



**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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# Authors' biography



- Linda R. Horton Partner, Brussels, Washington, D.C.
- Linda Horton counsels clients in the food, pharmaceutical, medical device, animal health and cosmetic industries on requirements of the EU regulatory authorities, the U.S. Food and Drug Administration (FDA), and similar agencies in other countries.
- Linda joined Hogan & Hartson in 2002 after a long career in the FDA's legislative, legal, and international policy offices. During her last eight years at the agency, she was director of international policy, leading activities on harmonization, agreements, trade, imports, exports, EU relations, and legislative models for national regulatory systems. Earlier she was Deputy Chief Counsel and legislative director.
- While in FDA and now in private practice, Ms. Horton has helped officials in other countries develop new food safety laws and regulations (e.g., Brazil, China, the European Commission, France, India, Ireland, Mexico, Russia, the United Kingdom). She also led agency activities on the UN Food Standards Programme (Codex Alimentarius) for 7 years, served as U.S. delegate or alternate U.S. delegate to Codex committee meetings, and authored the key U.S. document on “Precaution in the U.S. Food Safety System” at [www.foodsafety.gov](http://www.foodsafety.gov).

# Authors' biography



- Elisabethann Wright Counsel, Brussels
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- Former law clerk at the European Court of Justice and Senior Legal Officer/ Hearing Office at the EFTA Surveillance Authority.
- Extensive and varied experience of food and life science matters from the perspective of both private undertakings and that of international institutions.
- Extensive litigation experience before the Court of Justice, the Court of First Instance and the EFTA Court in matters including agriculture, food, pharmaceuticals, public procurement, trademarks, and free movement of goods, persons and services

# I. Executive Summary

- We examine some of 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

# I. Executive Summary

- The U.S. and EU share the goals of:
  - improving the safety of food imports
  - 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.

# I. Executive Summary

- Green beans and shrimp as case studies.
- 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 do differ are the U.S. and EU requirements for verifying compliance with their seafood and horticultural import standards.

# I. Executive Summary

- Offer recommendations for EU and U.S. cooperation
- 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.

## II. Why Green Beans and Shrimp?



## II. Why Green Beans and Shrimp?

- Two relatively representative categories of food commodities that are of interest to developing country exporters.
- Several developing countries successfully export green beans or shrimp to the U.S. or the EU markets and, in a few cases, to both.

## II. Why Green Beans and Shrimp?

- Green beans appeared to be a reasonable candidate for fresh produce or frozen food
  - they are generally cooked before consumption, reducing risk of pathogens
  - pesticides are used in their production, and green beans are eaten whole without husking or peeling
  - there are non-trivial plant health concerns involving imported green beans
  - trade data indicate that both the U.S. and the EU import green beans from certain developing countries.

## II. Why Green Beans and Shrimp?

- Shrimp seemed to be a good candidate for a protein food
  - Popular, high-value-added, and much-traded commodity in high demand by U.S. and EU importers
  - 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 U.S. and/or EU requirements for their shrimp
  - Their successes indicate that producers and regulators in other developing countries could achieve comparable success.

# III. The Timing of This Report

- 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.
- While the U.S. and the EU are under pressure to step up their scrutiny of food imports, developing countries have concerns about these initiatives.
  - One impediment to progress in the WTO 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 addressed.

# III. The Timing of This Report

- The U.S. and EU devote considerable energy and resources to providing information about their import requirements and to providing technical assistance to developing countries.
- 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.

# III. The Timing of This Report

- 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

- The report is based upon the premise that food must be safe.
- Developing countries need to require their exporting industries to meet the requirements of the U.S. and the EU when shipping food to these regions and ensure the safety of products consumed domestically.
- 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,
  - necessary for the protection of health
  - do not unjustifiably discriminate among foreign sources of supply
- The WTO SPS Agreement encourages governments
  - to work toward harmonization,
  - to base their national measures on the international standards, guidelines and recommendations developed by the WTO member governments in other international organizations.
  - But it also allows members to introduce or maintain measures resulting in a higher level of protection, if there is a scientific justification.

# V. Key Regulatory Similarities and Differences

- A. Food Safety, green beans and shrimp
- B. Green beans (Plant health)
- C. Shrimp (Animal health)

# 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
  - place the responsibility for a food product's safety, wholesomeness, identity and economic integrity with the producer or importer.
- The producer or importer must comply with the requirements issued under the relevant regulations
- Government authorities oversee the efforts by producers or importers to enforce compliance.

# A. Food Safety

- Both the U.S. and the 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.”
- 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.

