Endocrine disruptors - Frequently Asked Questions

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What has been voted on today?

The Member States voted in favour of the draft criteria to define endocrine disruptors in the area of plant protection products (PPPs) proposed by the European Commission after several discussions between the Commission and the Member States in a Standing Committee.

Are the scientific criteria protective enough for human health and the environment?

The scientific criteria identify known and presumed endocrine disruptors and evidence from animal, in-vitro or in-silico studies can be used to identify a substance as endocrine disruptor. They are based on the World Health Organisation's (WHO) definition of an endocrine disruptor that has gathered a wide consensus among scientists, Member States and stakeholders.

The criteria will apply after a short transitional period of 6 months. A review clause was introduced to allow assessing the experience gained with the criteria.

The Commission went beyond presenting criteria to identify **endocrine disruptors for human health** and **also presented criteria protecting the environment**.

The criteria endorsed by Member States today are strict, science-based criteria and will maintain the high level of protection of human health and the environment, set by the Plant Protection Product Regulation.

What will the criteria mean for the approval and use of plant protection products in the EU?

The EU legislation provides that active substances used in plant protection products are only approved for a limited period of time, and that these approvals are routinely reviewed.

The EU legislation for plant protection products also provides that active substances which are endocrine disruptors shall not be approved, unless there is negligible exposure in which case they may be approved under restricted conditions.

As regards the criteria for the environment, the specificity of some active substances which have endocrine modalities that affect target arthropods (e.g. insects) but do not affect vertebrates including humans has been acknowledged. These substances, of particular interest for integrated pest management, will be subjected to a specific risk assessment and only approved if there are no unacceptable effects on non-target organisms.

The question whether an active substance is an endocrine disruptor **will be assessed each time the substance is subject to an approval or a renewal of approval** at EU level.

What are the next steps in terms of procedure for these criteria?

The text agreed today will now be sent to the Council and the European Parliament. They will have three months to examine it before final adoption by the Commission.The text will enter into force 20 days after its publication in the Official Journal and be applicable six months after this.

How will the criteria be applied?

The scientific criteria will be applied to the scientific evaluations of all active substances used in plant protection products and will replace the interim criteria which were previously applicable but no longer scientifically up to date.

The scientific criteria will be applied 6 months after entry into force and will apply to the already on-going renewal/approval processes. This means that all the applicants, Member State authorities evaluating the substances, and the European Food Safety Authority will need to adapt very quickly their procedures and new data may need to be requested and produced.

In order to be ready to apply the criteria, EFSA and ECHA are preparing a joint Guidance document on endocrine disruptors. An outline was published on 20 December 2016 and a draft guidance document – already consulted with Member States and stakeholders - will be available for public consultation in

autumn. After this public consultation, the guidance document will be finalised before the criteria start applying. It is important to recall that the criteria will apply also to the on-going procedures reassessing the substances.

What is the EU doing to boost research as regards endocrine disruptors?

The EU is also funding basic and applied research to better understand endocrine disruption and to develop the necessary tools for their assessment and regulation.

The Commission will propose to allocate an important budget for substantive new research on endocrine disruptors in 2018 under the next Horizon 2020 work programme, where approximately 50 million euro is expected to be allocated to around 10 projects.

Will the criteria be applicable also in other areas which are not pesticides, in particular for consumer use?

The adopted criteria will provide a stepping stone for further actions to protect health and environment enabling the Commission to start working on a new strategy to minimise exposure of EU citizens to endocrine disruptors, beyond pesticides and biocides. This strategy will aim to cover toys, cosmetics and food packaging as well.

As for pesticides and biocides, the Commission will not delay any action and will already apply the criteria to substances for which assessment or re-evaluation is on-going.

What will happen to the texts presented in June 2016 but not voted today?

