USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 12/12/2014
GAIN Report Number: E14062

EU-28

Post: Brussels USEU

Endocrine Disruptors in the EU - Update

Report Categories:
Agricultural Situation
Trade Policy Monitoring

Approved By:
Jim Higgiston

Prepared By:
Tania De Belder and Marcela Rondon

Report Highlights:
On September 29, 2014, The European Commission (EC) launched an online public consultation to help define criteria for endocrine disruptors as required by the regulations on biocides and plant protection products. The purpose of the public consultation is to gather the views of stakeholders (including third countries) and the general public on the roadmap published in June 18, 2014, for the impact assessment (IA) of potential options for Endocrine Disruptors' criteria (EDs). The input received during the consultation will be used as part of the IA to evaluate different policy options and could therefore have a significant impact in the decision-making on the final criteria.

The EDs' public consultation comment period ends on January 16, 2015. This is the only opportunity for stakeholders to formally provide comments on the content of the roadmap.

The potential trade impact for major U.S. agricultural exports and substances to the EU at risk amount to nearly $4.1 billion since import tolerances would be set at default level of 0.01 ppm or be withdrawn. This may be the only opportunity for the U.S. agricultural sector to provide comments and help the European Commission make an informed decision based on science and

consistent with the World Trade Organization WTO/Sanitary and Phytosanitary (SPS) agreement.

General Information:

The EC has been working for several years on the development of detailed criteria for EDs to determine, for example, what substances will be considered as endocrine disruptors. Active substances used in plant protection products are banned for use in the EU according to hazard-based cut-offs, including substances considered having endocrine disrupting properties.

Insecticidal products widely used by farmers in the developed and developing world, on crops such as tree nuts, fruits, soybeans, and peanuts are commonly treated with, may be potentially affected if the EU bans or places significant restrictions on the use of substances categorized as EDs. Industry representatives (Crop Life International) estimate that nearly $80 billion (€65 billion) of total EU imports could potentially be affected by EDs cut-off criteria.

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.

The EU's Approach to EDs

The EC has taken a hazard-based approach when regulating these substances because of the "scientific uncertainty" of the low-dose effect from these chemicals. This means that it is not clear whether a safety threshold for exposure can be established or if increasing doses will result in predictable increases in the severity of its effect. However, assessing the potential endocrine disrupting properties of an active substance based purely on hazard and not on science is not consistent with the WTO's Sanitary and Phytosanitary (SPS) Agreement.

A Parliament resolution supports the EC's approach to regulate EDs based on hazard rather than on the potential risk of adverse effects from exposure, thus, providing justification for acting in the face of scientific uncertainty and as a tool for acting on the basis of early warnings, despite the reasoned opinion from the European Food Safety Authority (EFSA) which aligns with the United States Environmental Protection Agency (EPA) risk-based approach.

The Development of Scientific Criteria for EDs

Both the Plant Protection Products Regulation 1107/2009 (Pesticides) and the Biocidal Products Regulation 528/2012 (Biocides) introduced "endocrine disrupting properties" as one of the categories of hazard-based cut-off criteria, which enables the EU to ban certain products from the market based on hazard identification rather than risk assessment without taking any levels of exposure into account. The EC was required to develop a set of scientific criteria to define endocrine disrupting properties by December 14, 2013, as this was not determined at the time of adoption of these regulations.

Therefore, the Directorate General of Environment of the European Commission (DG ENVI) presented a draft proposal in February 2013 which laid out a set of criteria for the identification of EDs intended to be implemented at the same time in different sectors, such as pesticides, biocides as well as to general chemicals (REACH) and cosmetics. Other DGs involved did not support parts of the initial proposal, resulting in considerable delays to develop the required scientific criteria. At the same time, after internal consultation, the EC decided to conduct an impact assessment (IA) to evaluate the possible impact of this proposal along with other policy options for the final ED

criteria.

On June 18, 2014, the EC published the long-waited roadmap for the IA. A roadmap is a planning document outlining 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. The final criteria can only be adopted once the impact assessment is completed.

The EDs Public Consultation

The Commission's Roadmap presents four policy options to address EDs criteria, only referring to a hazard-based approach. The EC launched an online Public Consultation on the proposed policy options for the criteria to gather views from all stakeholders.

The comments received during the public consultation will be used as part of the IA, and will be considered by the EC as it prepares its final criteria. Therefore, the input could have a significant impact in the in the decision-making for the final criteria. The closing date for the online public consultation is January 16, 2015, and this is the only and last opportunity for stakeholders to formally provide comments on the content of the roadmap. The Joint Research Center (JRC) is currently conducting the IA and is expected to be completed during the course of 2015, after which the EC will come forward with legislative proposals for the final EDs criteria for pesticides and biocides.

EU Industry's Position on the EU's Hazard-Based Approach

The EU crop protection industry, represented by the European Crop Protection Association (ECPA), believes that criteria should evaluate endocrine active substances based on risk assessment, considering both hazard and exposure and that the final criteria should clearly distinguish those substances that are of high regulatory concern from those that are not.

ECPA believes that endocrine disruptors can be treated like most other substances of potential concern, and be subject to full risk assessment (with the use of the WHO/IPCS (2002) definition as a scientific starting point and as a basis for the criteria for the determination of *"endocrine disrupting properties")*, where both hazard and exposure are considered in regulatory decision making. A conclusion that has also been reached by the EFSA in March 2013, but as an important policy option has been omitted from ECs roadmap and the public consultation. Therefore, it will not be considered.

Potential Impact on U.S. Agricultural Exports

These hazard-based cut-offs could cause trade disruptions for major U.S. exports of agricultural commodities because it would capture the insecticidal products with which crops like tree nuts, fruits, soybean and peanuts are commonly treated. Active substances, that are used for crop protection and are considered to have endocrine disrupting properties, will be banned from the market eventually affecting established import tolerances. The respective Maximum Residues Levels (MRLs) could 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.