



May 10, 2013

Douglas Bell
Chair, Trade Policy Staff Committee
Office of the United States Trade Representative
500 E Street SW
Washington, DC 20436

RE: Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement. 78 FR 19566. April 1, 2013. Docket No. USTR–2013–0019.

Dear Mr. Bell:

CropLife America (CLA) is pleased to respond to the solicitation for "... public comments on the proposed [Transatlantic Trade and Investment Partnership] TTIP, including regarding [United States] U.S. interests and priorities, in order to develop U.S. negotiating positions."

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 U.S. Our member companies produce, sell, and distribute virtually all the crop protection technology products used by American farmers. Many members are multi-national companies who market products world-wide.

On April 10, 2013, CLA and the European Crop Protection Association (ECPA; CLA's counterpart in Europe) commented jointly to the Office of Management and Budget on "Promoting US EC [European Commission] Regulatory Compatibility," included here as an attachment. In this document we wish to flag the points of particular importance to the U.S. crop protection industry.

Lack of a Science-Based Risk-Assessment Approach

In 2009, the European Union (EU) adopted a new and divergent approach to pesticides regulation and the registration process (EU Regulation 1107/2009), one which moved it away from a science-based approach and the use of risk assessment to guide decision making. Regulation of pesticides by principles of science-based risk assessment is firmly entrenched in U.S. law and regulation, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). The lack of a risk-based approach in the EU is contrary to the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO), to which the U.S. and EU are signatories. The EU Regulation also runs counter to regulatory practice within the U.S., accepted international guidelines, and even the EU Precautionary Principle¹, which references a risk based approach.

The lack of a science-based risk-assessment approach in the EU is evident in (i) the use of hazard-based categories to define compounds, which precludes an examination of exposure; and (ii) the use of these categories to trigger 'cut-off' or removal of these products from the market.

¹ http://europa.eu/legislation_summaries/consumers/consumer_safety/132042_en.htm

Exposure assessment is a pre-requisite for risk assessment. It is not possible to determine the risk posed by chemicals and pesticides to human health and the environment without an exposure assessment, yet this is precisely what Regulation 1107/2009 precludes.

Trade in food, feed, and seed products produced using pesticides in the U.S. and around the world will be impacted by the EU approach. For example, the Maximum Residue Levels (MRLs) for imports, specified by the EU for products it categorizes as ‘endocrine disrupters’ is effectively zero, as current MRLs for such products would no longer apply, and even trace amounts of residues would prevent U.S. agricultural and food products from entering the EU.

This non-risk-based regulatory approach extends beyond just pesticide products and will also impact trade in industrial chemicals, hygiene products, and cosmetics – as the hazard-based approach to endocrine disruption applies across all four EU regulations for these compounds. However, the approach is not consistent, because under certain circumstances, an exposure assessment and an economic assessment are permitted for chemicals under the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH; EC 1907/2006) and the EU Biocides Regulation (EU 528/2012). But for plant protection products, this is completely precluded. This calls into question the legitimate purpose of the EU regulatory approach to pesticide products.

Specific Problems Impacting U.S. Crop Protection Industry

In addition to the general concerns expressed above, our comments focus on four highly problematic areas, which CLA members would like addressed:

1. Abuse of the Precautionary Principle² by the EU: Science-based risk assessment, as the foundation for regulatory decisions, must not be overruled by an incorrect (and politically driven) application of the precautionary principle, as currently applied by the EU;
 - a. For example: The announced suspension of uses of neonicotinoid insecticides, in contradiction of the weight of scientific evidence and of established administrative procedures;
2. The use of categorization and hazard-based cut-offs for regulating pesticides by the EU, without recourse to a risk assessment.
 - a. For example, the categorization of chemicals as endocrine disruptors currently taking place in the EU. This runs counter to the science based risk assessment approach used by the U.S. Environmental Protection Agency (EPA) and specifically, to the currently evolving U.S. policy on endocrine disruptors;
3. The lack of harmonization in setting pesticide MRLs, and the asynchronous timing of their implementation.
4. The lack of a transparent and accountable expert consultation process between the U.S. and EU when drafting new pesticides regulation – one which does not undermine the independent, science-based authority that the U.S.EPA has under FIFRA.

