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**Reconciling Food Safety with Import Facilitation Objectives:
Helping Developing Country Producers Meet U.S. and EU Food Requirements
Through Transatlantic Cooperation**

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IPC finds practical solutions that support the more open and equitable trade of food & agricultural products to meet the world's growing needs.

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I. Executive Summary¹

The U.S. and EU share the goals of improving the safety of food imports and of promoting economic growth in developing countries through increased trade opportunities, in particular in the agri-food sector. If the U.S. and EU pursue joint collaboration on technical assistance in developing countries and regulatory streamlining of their respective import requirements, they could better achieve both of these goals. Such cooperation would promote food safety and ensure that developing country producers are better able to take advantage of trade preferences, including a generous duty-free, quota-free package to the least developed countries.

In this report, we take two foods—green beans and shrimp—as case studies for examining the challenges faced by developing countries’ food producers in meeting United States (U.S.) and European Union (EU) requirements for food safety and for plant or animal health. We focus on a comparison of the requirements of the U.S. and EU, because these are two key markets for food exporters, particularly for producers in developing countries, but also because the EU and U.S. wish to pursue regulatory cooperation. We selected green beans and shrimp as case studies because these are produced in many developing countries and because a market exists for both products on both sides of the Atlantic. **We also chose these products because EU and U.S. food safety, animal and plant health requirements for horticulture and seafood themselves are not fundamentally different – unlike meat and biotech foods, which have been the subject of well-known and sharply contested EU-U.S. regulatory differences. What does differ, however, are the U.S. and EU requirements for verifying compliance with their seafood and horticultural import standards.** The report demonstrates that exporting horticultural products to the EU is an easier proposition for developing country producers, whereas the US market is more accessible for seafood producers in developing countries.

An examination of these differences then leads to a set of recommendations for EU and U.S. cooperation with the goal of improving the safety of food imports and increasing trade opportunities for developing country producers. We suggest that U.S. and EU authorities exchange information² concerning their inspections and audits in other countries, including developing countries, and coordinate their training and technical cooperation and assistance activities. We also urge the EU and U.S. to consider streamlining the means and procedures by which other countries must demonstrate their conformity with EU and U.S. standards. **Anything that could be done to make it possible for developing country producers to read one set of guidelines rather than having to read and compile two overlapping sets would leave producers more time to focus on important issues.**

¹ A previous draft of this paper was presented at IPC’s plenary meeting in Bogor, Indonesia on May 11 and has been further refined to take into account IPC members’ comments. The authors also wish to thank the following for helpful comments: the U.S. SPS interagency team; Mary-Lisa Madell of APHIS, Michael Scannell, Wolf-Martin Maier and Moustapha Magumu from the European Commission’s Directorate General for Health and Consumers; Doris Guenther of GTZ; Tim Leyland of DFID and Johannes Kern. Whereas IPC members agreed to publish this paper as a Position Paper, comments submitted by these other individuals do not signify their or their organizations’ consensus with the report’s findings and recommendations. IPC interns Christina Sabato and Gary Martin provided research assistance.

² Note that information exchange has been identified as a priority in both FDA’s Food Protection Plan and the Transatlantic Economic Cooperation Senior-Level Regulatory Cooperation Group.

This report emphasizes the paramount importance of food safety and refers to the provisions of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) that allow countries to establish measures and set their chosen level of protection while encouraging greater harmonization and use of international standards.

This report addresses official government standards and regulations, but a final section briefly addresses private sector standards, which are increasingly important – and in some cases more important – than official standards for agricultural and food production and trade.

II. Why Green Beans and Shrimp?

An effort to compare regulation of “food” on both sides of the Atlantic, would have proved a complex and unwieldy exercise. We therefore decided to select as case histories two relatively representative categories of food commodities that are of interest to developing country exporters. In each case, the existing “regulatory barriers” appear to be surmountable: several developing countries successfully export green beans or shrimp to the U.S. or the EU markets and, in a few cases, to both. Also, as noted earlier, the EU and U.S. do not have substantially different concerns about the potential risks involved in importing both products but do have rather different import procedures.

Green beans present a good case study because not only are they widely traded as fresh produce, but also as frozen or canned food.³ Beans present an intermediate-level of food safety because they are generally cooked before consumption, reducing risk of pathogens. On the other hand, pesticides are used in their production, and green beans are eaten whole without husking or peeling. Also, there are non-trivial plant health concerns due to the risk that they may lead to the entry of certain pests or plant diseases. Another reason green beans were selected as a case study is that trade data indicate that both the U.S. and the EU import green beans from certain developing countries (the U.S. from Latin America and the EU from Africa). Table 1 below provides the most recent available information concerning imports for green beans into the EU from third countries.⁴ Table 2 compares imports for green beans into the U.S. and the EU from their top five green bean providers, respectively.⁵ Some developing countries currently export green beans to both the U.S. and the EU, as illustrated by Table 3⁶. Finally, countries such as Kenya and Senegal are interested in expanding exports to both markets.

³ FDA regulations impose special requirements for canned food (both low-acid canned food and acidified food) that would have to be met if the exporting country decided that it wishes to export canned green beans or shrimp to the U.S. 21 CFR Parts 113 and 114.

⁴ Source: COMEXT database (Taken from Sustainability Impact Assessment (SIA) of the EU-ACP Economic Partnership Agreements – Phase 3: Horticulture in Eastern and Southern Africa, PricewaterhouseCoopers for the European Commission. Accepted by the Commission on 6 October 2006

⁵ Data for Tables 2 and 3 was obtained from the Food and Agriculture Organization of the United Nations’ Web site using TradeSTAT, <http://faostat.fao.org/site/537/DesktopDefault.aspx?PageID=537>. Note that values for the EU in Table 2 were obtained by adding together import data for all EU member states (as of 2005) and excluding imports/exports between member states.

⁶ See note 6.

Table 1: Share of EU main suppliers of beans *

	Morocco	Egypt	Senegal	Kenya	Zambia	Zimbabwe	Ethiopia
1988	6	35	6	28	0	0	4
1995	10	27	5	30	0	2	6
2004	52	17	3	18	1	1	2

* Values correspond to percentage of total green bean imports.

Table 2: Top 5 Importing Green Bean Countries to the EU and U.S. in 2005.*

	Morocco	Kenya	Egypt	Senegal	Ethiopia
EU	54.3	18.3	16.1	4.1	2.7
	Mexico	Guatemala	Canada	Nicaragua	Peru
US	87.5	5.3	4.9	0.9	0.5

* Values correspond to percentage of total green bean imports.

Table 3: Countries Importing Green Beans to Both U.S. and EU in 2005*

Country	Percent of Total Imports (EU)	Percent of Total Imports (US)
Canada	.001	4.860
China	.090	.420
Colombia	.002	.013
Dominican Republic	.240	.210
Egypt	16.080	.006
Guatemala	.190	5.330
Mexico	.006	87.500
Nigeria	.009	.019
Peru	.037	.500
Total	16.655	98.858

* Values correspond to the percentage of total green bean imports that each country ships to the EU and U.S. respectively.

Shrimp are a good candidate for a protein food, because it is a popular, high-value-added, and much-traded commodity in high demand by U.S. and EU importers and consumers. Global trade in shrimp is a \$13 billion industry, and in 2006 shrimp imports in the U.S. alone exceeded \$4 billion.⁷ Although shrimp is subject to strict U.S. and EU requirements, producers in a number of developing countries in Asia and Latin America have successfully met both U.S. and EU requirements for their shrimp.⁸ These countries include Argentina, Honduras, Venezuela,

⁷ Solidarity Center, *The Degradation of Work: The True Cost of Shrimp*. January 2008, at 7-8. One third of U.S. shrimp imports came from Thailand, followed by China, Ecuador, Indonesia, and Vietnam. UN Food and Agriculture Organization (FAO) Fisheries Department, “Shrimp Market Report—U.S., March 2007,” <http://www.globefish.org/index.php?id=3629>; statistics from U.S. National Marine Fisheries Service.

⁹Shrimp is imported into both the U.S. and the EU on a large scale. In 2007, leading suppliers of shrimp to the U.S. were Thailand, China, Ecuador, Indonesia, Viet Nam, Mexico, and India. Among EU countries, Spain is the largest

Mozambique, India, Madagascar, Thailand, Indonesia, Vietnam, Colombia, Malaysia, China and Ecuador.⁹ Their successes indicate that producers and regulators in other developing countries could achieve comparable success, if they also make an investment of resources in the industry and governmental infrastructure needed to produce safe food and in mastering subject-matter expertise needed to achieve regulatory compliance.¹⁰ Table 4 compares shrimp imports into the U.S. and EU from their top five respective providers.¹¹ As in the case of green beans, some developing countries export to both the U.S. and the EU, shown in Table 5.¹²

Table 4: Top 5 Importing Shrimp Countries to the EU and US in 2007.*

	Ecuador	Greenland	India	Argentina	China
EU	11.78	10.72	9.34	8.47	7.49
	Thailand	Ecuador	Indonesia	China	Mexico
US	33.8	10.58	10.58	8.7	7.26

* Values correspond to percentage of total shrimp imports.

importer of shrimp: its main sources were China, Ecuador, Argentina, Honduras and Morocco. During the same period, France imported shrimp from Brazil, Ecuador, India, the Netherlands, and Madagascar. The main suppliers to the UK in this period were Ecuador, China, India, and Spain.

⁹ Cf. U.S. Imports of Shrimp by Country, http://www.st.nmfs.noaa.gov/st1/market_news/doc74.txt; Fish INFOnetwork Market Report on Shrimp, <http://www.eurofish.dk/indexSub.php?id=3456&easysitestatid=-1217655562>.

