Proposal on US-EU Regulatory Cooperation

March 7, 2014

The European Crop Protection Association (ECPA) and CropLife America (CLA) propose the following areas of collaboration:

1. **Sectoral negotiation on agricultural chemicals:** ECPA and CLA propose to the EU and US negotiators a sectoral negotiation on agricultural chemicals as part of a single undertaking, which should aim to analyze the current divergences in both regulatory systems, explore ways to promote cooperation and harmonization, and find solutions to emerging trade problems.
2. **Risk assessment as the basis for the regulatory framework:** CLA and ECPA strongly support the use of risk assessment as the basis for the pesticide regulatory process for all active substances and plant protection products. Risk assessment includes hazard identification, hazard characterization, and exposure assessment. We request our EU and US negotiators to take necessary steps toward the inclusion of science-based risk assessment as the unified basis for pesticide regulation. Without science-based risk assessment as the basis of pesticide regulation, any additional requests for regulatory convergence are unattainable. Furthermore, risk assessment is a fundamental principle of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), to which the EU and US are signatories.
3. **Harmonization regarding Maximum Residue Levels (MRLs):** Under a risk assessment framework for pesticide regulation, ECPA and CLA seek significant harmonization in the processes for establishing MRLs. MRLs (and the MRL setting processes) are a key element of a unified framework among the EU and the US.
4. **Protection of intellectual property:** ECPA and CLA support robust protection of intellectual property, and specifically Confidential Business Information (CBI). The EU and US should agree to promote a common set of minimum standards in free trade negotiations with other countries. These standards should include 10 years for protecting regulatory data, and the protection of CBI, in line with Article 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

A harmonised risk assessment framework for pesticide regulation is necessary to ensure the highest level of consumer and environmental protection, while promoting international trade, creating jobs, and enhancing social and economic viability of the EU and the US.

Introduction

The European Crop Protection Association (ECPA[1]) and CropLife America (CLA[2]) are pleased to respond jointly to the solicitation of comments on "how to promote greater trans-Atlantic regulatory compatibility" and promote regulatory cooperation activities that would help eliminate or reduce barriers to trade. While ECPA and CLA have provided initial comments on these issues, this document further develops our views while focusing on areas where we believe that real progress can be achieved.

There are inevitable differences between the United States (US) and the European Union (EU) in the regulation of crop protection products that have arisen for various reasons. Our aim is to promote regulatory cooperation and harmonization to reduce the regulatory burden that results from such differences and improve efficiency. Our major area of concern relates to differences that may ultimately affect international agricultural trade, economic progress, and job creation.

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

1. The use of risk assessment as the foundation for regulatory decisions, including joint reviews;
2. The need for greater harmonization in the processes for establishing Maximum Residue Levels (MRLs); and
3. Protection of Intellectual Property, in particular, Confidential Business Information (CBI), which incentivizes innovation.

We would also take the opportunity to promote:

- Greater bi-lateral regulatory cooperation on issues of common regulatory interest and concern.
- The management of Good Laboratory Practice (GLP) standards to ensure acceptance of regulatory data by national regulatory authorities.

The challenges in regulatory cooperation

Increased regulatory cooperation must seek to enhance *convergence* of regulatory approaches while maintaining high levels of protection for human health and the environment. Notable examples of beneficial regulatory convergence are the reasonably similar approaches to the setting of MRLs and the protection of regulatory data in the US and EU.

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[1] 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 32 national crop protection associations in the EU and other countries within the wider European area.

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

Existing regulatory *divergences* have broad potential for intermediate and long-term negative impacts on trade in agricultural commodities, and raise costs for producers on both sides of the Atlantic. The primary divergence includes different approaches in assessing pesticides with different emphasis on the evaluation of risk and hazard. Allowing additional divergence in regulatory processes may contribute to potentially large negative impacts on trade in agricultural goods between the US and the EU.

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. How the EU and the US regulate pesticides is carefully monitored by other nations, large and small. 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. Furthermore, expert consultations between EU and US agencies on data requirements, guidance, and guideline development would help to avoid future divergence in regulation and assessment of substances.

Once risk assessment is adopted uniformly for both EU and US pesticide regulation, there is the possibility to harmonize MRL processes. Harmonization of MRL procedures offers an opportunity to maintain and promote trade in agricultural products between the EU and US, applying a robust evaluation system based on risk assessment. We would point to the Regulatory Cooperation Council established under the US-Canada Free Trade Agreement as a worthy and successful model to follow.