These immediate and ongoing actions will impact crop protection products now licensed for use by the EU, with a negative effect on the crop protection products U.S. farmers can use if they wish to ship their products to the EU. It will also impact the range and value of pesticide products and active ingredients manufactured in the U.S. that can be exported to the EU.

² As codified in Article 191 of the Treaty on the Functioning of the European Union.

Solutions

The forthcoming EU reevaluation of Regulation 1107/2009, and the current EU discussions around the regulation of neonicotinoids and endocrine disrupting compounds provide an opportunity to reassess that Regulation's effectiveness, its concordance with international trade rules, and how regulatory convergence can be enhanced in the context of a U.S.-EU Free Trade Agreement.

In the course of TTIP negotiations to achieve a U.S.-EU Free Trade Agreement, CLA specifically requests:

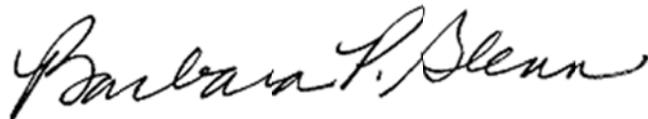
- the hazard based cut-off criteria in EU Regulation 1107/2009 should not impact U.S.-EU trade;
- the EU's use of suspension or bans of products to control product uses while avoiding risk assessments should not impact U.S.-EU trade;
- The U.S. Government should defend itself using authority of the SPS Agreement under WTO, if the EU pursues its proposed new regulatory regime for endocrine disruptors without an approach based on risk assessment.

CLA stands ready to provide supporting documentation.

This letter does not provide sufficient opportunity to spell out all of the regulatory differences that should be addressed in TTIP negotiations for crop protection products. The opportunity to develop cogent negotiating positions with broad-based support within the aggressive timeframe scheduled for the TTIP negotiations is a challenge for all. CLA recognizes the importance of the U.S. interagency consultations to these negotiations. CLA supports an ongoing consultancy process between relevant U.S. federal agencies and industry, with all parties at the table as the negotiations proceed. *We would request and welcome the opportunity to meet with the USTR and relevant federal regulatory agencies to provide additional information on our concerns.*

Thank you for this opportunity to provide comments. We stand ready to provide further detailed explanation of our concerns and solutions. Please contact me (bglenn@croplifeamerica.org; 202-833-4474) if you have any questions or comments.

Sincerely,



Senior Vice President, Science and Regulatory Affairs
CropLife America

Cc: James Jones, EPA
Steven Bradbury, EPA
Sheryl Kunickis, USDA

Attachment: ECPA-CLA comments to the US-EU High Level Regulatory Cooperation Forum, 4/10/2013



April 10, 2013

Boris Bershteyn
Acting Administrator, Office of Information and Regulatory Affairs,
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

RE: Comments to the US-EU High-Level Regulatory Cooperation Forum – Stakeholder Session

Dear Mr. Bershteyn:

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.

On November 14, 2012, ECPA and CLA commented to Docket No. USTR-2012-0028 on Promotion of US-EC (European Commission) Regulatory Compatibility. Today’s comments amplify on the concepts and messages spelled out there.

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 EU 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. There are inevitable differences between the US and the EU in the regulation of crop protection products that have arisen for good reasons. Our concern relates to those that may ultimately affect international agricultural trade, economic progress, and job creation. CLA and ECPA are continuing discussions of other issues and differences that should be amenable to

improved regulatory cooperation and harmonization. We look forward to a productive dialogue with US and EU authorities on the possibilities.

Many regulatory issues pertaining to pesticides could benefit from greater regulatory cooperation between pesticide regulatory authorities in the EU and the US. Our comments focus on three broad topics of high importance:

1. Science-based risk assessment, as the foundation for regulatory decisions, must not be taken over by the precautionary principle;
2. Maximum Residue Levels (MRLs) and the need for greater harmonization in the processes for establishing MRLs for pesticide residues; and
3. Protection of Intellectual Property, in particular, Confidential Business Information (CBI), which incentivizes innovation.

Increased regulatory cooperation must seek to enhance convergence of regulatory approaches. Yet, new national data requirements are emerging with no or only very limited consultation between the EU and US. Risk assessment and management is increasingly divergent. One notable examples of beneficial regulatory convergence is the reasonably similar regulatory data protection policies in the US and EU.