¹⁰ Labor and environment issues are beyond the scope of this paper but have been discussed in reports by non-governmental organizations. See, e.g., Solidarity Center, *The Degradation of Work: The True Cost of Shrimp*. January 2008 (alleging that unpaid wages, unsafe and unhealthy workplaces, harsh physical mistreatment, child labor, forced labor, physical intimidation, and sexual abuse of shrimp industry workers has occurred at shrimp processing facilities). Certain practices put food safety at risk, e.g., failure to provide workers with protective gloves when they de-head and peel shrimp and lack of access to sanitary facilities. *Id.* at 30. Certain of the environmental concerns about the rapid expansion of aquaculture relate to food safety: due to the challenges presented by animal waste in densely stocked shrimp ponds, and the related incidence of disease outbreaks and parasite infestations, processors turn to antibiotics, including uses of products not permitted by the FDA or the EU authorities. Food and Water Watch, “Suspicious Shrimp: The Health Risks of Industrialized Shrimp Production,” December 2006.

¹¹ Data for Tables 4 and 5 was compiled from External Trade, European Commission, available at <http://exporthelp.europa.eu/thdapp/comext/ComextServlet> and United States Department of Commerce, Bureau of the Census, available at http://www.ers.usda.gov/Publications/ldp/Aquaculture/Shrimp_Q_Yearly.xls.

¹² See note 12.

Table 5: Countries Importing Shrimp to Both US and EU in 2007

Country	Percent of Total Imports (EU)	Percent of Total Imports (US)
India	9.34	3.75
Ecuador	11.78	10.58
Bangladesh	5.05	2.33
Canada	6.79	0.79
China	7.49	8.70
Indonesia	3.49	10.58
Thailand	3.20	33.80
Mexico	0.21	7.26
Total	55.10	74.62

* Values correspond to the percentage of total shrimp imports that each country ships to the EU and U.S. respectively.

III. The Timing of This Report

In both the U.S.¹³ and in the EU,¹⁴ the issue of import safety is a frequent news topic. Current attention has focused on concerns about whether authorities in developing countries have the capability and willingness to police their exports. FDA and the other U.S. agencies that are supposed to make sure that imports are safe say they lack the authority and resources to do so.¹⁵ Similar concerns are regularly raised with EU authorities.

While the U.S. and the EU (the leading developed country markets for food) are under pressure to step up their scrutiny of food imports, developing countries have concerns about these initiatives. They often allege that present and proposed regulations on food imports act as trade barriers. For example, in the World Trade Organization (WTO), developing countries have alleged that both governmental requirements and private standards operate as unjustified barriers to the entry of their food exports to developed-country markets.¹⁶ **Indeed, one of the impediments to progress in the Doha Round is the conviction of many developing countries that they stand little to gain from enhanced trade liberalization, unless the issue of importing countries' regulations—which they view as thinly disguised trade barriers—is**

¹³ In the U.S., import food safety was in the news and the subject of Congressional hearings in 1993 (coinciding with Congressional consideration of the North American Free Trade Agreement), 1997 (with the launch of the President's Food Safety Initiative), and 2001 (following 9/11 and concerns that bioterrorists might contaminate food). In 2002, Congress enacted the first comprehensive reform of food safety law since 1938, and the U.S. Congress is considering granting FDA additional powers in this area.

¹⁴ EU concern about food safety spiked in the 1996-97 period in which "mad cow" disease and other transmissible spongiform encephalopathies, dioxin in chicken, and "Frankenfood" (biotech food) were front-page news. EU and Member State authorities responded with new legislation, a new European Food Safety Authority, and a range of activities to strengthen food safety.

¹⁵ Responses to these concerns include the FDA Food Protection Plan, www.fda.gov, as well as the Administration's Action Plan for Import Safety: A roadmap for continual improvement. A Report to the President, Interagency Working Group on Import Safety (November 2007). <http://www.importsafety.gov/report/actionplan.pdf>.

¹⁶ WTO News Items, Developing countries complain about pesticide residue requirements, 27 and 28 June 2007, http://www.wto.org/english/news_e/news07_e/sps_29june07_e.htm; WTO News Items, 'Untransparent' private standards criticized in a week of more transparency, 18 and 19 October 2007, http://www.wto.org/english/news_e?news07_e/sps_19oct07_e.htm

addressed. Developing countries do not contest the necessity of SPS measures since they recognize that all consumers need to be protected from unsafe food, and the environment from invasive pests and diseases. What they contest, however, is the proposed mechanisms for verifying compliance, which are often perceived as going beyond the minimum necessary to minimize risk, and hence become too expensive and complex for developing countries to implement.

The U.S. and EU devote considerable energy and resources to provide information about their import requirements and technical assistance to developing countries. Indeed, the U.S. Administration's import safety initiative, the FDA Food Protection Plan, and the draft import legislation under consideration in the U.S. Congress¹⁷ all have at their foundation an expectation that there will be a sharp increase in the level of international cooperation as a key part of strengthening food safety standards and their application and enforcement. Since 2004, the EU has initiated outreach activities and training in developing countries to inform exporters about EU SPS requirements.¹⁸

Although the trade, foreign affairs, and development components of EU and U.S. governments may view trade facilitation, including export opportunities for developing countries, as a key international objective, food regulators do not see trade or development as part of their job. Rather, their mission – often codified in law - is domestic consumer protection. This paper argues that trade and consumer protection objectives are equally valid and should not be seen as mutually exclusive, but rather as mutually reinforcing. The SPS Agreement (article 5.6) does indeed require that SPS measures are not more trade-restrictive than necessary, taking into account technical and economic feasibility. This paper suggests that a joint EU-U.S. initiative on technical assistance, information sharing, and regulatory streamlining would serve to improve the safety of food imports, increase export opportunities for developing country producers and make for a more efficient use of government resources.

One value of EU-U.S. regulatory collaboration vis-à-vis developing countries is to clarify requirements generally, particularly as to documentation of compliance, and to focus attention on the most important requirements, thus making compliance easier. Regulators will not have much interest in regulatory streamlining so as to improve market access for developing countries, since this is not their assigned mission, but they are likely to support such steps if they enhance compliance.

IV. Food Must Be Safe, Regardless of Source and Destination

The physical wellbeing and health of its citizens should be a key priority of any government and this report is based upon the premise that food must be safe. Developing countries are confronted with shortcomings in their physical infrastructure, such as lack of access in many cases to potable water, as well as the need to establish an effective regulatory infrastructure.¹⁹ Although

¹⁷ Rep. Dingell, Discussion Draft, "Food and Drug Administration Globalization Act of 2008" (April 16, 2008).

¹⁸ Better Training for Safer Food http://ec.europa.eu/food/training_strategy/index_en.htm

¹⁹ L. Horton, Food From Developing Countries: Steps to Improve Compliance, 53 FOOD AND DRUG L. J. 139-71 (1998). Another challenge for developing country exporters, trying to break into international markets, is to achieve

we focus here on exports to the U.S. and EU from developing country producers, food safety and animal and plant health are of equal importance for developing country consumers. Developing countries need to require their exporting industries to meet the requirements of the U.S. and the EU and ensure the safety of products consumed domestically. In fact, EU and U.S. requirements have been shown to increase the overall safety of food products in developing countries.²⁰

WTO members have an explicit right under the SPS Agreement to take measures to protect human, animal and plant health as long as these are based on science, are necessary for the protection of health, and do not unjustifiably discriminate among foreign sources of supply.²¹ In addition, while the SPS Agreement does encourage governments to work toward harmonization and to base their national measures on the international standards, guidelines and recommendations developed by the WTO member governments in other international organizations, it does allow members to introduce or maintain measures resulting in a higher level of protection, if there is a scientific justification.²²

V. Key Regulatory Similarities and Differences

A. Food Safety

Similarities

The core food safety systems are quite similar. Both the U.S. and the EU operate regulatory systems that put consumers first and place the responsibility for a food product's safety, wholesomeness, identity and economic integrity with the producer or importer, who must comply with the requirements issued under the relevant regulations. Government authorities oversee the efforts by producers or importers to enforce compliance.

Common expectations include the following:

- a. A general obligation on the operator to monitor safety of the food products and processes falling within his responsibility.
- b. This obligation applies to all stages of production, processing and distribution of food that is under the producer's control.
- c. The obligation encompasses compliance with the basic and relevant hygiene requirements specified in the legislation or regulations. General hygiene provisions for primary production include ensuring protection against various forms of contamination

economies of scale. Many buyers insist that exporters be able to supply speedy delivery of consistent quantities of product, meeting quality specifications.

²⁰ See, e.g., Report of the FAO-ASEAN Strategic Planning Workshop on Harmonization of Standards for Shrimp Export-Import, July 2004, § 3.1, available at <http://www.fao.org/docrep/007/ad502e/ad502e00.htm#Contents> (noting that "HACCP principles became mandatory in most [ASEAN] during the late 90s, which coincided with the U.S. FDA's (U.S. Food and Drug Administration) deadline for HACCP implementation (December 1997) for both domestic and overseas processing plants which supplied seafood products to the U.S. market.").

²¹ An Annex summarizes relevant provisions of the SPS Agreement.

²² Agreement on the Application of Sanitary and Phytosanitary Measures, article 4.3

from a wide range of sources (water, vermin, insects, filth, contaminants, etc.). Also producers may be permitted to take into account any processing that the products may undergo.

d. Food business operators must comply with legislative provisions relating to the control of hazards in primary production and associated operations, including measures to control contamination.

Both U.S. and EU authorities express strong support for the harmonization efforts of the Codex Alimentarius Commission, and have, at times, adopted Codex standards but obviously do not feel they need to “wait for Codex.” In addition, both the U.S. (e.g., HACCP²³) and the EU (e.g., traceability) have been leaders in development of regulatory initiatives that were later picked up in Codex and eventually reflected in its standards.

