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Substances for Screening Exercise on Endocrine Disruptors Published

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Report Highlights:
The European Commission's Joint Research Center (JRC) is currently conducting an Impact Assessment (IA) to define criteria to identify Endocrine Disruptors (EDs). On December 9, 2015, the JRC publically released the list of chemical substances that it is using in its screening exercise to assess the potential disrupting properties of approximately 700 substances. The substances in the list were selected based on the availability of toxicological data and are being used to test the different options outlined in the roadmap for the IA. After completion of the screening exercise, the JRC will also conduct a cost/benefit analysis of the criteria and the Commission will use these results to draft legislative proposals for the final EDs criteria for pesticides and biocides.

General Information:

Development of Scientific Criteria for EDs

The EC has spent several years on the development of detailed criteria for EDs to determine what substances should be considered as endocrine disruptors. According to Regulation (EC) No 1107/2009 on plant protection products (PPP), active substances used in plant protection products are banned for use in the EU based on hazard-based cut-offs, in which active substances are eliminated from the evaluation process based solely on their hazard classification. This includes substances considered to have endocrine-disrupting properties. Article 79(4) of the Regulation (EC) No 1107/2009 required the Commission to establish criteria for the identification of active substances with endocrine-disrupting properties used in plant protection products by December 14, 2013.

In June 2014, the Commission published a long-waited roadmap that presented four policy options (all hazard-based approaches) to identify endocrine-disrupting compounds. The roadmap also outlined how the IA will be conducted. The IA is a long term study of the potential impacts of a proposed legislative or regulatory change and is done alongside a public consultation before the final legislation or rule change is proposed.

JRC's Methodology for the IA

The Commission's Joint Research Center (JRC) was tasked with conducting the IA to define criteria to identify EDs. On November 6, 2015, the JRC presented its methodology to screen potential EDs to Member States (MS), Members of the European Parliament (MEPs), third countries, and other stakeholders. The scope of the screening methodology is intended to use the different options outlined in the roadmap to assess in a limited amount of time the potential endocrine-disrupting properties of approximately 700 chemical substances.

On December 9, 2015, the JRC published the list of substances it is using in the assessment. The list contains 324 substances falling under the Plant Protection Products (PPP) Regulation, 95 substances falling under the Biocidal Products Regulation, 149 substances under REACH and 45 substances under the Cosmetics Products Regulation. Some substances also fall under the Water Framework Directive. The substances in the list were selected based on the availability of toxicological data.

The JRC will publish the screening methodology and the results of the screening after completion of the screening exercise in the first quarter of 2016. The second part of the IA will use these results and will assess the costs/benefits of the different options in the roadmap for the IA. The JRC and possibly other external contractors will conduct the second part of the assessment.

The Commission expects the IA to be finalized during the third quarter of 2016. It will then decide on the most appropriate way forward based on the results of the impact assessment and further internal discussions. Adoption of a final measure, including its drafting and approval, will take approximately 9-12 months, which means that the criteria would only be adopted by mid-2017 at the earliest.

Background information:

What are Endocrine Disruptors? "Endocrine disruptors" (EDs) refer to substances with the potential to alter the endocrine systems of humans and wildlife. Some endocrine-disrupting effects are desired and caused intentionally (e.g. birth control pills, insulin) to interact with the endocrine system (hormonal system) with only a temporary effect. The real concern is with substances that may cause unintentional adverse health effects in humans and animals and irreversibly alter the functions of the endocrine system.

Potential Impact on U.S. Agricultural Exports: The development of hazard-based cut-off criteria for EDs by the EU means that endocrine active substances are not evaluated by a full risk assessment that considers both hazard and exposure. The United States believes that hazard-based cut-offs would fail to clearly distinguish those substances that are of high regulatory concern from those that are not. The EU hazard-based criteria could cause trade disruptions for major U.S. exports of agricultural commodities because it would also capture the insecticidal products with which crops like tree nuts, fruits, soybean and peanuts are commonly treated. These active substances would be banned from the market, possibly affecting established import tolerances. The respective Maximum Residues Levels (MRLs) would either be withdrawn entirely or set at a default level of 0.01 parts per million (ppm). According to an industry study, approximately $4.04 billion of U.S. exports to the E.U. of raw agricultural commodities could be affected by this policy change. The largest effects would be in exports of tree nuts and fruits ($1.577 billion), soybeans and groundnuts ($1.516 billion) and grains ($0.586 billion). Inclusion of processed food and feed products from these commodities would increase the potential effect to $4.77 billion. Globally, $80 billion (€65 billion) of EU imports could potentially be affected by ED cut-off criteria.