CORN REFINERS ASSOCIATION

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

Dear Mr. Mullaney:

The Corn Refiners Association (CRA) appreciates the opportunity to submit these comments in response to the Federal Register notice of September 28, 2012, "Promoting US EC Regulatory Compatibility: Requests for Comments" (USTR-2012-0028).

CRA is the national trade association representing the corn refining 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.

In general, CRA strongly supports this effort to harmonize regulations between the United States and the European Union and to launch a free trade agreement. As part of both the effort to achieve greater regulatory cooperation and to deepen economic ties through a free trade agreement, we believe that it would be beneficial to establish consultative committees comprised of government officials to continuously monitor proposed regulations to determine if they could result in trade disruptions and to suggest improvements or possible areas of regulatory coherence that could minimize disruptions and foster transatlantic trade. An ongoing dialogue between the United States and the European Union will also improve communication among stakeholders, thereby facilitating trade and preventing disruptions.

In addition to the comments below, we have also provided joint comments with the European Starch Industry Association (AAF), the EU starch association, addressing the issues of pesticides, food and feed contaminants/undesirable substances, certification programs, definitions for food and feed, Food Safety Modernization Act implementation, and Toxic Substances Control Act (TSCA) reform. We have attempted to rank our top priorities for regulatory cooperation, which include these six items and biotechnology.

I. Priority Items Jointly Submitted with AAF

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 U.S. and EU, thereby limiting the entry and sale of these foods in the U.S. or in the EU market.

U.S. 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 U.S.-EU working group would address practical prerequisites to meet the fundamental requirement underlying both the U.S. 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.

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.

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.

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.

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 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.

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.

II. CRA High Priority Item - Biotechnology

An area of key concern to our industry is regulations governing foods derived from modern biotechnology. Resolving this longstanding concern has the greatest potential to increase exports of refined corn products into the European Union. Regulation of foods derived from modern biotechnology are reviewed and approved using similar considerations and data sets, but with differing speeds. This leads to duplication of effort and asynchronous authorizations.

In the United States, foods derived from modern biotechnology are regulated by three agencies: the Department of Agriculture; the Environmental Protection Agency and the Food and Drug Administration. In the European Union, these products are regulated by DG SANCO and in some circumstances by the individual Member States. In the United States, relevant laws and regulations are the Plant Protection Act (7 CRF 340); the Food and Drug Act (FDA policy statement 57 FR 22984) and the Food Quality Protection Act and its predecessors (40 CFT Parts 152, 172 and 174). Counterpart requirements in Europe are found in Directive 2001/18/EC, and Council Regulations 1829/2003 and 1830/2003.

Despite a ruling from the WTO that the EU approval system has resulted in “undue delay” in disposition of applications for new biotechnology products, timelines for dealing with applications in the European Union remain among the longest in the world. The resulting “asynchronicity” in approvals between the European Union and major world grain and oilseed exporters has resulted in numerous trade disruptions and has contributed to critical shortages of feed ingredients for the EU feed and livestock industries.

First, the European Union should review and act on recommendations and observations contained in its own internal review of operation of the biotech approval process

(http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm). The European Union should respect its own statutory deadlines for action on biotech applications; reconsider the procedure it uses to evaluate stack events combining products that have already been approved individually; adopt a policy on low-level presence of products approved in the country of export but not yet approved in the European Union using guidelines of the Codex Alimentarius Commission; and extend the policy permitting trace (0.1%) amounts of unapproved products in feed to food as well. Both the United States and the European Union should enter into discussion about the potential of mutual recognition of each other's safety assessments for biotech products.

The difference in technical regulatory procedures for biotechnology has been the largest cause of agricultural trade disruptions in U.S.-EU trade since 1998. It has caused a virtual end to export/import of corn and corn products in the European Union and been a substantive contributor to the large decline in U.S. soy exports to Europe. This has affected producers on the U.S. side and consumers on the EU side (via increased feed and meat prices). Even a partial resolution of differences in biotech regulation would benefit both sides.

III. Additional Priority Items

Allergens – There are established thresholds/exemptions in the EU. However, the U.S. has not established thresholds and has not authorized exemptions with the exception of vegetable oils. There are circumstances where an allergenic protein is introduced into the manufacturing process (as an enzyme, for example) and is not detected in the finished product.

Allergen labeling requirements are regulated by FDA. FALCPA (Food Allergen Labeling and Consumer Protection Act) requires that, since a protein was introduced, a notification or petition for a labeling exemption should be submitted to FDA.

FDA should use the totality of science and the studies conducted by EU and other agencies to employ a more effective exemption process for products that no longer contain the protein according to best available scientific techniques.

First, a comparison should be conducted of U.S. and EU procedures relating to allergens, including the process to obtain an exemption or establish a threshold for processing aids made from materials that are known allergens, but have no detection in the finished product. It should then be determined if other approaches could be adopted to review/grant labeling exemptions, under specific circumstances, that would facilitate rather than prohibit trade. Establishing a more workable FDA procedure for exemptions would facilitate trade with EU in processed food products.

Joint research and development programs – The U.S. and EU should consider engaging in join research and development programs on food safety and the environment. The intent would be to share costs, reduce duplication of efforts, maximize resources, and increase intellectual capacity and access to data in a manner that is mutually beneficial. This objective would pertain to projects of significant size and scope.

Relevant agencies for joint research efforts are: FDA/NIH (National Institutes of Health)/EPA (Environmental Protection Agency) and EU Commission programs/EFSA. Each program has specific citations for its respective funding, program targeting or scope, and administration.