Current examples of regulatory divergence have broad potential for intermediate and long-term damage to international trade in agricultural commodities. Because of the potential for adverse influence on crop protection, ignoring or downplaying their importance now will make future corrective action that much more difficult.

- Increasingly frequent application of the precautionary principle in the assessment of pesticides in the EU.
- The anticipated suspension of uses of neonicotinoid insecticides, in contradiction of the weight of scientific evidence and of established administrative procedures;
- The use of hazard based cut-off criteria in the EU; for example consideration to categorize chemicals as endocrine disruptors in the absence of a risk assessment and ignoring evaluation of solid scientific data, both which are essential processes in the currently evolving U.S. policy on endocrine disruptors; and
- Lack of expert consultation between EU and US agencies on data requirements, guidance, and guideline development.

From time to time, agencies, directorates, and departments within a government come to diverging decisions and actions with respect to regulation of crop protection products. A mechanism is needed to alert the respective authorities to potential problems. Both the EU and US can benefit from transparent processes and avenues of high-level cooperation and appeal or reconsideration, occurring before decisions are made, before actions have been undertaken and reversal may be difficult, and well in advance of stakeholders considering litigation for “bad” decisions.

The EU and the US have the most highly developed pesticide regulatory systems in the world. Combined, the crop protection markets in these two regions overshadow the rest of the world. What the EU and the US do in this context is carefully monitored by other nations, large and small, and frequently implemented in similar fashion.

Consideration of the international consequences must be built into the decision-making processes for both governments. How this happens must be transparent to stakeholders in the US and the EU. Well-regulated in-person forums with multiple opportunities for reviewer-to-reviewer communications must be available for exchange of information between EU and US authorities as decisions are underway. We would point to the Regulatory Cooperation Council established under the US-Canada Free Trade Agreement as a worthy model to follow.

The American Chamber of Commerce to the European Union (AmCham) made a general statement in comments last Fall that is quite apropos for pesticide regulation:

“We would recommend EU and US regulators adopt a broader consultation process, including of affected industries, at the earliest stages. This will help to identify differences and potential opportunities to further cooperate to ensure minimum competitive impact before regulation is proposed and implemented. We believe agreeing on concrete processes to foster mutual recognition and other forms of cooperation for regulations and standard setting should be a key priority.”¹

1. Science-based Risk Assessment

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the US has a long record of science-based risk assessment to inform regulatory decisions by EPA for pesticides. A robust body of laboratory and field data must accompany an application for a new pesticide product, or a new use of an already registered product. Assessment of these data by EPA scientists and managers results in solid decisions that must withstand rigorous scientific scrutiny. The benefits for product uses are taken into consideration, and decisions are subject to periodic review to account for any new data requirements or new information regarding the use of the products. While the US Government system is not perfect, the EPA opens its procedures and processes to input from stakeholders on a continual basis to propose and recommend improvements. Government officials are accountable to the rule of law and to the people for their performance and the soundness of their decisions. The approach relies on conservative risk assessment to determine the conditions under which a product may or may not be registered. It requires exposure assessments for children, workers, other subpopulations, the general population, and wildlife.

In large part, the EU relies on very similar data requirements and body of data for a given chemical and product in making its corresponding pesticide regulatory decisions. As such, a science based evaluation should be expected. However, EU Regulation 1107/2009, which governs pesticide regulation in the EU, increasingly uses hazard-based cut-off criteria as the first step in the evaluation process, rather than undertaking risk assessment. Substances with certain hazard classifications do not reach the risk assessment stage. This leads to application of the precautionary principle at multiple levels:

- In defining the hazard classification;
- In the risk assessment (which already encompasses large safety factors); and
- In risk mitigation.

Excessive reference to and use of the precautionary principle leaves the process open to undue political influence. It can also lead to highly unlikely risk assessment scenarios, which are impossible in the real world, and are not used in engineering or in the assessment of pharmaceuticals. Furthermore, apparent freedom of EU Member States to implement or ignore regulations agreed by their representatives at the EU level complicates practical crop protection at the local level, and hinders international trade to and from Europe in agricultural commodities.

