October 31, 2012

Office of the US Trade Representative
600 17th Street NW
Washington, DC 20508

Electronically Submitted: www.regulations.gov

Re: "US-EU Regulatory Compatibility", 77 FR 59702. Docket: USTR-2012-0028.

Dear Sir or Madam:

The Grocery Manufacturers Association (GMA) appreciates this opportunity to provide comments on the above referenced public notice regarding how to promote greater transatlantic regulatory compatibility generally.

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The $2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over $1 trillion in added value to the nation's economy.

GMA is a strong and consistent advocate of free trade between the United States and its trading partners around the world. GMA strongly agrees with the stated objectives of the High Level Working Group (HLWG) on Jobs and Growth - that free and fair trade bolsters the economy and creates jobs for its citizens, while producers and consumers benefit from being able to select the from the best available ingredients and products at the most affordable prices.

General Comments

The EU is an important trading partner for the US. In 201, the value of US exported consumer oriented agricultural products, such as those manufactured by GMA companies, to the EU-27 was more than $4.6 billion, which was exceeded in magnitude only by Canada, Mexico, and Japan. Many GMA companies are multinational companies with establishments in both the US and the EU and/or import products as raw materials from the EU. In this regard, GMA recognizes the critical importance to US/EU trade of enhancing compatibility and coherence in

regulatory standards and approaches, reducing and eliminating technical barriers to trade and improving cooperation on the development of rules and principles on global issues of common concern. GMA strongly supports the goals of this initiative and agrees that if a comprehensive free trade agreement could be achieved between the U.S. and the EU, it would indeed create jobs and growth on both sides of the Atlantic.

General Concerns

GMA agrees that continued bilateral dialogue aimed at "strengthening the economic relationship and developing its full potential" is important. Saying that, GMA has submitted formal comments over many years to the USTR in preparation for the annual National Trade Estimate Report (NTE report) that identifies many EU regulatory measures that are not science based, are inconsistent with international standards and WTO commitments and result in blocking food trade from the U.S. Examples of these include antimicrobial agents in poultry, veterinary drug residues in beef and pork, products derived from biotechnology and, most recently, food colorants. The EU attempts to use international bodies such as Codex Alimentarius and the Organization for Economic Cooperation and Development (OECD) to legitimatize its "precautionary principle" approach, to undermine the science base of international standards and to introduce societal and cultural factors into decision making. The EU has also used an overly broad interpretation of geographical indications (GIs) to block access to generic products from the U.S. and other countries. The historical trading relationship with the EU has significantly and adversely impacted exports for food and agriculture products from the US and makes GMA skeptical that a "21st century agreement" to promote trade could be accomplished.

Achieving the Template of the Trans-Pacific Partnership (TPP)

In November 2011, the nine leaders of the Trans-Pacific Partnership (TPP) announced agreement on the broad outlines of "an ambitious, 21st century TPP agreement." In that statement, the leaders expressed confidence "that this agreement will be a model for ambition for other free trade agreements in the future…" Since then, the Administration has repeatedly stressed that the TPP will be ambitious, groundbreaking and intended to meet the new challenges of the 21st century.

Trade policy staff and industry have taken those commitments seriously and GMA and others have worked closely with US and other negotiators towards accomplishing these goals. We are excited about the potential to create a 21st century agreement that results in comprehensive liberalization, enhances intellectual property rights, builds regulatory coherence and cooperation and boosts transparency and science in food safety measures. We applaud the vision and dedication of the interagency team in their efforts to meet those goals. We look to the TPP as the template upon which to negotiate all future agreements.

GMA submitted comments to USTR related to the entry of new trading partners, Canada, Mexico and Japan. In those comments, GMA stated strong support for expanding the agreement to include Canada, Mexico and Japan "as long as they can satisfy the conditions stated by the partners" and as long as their entry does not undermine new elements that are under negotiation by the existing partners. GMA specifically called out the importance of text enhancing

regulatory coherence, underscoring science and clarifying the appropriate use of geographical indications. Since then, the significance of the TPP has increased, as Mexico and Canada are entering the negotiations under the terms of accepting previously negotiated text.