Key areas of focus:

1. Science- and Risk-based Assessment, including joint reviews

- ***CLA and ECPA strongly support the use of risk assessment as the basis for the pesticide regulatory process.***

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 active substance (called "active ingredient" in the US), or a new crop use of an already registered product. Assessment of these data by EPA scientists and managers results in solid decisions that must withstand rigorous scientific and policy 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.

The US approach relies on conservative risk assessment to determine the conditions under which a product may or may not be registered and used. It requires exposure assessments for the general population, children, workers, other subpopulations, and wildlife.

The legislative framework in the EU is set out in Regulation 1107/2009, and the EU relies on very similar data requirements and body of data in making its corresponding pesticide regulatory decisions, for a given active substance and product. An active substance or product shall only be approved if the risk assessment demonstrates risks to be acceptable, based on realistic "maximum exposure" conditions of its use in crop protection. While the EU's regulatory framework is risk based, Regulation 1107/2009 does introduce hazard-based criteria as the first step in the evaluation process; where substances with certain hazard classifications do not reach the risk assessment stage.

Risk assessment is an internationally agreed principle (e.g. WTO SPS Agreement), and a uniform approach of the EU and the US to risk assessment would provide further clarity and confidence for both farmers and consumers in EU and US markets, including for trade partners who adhere to a risk-based approach when setting import tolerances. Reliance on a hazard-based approach, to the exclusion of risk assessment, is not compliant with the WTO SPS agreement. Defining a common risk assessment approach would be one of the most valuable principles in creating a level playing field across the trans-Atlantic economy. If the EU and US had similar principles whereby pesticide regulations are based on risk assessment, this would enable the convergence that we request in the following technical issues. We fully realize the complexity of the task; but the TTIP negotiations offer an opportunity and a lever toward greater coherence.

- ***Joint reviews***

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) in 2004, 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 endpoint 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 and more consistent decision making, 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 still 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.

[3] http://www.oecd.org/fr/securitechimique/pesticides-biocides/33854658.pdf

2. Maximum Residue Levels

- ***ECPA and CLA strongly support greater harmonization of the processes for establishing MRLs.***

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 raw 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, from all geographic sources, which includes intermediate and final [processed] 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 financial value. Specialty crops (collectively) are second in financial value. For its part, 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 insist that commodities be acceptable in global trade. The financial risk of a commodity shipment 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 levels of residues from the active substances in crop protection products that may remain on or in food and feed products. Each MRL is expressed in terms of mg/kg or parts per million (ppm) of a specific active substance in a particular harvested crop commodity, reflecting the residues arising from the use of the crop protection product as recommended on the label. Each country is concerned about residues on crops grown in that country for domestic consumption (domestic MRLs); on foods imported from other countries (import MRLs); and on commodities, produce, and foods exported by its growers to other international markets. MRLs are compliance standards and not, as is commonly thought, directly related to the toxicity of the active substance.

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 of numerous different 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. If the appropriate MRL has not been established or accepted in one or more countries where the harvested crop might be shipped, growers will not be able to use particular crop protection product approved for this use by their home country, thus limiting their options to treat pests and disease. Absence of an adequate MRL for this product and crop use in importing countries restricts trade of the treated commodity and impedes 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, while not contributing to consumer safety. For example, the differences can –

- restrain trade in agricultural produce, food and feed commodities, and grains;;
- 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 relevant decisions must usually be made when the market for the harvested crop is yet unknown.

The net effect is unnecessary increase in crop-production costs, without enhancing the protection of human health and the environment.

To ensure international trade in agricultural products, a key element is the need to ensure a robust and harmonized system for the setting of MRLs. Trade difficulties between the EU and US arise when MRLs are required for imported agricultural products; this situation may arise where a crop is not grown in the importing country or region, or where a particular active ingredient is not authorized for use in the relevant crop in the importing country or region.

To allow trade, clear procedures are required to allow the setting of MRLs for traded products. Such procedures must be based on a system of robust risk assessment, and should not lead to higher barriers for active ingredients and crop uses that are not authorized in the evaluating region. We fear that political and administrative processes in the EU and US could place unnecessary hurdles in the evaluation system for such MRLs; in this context, we have particular concern about the EU's hazard-based cut off criteria. The crop protection industry however stresses the need for legislation governing the setting of MRLs to be based on a system of risk assessment, thus ensuring compliance with the WTO SPS provisions.