The forthcoming reevaluation of Regulation 1107/2009 is an opportunity to reassess its effectiveness, its influence on international trade, and how regulatory convergence can be enhanced in the context of an EU-US Free Trade Agreement.

We would concur with the following position expressed by AmCham:

“A uniform approach to risk assessment would provide clarity and confidence for both operators and consumers in EU and US markets. Different risk assessment procedures create barriers to entry in markets, cause confusion for consumers and by their nature, raise questions rather than provide answers to consumers looking for direction and guidance from “experts” in our regulatory regimes. Defining a common risk assessment approach would be one of the most valuable principles in creating a level playing field across the transatlantic economy.”²

International joint reviews, as introduced and guided by the vision on “A Global Approach to the Regulation of Agricultural Pesticides”³ developed by the Organization for Economic Cooperation and Development (OECD), have become the *de facto* process for bringing new crop protection products to the world market. The pesticide regulatory authorities of multiple countries collaborate to review the application and its supporting scientific data simultaneously, sharing the numerous tasks involved in risk evaluation, and accepting the results of each other’s reviews of studies. Ideally this approach reduces the workload for all, improves general understanding of the chemistry and uses of the product, results in better decisions, enhances convergence of regulatory approaches, and brings improved crop protection technology to more farmers more quickly.

However, we often observe that the same data set is evaluated multiple times, by different experts, who come to different conclusions. The US and EU use different approaches to describe and regulate the uncertainties in scientific study information. The lack of consistency drives further precaution, because the lowest common denominator is usually applied, leading to conflicting messages to the public. For example, how can the same substance be considered a carcinogen with relevance for human health in the EU but not in the US, or *vice versa*? In recent years, the EU has been a distant or reluctant participant in international joint reviews. We would strongly encourage the EU to actively reengage, so as to both contribute to and benefit from this most important endeavor. This is particularly important within the context of a Free Trade Agreement, where shared knowledge enables a more convergent approach to regulation.

2. Maximum Residue Limits

Despite 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 €98 billion in 2011. The biggest exporters are North and South American countries, where 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 of commodities is international in scope; the regulatory approaches to decisions should be similar. Today growers, traders and food processors require that commodities must be acceptable to be traded globally. The financial risk of being rejected at the port of entry due to the absence of legal or harmonized trading standards is not acceptable to the food chain.

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. Note that MRLs reflect the residues arising from the use of the crop protection product as recommended on the label. MRLs are not, as is commonly thought, directly related to toxicity of the product.

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. Growers may not be able to use a particular crop protection product approved for use on their crop in their country, if the MRL has not been established or accepted in one or more countries where the harvested crop might be shipped, thus denying the use of more effective and potentially safer technology.

Therefore, differences among the national systems for setting, maintaining, revising, and enforcing the MRLs can lead to multiple types of non-tariff trade barriers. Without improving consumer safety, such barriers can –

- restrain trade in agricultural produce, commodities, grains, and foods;
- complicate crop production decisions by growers at the field level;
- Prevent access to certain crop protection technologies; and
- limit growers' options for crop protection, as the crop is usually planted when the market for the harvested crop is yet unknown.

The net effects are unnecessary increases in crop production costs without enhancing protection of human health and the environment.

Both the EU and the US actively participate in two primary international standard-setting bodies heavily involved in pesticide regulation. First, under the auspices of the United Nations Food and Agriculture Organization (FAO) and the World Health Organizations (WHO), the Codex Alimentarius Commission (CAC) 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. This work is assigned to the Codex Committee on Pesticide Residues (CCPR), along with the supporting Joint Meeting on Pesticide Residues (JMPR) (see <http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/>). Second, OECD conducts a robust program to develop international standards for pesticide regulation to aid its member countries (see <http://www.oecd.org/env/ehs/pesticides-biocides/>). Despite their participation in these forums, the EU and US have differing approaches to and timelines for the recognition of Codex MRLs.