The goal is to establish multi-national framework programs to evaluate selected research topics. Both the U.S. and the EU have a shared interest in improving food safety and the environment. The proposed approach to implement this objective should be to define intellectual property rights and their transfer, funding proportions, target selection, and how the research programs would be administered. The net effect is that the U.S. and the EU would be in a position to share costs, reduce duplication of efforts and maximize resources, intellectual capacity and access to data, while achieving mutually shared goals of improving food safety and the environment.

Nutrition Labeling Claims - The is no common basis upon which the U.S. and the European Union currently grant nutritional assessments for labeling (nutrition and health claims), often making the ability to make a such a claim (e.g. "consuming oats lowers cholesterol") in both regions impossible. The U.S. uses structure-function claims and health claims based on significant scientific agreement (SSA), while the European Union uses Article 13 and Article 14 health claims. There is significant disparity here, especially between structure-function claims and Article 13 health claims. At a minimum, manufacturers that have already been granted the right to make a nutrition or health claim in the U.S. must refile in the European Union or vice versa, resulting in significant duplication of resources and/or possible denials.

Relevant agencies include FDA ONPLDS (Office of Nutritional Products Labeling and Dietary Supplements) and EFSA (European Food Safety Authority). Regulations involving nutrition labeling claims include U.S. Court decision on claims substantiation/freedom of speech in labeling; Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

There is a need to resolve significant differences in how nutrition and health claims are granted in the U.S. and the EU, and the basis for evaluating the scientific substantiation for these claims. The recent U.S.-EU Organic Equivalence Arrangement may provide insights concerning this objective.

The U.S. and the EU should establish common criteria and evaluation procedures for the review and approval of nutritional and health claims. As part of this harmonization process, the U.S. and EU may have to accept or deny existing claims as part of the future evaluation of requests for nutritional labeling. There is a public need to provide science-based nutritional and health claims in order to assist consumers in making more informed and improved dietary choices.

Pharmaceutical Specifications - Different pharmaceutical excipient specifications may be applied in the U.S. and EU, which causes undue burden and cost for international companies.

In the U.S., FDA delegates authority to publish pharmaceutical standards to outside organizations including the FCC (Food Chemicals Codex), USP (United States Pharmacopeia), and the International Pharmaceutical Excipient Council (IPEC). The United States

Pharmacopeia and The National Formulary (USP–NF) is a book of public pharmacopeial standards. It contains standards for chemical and biological drug substances, dosage forms, and compounded preparations, excipients, medical devices, and dietary supplements.

In the EU, pharmaceutical standards are published by the European Pharmacopeia and the British Pharmacopeia and are recognized by the European Directorate for the Quality of Medicines (EDOM).

In order to resolve these differences, we recommend developing analytical methods that would satisfy both U.S. and EU specifications. The organizations could develop a ring study for international participants in order to confirm feasible specifications for acceptable methods. By providing the same standards or analytical methods/tests internationally, regulatory agencies and companies would benefit by increased efficiencies and reduced costs.

Safety Standards – Varying safety standards across countries make it difficult for international companies to establish global policies for health and safety programs.

Regulatory agencies include the U.S. OSHA (Occupational Safety and Health Administration) and the European Agency for Safety and Health at Work (EU-OSHA). U.S. citations include the OSH Act and other relevant laws.

In order to make progress in this area, U.S. and European Union officials could consider developing an organization that takes the lead and provides direction for global health and safety programs. An example is the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The GHS, which the U.S. and European Union have adopted and are in the process of implementing, is a system for standardizing and harmonizing the classification and labeling of chemicals. The GHS itself is not a regulation or a standard, but rather supplies a mechanism to meet the basic requirement of any hazard communication system. By providing similar standards internationally, regulatory agencies and companies would benefit by consistent worker safety.

Toxicological Safety Evaluation for Food Additives and Contaminants – There are differing methods of risk assessments for toxicological safety evaluations used by regulators in the U.S. and European Union to evaluate food additives, food contact materials, and contaminants.

Food additives and contaminants are evaluated for safety in the U.S. by the Food and Drug Administration, with the assistance of systems developed by the Environmental Protection Agency to assess the safety of plant protection products and through evaluations conducted by the Department of Health and Human Services' National Toxicology Program. In the EU, safety evaluations are conducted for DG SANCO through the European Food Safety Agency and its' Panels on Food Additives and Nutrient Sources Added to Food and on Contaminants in the Food Chain. In the U.S., the food additive safety evaluation authority is found in 21 FR Parts 170 – 186. In the European Union, authority for safety evaluation of food additives is found in Regulation EC 1331/2008.

A wide variety of methods of toxicological safety evaluation and risk assessment exist. These various methods (e.g. benchmark dose modeling, margin of exposure modeling, dose-response modeling (both linear extrapolation and threshold), assumed acceptable daily intake and risk safety factors, etc.) have subtle differences that can lead to widely differing conclusions. Minor differences in study design, study population and data evaluation, even when using the same general method, may also lead to differing conclusions. These different results can be used in establishing differing regulatory limits for the same substance and same exposure.

In addition to the comparison of regulatory limits on food contaminants discussed above, it would be useful to have U.S. and EU regulatory authorities agree to commission an independent review of the methods of toxicological evaluation used by their respective expert agencies to determine where significant differences may exist and identify the differing outcomes that may result. In addition to national safety evaluation systems, such a review should also take into account the methodology applied by the FAO/WHO Joint Expert Committee on Food Additives and Joint Meeting on Pesticide Residues. Greater convergence of safety evaluation steps would be a core method to address regulatory differences that may disrupt trade.

Thank you for your consideration of these comments. We look forward to progress on these issues as the High Level Working Group and High Level EU-U.S. Regulatory Cooperation Forum continue their work.

Sincerely,

Audrae Erickson
President