As such, a free trade agreement with the EU must be based on those same principles. For the US to settle for anything less in an attempt to reach bilateral agreement with the EU would seriously undermine the ability to achieve important commitments within the TPP and would send a very strong and disturbing message to these very important APEC allies.

Geographical Indicators:

GMA supports the protection of proper geographical indications (GIs) – i.e., names associated with specialized foods from regions throughout the world, but GMA opposes any attempt to use GI protection to monopolize the use of common names that are now a part of the public domain. We believe the TPP negotiations will yield commitments that provide an opportunity for parties to promote a proper approach to protecting legitimate GIs, one which preserves the ability of producers and exporters to use common names.

GMA strongly opposes any inclusion of GIs in a broader US/EU trade discussion as well as any type of linkage of this issue to those discussions, whether that takes the form of an FTA or an endeavor limited to a handful of sectors or some other cross-cutting undertaking.

For instance, the wine industry has been successful in entering a bilateral EU/US Agreement on Trade in Wine that entered into force in 2006. That agreement provides the platform for and has been beneficial in continuing efforts to harmonize regulatory practices. The functioning of this bilateral agreement provides the forum for resolution of any wine issues that arise and should not be compromised or otherwise become linked to other sectors' regulatory issues.

Accordingly, negotiations on GIs, like cheese and wine names, should not be part larger multidiscipline agreement between the US and the EU.

SPS:

One of our principal goals for the TPP negotiations is a enforceable "WTO-Plus" SPS chapter – that is, an agreement that strengthens and reinforces the rules and disciplines of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) and underscores the importance of science-based regulation. In pursuing this goal we are responding to common complaints of producers, processors and exporters regarding SPS measures. They are encountering:

- unnecessarily trade-restrictive measures that are not science-based;
- new measures that are developed without opportunities for interested parties to comment;
- new measures that are implemented without adequate time for compliance;
- measures that do not conform to international standards;
- a reluctance to implement trade-facilitating policies such as harmonized certificates and the recognition of systems-based production methods; and

- the use of questionable testing methods to enforce standards.

To address these issues, which GMA members encounter in the EU, any US-EU agreement on SPS should include the same "WTO plus" terms that are in the TPP text.

Greater Compatibility

Market Access:

The US continues to struggle with obtaining market access to the EU; SPS, TBT, and tariff barriers are the problem.

Like the US, the EU has a facility registration requirement for imported food products - red meat, meat products, farmed and wild game meat, ratites, milk and milk products, seafood, bovine embryos and semen, porcine and equine semen, gelatin, animal casings and animal by-products. To export these products to the EU, they may only originate from EU approved US establishments. The EU leverages this scheme to limit US exports to the EU, making it difficult for US producers to obtain raw materials access. For instance, only one US poultry plant has been approved for EU registration.

The EU's requirements for food export certification and attestation also act to limit access to the EU market. The EU requires a separate attestation for each ingredient in a composite product. These attestation requirements do not take into account differences between food safety systems. For example, in the US, this means that a pizza manufacturer would have to obtain attestations for the various ingredients, which means that the manufacturer would have to go to FSIS to obtain a meat attestation and the Agriculture Marketing Service for the dairy products, etc. We have concerns related to the transparency of this requirement because we have not seen a risk assessment that shows why this requirement is needed/appropriate. The paperwork burden and cost associated with filling out multiple forms is high and the requirement does not increase food safety outcomes for the EU. Certification and attestation requirements should be risk-based and not duplicative.

In any free trade negation, tariff barriers to market access in all sectors should be eliminated; it should be no different in any US-EU negotiations. For example, the EU implements a non-preferential tariff rate quota of 43 percent on U.S. chocolate imports, creating a stiff barrier to market access for US produced chocolate products.

