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Global Agricultural Information Network

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European Commission Presents Criteria to Define Endocrine Disruptors

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Report Highlights:

On June 15, 2016, the European Commission presented two draft measures outlining scientific criteria to identify endocrine disruptors (EDs) under the Plant Protection Products Regulation (1107/2009) and Biocidal Products Regulation (528/2012), using the World Health Organization (WHO) definition for EDs as a basis. This means that the ‘hazard-based’ approach of the Pesticides Regulation will be maintained, not taking into account exposure to the substance. The new measures, which will apply immediately for the approval of new substances and re-approval of currently authorized products once adopted, could enter into force as early as the first half of 2017.

General Information:

On June 15, 2016, the European Commission presented two draft measures outlining scientific criteria to identify endocrine disruptors (EDs) under the [Plant Protection Products Regulation \(1107/2009\)](#) and [Biocidal Products Regulation \(528/2012\)](#), together with a Commission Communication and an Impact Assessment Report. [Note: Plant protection products guard plants against harmful organisms (examples are herbicides or insecticides used in agriculture). Biocides contain and control harmful organisms (examples are disinfectants used in hospitals).]

The scientific criteria in the new draft measures are based on the World Health Organization's (WHO) definition of an endocrine disruptor, which states that an ED is "an exogenous 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 Commission's proposal requires an evaluation of all relevant scientific (international) evidence in order to follow the weight of evidence approach outlined in the Classification, Labelling and Packaging Regulation of chemical substances (the CLP Regulation or [Regulation \(EC\) No 1272/2008](#)).

However, the new draft measures maintain the 'hazard-based' approach of the current Pesticides Regulation, which allows substances to be banned on the basis of hazard without taking into account exposure to the substance. The proposed measures do not explicitly call for consideration of other hazard characterization factors such as potency, one of the most important factors to distinguish between substances of high concern or low regulatory concern.

The European Food Safety Authority (EFSA) and the European Chemicals Agency (ECA) have been requested to examine whether already approved individual substances could be identified as endocrine disruptors according to the criteria in the draft texts in order to accelerate the process once the criteria are in force. The criteria will also apply to products imported into the EU and will therefore be notified to the World Trade Organization (WTO).

Next Steps

The two draft legal acts containing the criteria now need to be adopted by the Commission under the relevant procedures. The draft Commission Regulation specifying the criteria for pesticides will likely be discussed first at the Standing Committee on Plants, Animals, Food and Feed (PAFF) on July 11-12, 2016, and could be voted by Member States as early as in October under the Regulatory procedure with scrutiny. The draft delegated regulation for biocides will be discussed in a group of experts of Member States prior to adoption by the Commission. The non-objection of Council and the European Parliament will be required before the Commission can enforce both. If approved, the draft measures could be finalized by the end of 2016 and implemented during the first half of 2017. However, other scenarios may be possible if Member States cannot express a collective position on the proposal(s) at the Standing Committee or Council level. The Commission is expected to apply the criteria immediately without a transitional period for the approval of new substances and re-approval of currently authorized products.

Links: http://ec.europa.eu/health/endocrine_disruptors/policy/index_en.htm :

- Two draft legal acts to set criteria for endocrine disruptors for [Plant Protection Products](#) and [Biocidal Products](#)
- [Impact Assessment](#) and [Executive Summary](#)
- [Commission Communication](#)
- [Press release](#)
- [Q & A](#)