



November 13, 2012

RE: Promoting US-EC Regulatory Compatibility

The European Crop Protection Association (ECPA) and CropLife America (CLA) are pleased to respond jointly to the solicitation of comments on “how to promote greater transatlantic regulatory compatibility” and promote regulatory cooperation activities that would help eliminate or reduce barriers to trade. Both ECPA and CLA welcome and support the continued coordination between the United States (US) and the European Union (EU) on agricultural trade issues.

ECPA is the voice of the Crop Protection Industry in Europe, with a clear focus on the research and development of innovative crop protection solutions. The membership includes a wide range of corporate entities and industry associations involved in chemical crop protection throughout Europe. ECPA has 19 member companies and over 25 national crop protection associations in the European Union and other countries within the wider European area.

CLA is the not-for-profit national trade organization representing the nation’s developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the US. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers.

CLA and ECPA are committed to production of safe and nutritious food through modern agriculture. CLA and ECPA members develop products for use in crop protection based on sound science. We strongly support a scientific basis for the regulation of crop protection products. While there are multiple differences between the US and the EU in the regulation of crop protection products that ultimately affect international agricultural trade, economic progress, and job creation, our comments focus on (a) the issues surrounding maximum residue limits (MRLs) for pesticide residues in food derived from crops treated with crop protection products (known as tolerances in the US), and (b) protection of regulatory data and confidential business information (CBI). CLA and ECPA are continuing discussions of other issues and differences that should be amenable to improved regulatory cooperation and harmonization. We will provide further comments in the near future. We look forward to a productive dialogue with US and EU authorities on the possibilities.

Despite being globally subject to comparatively high tariffs and a host of non-tariff trade barriers, especially in the sanitary-phytosanitary (SPS) arena, trade of agricultural commodities continues to increase between the US and Europe. The EU is the biggest net importer of agricultural commodities (unprocessed products that are mainly traded in bulk, such as grains and oilseeds). The EU is also by far the biggest importer of agricultural products in general, which includes intermediate and final products. Total agricultural imports into the EU reached €8 billion in 2011. The biggest exporters are North and South American countries, where

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modern biotechnology crops, together with chemical crop protection tools, have contributed to higher productivity. In 2011, the US exported US\$136.3 billion in agricultural commodities to all countries. After meat and meat products, soybean exports are second in volume and third in monetary terms. Specialty crops (collectively) are second in monetary terms. Similarly, the US is a major importer of European wines and processed dairy products.

Trade in agricultural products between the EU and the US amounted to US\$31.5 billion (€22.5 billion) in 2011. The vast majority of crops are, of necessity, treated with crop protection products while growing in the field and/or post-harvest, in order to reduce losses caused by weeds, arthropod pests, and plant diseases. In order to protect public health, national laws and regulations throughout the world establish systems of MRLs or tolerances to govern the allowable limits of residues from the active substances in crop protection products that may remain on food. Each MRL is typically expressed in terms of parts per million (ppm) by weight of a specific active substance in a particular harvested crop. Each country is concerned about residues of active substances on crops grown in that country (domestic MRLs); on foods imported from other countries (import MRLs); and on commodities, produce and foods exported by its growers to other international markets.

Differences among the national systems for setting, maintaining, revising, and enforcing the MRLs can lead to multiple types of non-tariff trade barriers. Such barriers can restrain trade in agricultural produce, commodities, grains, and foods; complicate crop production decisions by growers at the field level; limit growers' options for crop protection; and increase crop production costs unnecessarily. As international trade in agricultural commodities increases, growers must constantly be aware of the changing regulation of pesticide residues internationally, because their crops may be sent to any number of international markets. If chemical analysis of imported food shipments reveals pesticide residues that (a) are not covered by MRLs or (b) exceed MRLs established in the importing country, the shipments may be denied entry. A grower may not be able to use a particular crop protection product approved for use in his country, if a MRL has not been established or accepted in one or more countries where his harvested crop might be shipped, thus denying him the use of more effective or safer technology.

Under the auspices of the United Nations Food and Agriculture Organization (FAO), the Codex Alimentarius Commission establishes international MRLs intended to foster international trade in agricultural products and to support countries lacking the regulatory and technical capacity to establish their own MRLs. The US and the EU have differing approaches to and timelines for recognition of the Codex MRLs.

US and EU regulatory authorities are in frequent contact and discussion regarding harmonization of crop protection regulations, and much progress has been made. Both the EU and US participate in long-standing committees and well-developed activities of the Organization for Economic Cooperation and Development (OECD), such as the pesticide Registration Steering Group (RSG).

Nevertheless, among these differences in national regulatory systems that should be amenable to further harmonization through regulatory cooperation are the following:

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1. Timelines required for the initial approval, subsequent periodic review, and revision as necessary of MRLs for specific crops and pesticide active substances.
2. Data requirements for consideration, evaluation, and approval of MRLs.
3. Regulatory processes for approving the MRLs.
4. Values for the MRLs, the regulatory rationale used to establish them, and the calculations used to derive them.
5. Grouping of agronomically or botanically similar crops to establish crop group MRLs.
6. Definitions of the chemical substances covered by the MRL, whether they include the active substance only, a significant metabolite only (as a marker of total residues present), or a combination of active substance plus additional metabolites or degradates.
7. Analytical methods used to monitor residues in food and enforce MRLs.
8. Approaches to and timelines for recognition of Codex MRLs.

As has already been mentioned, US and EU regulatory authorities are in frequent contact regarding the harmonization of crop protection regulations. This dialogue is also important to promote high standards in other markets. In particular, the US and the EU there is an effective protection of CBI and regulatory data to ensure that innovation receives the protection and reward that is required for companies to invest in new technologies. Through Free Trade Agreements with other countries, it is important that the EU and US reinforce this view, promoting the protection of CBI as well as setting minimum standards of 10 years for the protection of regulatory data. Further dialogue and cooperation between the EU and US would be helpful in order to develop a common standard in future free trade negotiations with other nations.

We would recommend further joint efforts of EU and US regulatory authorities along with our respective associations to address these concerns actively, building on programs and activities already in progress.