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Criteria to Identify Endocrine Disruptors Published

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Agricultural Situation

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Report Highlights:
On April 20, 2018, the Commission published Regulation 2018/605, identifying endocrine disrupting properties under Regulation 1107/2009 on plant protection products, in the Official Journal. The criteria to identify endocrine disruptors will apply as of October 20, 2018 to all on-going and future evaluations of active substances used in plant protection products. Meanwhile, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) are finalizing a technical Guidance document to implement the criteria for both biocides and pesticides. The Guidance document should become available by June 2018.

Current Status:
On April 20, 2018, the European Commission published Commission Regulation 2018/605, containing the criteria to identify endocrine disrupting properties in plant protection products, in the Official Journal. The criteria will apply starting on October 20, 2018. This ends a multi-year process by the Commission to move the criteria forward.

Background:
In June 2016, the European Commission (EC) published a draft legal act under the Plant Protection Products legislation (1107/2009)[1], which sets the criteria to identify endocrine disruptors. The EC's proposal takes a hazard-based approach, as it does not require information on a substance's potency, exposure, or other risk-based assessment factors to identify it as an endocrine disruptor. This proposal also included a derogation, which is allowing the setting of maximum residue levels (MRLs) and import tolerances for substances identified as endocrine disruptors, if there is negligible risk of exposure to humans.

Although the original Commission proposal included both the criteria for identifying endocrine disruptors and the derogation for use, the Commission separated the proposal in December 2016 and presented the criteria and the derogation as two separate acts. In a later stage, the Commission only presented the proposal for the ED criteria without the derogation.

The Commission presented a new draft regulation late 2017, leaving out a controversial paragraph for substances controlling targeted organisms other than vertebrates, after objections by the European Parliament. On December 13, 2017, the PAFF committee adopted the Regulation to identify endocrine disrupting properties under Regulation (EC) No 1107/2009 (on Plant Protection Products).

The Commission reminded the Committee that it would come forward again with a technical amendment to a derogation under the Plant Protection Products Regulation, once the draft criteria were adopted. Following the Member State experts' approval in December, the Commission sent the draft Regulation to the European Parliament and the Council for 3 months of scrutiny until April 9, 2018 in order to examine the draft measure and raise any objections (comitology procedure with scrutiny). The Commission then officially adopted the criteria, since neither the Parliament, or Council raised objections.

The criteria will apply to the active substance evaluations that are ongoing. There are many substances where the re-evaluation dossier has been submitted but a decision has not been taken. The Commission wants these evaluations to be updated to take the criteria into account.

EFSA and ECHA Guidance Document
EFSA and ECHA are preparing a joint Guidance document related to the implementation of the criteria,

[1] 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) as well as for the Biocidal Products Regulation (528/2012), using the World Health Organization (WHO) definition for EDs as a basis.

which will be finalized before the criteria go into implementation. According to the European Chemical Agency (ECHA) and the European Food Safety Authority (EFSA), the guidance document will be available in June 2018 when the criteria for biocides become applicable.

Technical Amendment to the Derogation

The Commission previously indicated that it would discuss the amendment to the derogation again after the adoption of the criteria, but it is still unclear when and how this will happen. For substances which are identified as endocrine disruptors, a derogation for use may be possible if there is negligible risk of exposure to humans (this amends the previous legislation that stated the derogation is only possible if there is negligible exposure) or if the substance is indispensable for agriculture. This derogation proposal would theoretically allow the setting of maximum residue levels (MRLs) and import tolerances. However, this kind of "regulation by derogation" is still likely to significantly disrupt trade of agricultural products.

Potential Trade Impact

According to an industry study, approximately $6,3 billion of U.S. exports to the E.U. of agricultural commodities could be affected by this policy change. The largest effects would be in exports of nuts /almonds ($2.4 billion), soybeans and groundnuts ($2 billion) and wheat ($208 million). Inclusion of processed food and feed products from these commodities would increase the potential effect to $4.8 billion. This issue is of major concern to the EU's trading partners.