Statement of Dr. Barb Glenn, Senior Vice President, Science & Regulatory Affairs, CropLife America (CLA) on behalf of CLA Request for Comments Concerning Proposed Transatlantic Trade and Investment Agreement HEARING MAY 29-30, 2013

Good afternoon. I am Dr. Barb Glenn, Senior Vice President of Science & Regulatory Affairs at CropLife America CropLife America welcomes and supports the continued coordination between the U.S. and the European Union (EU) on TTIP and agricultural trade issues. In spite of the opportunities, there are specific problems regarding regulatory convergence impacting the U.S. Crop Protection Industry

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. Many members are multi-national companies who market products world-wide.

CLA recommends that with respect to agriculture that the US Government work to achieve regulatory convergence within the TTIP. The lack of a science-based risk-assessment approach in the EU's regulation of pesticides is a major hurdle.

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 1107/2009 also runs counter to regulatory practice within the U.S., accepted international guidelines, and even the EU Precautionary Principle as outlined in law and treaty, 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.

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.

For example, the categorization of chemicals as endocrine disruptors currently taking place in the EU, 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.

In addition, CLA is concerned about the abuse of the Precautionary Principle 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. Where there is an element of risk, governments must regulate based on science and not on public opinion.

For example, the announced suspension of uses of neonicotinoid insecticides, is in contradiction of the weight of scientific evidence and of established administrative procedures.

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.

CLA offers the following 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, CLA specifically requests:

- First, that the hazard based cut-off criteria in EU Regulation 1107/2009 should not impact U.S.-EU trade;
- Secondly, that 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;
- Thirdly, 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.
- Finally, there must be 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.

CLA recognizes the importance of the U.S. interagency consultations to these negotiations. 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.