Both U.S. and EU authorities apply the Hazard Analysis Critical Control Points (“HACCP”) system for production of safe food. HACCP is a tool to systematically assess and document potential hazards throughout the food production process, identify control points and tolerances, and establish processes to take corrective action if measurements at the critical control points deviate from the acceptable range. Obviously, the prevention of adulteration via process-based control systems is more effective than the reliance on end-product testing alone.²⁴ Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments. Its successful operation requires attentive industry

²³ Hazard Analysis Critical Control Points (HACCP). See the discussion in the text following this footnote.

²⁴ FDA, HACCP: A State-of-the-Art Approach to Food Safety, <http://www.cfsan.fda.gov/~lrd/bghaccp.html>. The program involves seven principles which are the same than in the EU: GUIDANCE DOCUMENT Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses. http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf.

The principles can be described as follow:

1. **Analyze hazards.** Potential hazards associated with a food and measures to control those hazards are identified. The hazard could be biological, such as a microbe; chemical, such as a toxin; or physical, such as ground glass or metal fragments.
2. **Identify critical control points.** These are points in a food's production--from its raw state through processing and shipping to consumption by the consumer--at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection.
3. **Establish preventive measures with critical limits for each control point.** For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any harmful microbes.
4. **Establish procedures to monitor the critical control points.** Such procedures might include determining how and by whom cooking time and temperature should be monitored.
5. **Establish corrective actions to be taken when monitoring shows that a critical limit has not been met**--for example, reprocessing or disposing of food if the minimum cooking temperature is not met.
6. **Establish procedures to verify that the system is working properly**--for example, testing time-and-temperature recording devices to verify that a cooking unit is working properly.
7. **Establish effective recordkeeping to document the HACCP system.** This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems. Each of these principles must be backed by sound scientific knowledge: for example, published microbiological studies on time and temperature factors for controlling foodborne pathogens.

management, capable of identifying and assessing changes in processes and of adapting process controls when necessary.

Differences

Despite the numerous similarities, the institutional food safety regimes are different from each other. In one respect the EU system is more of a one-stop shop: the same Directorate-General of the European Commission has jurisdiction to enforce food safety, animal and plant health issues throughout the food and feed chain. However, border controls are applied by Member State officials of 27 countries. The U.S. system, on the other hand, involves a number of federal agencies, most importantly FDA, part of the Department of Health and Human Services, and APHIS and FSIS within USDA, the Department for Homeland Security and the Environmental Protection Agency (EPA). Retail sales and restaurants are handled principally by state and municipal departments of agriculture or health.²⁵

In the U.S., HACCP based controls are mandatory for meat products regulated by USDA and for juices, fishery products and low acid canned food regulated by FDA. In the EU, HACCP is mandatory across all food and feed operations, including feed mills, retail sales and restaurants. The process of canning green beans would be subject to mandatory HACCP under both U.S. and EU requirements, whereas frozen beans would not be subject to mandatory HACCP under U.S. requirements. HACCP is required for seafood, thus also shrimp, under both regulatory systems.

Whereas both the EU and US require official pre-approval of imports of meat and poultry, the EU also requires such pre-approval for seafood and the US for horticultural imports. These differences will be demonstrated in the case studies on beans and shrimp exports.

B. Green Beans

Similarities

Both the U.S. and the EU maintain regulatory systems aimed at preventing the introduction of pests or plant diseases that could harm agricultural production. Major diseases are root rots, white mold (*Sclerotinia*), gray mold (*Botrytis*) and bacterial blight.²⁶ Both the U.S. and the EU

²⁵ Each of these agencies can issue regulations imposing requirements for food marketed in the United States. In the eyes of producers, U.S. agencies' regulations are sometimes viewed as a confusing quagmire of rules from various sources that food processors must attempt to decipher and obey. See Lou Smyrlis, *The Main Obstacles to a Secure Border May be the Agencies Entrusted With Creating It*, CANADIAN TRANSP. LOGISTICS 107: 2, Feb. 1, 2004, at 4 ("Over-lapping rules from competing U.S. government agencies are confusing shippers and carriers, increasing frustration and costs, and likely reducing participation, and compliance.").

²⁶ Additionally, with regard to green beans, the USDA advises Customs and Border Protection officers and agricultural specialists and Plant Protection and Quarantine officers to inspect the pods and seeds of legumes for holes bored by *Maruca testulalis* (bean pod borer), *Epinotia aporema* (bean shoot borer), or *Cydia fabivora* (tortricid moth). USDA, FRESH FRUITS AND VEGETABLES IMPORT MANUAL 2-15, available at http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/fv.pdf

operate science-based and risk-based phytosanitary control systems. Both participate actively in international fora such as the IPPC²⁷ and regional phytosanitary organizations.

Differences

On the food safety side, there are some differences in the pesticides permitted to be used and the relevant acceptable tolerance or maximum residue levels.²⁸

On the phytosanitary side, both the EU and U.S. are concerned about the introduction of plant pests and diseases but administer their phytosanitary controls quite differently. APHIS administers a pre-qualification system for each product, whereas the EU relies on phytosanitary certificates issued by the “competent authority” in exporting countries for a certain number of identified products.

A country interested in exporting green beans to the U.S., therefore, must gain approval before doing so. Since 1987, APHIS approves most new imports through a rulemaking procedure. The process is initiated when APHIS receives an import request for a specific product, e.g., green beans. APHIS follows up by undertaking a risk assessment for green beans grown in that country. Once a risk assessment is favorably concluded, APHIS publishes a “proposed rule” in the U.S. Federal Register which provides an opportunity for stakeholders to submit comments on APHIS’ proposal to allow in green beans from that particular country. APHIS, in turn, is obligated to respond to all substantially significant comments submitted by stakeholders, after which it can publish a final rule to authorize imports if so appropriate.

The lack of good data on pests that could be introduced through new trade as well as limited regulatory infrastructure in developing countries to implement necessary mitigations make it particularly challenging to complete the necessary risk assessments and develop appropriate import conditions. In addition, the requirement for product specific and country specific rulemaking can cause lengthy time-frames for APHIS consideration of import requests.

Conscious of the need for more timely import approval, APHIS recently announced a change in its procedures for approving new fruit and vegetable imports in situations where the plant health risks presented by a commodity can be addressed through use of one or more means prescribed

²⁷ Principles and concepts for the protection of plant health are embodied in the New Revised Text of the International Plant Protection Convention, the IPPC (1997). It covers principles related to the protection of plants, including cultivated and non-cultivated/unmanaged plants and wild flora, principles regarding the application of phytosanitary measures to the international movement of people, commodities and conveyances, as well as other principles and concepts inherent in the objectives of the IPPC (1997). The standard is not intended to alter the IPPC (1997), extend existing obligations, or interpret any other agreement or body of law.

²⁸ In the U.S., the Environmental Protection Agency (“EPA”) determines acceptable levels for pesticide residues in food (“tolerances”) and FDA enforces these tolerances. U.S. EPA, Setting Tolerances for Pesticide Residues in Food, <http://www.epa.gov/opp00001/factsheets/stprf.htm#studies> (last visited June 6, 2008). In 2005, the EU adopted a regulation that provides for Maximum Residue Levels (“MRLs”) for pesticides in food at an EU-wide, as opposed to a Member-State, level. See EUROPA, Plant Protection–Pesticide Residues, http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm (last visited June 6, 2008). The authorization and use of pesticides is heavily regulated in the EU with permitted substances, the products for which they are approved, and permitted MRLs all subject to legislation harmonized at the EU level.

in an APHIS regulation.²⁹ In these cases, APHIS does not need to go through full rulemaking, and can issue a notice advising the public that a risk assessment has been conducted and that APHIS believes that it should allow the import of this commodity. The pest risk analysis will be published in the Federal Register for public comment, and if no substantive concerns are raised, APHIS can publish a final notice informing the public that it will begin issuing import permits for the commodity. Changes such as this have been welcomed by U.S. trading partners as valuable streamlining.

Recently there have been several approvals of imports of fruits and vegetables from African countries. For example, on October 19, 2007, APHIS issued notices of decisions to issue permits for the importation of eggplant and okra from Ghana and of husked, silk-free baby corn and peeled baby carrots from Kenya.³⁰ APHIS had announced the availability of a pest risk analysis for each of these commodities on July 24, 2007.³¹ In accordance with its new procedure, APHIS considered public comments received on or before September 17, 2007,³² before announcing its decision to begin issuing permits for importation approximately one month later. Similarly, in a press release issued May 15, 2008, APHIS announced a proposal to allow importation of baby squash and baby zucchini from Zambia into the United States, provided certain conditions of entry are met; this did not occur under the new streamlined approach.³³

APHIS posts a list of pending pest risk assessments being evaluated by the agency that meet the requirements of 7 CFR § 319.5.³⁴ African countries that have pending requests as of April 29, 2008 included: East Africa (Kenya, Tanzania and Uganda) for passion fruit, ECOWAS³⁵ for mango, papaya, and tomato, Kenya as to beans, chili pepper, and peas, Madagascar as to litchi, Senegal as to asparagus and melon, South Africa as to a number of products (allium, apricot, cherry, plumcots, and pluots, avocado, gooseberries and currants, litchi, and persimmon),

²⁹ *Id.* at 39504; 7 CFR § 319.56-4 (b): inspection upon arrival, importation from a pest-free area, certain treatments were carried out, inspections were carried out in the country of origin by an inspector or official.

