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Still No Consensus on EU Endocrine Disruptor Criteria

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Report Highlights:

On Tuesday, February 28, the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) again failed to reach a qualified majority on the proposal on endocrine disruptor (ED) criteria. The European Commission took an indicative vote but chose not to move to a formal vote when it was clear that there was again no qualified majority. Eleven countries voted in favor of the criteria, while eight voted against and eight abstained. At this time, the Commission has given no indication on the proposal's next steps.

Background

In June 2016, the European Commission (EC) published a draft legal act under the Plant Protection Products legislation 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. 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.

Member States have been strongly divided on the proposal. While some Member States are in favor of the criteria and the derogation, others (particularly France, Sweden, and Denmark) strongly oppose the proposed criteria because they believe that the burden of evidence is too high to prove that a substance is an endocrine disruptor. Others, as well as the European Parliament's ENVI Committee, believe that the EC has exceeded its legal mandate by proposing the derogation to the existing legislation. A number of Member States are unable to come to an internal consensus because of divisions between their agricultural and environmental ministries over the proposal. In November 2016, the EC published revised draft criteria after taking into account Member State feedback and input after several consultations.

Technical Amendments Separated from Revised Criteria

In an unexpected move in early December, the EC split the proposal into two separate parts: 1) a proposal for ED criteria; and 2) a proposal to amend the derogation. Splitting the proposal introduces a risk that the proposal on the criteria could be approved while the derogation proposal may be refused by Member States and/or the Parliament. The United States, other trading partners, and European industry groups are concerned that the EC is likely seeking to move the proposal with the revised criteria forward as quickly as possible and is willing to sacrifice the derogation in order to gain approval for the criteria. If the derogation is rejected, it would be almost impossible to establish MRLs or import tolerances and would likely lead to major trade disruptions.

The SCoPAFF met to discuss the two draft regulation for endocrine disruptors on December 21, 2016, but did not proceed to a formal vote when no qualified majority was reached on either the criteria or the derogation in an indicative vote.

No Qualified Majority in February SCoPAFF

For the February 28 SCoPAFF meeting, the Commission chose to put only the proposal for the criteria up for discussion, likely in the hope that it could be approved more quickly without the proposal for the

derogation. However, the Committee again failed to reach a qualified majority on the criteria proposal. When an indicative vote showed that there was still no possibility of a qualified majority, the Commission chose not to move to a formal vote. Eleven countries voted in favor of the criteria, while eight voted against and eight abstained (see table below). Many of the Member States asked for the re-introduction of the derogation that would allow for maximum residue levels and import tolerances to be set if a critical plant protection product is banned under the criteria. The need for reintroduction of the derogation reportedly led Member States to vote in very different ways: some voted for the criteria but expressed the need for the derogation, while others voted against the criteria because of the absence of the derogation. Others reportedly abstained because of the lack of the derogation.

Results of the Indicative Vote

At the February 28 meeting, Member States voted in the following way:

In favor of the criteria:

Germany, Bulgaria, Spain, Italy, Croatia, Luxembourg, the Netherlands, Austria, Portugal, Romania, Finland

Against the criteria:

France, Sweden, Denmark, Estonia, Latvia, Slovenia, Slovakia, Czech Republic

Abstained:

Belgium, Ireland, Greece, Cyprus, Hungary, Malta Poland, United Kingdom

*Lithuania was not present

Procedural Next Steps

At this time, the Commission has given no indication on how or when it will move forward with the proposal. The ED proposal is going through the decision-making procedures known as the [Regulatory Procedure with Scrutiny](#), which is the method used to adopt measures that amend non-essential elements of basic legal acts adopted by co-decision. In this procedure, the SCoPAFF can move the proposal forward only after it holds a formal vote, regardless of whether it reaches a qualified majority (for or against) or a negative opinion (no majority). After a formal vote, the SCoPAFF can submit the proposal to the Council, which has two months to consider the proposal. If the Council approves or fails to act, then the proposal moves to the European Parliament. The Council and Parliament can only approve or veto a proposal under this procedure and are unable to add amendments. In the event that the Council or Parliament opposes a proposal, the measure cannot be adopted by the Commission. The Commission would then decide whether or not to submit an amended proposal.