Standards:

The US and EU should work toward harmonizing or mutual recognition of standards; this would allow for trade to flow more freely between the US and EU.

The Expert Panel of the Flavoring and Extract Manufacturing Association (FEMA) has served as the primary body for the safety evaluation of food flavorings for the flavor industry, and the public through its "generally recognized as safe" (GRAS) assessment of flavoring substances. Flavoring substances are determined to be GRAS by the FEMA Expert Panel pursuant to the

authority granted in Section 201(s) of the U.S. Federal Food, Drug, and Cosmetic Act, which is administered by the FDA. Based on the conclusions of the Expert Panel, FEMA GRAS flavoring substances are accepted as safe food ingredients in many countries around the world. However, recently, the EU approved a Union List of flavorings that are considered safe in the EU. Although very similar, the lists are slightly different, which hinders trade of food products with the flavorings not included in the Union list, even though they are considered "safe" across much of the globe.

Currently, the European Food Safety Authority (EFSA) is planning to prepare a background document on the current knowledge in the field of nanotechnology and prepare an inventory of food additives/food contact materials/feed additives applications of nanotechnologies currently used and/or reasonably foreseen to be used. This would be an ideal time for EFSA to communicate with the US Food and Drug Administration (FDA) on the science available on the subject matter.

Labeling:

Another area that could benefit from regulatory coherence is labeling of foods derived through biotechnology. In the US, the legal requirements for food labeling are based exclusively on scientific evidence and data that ensure the safety of the product and its nutritional composition. EU legislation requires all food and feed produced from or containing at least 0.9% of biotech ingredients to be labeled as such. Mandatory specific labeling of the presence of genetically engineered ingredients in food products is misguided and unnecessary, and provides no additional significant or useful information to consumers about the product. These differences in the labeling requirements between the US and the EU negatively affect trade of safe food products and result in a higher economic cost to both the producer and the consumer. GMA does not support mandatory food labeling based solely on the process of production.

GMA stresses a strong commitment to food safety and to science-based food policy, and is confident in the safety of foods derived through biotechnology. GMA believes that biotechnology and emerging food technologies are critical to world food security and the protection of the environment, and looks forward to the development of new food products that provide visible and meaningful benefits to consumers through enhanced safety, nutritional properties, improved shelf life and more.

Risk Assessment Communication:

One way to improve regulatory compatibility would be regular dialogue between the US and EU's risk assessment authorities. Many regulations and market trends are driven by risk assessments, and the European or American scientific authority on an issue frequently has varying views on those assessments. The US and EU should consider consulting with one another before a risk assessment is released because the risk assessment body may not always completely understand the ramifications of its risk assessment to the global marketplace.

For example, EFSA looked to a 2007 study from the University of Southhampton to determine that 6 colorings used in food cause hypertension in children. Now, food products with these

colorings must bear warning labels in the EU even though the study used to justify this regulation has its criticisms. EFSA's willingness to look at other expert research could have changed the regulatory landscape for these products in the US.

In that regard, GMA supports a robust regulatory process including risk assessment to ensure the safety of new products and we have actively participated in the development on the International Standards developed by Codex Alimentarius.

Conclusion

GMA welcomes the opportunity to provide these comments and agrees with the important goal of identifying promoting greater transatlantic regulatory compatibility generally. GMA underscores the importance of continuing bilateral dialogue with the EU in an attempt to eliminate trade barriers, build regulatory coherence and create jobs and growth. However, GMA believes that achieving the commitments and goals of the TPP are a first priority. GMA supports a comprehensive agreement. GMA could not support an EU agreement that would either carve out food and agriculture or would undermine efforts to reinforce science based regulatory commitments.

GMA looks forward to working with the USTR and the interagency trade policy staff to achieve meaningful results for the food and consumer products industry.

Sincerely,

Carmen Stacy

Carmen Stacy
Director, Global Issues & Multilateral Affairs