³⁰ Notice of Decision to Issue Permits for the Importation of Eggplant and Okra from Ghana into All Areas of the United States and the Importation of Peppers from Ghana into the Continental United States, 72 Fed. Reg. 59,239 (Oct. 19, 2007); Notice of Decision to Issue Permits for the Importation of Husked, Silk-Free Baby Corn from Kenya into the Continental United States, 72 Fed. Reg. 59,239 (Oct. 19, 2007); Notice of Decision to Issue Permits for the Importation of Peeled Baby Carrots from Kenya into the Continental United States, 72 Fed. Reg. 59,240 (Oct. 19, 2007). The APHIS Fresh Fruit and Vegetable Manual posted on Web site is up-to-date (last updated April 24, 2008) lists a number of approved fruits and vegetables from African countries (including Algeria, Angola, Benin, Botswana, Burkina Faso, and Burundi).

http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/fv.pdf.

³¹ News Release, APHIS, USDA Announces Availability of Four Pest Risk Analyses for the Importation of Fruits and Vegetables from Africa (July 24, 2007), <http://www.aphis.usda.gov/newsroom/content/2007/07/fourpra.shtml>; *see, e.g.*, Notice of Availability of a Pest Risk Analysis for the Importation of Eggplant and Okra from Ghana into All Areas of the United States and the Importation of Peppers from Ghana into the Continental United States, 72 Fed. Reg. 39,379 (July 18, 2007).

³² *See* News Release, APHIS, USDA Announces Availability of Four Pest Risk Analyses for the Importation of Fruits and Vegetables from Africa (July 24, 2007), <http://www.aphis.usda.gov/newsroom/content/2007/07/fourpra.shtml>.

³³ News Release, APHIS, USDA Proposes to Allow the Importation of Zambian Baby Squash and Baby Zucchini (May 15, 2008), <http://www.aphis.usda.gov/newsroom/content/2008/05/babyveg.shtml>; *see also* Importation of Baby Squash and Baby Courgettes from Zambia, 73 Fed. Reg. 28,372 (May 16, 2008).

³⁴ http://www.aphis.usda.gov/import_export/plants/plant_imports/pralist.shtml

³⁵ ECOWAS consists of 15 countries, Benin, Burkina Faso, Cape Verde, Cote d' Ivoire, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

Uganda as to avocado, banana and plantain, and Zambia as to baby squash and courgettes, fine green beans, garlic and leek, okra, and pepper.³⁶ APHIS does not indicate how long these requests have been pending, and a number of these have been pending for more than five years.

Under APHIS regulations, importation is forbidden if no import request has been made, or where an import request has been made but an assessment of quarantine risk has not yet been completed. APHIS has defended its system against criticism³⁷ that it is inconsistent with U.S. obligations under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement).³⁸ Although APHIS has convincing arguments in favor of its position, there may be benefits in exploring whether the EU approach has anything to offer.

³⁶ Although it remains unclear at this point how long it will take APHIS to approve a commodity for import from start to finish using the new “notice-based” procedure, i.e., how long it will take from the time a developing country requests a pest risk analysis until the time APHIS issues a notice of decision to issue permits for importation, APHIS believes the new procedure will result in considerable time savings. *See* 72 Fed. Reg. 39,481, 39,494–95 (July 18, 2007). The old procedure required, on average, anywhere from eighteen months to three years to approve a new import. *Id.* at 39,495. APHIS reports that the new procedure “will reduce the time needed for the administrative portion of the approval process of some fruits and vegetables for import without eliminating opportunity for public participation in [the] analysis of risk and without affecting the science-based review of the request.” *Id.* APHIS also believes the new procedure will “help relieve the burden on the APHIS regulatory mechanism, given the volume of new commodity report requests APHIS has been receiving, and the large volume of rulemaking initiatives already underway in APHIS.” *Id.*

³⁷ APHIS, 7 CFR Parts 305, 319, and 352, Revision of Fruits and Vegetables Import Regulations; Final Rule; 72 Fed Reg. 39482, 39491 (July 18, 2007):

One commenter stated that the proposed changes did nothing to address the fact that APHIS' regulations continue to prohibit the importation of fruits and vegetables for which no import request has been made, or for which an import request has been made but an assessment of quarantine risk has not yet been completed. The commenter stated that this “a priori” prohibition on the importation of fresh fruits or vegetables into the United States is inconsistent with the APHIS' obligations under the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), as they are not based on an assessment of risks or scientific principles, nor maintained with sufficient scientific evidence.

We believe it is appropriate to make a distinction between commodities that are “prohibited” and disciplined by Article 5 of the SPS Agreement, and commodities that are “not yet approved” or “pending evaluation” and disciplined by Annex C of the SPS Agreement. Articles that are prohibited have been evaluated and prohibition is the measure that has been determined to be appropriate. This status may be changed based on new information and a reevaluation using pest risk analysis. Likewise, pest risk analysis is used to evaluate the risk associated with a request for a new commodity not previously evaluated.

It is true that our regulations do not make the distinction between (1) commodities that have been evaluated and prohibited, (2) commodities that are not currently allowed importation but that are undergoing risk evaluation, and (3) commodities that are not allowed importation and for which no request for risk evaluation exists. We recognize that our regulatory terminology is not the same as that used in the SPS Agreement; however, regardless of the terminology, APHIS only allows new imports of fruits and vegetables following the completion of a risk analysis that enables us to determine that the pest risks posed by the commodity are known, and that the risks can and will be mitigated. We believe that this policy is entirely consistent with the SPS Agreement.

³⁸ APHIS, 7 CFR Parts 305, 319, and 352, Revision of Fruits and Vegetables Import Regulations; Final Rule; 72 Fed Reg. 39482, 39491 (July 18, 2007). At the time of publication of this rule, approximately 400 commodity import requests were pending at APHIS. *Id.* at 39495.

To its credit, APHIS provides a great deal of technical assistance for countries seeking import permissions. The recent favorable decisions upon requests from Ghana, South Africa and Kenya followed significant technical cooperation and assistance activities in those countries.³⁹

In contrast to the U.S. system, there is no a priori EU ban on importation of fresh fruits and vegetables from countries that have not filed import requests, nor is a pre-notification procedure required. EU regulation includes a list of products, imports of which must be accompanied by a phytosanitary certificate issued by the regulatory authority of the exporting country.⁴⁰ This list includes plants and seeds intended for planting and a limited number of fruits and vegetables or parts thereof imported for consumption, which are perceived as presenting particular phytosanitary concerns in the EU. A phytosanitary certificate is essentially a statement issued by the exporting country authorities that the plants or plant produce or products to which it relates have been officially inspected in the country of origin (or country of dispatch), comply with statutory requirements for entry into the EC, are free from certain serious pests and diseases, and are substantially free from other harmful organisms. Products not listed – including green beans imported for consumption – do not require such certification.

However, the European Commission has power to establish a list of food of non-animal origin (including composite products) that, on the basis of known or emerging risks, should be subjected to an increased level of official controls upon introduction into the EU and need to be presented at a designated point for checks.

C. Shrimp

Similarities

The U.S. and the EU apply similar animal health requirements for shrimp. Both have maintained strict surveillance of imports for use in shrimp production of forbidden substances that present

³⁹ For example, an APHIS representative was chosen to serve as a Pest Risk Assessment Advisor for USAID's West Africa Regional Program ("WARP") in 2004. *See* USAID, USAID West Africa: The Trade Initiative, <http://www.usaid.gov/missions/westafrica/mission/trade/index.htm> (last visited June 6, 2008). The purpose of the Pest Risk Assessment Advisor, who is based at the WARP mission in Accra, Ghana, is to expedite the APHIS risk assessment process for commodities that West African countries would like to import to the U.S. *See* USAID, WARP/Ghana Welcome: West African Regional Program, <http://www.usaid.gov/missions/westafrica/newsletter/archive/1qtr05/focus/index.htm> (last visited June 6, 2008). To this end, the Advisor's responsibilities include targeting commodities with a good chance of eventually being approved for import by APHIS; facilitating communication between APHIS and exporting countries; acquiring information on pest problems from plant protection agencies, local scientists, and growers to accurately and timely complete risk assessments; reviewing and revising all West African risk assessments before submitting them for APHIS review; and advising WARP on how best to use funds to support phytosanitary capacity building. *Id.* Along similar lines, four SPS experts traveled to Kenya on an USDA/APHIS product evaluation mission from January 21 to February 2, 2007. KENYA HORTICULTURAL DEVELOPMENT PROGRAM, UPDATE ON KENYAN HORTICULTURE 3 (2007), available at <http://www.fintrac.com/docs/kenya/KHDP%20Update%20January%2007.pdf>. The experts made stops at exporter farms, packhouses, airport facilities, government departments, and private-sector associations involved in export horticulture "to evaluate Kenya's capacity to meet US market specifications." *Id.*

⁴⁰ Directive 2000/29/EC as amended lists all plants and some categories of plant produce and products that are permitted to enter the EU Member States from non-EC countries which must be accompanied by a phytosanitary ("plant health") certificate. The Directive covers all major fruit (other than bananas and grapes), cut flowers, some leafy vegetables, seeds and potatoes from a limited number of countries

hazards to human consumers. (Aquaculture farms try to control bacterial infections, diseases, and parasites by using antibiotics, fungicides, and other pesticides.) Thus, both the FDA and EU authorities have imposed strict prohibitions against entry of shrimp that had been treated with certain veterinary drugs. For example, both have barred imports of shrimp containing residues of chloramphenicol, nitrofurans, malachite green, and other antimicrobials used by developing country producers to prevent or treat diseases in densely populated seafood production areas.⁴¹ These substances are associated with serious hazards to human health.