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

a. Regulatory processes for approving MRLs:

Regulatory approval processes in the EU and US are not similar. The differences in the current regulatory systems in the EU and the US are linked to the historical procedures in place, and little effort has been made to improve synchronization. While there are specific areas where greater synchronization may be achieved through greater dialogue, we would support a more detailed review to consider how the two regulatory processes can be brought together – to ensure efficiency in the evaluation process and in the decisions on use authorizations.

b. Timelines for the MRL approval process differ between the US and the EU (initial approval, subsequent periodic review, and revision as necessary of MRLs for specific crops and pesticide active substances). Authorities in both regions should investigate how they could modify procedures to meet each other's legal obligations for review.

Under the re-registration program initiated in the EU in the early 1990s, the number of registered crop protection active substances (called “active ingredients” in the US) was reduced by more than two-thirds. Many of the active substances cancelled in the EU are still on the US market, and thus treated commodities are in international trade. Where the EU generally (with some exceptions) reviews the approval of active substances every 10 years, the US conducts registration review on a 15-year schedule. These two review programs are not synchronized, and serious attempts to do so have never been undertaken.

An MRL is defined as “... the upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with [EU Regulation No. 396/2005], based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.”⁴ MRLs are established for each pesticide active substance on each food commodity for the crop where its use is authorized. The US law and regulations call MRLs “tolerances,” and the process of establishing them as federal regulations is similar.

As long as EU MRLs and US tolerances can be maintained, the lack of synchronicity is not necessarily harmful – provided important technical parameters remain harmonized, as explained in more detail below. For new active substances (for which MRLs and US tolerances have yet to be established), several OECD member countries have agreed on a vision³ and established a joint effort to jointly review new active substances to increase trust in each other's decision, increase credibility among the public, and share resources. Joint reviews have been a reality among EU Member States for a long time, with a strong coordinating role of the European Food Safety Authority (EFSA). This is similarly true between the US and Canada.

However under Regulation 1107/2009 neither the EU nor EFSA is authorized or encouraged to participate in global joint reviews. In fact there is no legal basis for EFSA to be fully part of joint reviews, as it is mandated to follow the EU timelines only. Still, a number of EU Member States have cooperated with the US authorities on a voluntary basis in joint reviews in their role as rapporteur Member States under Regulation 1107/2009. Such initiatives have significantly increased the dialogue among regulators across the Atlantic.

US and EU conclusions may differ due to differences associated with science-based risk-benefit assessment conducted in the US under FIFRA. Without the participation of EFSA, it will prove difficult to develop and improve and benefit from these joint reviews. Consideration needs to be given to a more streamlined EU system that will better support the joint review system. While the participation of individual Member States in a global joint review has been useful, the benefits are limited, as their evaluations are subject to further changes within the EU approval process.

- c. **Data requirements** for consideration, evaluation, and approval of MRLs.
- d. **Numeric Values for the MRLs**, the regulatory rationale used to establish them, and the calculations used to derive them.
- e. **Crop grouping** of agronomically or botanically similar crops to establish crop group MRLs.

Crops may be grouped according to agronomic and/or botanical similarity in order to establish an MRL for the entire group, using a reduced data set from representative crops. Crop groups used in the US for establishing US tolerances are very similar to the crop group classification used by Codex Alimentarius, but differ quite frequently from those used in the EU. This can result in US tolerances set for crop groups that might apply in the EU to only a subset of individual crops from the group. Under such circumstances, additional data must be provided to the EU for setting the MRLs for additional crops in order to enable trade.

f. **The Residue Definition for MRL enforcement:**

Differences in Residue Definitions can often be the source of real and perceived trade barriers. The Residue Definition for enforcement of an MRL in the EU is typically the active substance or a significant metabolite or degradation product that can be used as a marker and analysed readily to determine residue levels. In recent years during the EU review program, the Residue Definition for risk assessment has been changed for a number of active substances to include

additional metabolites or degradates. A conversion factor is typically used to convert monitored residues into values suitable for risk assessment when required. In the US there is usually no distinction between the Residue Definitions for enforcement and risk assessment. The Residue Definition for enforcement in the US can include metabolites and degradation products which would typically be monitored by analysing for a common moiety rather than a specific chemical entity.

g. Approaches to and timelines for recognition of Codex MRLs:

