December 3, 2012

Mr. Jim Jones
Acting Assistant Administrator
Office of Chemical Safety and Pollution Prevention (OCSPP)
USEPA Headquarters (7101M)
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Consideration of Endocrine Disruptors in the EU

Dear Mr. Jones:

The American Chemistry Council (ACC)[1] and CropLife America (CLA)[2] have been monitoring plans of the European Commission (DG Environment / DG ENV) to regulate pesticide and other chemicals which may exert adverse effects through endocrine pathways. ACC and CLA have serious concerns that the Commission's proposed regulatory categorization process would trigger negative and far reaching impacts on global commerce.

As the deliberations of the High-Level Working Group on Jobs and Growth on "Promoting U.S. EC Regulatory Compatibility" (77 FR 59702; 9/28/2012) near their conclusion, we want to highlight our concerns to EPA and other relevant U.S. government agencies, and request that these be considered in ongoing discussions on US-EU regulatory cooperation and, where appropriate, raised directly with relevant EU and member state counterparts.

In early November 2012, the EU DG ENV released a proposal for the definition, identification and categorization of Endocrine Disruptors. Although initially proposed for use in EU Plant Protection Product regulations, the Commission proposal, if implemented, would set a precedent for other EU regulatory programs, including REACH.

The basis for our concern is that a hazard classification or categorization of chemicals as endocrine disruptors is inappropriate, because endocrine disruption is a mode of action, not an adverse effect. Where adverse effects are shown, such chemicals should be classified accordingly under existing hazard classification standards. The endocrine system is complex, with natural variations in hormone levels and reversible or transient changes that are not considered adverse, and exogenous substances can interact with the endocrine system by a variety of mechanisms. Results from screening assays that indicate a substance

[1] The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $760 billion enterprise and a key element of the nation's economy. It is the largest exporting sector in the U.S., accounting for 12 percent of U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

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

interacts with a component of the endocrine system through one of those mechanisms, however, do not provide evidence as to whether that substance will cause adverse biological effects, because such assays do not represent the biological complexity of the intact endocrine system of an organism.

If results from short-term assays suggest the potential for endocrine activity, longer term *in vivo* studies, in which exposures are evaluated in the complete and intact endocrine system and encompass critical life stages and processes, are necessary to fully characterize potentially adverse endocrine-mediated health effects. If validated tests determine that these chemicals produce adverse effects (e.g., birth defects, developmental defects, adverse neurological effects, cancer, or reproductive toxicities) via a primary endocrine mode of action, then categorization or classification should occur under existing internationally accepted regulatory standards.

The DG ENV proposal also provides for substances to be listed as "known or presumed endocrine disruptors," "suspected endocrine disruptors," and "potential endocrine disruptors." Categorization and development of lists of chemicals according to such categories would likely precipitate decisions to stop using those products or promote the switch to alternatives whose health effects may be less well understood, without any scientific justification. In turn, these decisions could result in significant and unwarranted dislocations in the economy. In addition, the decisions could have the effect of denying access to useful products and technologies and expose the public to unknown and potentially more serious risks.

In particular, the terms "presumed", "suspected", and "potential", as used in the EU proposal, are vague. The proposal provides no specific criteria to evaluate data sets to determine what the specific properties are, what responses would qualify, what methods to use to assure scientific validity, or what magnitude of effects would be needed to meet these terms. They appear to have been constructed in order to legitimize the use of and provide inordinate weight to information and results from non-standardized, non-validated, short-term, mechanistic studies.

This approach contrasts significantly with U.S. EPA's Endocrine Disruptor Screening Program (EDSP), in which internationally harmonized procedures are used to screen for endocrine activity and to test for adverse effects. The EDSP tiered hierarchical scientific framework relies on validated screening assays to identify substances with endocrine activity. EDSP tests such substances using validated, harmonized protocols to identify adverse effects caused by endocrine modes of action. Definitive tests (e.g., EPA EDSP Tier 2 Tests) clearly outweigh or supersede results from screening assays. The Tier 2 tests are designed to "… identify any adverse endocrine-related effects caused by the substance, and establish a quantitative relationship between the dose and that endocrine effect…,"[3] which can be used in risk assessment.

The DG ENV proposal appears to make no use whatsoever of exposure information or data in reaching a determination. In fact, the proposed scheme is entirely hazard-based. This is both scientifically unjustified and unwise policy. Risk is a function of both hazard and exposure. There are countless examples of substances with high hazards that can and are used safely to provide beneficial products for humans and our environment. Such substances can and are used safely, because the uses are controlled in such a manner as to assure exposures are below levels which would produce risks to health or the environment.

The implications of the DG ENV proposal are readily illustrated by its application to food items. For example, in applying this scheme to products or foods[4] that contain phytoestrogens, many, if not all could be

[3] 75 FR 70558, Nov. 17, 2010, Draft Phase 2 EDSP Policies and Procedures, at 70560.

[4] Food substances that contain natural phytoestrogens include: flaxseed, sesame seeds, pistachio nuts, sunflower seeds, chestnuts, almonds, walnuts, cashews, hazelnuts, soybeans, lentils, navy beans, kidney beans, pinto beans, fava beans, chickpeas, winter squash, green beans, collard greens, broccoli, cabbage, alfalfa sprouts, asparagus, bok choy, carrots, green peppers, potatoes, zucchini, dried prunes, peaches, raspberries, strawberries, and grains (wheat, rye, oats and barley).

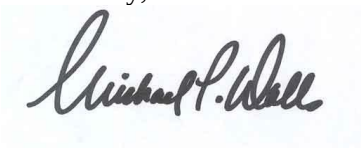
categorized as containing "known or presumed endocrine disruptors", "suspected endocrine disruptors" or "potential endocrine disruptors" because phytoestrogen compounds have been shown to have endocrine activity in certain assays.

If the DG ENV proposal were put into place, it is likely that any foodstuff of U.S. origin that contains residues of a pesticide active ingredient that meets the proposed EU definition of "known or presumed endocrine disruptors", "suspected endocrine disruptors" or "potential endocrine disruptors" would be impacted in global trade, even if such residues were the result of fully legal use of a registered pesticide product evaluated under the U.S. EDSP.

Trade in commodity chemicals could be similarly affected because hazard-based categorization would apply not only to the commodity substances themselves, but also to products derived from these that may contain trace levels of the building block materials. It would create confusion throughout the global value chain for basic commodity chemicals that are in everyday products such as seat belts, child car seats, and bike helmets (just to name a few) that have made all our lives healthier and safer.

The potential adoption of a regulatory approach in the EU that would likely result in significant impact on U.S. commerce and international trade is of serious concern to ACC, CLA, and all of our member companies. In addition, the adoption of an approach in the EU that differs so substantially from EPA's EDSP program would likely put in place precisely the kind of regulatory barriers that a potential US-EU Free Trade Agreement would be designed to address.

Sincerely,



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cc: David De Falco, Director, Office of the European Union, Department of Commerce
David Weiner, Deputy Assistant U.S. Trade Representative for Europe, USTR
Julia Doherty, Senior Director for Non-Tariff Measures, USTR
Jane Nishida, Director of the Office of Regional and Bilateral Affairs, OITA, EPA
Wendy Cleland-Hamnett, Director, Office of Pollution Prevention and Toxics, EPA
Steven Bradbury, Director, Office of Pesticide Programs, EPA