- a. For example, in 2001, the EU decided to impose 100% import checks on shrimp products imported from China, Thailand, Vietnam, Indonesia and other countries because residues of the antibiotics chloramphenicol and nitrofurans had been repeatedly found in routine inspections. Finally, the EU banned the import of shrimp from China (2002 - 2004), imposed severe restrictions on Thai imports during 2001, and banned shrimp from Benin from July 2003 to early 2005. Earlier, European authorities had banned shrimp from Bangladesh for five months in 1997 and had banned shrimp from Tanzania and Uganda in 1999.
- b. In 2002, FDA stepped up its sampling of imported shrimp, looking for chloramphenicol. FDA has likewise found it necessary to block entry into the United States of shrimp from several leading Asian exporters, including Bangladesh, Hong Kong, Indonesia, Taiwan, and Thailand, due to salmonella, decomposition, and filth.⁴²

Under this program, known as Detention Without Physical Examination (DWPE), only individual companies in these countries that can demonstrate their compliance with FDA requirements are permitted to continue or resume shipments to the United States.⁴³ This document consists largely of a long list of seafood exporting companies in Bangladesh, Hong Kong, Indonesia, Taiwan, and Thailand whose shrimp are allowed to be imported into the U.S. due to acceptable laboratory results despite the general ban on shrimp imports from these countries.

Both the U.S. and the EU have also imposed the HACCP approach to the processing of seafood, including shrimp. For shrimp producers wishing to import into the United States, for example, the U.S. HACCP requirements⁴⁴ demand that they conduct a hazard analysis to determine whether there are “safety hazards that are reasonably likely to occur,”⁴⁵ and identify preventative measures to those hazards. The HACCP plan then must list such hazards, the critical control points for the hazards,⁴⁶ the limits that must be met at each control point,⁴⁷ the monitoring

⁴¹ Between 2002 and 2006, FDA rejected shrimp shipments from China, Malaysia, Peru, Thailand, Venezuela, and Vietnam due to chloramphenicol residues. FAO, Code of Conduct for Responsible Fisheries, State of World Food Fisheries and Aquaculture 2006, 2007, at 16.

⁴² See FDA Import Alert IA#16-18- Revision, 11/14/96, Attachment Revised 10/11/07.

⁴³ See *id.*

⁴⁴ These requirements are found at 21 C.F.R. § 123.6.

⁴⁵ This corresponds to principle 1 of HACCP.

⁴⁶ This corresponds to principle 2 of HACCP.

⁴⁷ This corresponds to principle 3 of HACCP.

procedures used to ensure compliance to the critical limits,⁴⁸ corrective action plans,⁴⁹ and verification procedures.⁵⁰ A recordkeeping system is also required to ensure compliance.⁵¹ The EU applies the same HACCP requirements.

Differences

The EU regulates shrimp under the general hygiene provisions for animal-derived foods and imports of all animal derived foods can only occur after exporting countries have received a positive evaluation by EU authorities. In the U.S., a similar pre-import qualification process is in place for imports of meat and poultry regulated by USDA, but a less regimented process for seafood imports, which are regulated by FDA.

Animal-derived foods, including seafood, can be imported into the EU only from eligible countries and eligible establishments within those countries. A non-EU country interested in exporting shrimp to the EU must verify the ability of its veterinary and public health authorities to enforce either EU standards or domestic standards which provide an equivalent level of protection.⁵² The EU's Food and Veterinary Office (FVO) determines whether standards are satisfactorily enforced. The FVO also undertakes verification audits to ensure that the level of protection is maintained. The exporting country authorities, in turn, identify eligible national establishments, which meet EU performance standards. Compliance with EU standards must be certified by designated, competent authorities of the exporting country; this original veterinary certificate must accompany exports to the EU. Food of animal origin can only enter the EU via designated border inspection posts where Member State authorities are stationed, and this food must be accompanied by the original veterinary certificate issued by the exporting country's authorities. Prior notification of these shipments is mandatory, and all consignments are subject to documentary checks of eligibility. Physical inspections and laboratory analyses are conducted on a random basis; violations trigger enhanced controls and other safeguard measures.

For shrimp destined for the EU, food business operators importing shrimp and other products of animal origin must ensure that the products:

- Come from a non-EU country that appears on an EU list of permitted exporting states;
- Come from an establishment that appears on a list of approved establishments (where applicable);
- Carry a health or identification mark (where applicable);
- Are accompanied by a certificate issued by the representative of the competent authority of the non-EU country (where applicable);
- Are made available for control in a Border Inspection Post; and

⁴⁸ This corresponds to principle 4 of HACCP.

⁴⁹ This corresponds to principle 5 of HACCP.

⁵⁰ This corresponds to principle 6 of HACCP.

⁵¹ This corresponds to principle 7 of HACCP.

⁵² The competent authorities of third countries are the only bodies entitled to officially declare that establishments fully comply with EU legislation requirements. Therefore production of goods intended to be exported to the EU can start from the date on which the amendments to the lists have been communicated to the European Commission by the competent authority of the third country. However, certification of such goods must only be carried as from the date of entering into force of the updated list, which is 10 working days after it is published on the European Commission Directorate General Health and Consumer Protection website.

- Comply with relevant animal health requirements.

In the U.S., fishery products manufacturers, such as shrimp manufacturers or processors, must meet current good manufacturing practices,⁵³ develop and verify the adequacy of a HACCP plan for the specific product,⁵⁴ keep adequate records,⁵⁵ meet sanitation control procedures,⁵⁶ and meet special requirements for imported products. These special requirements demand, on threat of being denied entry, that an importer verify the quality of the product. FDA regulations describe two ways for importers to satisfy their verification obligations. First, they can obtain products from a country that has an active equivalence agreement or compliance agreement with the FDA covering fish and fishery products. Alternatively, if no such agreement exists (which is generally the case), importers must take their own 'affirmative steps' to verify that the products they are importing have been processed in accordance with the regulations.⁵⁷ The regulation does not specify what would constitute satisfactory 'affirmative steps' but does give the following examples: obtaining a continuing or lot by lot certificate from a competent private party or from an appropriate foreign government inspection authority attesting that the products were produced in accordance with U.S. requirements.⁵⁸ The inspection authorities of some countries issue lists of processors that are in good standing with the authorities and are processing in accordance with the U.S. requirements. As of October 2007 the foreign government inspection authorities who maintained such lists were Canada, Japan, New Zealand, and Thailand.

Therefore, a producer or exporter of shrimp, interested in accessing the EU market, can do so only once the country of origin as a whole has been deemed fit to be listed as an approved country of origin. Consignments without official certification cannot be imported. For the same producer/exporter to access the U.S. market, the U.S. importer must vouch for compliance with U.S. requirements both directly with the producer or with a regulatory body or a private sector certification body. The U.S. approach thus provides greater flexibility as it offers several alternatives and facilitates imports from businesses in countries with a weak regulatory capacity.

The EU legislation seeks to implement the equivalence provisions of Article 4 of the SPS Agreement by permitting the EU's trading partner to demonstrate that it operates SPS measures that are equivalent to EU requirements and thereafter to operate under its own equivalent requirements. Such an approach avoids redundant formal checks and is advantageous for countries with a well developed food safety regulatory system. **Yet, interestingly, the question arises whether an equivalence approach is necessarily always in the interest of producers in developing countries. For example, a facility with an excellent compliance record that happens to be situated in a country with overall poor safety records or very poor regulatory agencies will be able to access the U.S. market but not the EU market.** The EU

⁵³ See 21 C.F.R. § 110 for a list of these requirements.

⁵⁴ This HACCP plan must include the food safety hazards, critical control points for each hazard, critical limits, procedures and frequency of monitoring, corrective action plans, verification procedures and provide for a recordkeeping system. 21 C.F.R. § 123.6.

⁵⁵ § 123.8.

⁵⁶ § 123.11.

⁵⁷ 21 C.F.R. § 123.12.

⁵⁸ 21 CFR 123.12(a)(2)(B).

requirement has been recognized as a bottleneck in the EU's fishery products import program, *i.e.*, by the Dutch Centre for the Promotion of Imports from developing countries:

All fishery products (whether fresh, chilled, frozen, canned, salted, smoked or dried) imported from third countries into the EU must come from a preparation, processing, packaging or storage facility which is approved by a competent authority in the exporting country itself. In many developing countries a proper infrastructure to fulfill this requirement is lacking.⁵⁹

Both jurisdictions sample and test a percentage of shrimp. However, while FDA reportedly sampled less than 2% of the nearly 860,000 shipments of imported seafood in 2006,⁶⁰ EU authorities are supposed to sample either 20% or 50% of seafood shipments depending upon the risks presented by the type of seafood.⁶¹

VI. Reconciling Food Safety with Import Facilitation Objectives

This report is in no way intended to be a comprehensive examination of the respective food safety and animal and plant health regulations; rather, it offers a general description of the regulations applying to the import of two specific products, namely green beans and shrimp, so as to illustrate that there are significant similarities as well as differences in U.S. and EU approaches. This final section of the report will address how the U.S. and EU can jointly better reconcile their shared objectives of ensuring the safety of food imports and contributing to greater economic growth and poverty alleviation in developing countries by facilitating greater agricultural production and exports. **Advocates for increasing imports from developing countries may perceive stringent import standards as obstacles. Food safety and animal and plant health regulators, on the other hand, whose statutory obligation is to protect consumers, will not see their responsibility as encompassing import facilitation. This report argues, however, that these two objectives need not be mutually exclusive.**

A. Technical Cooperation and Assistance

Education, outreach, and technical assistance can help to meet both objectives, and the U.S. and EU actively pursue such activities. These efforts are crucial because education and capacity building to meet specific requirements are essential to facilitate trade and have, in fact, often led to compliance and market access for producers in developing countries.⁶²

When FDA develops a new food safety requirement or guidance, such as the mandatory seafood HACCP regulation in 1995 or the Good Agricultural Practice Initiative of 1999, the agency typically schedules a series of workshops and training opportunities for U.S. and international

⁵⁹ From CBI document prepared for UNCTAD Export meeting October 2-4, 2002

⁶⁰ Food and Water Watch, Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections 8 (2007), available at www.foodandwaterwatch.org/fish/publications/reports/import-alert ["Food and Water Watch Alert"].