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 "Codex MRLs" intended to foster international trade of agricultural products, avoid trade irritants, and protect the consumers of all countries. The effort also supports countries lacking the regulatory and technical capacity to establish their own MRLs. This work is assigned to the Codex Committee on Pesticide Residues (CCPR), supported by the 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.

With the aim of enhancing convergence of regulatory approaches and achieving decisions that will avoid trade irritants, while safeguarding the safety of consumers, ECPA and CLA see a need

of cooperation towards more harmonization, primarily in the following processes (see Annex for detailed explanation):

a. Regulatory processes for setting MRLs
b. Timelines for the MRL setting process differ between the US and the EU
c. Crop grouping to establish crop group MRLs.
d. The Residue Definition for MRL enforcement
e. Recognition of Codex MRLs
f. Data Submission formats

CLA and ECPA strongly support efforts to achieve greater harmonization in the processes for establishing MRLs.

- ***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, while EU MRLs/US tolerances are not established simultaneously. Today's growers, traders and food processors produce for worldwide customers, and therefore require that commodities can be traded globally. The financial risk of goods being rejected at the port of entry is not acceptable by the food chain and is misinterpreted by the consumers as a health concern.

New innovative active substances can offer farmers more security for a good harvest of higher quality with reduced environmental burden. They are often more suitable for integrated pest management (IPM), as well as responsible resistance management, which are key factors to respond to current and future food and feed demands. Ideally a new active substance should be authorized in parallel in US and EU, while MRLs and Import Tolerances should be set concurrently for the domestically produced and imported produce. The current [US?] requirement for providing a registered label from the country where the product is registered in support of an Import Tolerance submission effectively promotes a step-wise process and slows synchronization of MRLs between the EU and US.

Another option that can be explored is the use of temporary "provisional" MRLs in either the EU or US, relying on initial approval by the other party. The "provisional" MRLs can be confirmed or revised later, based on subsequent review under the current respective systems.

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. A workable regulatory process for setting MRLs, agreed and applied by the leaders, could then be extended as a model to other regions of the world.

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.

- ***On Maximum Residue Levels, steps that the EU and US should consider:***

As a first step, we would support the establishment of a specific working group charged with responsibility for overcoming differences in processes impacting review timelines, technical matters, and regulatory policies. The points to harmonize, are, in priority order:

- By default, jointly and concurrently review EU 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 requirement 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. This has been shown in extensive studies conducted under the OECD and Codex umbrellas.
- Identify technical and policy-related reasons for differences in MRL proposals, and work to overcome them.
- Agree on common formats for submission of study reports. The US may need to update the reporting requirements in its 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.
- Agree on the use of the OECD guidance document on the residue definition[4] 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 (or compatible) evaluation format to be used by US-EPA, EU Member States, and EFSA, in order 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

ECPA and CLA strongly support that the EU and US continue to promote (a) minimum standards of 10 years for protecting regulatory data, and (b) protection of CBI through Free Trade Agreements with other countries, where protection of regulatory data is sub-optimal. Protection of regulatory data from unauthorized use by competitors is essential 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

[4] 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

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), under the World Trade Organization (WTO).

Intellectual property can be protected in a number of specific ways that are well recognized and regulated under national and international laws. Aside from patents, pesticide regulatory authorities have direct responsibility under corresponding national legislation for protecting information correctly 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 formally consents and/or 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 (a) minimum standards of 10 years for protecting regulatory data, and (b) protection of CBI through Free Trade Agreements with other countries, where protection of regulatory data is sub-optimal. We hope that the Trans-Pacific Partnership (TPP), now under negotiation, will raise the standard to 10 years for some of these countries.

<u>On Protection of Intellectual Property Rights, Steps that the EU and US should take:</u>

- Ensure a common approach in free trade negotiations with all countries to promote a minimum 10 year standard for the protection of regulatory data;
- Develop a common framework for the protection of CBI, to be included in a Free Trade Agreement between the EU and US, as a clear example for all other multilateral Free Trade Agreements worldwide;
- Provide training routinely 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.

Opportunities for bi-lateral regulatory cooperation on issues of common regulatory interest and concern.

ECPA and CLA emphasize that the top priority to achieve regulatory convergence is to harmonize pesticide regulation to include the science-based risk assessment. 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. To improve cooperation and harmonization, 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. We recommend that EU and US regulators adopt a broader consultation process, at the earliest stages. This will help to identify differences and potential opportunities to further cooperate and ensure minimum unfair 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.

