# Chapter 22
# International Food Regulation Foundations

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## Learning Objectives

- Identify key international organizations related to food safety.
- Describe how the US government and US industry interact with the Codex Alimentarius to shape food safety policy at the national level.
- Identify the key regulatory authorities in the Food Safety Modernization Act that apply to imported food safety.
- Describe how inspection methods adapt in order to account for the globalization of the US food supply.

## Introduction

Today, almost 15 % of all food consumed by Americans is imported (USDA Economic Research Service 2014). Food imports come from more than 150 countries and typically include seasonal fruits and vegetables, seafood, spices, and processed food ingredients (HHS 2013). Although international organizations such as the Codex Alimentarius have been established to protect the health of consumers and promote harmonized global standards, there remain differences in food safety

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measures around the world. Some of these differences occur because some countries may lack the resources and technical capacity to address food safety hazards, and in other cases what one country perceives as a risk may not be considered a risk in another. Globalization has rapidly increased the number of countries exporting food to the US, thus requiring the government to put in place new strategies to ensure safe food.

The recent enactment of the Food Safety Modernization Act (FSMA, Public Law 111-353) has provided US food systems new tools to ensure the safety of both domestic and imported foods. FSMA includes more emphasis for FDA to engage in international harmonization efforts, strengthen their communications with inspection agencies outside of the United States, and build partnerships with public and private sectors including industry. This chapter addresses key international organizations and how experts from the US government and industry are working together to improve food safety.

## Key International Organizations Related to Food Safety

Key national and international organizations share common principles with respect to food safety. At the country level, national authorities have developed regulations to ensure safe and nutritious foods; they put in place standards of practice for food producers and processors and follow fair food trade practices established in the global community. Examples of national and supranational food safety authorities include the European Food Safety Authority (EFSA, www.efsa.europa.eu), mandated to identify and characterize emerging risks (i.e., risk assessments) in the fields of food and feed safety that apply to the European Union (EU) and its food and feed chain. The role of the US Food and Drug Administration (FDA) (www.fda.gov) is to provide the safety oversight of all domestic and imported food, medical devices, drugs, and cosmetics. Food Standards Australia New Zealand (FSANZ, www.foodstandards.gov.au) is a binational government agency that develops and administers a food code of practice for industry and coordinates assessment and surveillance of both domestic and imported foods. The national authority Health Canada is responsible for establishing food safety regulations and enforcing standards for food sold in Canada, as well as providing surveillance, prevention, control, and research of disease outbreaks (www.hc-sc.gc.ca).

The formulation of international food safety organizations grew from a recognized need to address global food safety problems and ensure fair trade practices. The United Nations (UN), Food and Agriculture Organization (FAO, www.fao.org), and World Health Organization (WHO, www.who.org) have taken on a significant role in actively addressing safe solutions to global food safety issues. WHO is a UN-specialized agency, established in 1948, to assist all people to attain a high level of health. The main function of WHO is to act as a directing and coordinating authority on public health. WHO is governed by 192 member states who meet annually at the World Health Assembly (WHA, www.who.int/mediacentre/events/

governance/wha/en/) to set international health regulations for its member nations. As a result, a core function of WHO is to strengthen national food safety systems by providing technical support, developing standards, and monitoring foodborne illness. WHO has established a food surveillance system and a food safety emergency network made up of national health department representatives. The International Food Safety Authorities Network (INFOSAN, www.who.int/foodsafety/fs_management/infosan/en/) is located at the WHO building in Geneva, Switzerland, and proactively exchanges food safety risk and information in six languages with governments around the globe.

The FAO and WHO work together to address various key food safety activities, including chemical risk assessments and provide capacity-building programs for developing countries (e.g., Food Quality and Standards Service, Economic and Social Development). Many food-related subjects–including scientific advice and training courses relevant to laboratory, inspection, and good manufacturing practices –are a key function of the joint work of FAO and WHO. The bodies providing independent scientific advice include the Joint Expert Committee on Food Additives (JECFA, http://www.Codexalimentarius.org/scientific-basis-for-Codex/jecfa/en/), Joint Meeting on Pesticide Residues (JMPR, http://www.Codexalimentarius.org/scientific-basis-for-Codex/jmpr/en/), and Joint Expert Meeting on Microbiological Risk Assessment (JEMRA, http://www.Codexalimentarius.org/scientific-basis-for-Codex/jmpr/en/). The outcomes of the expert meetings include identification of risk-based exposure concerns, factors that influence exposure to risk, analytical methods, and sampling plans. The expert opinions published by the FAO and WHO are used to set standards and guidelines in the Codex structure and for member states (i.e., national authorities) to establish their own national food standards. Specific areas of safety evaluation and risk assessment include:

- JECFA has evaluated more than 2500 food additives, approximately 40 contaminants and naturally-occurring toxicants, and residues of approximately 90 veterinary drugs. JECFA publications include specifications, analytical methods, and guidelines on conducing safety assessments of food additives and contaminants (FAO 2014a).
- JMPR reviews analytical aspects of pesticides, reviews toxicological data, and estimates acceptable daily intakes for humans (WHO 2014a).
- JEMRA provides microbiological risk assessment for pathogen and food combinations that are associated with foodborne illness. JEMRA has published risk assessment findings to provide guidance for hazard characterizations (FAO 2014b).