# A. Food Safety

## Differences

- Despite the numerous similarities, the institutional food safety regimes are different from each other.
- 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 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.

# A. Food Safety

- 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, and thus 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.
  - Both the U.S. and the EU operate science-based and risk-based phytosanitary control systems.
  - Both participate actively in international fora such as the IPPC and regional phytosanitary organizations.

# B. Green Beans

- 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.
  - 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.

# B. Green Beans

- The US
  - Since 1987, APHIS approves most new imports through a rulemaking procedure.
  - The requirement for product specific and country specific rulemaking can cause lengthy time-frames for APHIS consideration of import requests.
    - 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

# B. Green Beans

## – The US (continued)

- 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 in an APHIS regulation.
  - In these cases, APHIS does not need to go through full rulemaking
  - APHIS 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.
  - If no substantive concerns are raised, APHIS can publish a final notice authorizing the issuance of import permits
- 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.

# B. Green Beans

- The EU
  - 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.
    - 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.
    - 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
  - Both 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 hazards to human consumers.
  - Both the FDA and EU authorities have imposed strict prohibitions against entry of shrimp that had been treated with certain veterinary drugs.
  - Both the U.S. and the EU have imposed the HACCP approach to the processing of seafood, including shrimp.

# C. Shrimp

- 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.

# C. Shrimp

- In 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
    - Comply with relevant animal health requirements.

# C. Shrimp

- In the US
  - Fishery products manufacturers, such as shrimp manufacturers or processors, must
    - Meet current good manufacturing practices,
    - Develop and verify the adequacy of a HACCP plan for the specific product,
    - Keep adequate records,
    - Meet sanitation control procedures,
    - Meet special requirements for imported products.

# C. Shrimp

- 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.

# C. Shrimp

- 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.
  - This approach avoids redundant formal checks and is advantageous for countries with a well developed food safety regulatory system.
- Question: Is an equivalence approach 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 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

# VI. Reconciling Food Safety with Import Facilitation Objectives

- 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.

# VI. Reconciling Food Safety with Import Facilitation Objectives

- A. Technical Cooperation and Assistance
- B. Information Exchange
- C. Regulatory Streamlining
- D. Transatlantic Regulatory Cooperation
- E. The Importance of International Standards

# 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.
  - When FDA develops a new food safety requirement or guidance, the agency typically schedules a series of workshops and training opportunities for U.S. and international regulatory officials and industry representatives.
  - 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.
  - APHIS has also made efforts to provide education and training assistance to developing countries seeking to export agricultural products to the U.S.

# A. Technical Cooperation and Assistance

- 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 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.
- 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.

# A. Technical Cooperation and Assistance

- 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.
- 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.

# A. Technical Cooperation and Assistance

- 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 (where applicable) vessels;
  - to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, products;
  - to use potable water, or clean water, whenever necessary to prevent contamination;
  - to ensure that staff handling food are in good health and undergo training on health risks;
  - as far as possible to prevent animals and pests from causing contamination;
  - to store and handle wastes and hazardous substances so as to prevent contamination;
  - to 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
  - to use plant protection products and biocides correctly, as required by the relevant legislation.

# A. Technical Cooperation and Assistance

- 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.
  - 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):
  - 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 be taken when monitoring shows that a critical limit has not been met.
  - Establish procedures to verify that the system is working properly.
  - 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.
- An ongoing exchange of inspection reports on seafood facilities or regulatory approaches could prove helpful.
- While an improved information exchange between the U.S. and EU seems like an easily attainable goal, 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.

# Regulatory Streamlining

- 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.
- Some technical cooperation and assistance initiatives have addressed, to some degree, the challenges presented by differences between EU and U.S. regulatory requirements.
- 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.

# Regulatory Streamlining

- 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.
- 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.

# Regulatory Streamlining

- 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.
- 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” 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 (TEC), formed in April 2007.
- TEC aims to remove restrictive regulations and standards that substantially raise costs for companies wishing to do business across the Atlantic. Import safety has also been identified as a priority area.

# D. Transatlantic Regulatory Cooperation

- 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. This could be a less difficult topic than reconciling regulatory differences affecting U.S.-EU trade, of which there are several longstanding ones.
- 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.

# 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.
- 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.
- To the extent 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.
- Non-EU and non-U.S. producers who have the resources to comply with private standards are able to access the world's more valuable markets
  - 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.

# VII. Private Standards

- Some developing countries view private standards as barriers to trade
  - Thus, private standards should be controlled by the governments in whose territory the organizations administering or applying the standards reside.
- But 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.
- 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.

**Any Questions?**