A number of areas offer opportunities for cooperation in the short to medium term:

- **Endocrine disruptors – ECPA and CLA support a risk assessment approach to evaluation of endocrine disruptors.** It is clear that the EU and US have taken very different approaches to managing endocrine disruption screening, testing, and regulation. It should be highlighted that there are still opportunities for regulatory convergence in the data requirements and the scientific assessment and risk assessment procedures.

- **Nanotechnology** – This is an area with significant and divergent regulatory developments in the EU and US. There are clearly some opportunities to further consider common solutions.

- **Low-dose effects** – With this issue being high on the current political and regulatory agenda internationally, there are clear opportunities to cooperate in ensuring a common understanding of the issues to be considered, and to ensure proportional and coordinated regulatory action.

- **Pollinators** – This is an area where available data have led to very different conclusions in the US and EU. It would be helpful to promote further cooperation, in particular with the aim of ensuring a better common understanding of the management of pollinator populations and the role played by pesticides in that management.

In addition to cooperation on such specific scientific issues, ECPA and CLA would support greater cooperation among the relevant scientific committees and panels that provide support for the regulatory agencies in the EU and US. Due to the increasing detail and complexity in many areas of pesticide regulation, there is limited available expertise in some science and policy areas, and further cooperation would help to ensure that this expertise is part of the scientific dialogue in both trading blocks.

Additional specific areas where policy developments could help regulatory cooperation

- ***The management of Good Laboratory Practice (GLP) standards to ensure acceptance of regulatory data.***

Adherence to GLP standards by industry, along with enforcement by governments, are essential to ensure that the studies and data supporting decisions on pesticide registration, MRLs, and tolerances are robust, reliable, repeatable, and accurate. Human health, worker safety, crop protection, environmental quality, and public confidence are at stake. US and EU governments must collaborate on (a) continued recognition of common GLP standards, (b) Mutual Acceptance of Data (MAD) developed according to GLP from their respective countries, (c) rigorous supervision of GLP labs and studies, (d) adequate frequency of inspection programs, and (e)

adequate resources to assure one another of GLP compliance, so that GLP studies conducted in one region can be considered by another, without doubts concerning data quality. GLP Guidelines applicable to crop protection products have been published by OECD, US-EPA and US-FDA, and tare harmonized to a large extent[5]..

Conclusions

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.

- **ECPA and CLA strongly support a risk assessment approach to regulation of pesticides which includes a hazard identification, hazard characterization, and exposure assessment.**
- 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 trans-Atlantic economy.
- Enhancing effective protection of intellectual property and CBI will foster a climate of innovation, and set a standard for the rest of the world.
- Harmonization of MRLs and the MRL setting process will reduce costs in the entire food chain.

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. **CLA and ECPA 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.**

[5] A very useful comparative analysis "Comparison Chart of FDA and EPA Good Laboratory Practice (GLP) Regulations and the OECD Principles of GLP" has been published by the Division of Compliance Policy (HFC-230) of FDA's Office of Regulatory Affairs (ORA) in 2004 and it's available for consultation online at http://www.fda.gov/ora/compliance_ref/bimo.

ANNEX
CropLife America and European Crop Protection Association Comments on US-EU Regulatory Cooperation

Detailed Explanation of Key Area of Focus, Maximum Residue Levels

a. Regulatory processes for setting MRLs

Regulatory approval processes in the EU and US differ in important ways. The differences are linked in large part 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 decisions on use authorizations.

b. Timelines for the MRL setting process differ between the US and the EU

For 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 commodities treated with them are in international trade. As long as EU MRLs and US tolerances can be maintained, the lack of synchronicity in regulatory decision making does not necessarily affect trade.

For new active substances (for which MRLs and US tolerances have yet to be established), several OECD member countries have agreed on a vision and established a joint effort to review new active substances by shared resources, in order to increase trust in each other's decisions and credibility with the public. 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, there is no encouragement nor benefit for the EU Member States and EFSA to participate in global joint reviews, with EFSA mandated to follow the EU timelines only. Still, a number of EU Member States have cooperated in joint reviews with the US authorities, on a voluntary basis, in their role as rapporteur Member States under Regulation 1107/2009. While such initiatives have significantly increased the dialogue among regulators across the Atlantic, the implementation of the EU process as a separate step might lead to a different MRL decision. US and EU conclusions may differ due to differences associated with the risk assessment evaluation principles applied. This makes the participation of EFSA a necessity to develop improved processes for the benefit of all participants of the joint reviews. Consideration needs to be given to a more streamlined EU process in support of the decisions in joint reviews and their integration within the EU approval process, where EFSA is permitted and encouraged to participate in the joint review process.

c. Data requirements for consideration, evaluation, and approval of MRLs.

