October 31, 2012

Mr. Daniel Mullaney
Assistant U.S. Trade Representative for Europe and the Middle East
United States Trade Representative
600 17th Street NW
Washington, DC 20508

To whom it may concern
European Commission
Directorate General for Trade
Unit F3
Rue de la Loi, 200
1043 – Brussels

Dear Mr. Mullaney, dear Official in charge in European Commission DG Trade :

RE: EU and US call for input on regulatory issues for a possible future trade agreement

The Corn Refiners Association (CRA) and the European Starch Industry Association (AAF) are pleased to jointly submit these comments in response to the Federal Register notice of September 28, 2012, "Promoting US EC Regulatory Compatibility: Request for Comments" (USTR-2012-0028).

CRA is the national trade association representing the corn refining (wet milling) industry of the United States. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil and feed products from corn components such as starch, oil, protein and fiber.

AAF is the trade association which represents the interests of the EU starch industry both at European and international level. Its membership comprises 24 EU starch producing companies, together representing more than 95% of the EU starch industry, and, in associate membership, 7 national starch industry associations.

As the EU and U.S. work to promote greater regulatory coherence through the High Level Working Group on Jobs and Growth and the U.S.-EU High Level Regulatory Cooperation Forum, AAF and CRA would like to present the following issues of mutual concern. Harmonizing regulations in these areas would improve efficiencies in trade.

I. Pesticides

The Federal Food Drug & Cosmetic Act has a "no threshold" approach to pesticides found in foods when that pesticide does not have a specific tolerance provided by the Environmental Protection Agency (EPA) or an exemption from the requirement of a tolerance. Specifically, Section 402(a)(2)(B) of the Federal Food, Drug, & Cosmetic Act deems a raw agricultural commodity or a processed food or feed to be adulterated and subject to FDA enforcement action if it contains either: a pesticide residue at a level greater than that specified by a tolerance or

food additive regulation; or a pesticide residue for which there is no tolerance, tolerance exemption, or food additive regulation.

Likewise, in the EU, in the absence of a specific maximum residues level (MRL) under EU Regulation 396/2005, a very low default MRL (10 ppb) applies and materials exceeding it cannot enter the EU food and feed chain. Pesticides tolerances/MRLs are set in each geography further to submissions by producers of pesticides and experience shows that the uses they support often differ across geographies, resulting in asymmetric tolerances/MRL between US and EU, thereby limiting the entry and sale of these foods in the U.S. or in the EU market.

US and EU should explore which initiative they might introduce in their respective procedures and regulatory standards to take into consideration the MRL/tolerance of the other party (e.g. prerequisites and feasibility of a mutual recognition approach). In a first step it is suggested that a joint US/EU working group would address practical prerequisites to meet the fundamental requirement underlying both the US and EU legislation that MRLs/pesticides tolerances must be set at a level that is sufficiently protective of human and animal health. In particular this working group should define standard methodologies to assess to which extent a mutual recognition process might increase exposure to acceptable/unacceptable extent.

II. Food and Feed Contaminants/Undesirable Substances

Both the U.S. and the EU maintain regulations to prevent consumer exposure to a broad array of food contaminants (also known in EU regulation as "undesirable substances"). In the United States these substances are regulated by the Food and Drug Administration and in Europe by DG Sanco.

The relevant regulation in the U.S. is found in Section 402(a)(1) of the Federal Food, Drug and Cosmetic Act. In Europe, contaminants are regulated under Commission Regulation (EC No 1881/2006 (food) and Directive 2002/32 EC (feed).

Consumers in both the United States and Europe consume a widely varied diet in comparison to other regions of the world where diets are often characterized by heavy consumption of a few staple crops. Both the U.S. and Europe also have advanced food processing industries. While there are differences in U.S. and European diets, such as the type of grain, oilseed and animal products consumed, overall exposure to foods that may contain minor amounts of contaminants such as heavy metals, mycotoxins and chemical contaminants is generally similar. However, standards for maximum or action levels for these contaminants are often different between the U.S. and EU regulations. These differences can lead either to direct disruptions in trade when a non-compliant product is detected, and to producers, ingredient suppliers and food manufacturers having to alter what would be efficient and economical sourcing practices to account for regulatory differences. Harmonizing these regulations as much as possible would contribute to greater efficiencies in trade.

In order to address these horizontal differences, under the guidance of the HLWG, the relevant U.S. and EU regulatory agencies should create a side-by-side inventory of contaminant levels in food and feed (whether they are maximum limits, action levels or guideline levels), including levels adopted by the FAO/WHO Codex Alimentarius Commission. This document could be used to identify the most important and economically-significant differences in U.S. and EU

contaminant regulations and be a basis for regulators to determine where harmonization is possible while still maintaining appropriate consumer protection in both regions.

III. Definitions for Food and Feed

There is a need to develop common definitions for food and feed products in the U.S. and the European Union. The EU is systematically reviewing and reauthorizing its food additives and flavorings; whereas the U.S. uses several mechanisms to set specifications for food and feed, including specifically listing in the CFR text, listing by state agriculture departments, or by reference to third party standard setting organizations like the Food Chemicals Codex (FCC) and Association of American Feed Control Officials (AAFCO). Definitions should insure harmonization.

These specifications are set by FDA/AAFCO in the U.S. and EFSA in the European Union. Relevant provisions are 21 CFR and AAFCO Official Publication and EU community new list of feed materials.