⁶¹ European Commission, EU import conditions for seafood and other products.

⁶² The authors are grateful to participants in a U.S. government interagency meeting held at the Office of the United States Trade Representative (USTR) on April 17, 2008, who pointed to several successful efforts undertaken by US agencies, such as: the approach used by FDA and USDA to assist Serbia expand its dairy exports to the US and EU; and FDA/USDA efforts in El Salvador to greatly improve its cheese production and export.

regulatory officials and industry representatives. At present, many of the agency's international food safety initiatives are focused on China.

Since 1999, FDA has conducted training and outreach activities to enhance the safety of fresh produce. FDA has developed training for states, foreign governments, third parties, and FDA staff to do farm investigations in conjunction with states, industry representatives, and regulatory officials from Mexico and Canada. Farm investigations conducted by FDA, states, foreign governments, and third parties focus on farm layout, manure management, sewage use, animal management, harvest tools and equipment, and processing and packing facilities. These investigations also include transportation, environmental and product sampling, water sources and worker health and hygiene. The purpose of these investigations is to determine the source, patterns, and practices leading to contamination.⁴ In addition to this program, FDA has hosted and continues to host international workshops regarding safe food handling and processing⁶³ and has held briefings with industry trade associations and others to discuss fresh produce, answer questions, and address concerns about the guide and the import and domestic produce survey.⁶⁴

APHIS has also made efforts to provide education and training assistance to developing countries seeking to export agricultural products to the U.S.⁶⁵ For example, in May 2003 APHIS assigned two officers to Zambia to help with pest risk assessments on farms.⁶⁶ Similarly, after USDA conducted a series of nine seminars in Sub-Saharan Africa focused in part on conducting risk assessments, it assigned three risk assessment advisors trained by APHIS to trade hubs in Botswana, Uganda, and Ghana.⁶⁷ The advisors' responsibilities include assisting countries in conducting pest risk assessments for agricultural products that have the potential for export to the U.S.⁶⁸

Similarly, the European Commission provides training, technical assistance and facilities for institutional capacity building to help developing countries comply with EU rules. The European Commission Directorate General for Food and Consumer Protection has an initiative known as

⁶³ For example, in April 1999, FDA cosponsored a three-day workshop, "Enhancing the Safety of Fresh Produce at the Source: Training Modalities and Methods, Needs and Opportunities" with other U.S. departments and agencies and a partnership with the University of Maryland known as the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). The goal of this international workshop was to identify training needs for growers and producers who export fresh produce to the United States. The workshop attracted 175 participants from 24 countries on four continents and included government experts, education and training counselors, scientists, farmers, producers, worker groups, academic institutions and international organizations.

⁶⁴ As a result of these meetings, FDA and industry representatives have agreed that: (1) timely sharing of the results of the surveys will aid both government and industry in efforts to improve practices; (2) in addition to a visit to the farm associated with a violative sample, visits should also be made to growers of similar products also sampled but found free of pathogens; and (3) information should be shared and compared to determine any specific practices that may be affecting the pathogen level in the sampled products.

⁶⁵ APHIS describes its "international mission" as protecting and promoting "U.S. agricultural health through internationally-based animal and plant health expertise." APHIS, International Safeguarding, http://www.aphis.usda.gov/international_safeguarding/index.shtml (last visited June 6, 2008).

⁶⁶ COMESA, Update on AGOA Implementation, <http://www.comesa.int/trade/multilateral/agoa-alinc/UPDATE%20ON%20AGO%20IMPLEMENTATION/en/view> (last visited June 6, 2008).

⁶⁷ See Patricia R. Sheikh, Deputy Adm'r, Int'l Trade Policy, Foreign Agric. Serv., From Aid to Trade, AfriCANDO 2004 Conference 1-2 (Sept. 16, 2004); see also *supra* note 39 and accompanying text.

⁶⁸ Patricia R. Sheikh, Deputy Adm'r, Int'l Trade Policy, Foreign Agric. Serv., From Aid to Trade, AfriCANDO 2004 Conference 2 (Sept. 16, 2004).

Better Training for Safer Food that aims to train regulatory officials in the EU Member States, EU candidate countries, such as Turkey and Croatia, and other countries that ship foods to the EU about food safety.⁶⁹ The Better Training for Safer Food initiative covers HACCP principles. The course is mainly for competent authority control staff of EU Member States and candidate countries responsible for verifying compliance with EU rules by food and feed businesses. Places are also available for competent authority staff from European Free Trade Association, European Neighbourhood Policy and selected third countries. In all, the program should train approximately 400 people.

In 2006, contractors engaged by the European Commission provided training at 34 events, boasting 1,400 participants. Of the 34 events, 20 focused on HACCP; 6 on EU import standards for fruit, vegetables and fishery products; 4 on animal by-products; and 1 each on avian flu control, airport Border Inspection Posts, seaport Border Inspection Posts, and animal welfare requirements.⁷⁰ Non-EU participants in the HACCP events included participants from India, Morocco, the Maldives, Kenya, Botswana, Ghana, Jamaica, Tanzania, and Thailand.⁷¹ The Commission also sponsored seven training missions in which experts were seconded to assist in on-the-job training on the issue of avian flu control.

Considering the many similarities of U.S. and EU objectives and requirements for food safety and animal and plant health, cooperation in training efforts to assist producers in developing country in meeting common EU and U.S. requirements should be encouraged. For example, clear and up-to-date guidance for producers to achieve compliance in both markets seems advisable. Where possible, common guidelines, manuals, and training materials could be considered. The authors believe that improved clarity and understanding of requirements among the governments and producers in developing countries, including joint guidelines and manuals for producers, would enhance food safety compliance and the achievement of high levels of protection for plant and animal health to which both the U.S. and EU are committed.

There are many areas where common expectations could support joint initiatives to support food safety in developing countries in a harmonized and congruent way. As demonstrated, EU and U.S. requirements for seafood are essentially similar, but their methods of verifying the compliance with those requirements differ. Joint training, technical assistance and capacity building efforts therefore is practically advisable.

1. To meet both EU and U.S. requirements, food business operators producing or harvesting plant products or shrimp must take adequate measures, as appropriate, to:

- Keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles, and vessels (where applicable);
- Ensure, where necessary, hygienic production, transport, and storage conditions for, and the

⁶⁹ See Commission Communication COM (2006) 519 on Better Training for Safer Food on September 20, 2006. http://ec.europa.eu/food/training/communication_final_report_en.pdf. The authors are grateful to the European Commission for supplying this report, due to its relevance to its project.

⁷⁰ Details are provided in an annual report for 2006, available from the Web site of the Directorate General for Consumer Protection and Health, at page 17.

⁷¹ For a list of current programs under the Better Training for Safer Food initiative see http://ec.europa.eu/food/training_strategy/news/index_en.htm.

cleanliness of, products;

- Use potable water, or clean water, whenever necessary to prevent contamination;
- Ensure that staff handling food are in good health and undergo training on health risks;
- Prevent animals and pests from causing contamination, to the extent possible;
- Store and handle wastes and hazardous substances so as to prevent contamination;
- Take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health; and
- Use plant protection products and biocides correctly, as required by the relevant legislation.

2. The food business operator must monitor the food safety of products and processes under his responsibility. This includes:

- Observing general hygiene requirements for primary production; and
- Obeying any applicable microbiological requirements.

3. The food business operator must apply the seven HACCP principles aimed at consistently safe food production (the paradigm is that one cannot “test onto the market,” as samples might miss hazards):⁷²

- Analyze hazards;
- Identify critical control points;
- Establish preventive measures with critical limits for each control point;
- Establish procedures to monitor the critical control points;
- Establish corrective actions to take when monitoring shows that a critical limit was not met;
- Establish procedures to verify that the system is working properly; and
- Establish effective recordkeeping to document the HACCP system.

B. Information Exchange

Beyond increased cooperation in providing training, U.S. and EU regulators would benefit from a more systematic information exchange. It would be advisable, for example, to explore whether the EU authorities have information on non-EU countries’ plant risks and regulatory systems that might be helpful to APHIS in its risk analysis process and in considering import requests. Likewise, an ongoing exchange of inspection reports on seafood facilities or regulatory approaches could prove helpful.

There is, in fact, a growing awareness among food safety regulators that relying solely on inspections at the border or inspections carried out in countries of origin is no longer feasible in a global market. As articulated by HHS Secretary Mike Leavitt, “trying to inspect everything to assure safety . . . could bring global commerce to a standstill.”⁷³ Secretary Leavitt also has

⁷² “There are many constraints to developing and implementing HACCP in developing countries. The first that most food safety professionals will think of is the technical issues. The sanitation standards, quality systems and commitment to safety in food processing and handling operations in these nations is often well below those in developed countries. . . There are regulatory issues, cultural concerns, problems in the educational systems, economic pressures and good old politics.” R. Stier, M. Ahmed, and H. Weinstein, Constraints to HACCP Implementation in Developing Countries, *Food Safety Magazine* (May 2002), at 36.