The 15th of June, 2016, two legal acts were presented to specify the criteria to identify endocrine disruptors:

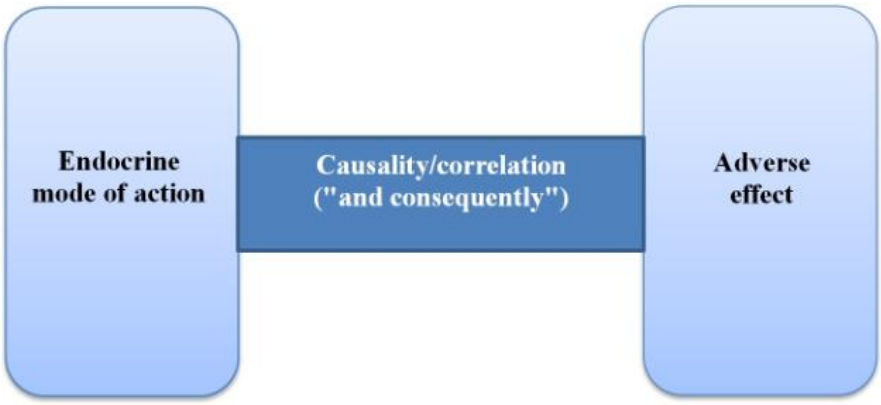
- a delegated act applicable to the chemical substances falling under the Biocidal Products Regulation; and
- a Commission Regulation applicable to the chemical substances falling under the Plant Protection Products Regulation. This Regulation also contained a technical amendment to a derogation which was already foreseen in the legislation.

The Commission decided to proceed with the criteria for the pesticide legislation first, because Member Stated had to vote them. This is done with the aim to ensure consistency between these two legislations, which is particularly important because the properties which make a substance a endocrine disruptor do not depend on the use of the substance. The criteria for biocides should be adopted soon by the Commission.

What are endocrine disruptors?

Endocrine disruptors are chemicals which impact on the hormone system of animals and humans. They have three cumulative characteristics: a hormonal function, an adverse effect, and a causality between the two.

The World Health Organisation (WHO) defined in 2002 an Endocrine Disruptor as a 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 main characteristic compared to other chemicals is that we do not only look at the effect, but also at a mode of action. In fact, endocrine disruption is a relatively recent way of looking at the toxicity of chemicals, which helps to understand how certain adverse effects happen. The usual approach to defining the toxicity of chemical substances is "end points" – whether there is an adverse effect. The new, additional, element is the concept of "mode of action", the way in which a chemical substance has an impact.

Are endocrine disruptors already taken into account in EU legislation?

Yes. EU regulatory agencies, independent scientific committees, the Commission and Member States already look at endocrine disruptors. This work is regulated through sectorial legislation in areas including human health (including for consumers and workers), animal health, and environment. Examples are the EU legislation on occupational safety and health (where the legislation on chemical agents at work[1] includes all chemical agents, including endocrine disruptors), food and feed safety (where toxicological risks, including those stemming from endocrine disruptors, are subject to comprehensive risk assessment), and consumer products (including for example cosmetics and toys, REACH), as well as environmental legislation. Moreover, in the specific areas of Biocides[2] and Plant Protection Products[3] the legislation already determines the regulatory consequences for endocrine disruptors and interim criteria are in place so far *(please see next question).*

How does EU legislation regulate endocrine disruptors in plant protection products?

The EU has one of the strictest systems in the world for the assessment of plant protection products ("pesticides", e.g. herbicides). Hundreds of substances have gone through, or are going through, a stringent scientific assessment process. The EU approval of an active substance is only granted for a limited period of time (up to 15 years) and must be renewed regularly.

In practice, EU legislation requires that allchemicals used in plant protection products (PPP) are approved at EU level before being placed on the market. This is called "prior approval". It means that all chemicals are allowed on the market - and for use – only once their safe use is proved according to a thorough scientific assessment. In addition, particularly hazardous substances like substances which may cause cancer, effects on reproduction, or endocrine disruptors are not even going through this risk-assessment but are *per se* not approved or approved under restrictions in case the foreseen specific derogations are applicable.

Finally, in case of relevant new scientific and technical knowledge, approvals can be reconsidered at any time and their status can change into non-approval or a more restrictive condition of use. Because of this "prior approval" system, the extensive data requirements, and the hazard approach for decision making, the European legislation for Plant Protection Products is considered to be one of the most solid worldwide.

The technical amendment, which was presented according to the mandate set out in Article 78 of the Plant Protection Products Regulation, was separated from the criteria into a second Commission Regulation in order to facilitate the decision making process and to allow all institutions involved to express their opinion on each aspect separately. The adoption of the criteria has been given priority and the discussion on the technical amendment will be resumed once the criteria are adopted.

For more information

Press release: Endocrine disruptors: major step towards protecting citizens and environment

DG SANTE Endocrine disruptors

[1] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p.11).

[2] Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

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