For chemicals with acceptable dietary risk assessment, the EU proactively adopts import MRLs based on established Codex MRLs, resulting in greater MRL harmonization between the EU and countries that defer to Codex. The US does not have a similar policy, and does not adopt Codex MRLs unless formally petitioned by the registrant. This process is impeded by registration fees for establishing tolerances, resulting in common disharmony between the US and countries deferring to Codex, many of which are in Latin America and should be natural trading partners for the US

h. Submission formats:

The EU and US specify different reporting formats for registrants to summarize study information, and the authorities themselves favor different reporting formats for their own evaluations of the studies. The levels of detail requested by reviewing authorities in the EU and the US can also differ significantly. This makes the exchange of their reviews for peer review purposes more difficult, and leads to longer review times and higher costs for authorities. While the EU requires a modified OECD reporting format for summarizing study information, the US uses a different format, and even has special requests for individual study reports. Recent proposals indicate that the EU intends to use a modified version of the OECD format in the future. Whether the new format has been agreed with non-EU countries in OECD is not known. It is recommended that the North American and EU Authorities focus on establishing a common electronic format, such as XML templates, to accommodate desired customized reports, yet relying on a common input data set.

Trade impact

New active substances authorized more quickly in the US than in the EU, and *vice versa*, can only be used by farmers to a limited extent in those countries where the registration has been used first if MRLs/US tolerances are not established simultaneously. Where many commodities were in the past only produced for the domestic market, today's growers, traders and food processors require that commodities can be traded globally. The financial risk of being rejected at the port of entry due to the absence of legal trading standards is not accepted by the food chain.

Furthermore, new innovative active substances offer farmers more security for a good harvest, increase their productivity, reduce the environmental burden, and are safer for wildlife and operators. Intensification of integrated pest management as well as responsible resistance management are key factors to respond to current and future food and feed demands. Therefore, ideally EU MRLs and US tolerances should be granted in the same year. A delay in the US or in the EU has a significant impact in trade. To this end, it is imperative that US EPA and EU accept and review import tolerance petitions during the time period which a new active

substance, or new uses for an already registered active substance, are being evaluated and approved by the authority of the exporting country/region. Another option that can be explored is the use of “provisional” MRLs based on the initial approval in either the EU or US depending on who grants the first approvals. The Regulatory Systems in the EU and US are the most advanced in the world and adopting provisional MRLs automatically by either the EU or the US will demonstrate trust in the decision-making by the Authorities in each region. The “provisional” MRLs can be confirmed or revised later based on subsequent review under the current respective systems. This can also be extended to other regions of the world once established as a workable process under the most advanced regulatory systems.

As previously pointed out, not only timing is relevant. Industry acknowledges the efforts in the US and the EU to harmonize data requirements, but significant further efforts are necessary to overcome technical barriers, as even already established MRLs and tolerances can be impacted and lead to major trade impediments.

Steps that the EU and US should consider:

- As a first step, we would support the establishment of a specific working group which is responsible for overcoming differences, in processes impacting review timelines, technical matters and regulatory policies.
- By default, jointly and concurrently review MRL/US tolerance dossiers.
- Both EU authorities and US agencies need to give a clear commitment to adhere to agreed timelines.
- Both parties should mutually accept all residue studies conducted in the EU and the US, provided the Good Agricultural Practices (GAP) are comparable. The demand for local studies should be reduced, as the GAP and cropping practices are the dominant factors for the variability of residue levels, not the location/country or climate.
- Identify technical and policy related reasons for differences in MRL proposals, and work to overcome these reasons.
- Agree on and establish identical formats for submission of study reports. US may need to update the reporting requirements in PR Notice 2011-3 to conform.
- Agree on the OECD Tier 2 format for data summaries, which allows for customization of the output but is common with respect to data input.
- Advise regulatory authorities to consequently use the OECD guidance document on the residue definition⁵ to establish residue definitions for MRL setting. Furthermore, look for opportunities to rely upon the scientific evaluations of other reputable Authorities in order to minimize redundancies in effort that lead to longer review timelines.
- Agree on one common evaluation format to be used by US-EPA, EU Member States, and EFSA to enhance efficiency.
- Both partners should agree to adopt a common classification for crop groups, preferably according to the Codex Classification. This would mainly require a change in regulation EC 396/2005.