⁷³ Press briefing with Secretary Mike Leavitt, US Department of Health and Human Services, May 19, 2008 – <http://geneva.usmision.gov/Press2008/May/0519Leavitt.html>.

referred to the duplication which takes place as far as foreign inspections are concerned: “Does it make sense for the United States to inspect those facilities and the next day for the UK to inspect them, and the day after for the Germans to do it, and the week after the Canadians, and the day after that for the Australians to come and inspect the same facilities? It likely does not.”⁷⁴

While an improved information exchange between the U.S. and EU seems like an easily attainable goal,⁷⁵ reliance on a shared foreign inspection regime or a commonly accepted independent certification regime would, of course, be a more far-reaching recommendation. A deliberate exploration of such cooperation—not necessarily limited to the EU and U.S.—would be advisable. In addition to facilitating trade and improving food safety, common approaches have the additional attraction of potential government resources savings.

C. Regulatory Streamlining

Arguably more difficult than EU-U.S. cooperation on training, outreach, and information exchange is a streamlining of the respective sets of food safety and animal and plant health regulations. **Different animal or plant diseases may pose different threats in different countries of destination and a complete harmonization of standards is certainly not well advised in those cases. Yet, to the extent that the process of verification with standards could be streamlined, this would appear to not only facilitate trade but also the safety of imports.**

We note that some technical cooperation and assistance initiatives have addressed, to some degree, the challenges presented by differences between EU and U.S. regulatory requirements, such as those affecting seafood production in Vietnam. For example, in 1999, FDA participated in efforts that assisted seafood producers in Vietnam to comply with applicable requirements.⁷⁶ The FDA sent inspection teams to Vietnam, Ecuador, The Philippines and Taiwan to engage in compliance inspections, develop relationships with authorities, and train individuals in the industry and the government.⁷⁷

Another important step, however, would be to consider the ways in which U.S. and EU requirements—and the means required to demonstrate compliance with these requirements—could be further harmonized.

The U.S. and the EU have strong but separate regulatory systems and must dedicate substantial resources toward overseeing both major food production within their territories as well as that of significant and growing food producers abroad. Consider the leadership role that the U.S. and the EU could play if they could implement harmonized processes for confirming compliance with requirements that are both rigorous and yet streamlined. The need to wade through multiple laws, regulations, guidances, and forms from just the U.S. and the EU regulatory agencies must be overwhelming to even the most literate and

⁷⁴ Ibid.

⁷⁵ These normally require the conclusion of a confidentiality agreement, as exists between DG Sanco and FDA.

⁷⁶ This was brought to our attention by the US interagency SPS team.

⁷⁷ FDA’s Evaluation of the Seafood HACCP Program for 1998/1999, Dec. 8, 2000, <http://www.cfsan.fda.gov/~comm/seaeval.html>.

attentive of producers.⁷⁸ This is true even if all of the information is on the relevant Web sites. We would find it understandable if this were one reason why many exporting producers aim to ship to either the EU or the U.S. market, but rarely to both.

There could be an effort to harmonize and streamline such documentation requirements as lists of authorized producers and export certificates. Simplification of the procedures for demonstration of conformity with requirements would not lessen food safety but would support it, and the same is true of streamlining of procedures to demonstrate compliance with requirements aimed at animal and plant health protection. These efforts would be aided by documents already prepared by the international standards bodies recognized in the WTO SPS Agreement,⁷⁹ such as model certificates and other means of verification of compliance. Both U.S. and EU officials have participated actively in efforts by the Codex Alimentarius Commission's committee on food import and export certification systems to develop useful documents to guide national authorities in use of certificates to document compliance. Because certain current documentation requirements by both the U.S. and the EU are dissimilar and in some cases unduly burdensome, the U.S. and EU should seek to identify, and to agree upon, best practices with respect to the demonstration of compliance with the importing country's requirements, and to consider use of the documents already developed at international level.

With regard to fishery products, the EU and FDA should explore whether they could develop streamlined procedures for updating the lists of seafood producers on each side that are eligible to export to the other market.

Streamlining verification procedures may be considered controversial, but should be less controversial than streamlining actual requirements. Here, too, however, there may be some scope for harmonization.

Just as the food industry, under HACCP, is supposed to focus its control system upon the identified Critical Control Points, so too might EU and U.S. regulators identify and agree on “Regulatory Critical Control Points” that need the most attention and then eliminate unimportant features of their separate systems that add burden without commensurate benefit. Thereafter, the U.S. and the EU should work together to minimize differences between the U.S. and EU requirements.

D. Transatlantic Regulatory Cooperation

While there are still some U.S.-EU disputes over “traditional market access”⁸⁰ issues, regulatory differences have become an increasingly important focus in bilateral trade relations. EU and U.S. authorities have expressed significant interest in pursuing “regulatory cooperation,” and the most recent initiative is the Transatlantic Economic Council, formed in April 2007, which aims

⁷⁸ See Smyrlis, *supra* note **Error! Bookmark not defined.** (quoting Phil Cahley, the executive director of the Canadian Courier and Messenger Association that FDA import pre-notification requirements create “such a complicated process [that he is] not sure everybody understands the details”).

⁷⁹ The international standards bodies recognized in the WTO SPS Agreement are the Codex Alimentarius Commission as to food safety, the International Plant Protection Convention (IPPC) as to plant health, and the Office of International Epizootics (OIE or World Animal Health Organization) for animal health.

⁸⁰ By “traditional market access issues” we refer to tariffs and subsidies.

to remove restrictive regulations and standards that substantially raise costs for companies wishing to do business across the Atlantic. As part of the Transatlantic Economic Cooperation program (“TEC”), import safety has been identified⁸¹ as a priority area:

The U.S. and the EU are confronted with very similar challenges arising from imported food and non-food products from, in particular, China. There is thus good potential for enhanced cooperation on increased overall efficiency of our respective market surveillance and enforcement systems, as well as on import safety.

Due to shared concerns about the safety of food imports from other countries (many of them developing countries), EU and U.S. authorities have reported that they are working to identify opportunities for further cooperation to ensure the safety of imports as part of ongoing discussions of the High Level of Regulatory Cooperation Group.

Examining potential regulatory streamlining, with the purpose of facilitating imports from developing countries while promoting greater import safety, would have the advantage of adding a “development aspect” to TEC that should be very much welcomed by developing countries. Moreover, such an initiative could be useful because it would involve transatlantic regulatory cooperation vis-à-vis third countries in SPS affairs, which could be a less difficult topic than reconciling regulatory differences affecting U.S.-EU trade, of which there are several longstanding ones.⁸²

The idea behind such initiatives as the Transatlantic Economic Council, which was inaugurated by German Chancellor Angela Merkel and U.S. President George Bush, is to give a high-profile push on regulatory cooperation, with the hope that the priority being given this topic might help overcome the reluctance prevalent in many national regulatory agencies to think beyond their national domains. **Another—and less high-profile—approach towards regulatory cooperation is for the regulatory agencies themselves to take the initiative and create ongoing dialogues with their counterparts across the Atlantic. These types of dialogues with a view towards facilitating greater and safe food imports from developing countries—should also be encouraged.**

It is interesting to note the progress that has been achieved in transatlantic regulatory cooperation in the area of pharmaceuticals. Already FDA and its EU counterparts are collaborating on a Transatlantic Initiative on Administrative Simplification in Pharmaceuticals, building upon earlier collaborations, such as the International Conference on Harmonization of the Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) and confidentiality agreements starting in 2003, and a commitment in June 2007 to intensify regulatory cooperation in the area of pharmaceuticals.⁸³

⁸¹ Brief description of 2008 TEC objectives (17 April 2008); European Commission, Press Release, EU-US High-level Regulatory Cooperation Forum meets in Brussels today (25 April 2008): “Today’s meeting will discuss joint efforts to strengthen transatlantic cooperation on the safety of imported products...”

⁸² Among these differences are divergent regulatory approaches on genetically modified crops; the use of hormones as growth promoters; BSE and the use of antimicrobial treatment used on poultry meat.

⁸³ <http://www.emea.europa.eu/pdfs/general/direct/pr/regcoopexpanded.pdf>

An early success by the Transatlantic Initiative on Administrative Simplification in Pharmaceuticals concerned orphan medicines, *i.e.*, medicines for rare diseases. Here, again, the EU and U.S. have separate but similar laws, and discussions have been ongoing for several years about the best practice in designations of orphan diseases. That collaboration is now being intensified through the publication in November 2007 of a common format that can be used by industry to apply to both the FDA and the European Medicines Agency seeking the designation of a pharmaceutical as an orphan product. This [common application form](#) for drug developers seeking approval for orphan medicines on both sides of the Atlantic takes into account the fact that there are substantive differences in the laws of the two regions, but this fact did not bar the adoption of a common format taking into account both the statutory similarities and the differences. Also, both regulatory bodies will continue conducting independent reviews to ensure compliance with their respective scientific requirements. Nevertheless, the industry and the general public benefit from the streamlining of the paperwork requirements.

What is now being discussed in the Transatlantic Pharmaceutical Initiative includes a number of topics and activities that have counterparts in the area of food safety, where the same types of joint efforts would be equally mutually beneficial:

- “Upstream” regulatory cooperation, including the possible exchange of information on advance drafts of legislation and regulatory guidance documents;
- Exchange of non-public information related to ensuring the quality, safety and efficacy of medicines for human and veterinary use, including orphan medicines, authorized or under review both in the U.S. and the EU;
- Ad hoc exchange of papers on regulatory issues prior to the drafting of new legislation, advance drafts of legislation in the EU, and drafts of regulations in the U.S., draft guidelines, etc.;
- Staff exchanges for educational purposes and to strengthen regulatory cooperation between the organizations;
- Ad hoc meetings and workshops on regulatory issues of mutual concern, such as a Transatlantic Administrative Simplification Workshop hosted by the EU in Brussels on November 28, 2007, which sought to identify opportunities for administrative simplification of regulation through U.S.-EU cooperation and provide a basis for roadmaps for future harmonization work;⁸⁴ and
- Sharing of information on urgent issues relating to drug safety or public health.