There is already a fair amount of consistency between the EU and US in the regulatory data requirements for setting domestic and import MRLs, but certain persistent differences are problematic. For example, the cost of generating and reviewing regulatory residue data could be streamlined if regulatory experts from both sides could agree on common representative crops for generating crop group residue data; have common rules for the extrapolation of residue data from one crop to another; and agree on a common minimum number of residue trials to be generated for each crop for the purposes of registration and MRL/Tolerance setting. Just to illustrate the problem, five residue trials conducted on cherries (as one a representative crop for the Stone Fruits crop group in the US) are not enough to obtain an import MRL for cherries in the EU.

Work under OECD initiatives is addressing such differences, but unless the resulting OECD guidelines and guidance documents are unequivocally accepted and adopted into regional/national data requirements in the EU and US, no real value is obtained from such work.

d. Numeric Values for the MRLs, the regulatory rationale and the calculations used to derive them.

Methods to calculate MRLs have differed in the past between the US and EU, leading to significant numeric differences in EU MRLs and US tolerances derived from the same or similar sets of residue data. However, with the introduction of the OECD MRL Calculator, and the commitment from both sides to use the Calculator, better predictability in the MRL setting process is achieved and greater harmonization between EU MRLs and US Tolerances occurs. Consistent use of the Calculator is encouraged so that this positive step toward MRL harmonization may continue, especially in setting import tolerances, which relies upon the evaluation and use of foreign residue data from the exporting country. Thus, the MRL established in the importing country should be the same as that established in the exporting country, when the same data set is used.

e. Crop grouping to establish crop group MRLs.

Crops may be grouped according to similarity in botanical and morphological characteristics, as well as agronomic production practices, which combined may favor similar residue levels, in order to establish a common MRL for all crop commodities in the entire group. In such a case, the whole group is covered, using a reduced data set derived from representative crops. Differences between the US and EU crop group systems inevitably create problems with MRL harmonization and ultimately hinder trans-Atlantic trade. The International Crop Grouping Consulting Committee (ICGCC), led by the IR-4 Project with strong input from the US, EU, Canada, and more than 30 other nations, is driving the much-needed revision of the crop groups of the Codex Classification of Foods and Animal Feeds. Acceptance of the revised, updated Codex crop groups and their corresponding representative crops (including the flexibility of different representative crops, depending on country) by both the US and EU would help rationalize residue data generation and lead to greater MRL harmonization. The ultimate goal in this area would be recognition and acceptance of crop group tolerances/MRLs by either side for setting import MRLs.

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 analyzed readily to determine residue levels. Residue definitions for enforcement and risk assessment may differ in the EU; if possible a conversion factor is used to convert the residue monitored to the residue definition used in risk assessment. In recent years during the EU registration review program, the Residue Definition for risk assessment has been changed for a number of active substances to include additional metabolites or degradation products.

In the US there is usually no distinction between the Residue Definitions for enforcement and for risk assessment. The Residue Definition for enforcement in the US can include metabolites and degradation products, which would typically be monitored by analysis of either a common chemical moiety, or each of the specific chemical entities.

g. Recognition of Codex MRLs

New Codex MRLs which meet EU requirements are considered annually for adoption into EC Reg No 396/2005, resulting in greater MRL harmonization for some active ingredients between the EU and the countries following Codex. Unlike the EU, the US does not automatically consider the adoption of newly established Codex MRLs as US tolerances, but rather EPA considers whether alignment with existing Codex MRLs is possible during its regulatory reviews of active ingredients involving Tolerance setting. In the absence of an EU MRL or a US tolerance, respectively, none of the EU Member States nor the US defer to Codex MRLs for the monitoring of imported produce. This is an unfortunate situation because it results in MRL violations. If the laws were amended in the EU and US such that Codex MRLs could be accepted as the reference compliance standards for the purposes of monitoring imported foods in the absence of national/regional MRLs, international trade would be facilitated in general on both sides.

h. Data Submission formats

The EU and US specify different reporting formats for registrants to summarize study information, and use different reporting formats for their evaluations. 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. Preferably, the North American and EU Authorities should focus on establishing a common electronic format, such as XML templates, to accommodate desired customized reports, while relying on a common input data set.

The OECD dossier format is used in the EU and an option in the US. Consideration should be given to using the same evaluation reports (monographs) and dossiers in both countries .