3. Protection of Intellectual Property

Regulatory data protection is one of the essential elements for stimulating investment in research and development of agricultural crop protection products. This protection provides benefits to

all stakeholders – from farmers to consumers – ultimately contributing to the economic development of industrialized and developing countries alike. The requirement to protect data from disclosure and “unfair commercial use” is recognized under Article 39 of the World Trade Organization’s (WTO’s) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Intellectual property can be protected in a number of specific ways well recognized and regulated under national and international laws. Aside from patents, pesticide regulatory authorities have direct responsibility under corresponding national legislation for protection information claimed as CBI. Furthermore, strong national pesticide legislation prohibits use of regulatory data belonging to one company from being used by another company to support a product registration for a reasonable period of time, unless the data owner is compensated appropriately. It is critical that industry and regulatory authorities work together to safeguard regulatory data, especially CBI. Regulatory authorities must be properly trained, in order to take affirmative steps to safeguard data against unfair commercial use.

It is important that EU and US continue to promote minimum standards of 10 years for protecting regulatory data, and protection of CBI through Free Trade Agreements with other countries, where protection of regulatory data is sub-optimal. These include Mexico, New Zealand, Argentina, India, and Paraguay. We hope that the Trans-Pacific Partnership (TPP), now under negotiation, will raise the standard to 10 years for some of these countries.

Steps that the EU and US should consider:

- Ensure a common approach in free trade negotiations with all countries to promote a minimum 10 year standard for the protection of regulatory data;
- A common framework for the protection of CBI to be included in a Free Trade Agreement between the EU and US.;
- Provide training to regulatory authorities to ensure protection of regulatory data against unfair commercial use; and
- Ensure that Article 39 of TRIPS is enforced in all WTO member countries.

Conclusions

International trade enhances society. By trading with others, consumers and producers can buy and sell a greater variety and abundance of goods or services. Global trade is a key element in guaranteeing food security. The EU and the US share a common objective: ensure and maintain excellent food safety standards, while maintaining a sustainable and affordable food supply. Relatively similar safety standards exist, but a few significant differences still prevail. We therefore jointly encourage the US and the EU to intensify their cooperation, take the lead to overcome existing barriers, and jointly send a strong signal to other countries, such as OECD member countries and other trading partners.

A uniform approach to risk assessment in the regulation of crop protection products would provide clarity and confidence for both operators and consumers in EU and US markets. Defining a common risk assessment approach would be one of the most valuable principles in

creating a level playing field across the transatlantic economy. Further effective protection of intellectual property and confidential business information will foster a climate of innovation. Harmonization of MRL settings will reduce costs in the entire food chain. All these measures create a stimulating growth environment, ultimately creating and securing highly qualified employment opportunities. In these comments, ECPA and CLA have presented concrete suggestions on how to make regulatory regimes for agricultural crop protection products more compatible and thus facilitate international trade in key agricultural commodities between the US and the EU.

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. **The crop protection industry represented by CLA and ECPA is willing to assist and participate in any projects related to facilitating a more positive and productive agricultural trade relationship. We would appreciate and welcome the opportunity to meet and engage in discussion with authorities on these matters. We offer our support and assistance as the EU and the US government work to enhance their trade relationship.**

Sincerely,



Jay Vroom
President & CEO
CropLife America



Friedhelm Schmider
Director General
European Crop Protection Association

References:

¹ American Chamber of Commerce to the European Union, AmCham EU's response to the European Commission Public consultation on the future of EU-US trade and economic relations. P. 5. 9/27/2012.

http://www.amchameu.eu/DesktopModules/Bring2mind/DMX/Download.aspx?TabId=165&Command=Core_Download&EntryId=8053&PortalId=0&TabId=165

² AmCham, op cit. P. 4.

³ <http://www.oecd.org/fr/securitechimique/pesticides-biocides/33854658.pdf>

⁴ Regulation (EC) No 396/2005 Article 3.2.(d)

⁵ Organisation for Economic Co-operation and Development. 28-Jul-2009. Series on Testing and Assessment No. 63 and Series on Pesticides No. 31. Guidance Document on The Definition of Residue. Rev. 2009. ENV/JM/MONO(2009)30.

[http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2009\)30&doclanguage=en](http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)30&doclanguage=en)