E. The Importance of International Standards

Food safety in both the U.S. and the EU will be well served by bilateral efforts that promote food safety, in particular if both the U.S. and the EU maintain and increase the level of commitment to Codex Alimentarius, the IPPC and OIC.

⁸⁴http://www.ustr.gov/assets/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/asset_upload_file108_11107.pdf

Developing countries are more likely to accept the legitimacy of developed-country requirements when the requirements are harmonized, through international organizations or bilaterally, and based on international standards. Where major importing and exporting regions like the U.S. and EU maintain requirements that are disharmonized, the very differences suggest a degree of arbitrariness, or a lack of basis in science, that undermines compliance by developing-country producers.

With regard to an international standard governing green beans, the Codex Alimentarius provides some very basic guidelines. In terms of general quality, the Codex Alimentarius provides that green beans “shall be safe and suitable for human consumption,” “free from abnormal flavour, odours, and living insects,” and “free from filth (impurities of animal origin, including dead insects) in amounts which may represent a hazard to human health.”⁸⁵ Additionally, and more specifically, green beans “shall be free from heavy metals in amounts which may represent a hazard to health” and “shall comply with those maximum residue limits established by the Codex Alimentarius Commission for this commodity.”⁸⁶

HACCP requirements for seafood producers are essential but should be based upon the relevant standards developed by Codex.⁸⁷ Concerning shrimp, the Codex Alimentarius Commission has emphasized adoption of HACCP by seafood producers generally and, beyond that, has not engaged in significant standard setting activity.⁸⁸ Some countries, such as Brunei, Cambodia and Lao PDR are reportedly lacking in control systems for the import and export of fish and fishery products.⁸⁹ Many shrimp-exporting countries in the ASEAN area, however, have largely adopted HACCP standards for exporting facilities in order to sell shrimp to the U.S.⁹⁰ Thus, more could be done at international level to support adoption of HACCP as a harmonized food safety system.

To the extent that U.S. and EU authorities can agree upon what principles must be observed to ensure food safety, and reflect these principles in their requirements and the initiatives they espouse in Codex, they can expect a higher degree of developing-country respect for these requirements.

VII. Private Standards

This report has focused on government standards. However, private standards are increasingly common in the EU, the U.S., and elsewhere and are of a growing importance for food and food production. They often are established by both large retailers and producers groups.

⁸⁵ Codex Standard for Certain Pulses, available at <http://www.codexalimentarius.net/search/advancedsearch.do> (search “Text in Document” for “Phaseolus”).

⁸⁶ *Id.* Compare *supra* note 28.

⁸⁷ The main differences that may be found refer to the content and scope of the HACCP plan and the way, in which, prerequisite programs are to be implemented, documented and verified.

⁸⁸ See Report of the FAO-ASEAN Strategic Planning Workshop on Harmonization of Standards for Shrimp Export-Import, July 2004, § 3.1, available at <http://www.fao.org/docrep/007/ad502e/ad502e00.htm#Contents> (noting “[s]hrimp farming and processing in ASEAN is targeted at the export market which means that the quality and standards of shrimp products depends largely on the requirement of importing countries.”).

⁸⁹ *Id.*

⁹⁰ *Id.*

An example of a private standard is the GlobalGAP (Good Agricultural Practices) System. It applies ISO 65 020. 01 standards. It is a pre-farm gate standard that covers the entire agricultural production process of certified products from pre-planting (origin of seed and propagation material control points) to non-processed end product after harvest (no processing or manufacturing is covered) The objective is to form part of the verification of Good Practices along the whole production chain. GlobalGAP includes food safety issues, environmental issues and social issues related to primary production.

The private sector has a pivotal role to play in food safety. To quote Secretary Leavitt again, in a speech before the U.S.-India Business Council he stated that “markets not mandates” best assure product safety. Terming this concept the “red pepper principle,” Secretary Leavitt described how Indian spice producers readying their wares for shipment to McCormick’s processing facility in the United States had marked each bag with a simple tag identifying the farm where the spices were grown. In this way, McCormick’s could maintain complete traceability and thus, if anything went wrong, hold the supplier accountable for any shortcomings in the product. Secretary Leavitt postulated that the “red pepper principle” shows that “markets not mandates” should be the foundation for food safety in international trade.⁹¹ This principle would support the view that food safety might depend more upon private-sector commitments than governmental actions, and that contractual relationships between developed-country importers and developing-country suppliers might be more effective than exporting-country regulation, or importing-country regulation, in assuring product safety and compliance.

Non-EU, non-U.S. producers who, either individually or through trade organizations, have the resources to comply with private standards, and thus to access the world’s more valuable markets benefit greatly. However, many smaller producers with fewer resources find that they can not meet private standards or cannot afford costly certification due to a lack of adequate economies of scale. The net result is that those who have arguably the greatest need to increase access to such markets find themselves excluded from opportunities and incentives to do so. This is particularly true where the buyer imposes on the seller an expensive third-party audit requirement, in addition to self-declaration of conformity to a private standard.

Some developing countries, therefore, view private standards as barriers to trade that should be controlled by the governments in whose territory the organizations administering or applying the standards reside. In the World Trade Organization’s SPS committee, several meetings and workshops have been held to discuss the growing impact of private standards on global trade in food. No consensus has been reached.

Under EU and U.S. law, unless companies are dominant in a specific sector, there is nothing that can be done legally to prevent private companies from imposing expectations and standards that are higher than those imposed by requirements even if, as a result, producers, whether in that country or abroad, are excluded from elements of the market.

⁹¹ Remarks by HHS Secretary to the US-India Business Council, March 18, 2008

U.S. and EU authorities could also play a more effective leadership role in discussions of private standards at the international level. Such standards can contribute to food safety, but the question is how to avoid undue costs that have the effect of shutting out developing countries' products from key markets.

Annex A: The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).⁹²

This agreement pertains to those measures intended: 1) to protect animal or plant life or health within a territory from risks arising from the entry, establishment, or spread of pests, diseases, disease-carrying organisms, or disease-causing organisms; 2) to protect human or animal life or health within a territory from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs; 3) to protect human life or health within a territory from risks arising from diseases carried by animals, plants, or products thereof, or from entry, establishment, or spread of pests; or 4) to prevent or limit other damage within a territory from the entry, establishment, or spread of pests.⁹³ Thus, “sanitary” refers to the protection of people and animals; “phytosanitary” refers to the protection of plants.

SPS measures include measures “to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods, beverages or feedstuffs”⁹⁴ SPS measures include “all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures . . . provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.”⁹⁵ Examples of SPS measures are FDA safety requirements for additives, contaminants, and microbial adulteration.

To harmonize SPS measures on as wide a basis as possible, the SPS Agreement encourages Members to base their SPS measures on international standards, guidelines, or recommendations.⁹⁶ Like the TBT Agreement,⁹⁷ the SPS Agreement encourages “harmonization” (the “establishment, recognition and application of common sanitary and phytosanitary measures by different members”⁹⁸) and the use of international standards therefor. There are important exceptions to harmonization, however. A member may set higher standards if there is a scientific justification, or as a consequence of the level of protection the importing country determines to be appropriate.⁹⁹

SPS measures must be based on scientific principles, may not be maintained without sufficient scientific evidence, and must be based on an assessment of the risk to health that is appropriate to the circumstances.¹⁰⁰

Furthermore, countries are strongly encouraged to use standards set by certain international bodies, including the food safety-related standards of the Codex Alimentarius Commission.¹⁰¹

⁹² SPS Agreement, *supra* note 125.

⁹³ *Id.*, annex A.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*, art. 3.1.

⁹⁷ TBT Agreement, *supra* note 113, art. 2.4, 2.6, 5.5, 9.1.

⁹⁸ SPS Agreement, *supra* note 125, art. 3, 12.4; annex A.2.

⁹⁹ *Id.*, art. 3.3.

¹⁰⁰ *Id.*, art. 2.2, 3.3, 5.

¹⁰¹ *Id.*, art. 3.2, 3.4. TBT Agreement, *supra* note 113, art. 2.5.

The effect is to give countries an incentive to accept Codex standards. Members who do so need not justify their sanitary measures. Members who do not base their requirements on Codex may need to justify them, either as scientifically based or as a consequence of the country's desired level of protection.

Because the SPS Agreement contains provisions both to induce countries to follow Codex standards, and to excuse a country from doing so as a result of a scientific rationale or its chosen level of protection, the outcome of WTO disputes based on a country's choice to enforce requirements stricter than Codex cannot be predetermined but will be handled on a case-by-case basis under the WTO Dispute Resolution Understanding.¹⁰²

¹⁰² DSU, *supra* note 129.

Annex B - Summary of Key EU and U.S. Differences

	U.S.	EU
Institutional Set-Up	<p>Many food safety agencies – FDA, USDA – FSIS, USDA – APHIS, EPA, etc.</p> <p>Different regulatory framework for seafood than other animal-derived foods</p>	<p>One EU Directorate General for Health and Consumer Protection; border controls carried out in member states</p> <p>One regulatory framework for all animal-derived foods and another for plant-derived foods</p>
HACCP	Mandatory for meat products regulated by USDA and for juices, fishery products and low acid canned food regulated by FDA	Mandatory for all food and feed
Horticultural Imports	<p>Food Safety regulated by FDA and EPA; plant health by APHIS</p> <p>Pre-qualification system for imports under APHIS</p>	<p>Regulated by EU Directorate General for Health and Consumer Protection</p> <p>No pre-qualification system but production needs to be in keeping with EU legislative requirements; positive list of products which require phytosanitary certificate</p>
Seafood Imports	US importer must vouch for safety of product	Official Pre-qualification system for imports; requirement for original veterinary certificate to accompany imports