the 'Community strategy for endocrine disruptors'. Two decades later, the Pesticides Regulation (EC) 1107/2009, followed by the Biocides regulation (EU) 528/2012, became the first pieces of EU law to set clear cut-off criteria for EDCs, as they do with other hazardous substances (e.g. which cause cancer, gene mutations or toxicity in reproduction). Hence, if a substance is an EDC for human and/or non-target organisms, it should not be authorised for use (there are certain exceptions/derogations in both regulations). Despite the provisions, the Regulation was missing a set of criteria to identify EDCs, which were finally set in 2018, after almost 5 years of delay. Civil society organisations, Member States, and the Endocrine Society criticised the criteria for being too narrow and for setting the burden of proof too high: only certain classes of EDCs are addressed, and for each chemical they require to identify the endocrine mode of action, the adverse effect and the plausible biological link between the two³. This means that a chemical may not be classified as an ED even when endocrine-related adverse effect has been observed. Considering the science knowledge gaps in the exact mechanism of action of endocrine disruptors, there is an enormous risk of misclassifying ED pesticides or biocides as 'safe'. The criteria have been implemented for a few months in the safety assessment of biocides and pesticides, but their effectiveness in correctly identifying substances that are EDCs remains to be seen. Specific ED-tests are still not mandatory. So far, just one biocide substance has been classified as an EDC, whereas several pesticide

¹ Link to public consultation and roadmap: https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-2470647_en

² Transade et al, 2015. Estimating Burden and Disease Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union. JCEM 100:1245-1255 <https://doi.org/10.1210/jc.2014-4324>

³ PAN Europe briefing on Commission's criteria proposal (<https://bit.ly/2xFLkNH>)

and biocide substances remain unidentified and are still in the market. Undoubtedly, regulating EDCs is a slow process, even when the law has been established.

In line with the 7th Environmental Protection Programme, the European Commission had committed to deliver an updated Union Strategy on EDCs by 2018, with specific goals to phase out the use of EDCs as soon as possible and promote non-toxic alternatives. Instead, the Commission launched a communication⁴, a “strategic” plan to do a fitness check on the various ED policies before any action is taken. The European Parliament⁵, and later the European Council⁶, expressed their concerns about the Commission’s communication and its failure in setting concrete measures to minimise EDC exposure.

A fitness check at this moment not only risks delaying taking any drastic measure to start eliminating EDCs from our daily lives, but it is also totally premature, since existing EU policies on EDCs have hardly been implemented. The criteria to regulate biocides and pesticides with endocrine disrupting properties came into force in June and November 2018, respectively- the latter just few days after the Commission published its communication.

Feedback:

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PAN Europe welcomes the European Commission’s scope to have EU-wide legislative measures that ensure a high level of protection of human health and the environment from all hazardous substances including endocrine disruptors (EDs).

However, the ED-related legislative measures have been slow, and have hardly been implemented or in some cases even established. Therefore, investing resources towards a fitness check at this stage not only seems premature, but also poses a risk of additional and unnecessary delays in implementing EU law provisions, while human beings and the environment continue to be exposed to these dangerous chemicals. Resources should be spent on the implementation of the current EU law measures that address EDs, application of available OECD ED testing for dangerous chemicals in the market (pesticides and biocides), development and endorsement of new scientific methods to identify EDs, establishment of an assessment method to address chemical mixtures (required by EU law since 2005) and development of non-chemical, safe alternatives.

In the case of pesticides and biocides - two chemical classes with biological activity, hence the risk they may interfere with the endocrine system is high - the Regulations call for substances that meet certain ED scientific criteria not to be authorised, with some exceptions on restricted use (e.g. negligible exposure or if needed to protect serious damage to human/plant health). These criteria were due in 2013 but entered into force recently (June 2018 for biocides, November 2018 for pesticides) and only address certain classes of EDs. Only one biocide substance has been recognised so far as an ED (cholecalciferol) and its use has been restricted. For pesticides, during the 2016 Impact assessment exercise⁷ the Commission identified 32 pesticides authorised in the EU to be EDs, but so far none of these have been classified as EDs. Even with this set of rather

⁴ Read PAN Europe analysis: [Why are regulators so reluctant to protect us from hormone disruptors?](#)

⁵ European Parliament resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors ([2019/2683\(RSP\)](#))

⁶ Council Conclusions on Chemicals 26 June 2019 (<https://bit.ly/2S1asb2>)

⁷ Commission Staff Working Document; Impact Assessment (defining criteria for endocrine disruptors) [SWD\(2016\) 211](#)

narrow scientific criteria, it remains to be seen whether any of these pesticides will be identified as EDs at all. For the moment, testing pesticides using the available ED tests (OECD) is not mandatory and in most cases ED analysis is based on non-ED specific tests and speculations. Despite the regulatory measures in place, unfortunately humans and the environment keep being exposed to ED pesticides and biocides.

PAN Europe agrees with the horizontal approach for the scientific identification of EDs across EU legislations; scientifically, a substance cannot be classified as an ED under one legislation but not under another. The Commission should create another class of potential EDs in line with WHO (WHO, 2002)⁸. This will allow for the identification of potential EDs which are of concern that should be excluded from uses that come in contact with humans and the environment. PAN Europe calls to expand the ED definition for biocides and pesticides as well, potential EDs should also be regulated and should never be considered low-risk substances.

The EU should have different regulatory approaches in the different pieces of chemicals legislation. Chemicals have divergent properties and applications and should be regulated accordingly. The higher the chance of human and environmental exposure to dangerous substances, the stricter the regulation should be. Pesticides that are biologically active and used on open fields - exposing not only farmers but also residents, bystanders, consumers (through residues in food), the environment and its species - must not be EDs, as such chemicals should pose no human health or environmental risk.

Priority should always be given to human health and the environment - the pivotal factors for human wellbeing - and the focus should remain on the implementation of EU legislative measures aiming to ensure a high level of protection for humans and the environment.

⁸ [State of the Science of Endocrine Disrupting Chemicals \(WHO, 2002\)](#)