Efforts should be made by the U.S. and the European Union to establish common specifications, thereby harmonizing definitions to facilitate trade. One option to achieve this objective could be to publish a Federal Register notice (and an equivalent public notice in the European Union) inviting comments on items that should be prioritized for harmonization. The U.S. and the EU should harmonize already approved food additives and ensure equivalent specifications and standards moving forward for food and feed products. Such harmonization would facilitate increased trade and compliance; however, the process to achieve harmonization could take several years with significant stakeholder input. Although progress on this issue would likely be slow, an incremental process aimed at implementing harmonization would still yield meaningful results.

IV. Certification Programs

Various certification programs are required by food and feed regulatory agencies as a condition of import. However, some certifications may not be consistent, reciprocal, or even needed at this time. Certification programs are often introduced in response to a specific trade problem or emergency situation. Once instituted, these programs may be continued well after the specific problem has been resolved.

Food and feed imports into the United States and the European Union are subject to a wide variety of government-mandated certification programs as a condition of entry. These may be health-related (phytosanitary certificates) or related to product composition. A comprehensive list of EU-required certification programs for food and feed has been developed by USDA and contains the specific legislation/regulation in the EU mandating certification (http://www.fas.usda.gov/gainfiles/200810/146296188.pdf). We are not aware of a similar comprehensive list of U.S. certification requirements.

An examination by regulatory authorities can be conducted to determine if there are outdated requirements which could lead to reduced burdens on business operators and importation officials. Using the USDA inventory as a guide, the European Union could prepare a similar list of certificates which EU exporters are required to present in order to enter food and feed

products into the United States. Both sides could then review these comprehensive lists and identify outdated or unnecessary certification programs that could be eliminated by mutual agreement. Elimination of unnecessary or outdated certification programs would reduce paperwork burdens both for industry and the regulatory agencies involved.

V. Food Safety Modernization Act (FSMA) Implementation

There are two regulatory issues relating to the implementation of FSMA: pathogens and the creation of a Foreign Supplier Verification Program. Implementation and enforcement of FSMA falls under the jurisdiction of the U.S. Food and Drug Administration.

Currently, there is a lack of clarity of what constitutes a pathogen and what products need to be tested. Our customers often ask for specific "pathogen-free" batch-wise testing. However, pathogens are neither defined, nor is the batch-wise testing for any product requested. Testing of this type is unnecessary for starches and other dry products. This issue has arisen since the U.S. Food Safety Modernization Act (FSMA) went into effect.

The U.S. FDA and its European counterpart should start a dialogue on the issue of pathogens and testing standards and validation methods to encourage harmonization of standards. Greater consistency between guidelines in the United States and European Union will make it easier for CRA and AAF member companies and their customers to know when pathogen testing is necessary.

FSMA also requires the establishment of a Foreign Supplier Verification Program. U.S. importers must have a program to verify that imported food is produced in accordance with U.S. requirements. Although it is still developing its guidelines, FDA may require the following: monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and preventative controls of the foreign supplier, and periodically testing and sampling shipments.

As the regulation for the Foreign Supplier Verification Program is established, we would encourage the FDA to consider ways to implement it so that trade between the United States and the European Union is not hindered unnecessarily in the process of ensuring a safe food supply.

VI. Toxic Substances Control Act (TSCA) Reform

The Toxic Substances Control Act ("TSCA") imposes a number of recordkeeping and reporting obligations that are burdensome because of the difficulties that companies face in often having to track a small portion of overall production that is used for TSCA-regulated purposes. Most burdensome are the recordkeeping obligations under Section 8 (c) of TSCA and the reporting obligations under Section 8(b) of TSCA, notably Chemical Data Reporting ("CDR"). The food processing part of the industry is already heavily regulated by the Federal Food and Drug Administration ("FDA") and the overlapping regulation under TSCA results in duplicative and unnecessary additional paperwork. Food-derived substances have a long history of safe use and, accordingly, the existing TSCA recordkeeping and reporting obligations impose burdens and cost on our industry without a substantial health or environmental benefit.

TSCA reform should focus on the evaluation and appropriate management of high risk chemicals and provide incentives, rather than disincentives, for the development of safer chemicals. In that

regard, pre-manufacture review of new food-derived substances should be streamlined under Section 5 of TSCA in order to provide incentives for the industry to develop alternatives to traditional industrial chemicals. Any substances that are approved for use by the FDA should benefit from reduced data requirements and review time frames relative to traditional industrial chemistries. The new safety determination process for existing chemicals under Section 6 of TSCA should assign a low priority to food-derived substances because it is unnecessary to subject substances already evaluated by the FDA and found to be safe for consumption to a separate safety determination under TSCA. Consistent with the goal of providing incentives for the development of safer alternatives to traditional industrial chemicals, the recordkeeping and reporting obligations under the CDR should impose fewer requirements on FDA-approved food-derived substances.

By learning from each other, regulatory agencies and industry will avoid the significant and wasteful expenditures of time and money to reestablish what was clear at the outset, i.e. that sugars, food-grade gums, vegetable oils and fats, etc. are safe. To date, we understand the consortium working on vegetable oils and fats in Europe has spent in excess of 1.5 million euro to register 66 closely-related substances under REACH.

In conclusion, thank you for your consideration of these comments. We look forward to working with you on these issues to improve efficiencies in trade for our industry's products.

Sincerely,

Audrae Erickson
President

Corn Refiners Association

Jamie Fortescue
Managing Director

European Starch Industry Association