Agreement on criteria for endocrine disruptors

On 4 July 2017, the European Commission's Standing Committee on Plants, Animals, Food and Feed (SC PAFF), made up of experts from the EU Member States, voted on the Commission's draft regulation setting out criteria for identifying endocrine disruptors in the area of plant protection products (PPPs). The vote was preceded by several meetings in which the Commission presented revised versions of its drafts. The European Parliament and the Council of the EU now have three months to examine the agreed text.

Background

Endocrine disruptors, or endocrine-disrupting chemicals (EDCs), are substances that impact on the functioning of hormones, with potentially harmful effects on health. A wide range of chemicals, commonly used for a number of everyday products, are suspected of having a potential for endocrine disruption under certain circumstances. On 15 June 2016, the Commission presented the long-awaited proposal on the scientific criteria for the identification of EDCs, including a draft implementing act applying to the chemical substances falling under the **Plant Protection Products Regulation** (PPPR) and a draft delegated act applicable to the **Biocidal Products Regulation** (BPR). Both draft acts need to be adopted according to the relevant procedures. The SC PAFF held several discussions at which the Commission presented successively modified drafts. The Commission states that it proceeded with the **criteria for PPPs** first, because Member States had to vote them, and that the **criteria for biocides** 'should be adopted soon'.

Proposed scientific criteria for identifying endocrine disruptors

According to the Commission fact sheet, the criteria are based on the relevant WHO definition and will allow the identification of known and presumed EDCs. To determine if a substance should be classified as an EDC, evidence from *in vivo*, *in vitro* or *in silico* studies can be used. A review clause will make it possible to assess the experience gained in applying the criteria. In the agreed draft, the technical amendment to the clause on 'negligible exposure', presented in accordance with Article 78 PPPR, was separated from the criteria and will be published as a second Commission regulation. As per the Commission, this was done to facilitate decision-making and to allow the institutions involved to express their opinion on each aspect separately. Parallel discussions on the above-mentioned technical amendment are due to resume 'once the criteria are adopted'.

Stakeholder views

Stakeholders on all sides have criticised the criteria throughout the process. Parliament notably condemned the delay in their adoption. Ahead of the vote, the Endocrine Society, the European Society for Endocrinology and the European Society for Paediatric Endocrinology claimed that the proposed criteria would fail to identify EDCs that are currently causing human harm. The European Consumer Organisation (BEUC) argues that this definition would hamper the EU's ability to effectively protect its citizens and the environment against EDCs. On the pesticide industry side, the European Crop Protection Association (ECPA) reportedly said that the criteria would hit European farmers without providing additional protection for health and the environment.

Next steps

The agreed text will be sent to the Parliament and the Council, which will have three months to examine it before its final adoption by the Commission. It will enter into force 20 days after its publication in the Official Journal and will become applicable six months later, replacing the interim criteria. During the transitional period, the European Chemicals Agency (ECHA) and the European Food European Food Safety Authority (EFSA) will finalise a guidance document on the implementation of the criteria. An outline of the draft guidance document was published on 20 December 2016; the document itself is due out in the autumn.

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