## *Codex Alimentarius*

In 1962, the Codex Alimentarius Commission (Fig. 22.1) was established jointly by the FAO and the WHO and has become the single most important international reference for food standard development. The Codex Alimentarius (Latin for "food


**Fig. 22.1** Codex Alimentarius plenary meeting, Rome, 2007 (Used with permission from Sepp Hasslberger. http://www.newmediaexplorer.org/sepp/2007/10/15/codex_alimentarius_will_eu_laws_become_world_standard.htm)

code") is a collection of internationally-adopted food standards covering all the principal foods traded (including raw and processed) and is supplemented with residue limits for pesticides and veterinary drugs in food, along with acceptable levels of food additives and contaminants.

The primary objective of Codex Committee meetings is to harmonize international food standards by bringing together scientists, technical experts, government regulators, and international consumer and industry groups. There are 186 Codex member countries, with each member country having one vote. Observer status of more than 200 organizations has been granted to industry and consumer representatives to participate in Codex meetings, although no observers may vote. The preparation of draft food standards takes place in Codex committees—taking into consideration member views and scientific advice from expert committees. The proposed Codex standard is reviewed by governments and interested parties, and if agreement is reached, the standard is endorsed by general Codex Committees and formally adopted by the Codex Commission. The standards, along with guidelines for food safety risk assessments and recommendations concerning sampling, analysis, and inspection, are available on the Codex website: www.Codexalimentarius.org. Although non-mandatory in nature, since 1995, the Codex standards have been a reference for international food trade under agreements of the World Trade Organization (WTO, www.wto.org).

### *International Plant Protection Convention (IPPC)*

The International Plant Protection Convention (IPPC, www.ippc.int) is an international organization that facilitates trade agreements to protect plant health and prevent the spread of pests. Similar to the other international standard-setting bodies, the IPPC is made up of signatory members with an appointed national contact point to act as a liaison and foster information exchange between organizations. The primary function of the IPPC is to develop standards, enhance plant health inspection systems, and strengthen biological control.

### *World Organisation for Animal Health (OIE)*

The World Organisation for Animal Health (OIE, www.oie.int), or Office International des Epizooties, was created to provide transparency of animal diseases around the world. The OIE collects data and makes the data available to appointed technical delegates (e.g., veterinarians) from each member country. The OIE develops standards for international trade of animal products and provides expertise and technical support to animal control. The international standards developed by the OIE are published in the Terrestrial Animal Health Code and the Manual of Standards for Diagnostic Tests and Vaccines.

### *World Trade Organization (WTO)*

The World Trade Organization (WTO, www.wto.int) was established in 1995 around a system of rules aimed at governing international trade among countries. The WTO provides a forum to (1) allow governments to negotiate trade agreements, (2) notify members of draft food safety measures, and (3) raise an issue when members fail to comply. Key provisions of the WTO trade agreements are related to non-discrimination, scientific justification, consistency, and transparency. Two important food-related agreements include the Sanitary and Phytosanitary (SPS) Agreement, which ensures that nations may enact health and safety measures, but they must be based on sound science, and the Agreement on Technical Barriers to Trade (TBT), which ensures that national technical regulations do not create unnecessary barriers to international trade.

When WTO members fail to comply with international food standards, they can be challenged by another member state by requesting a dispute settlement with the SPS or TBT committee. Disputes generally involve the claim that a member state failed to base sanitary or phytosanitary measures on sound science or that the regulations are discriminatory.

## How the US Government and US Industry Interact with Codex to Shape Food Safety Policy at the National Level

The US considers Codex as a key international organization to drive science-based standards. Therefore, in 2012, the US Codex Office developed a 5-year strategic plan to work with international experts and engage domestic stakeholders to collaboratively safeguard the food systems worldwide. The US Codex Office is based in Washington, DC, and is managed within the US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). The US Codex Office holds policy and technical meetings to engage stakeholders across agencies, industry, and academia to develop the US response during Codex Committee meetings. Public meetings are regularly held to provide information and receive public comments on agenda items and draft US positions to be discussed at upcoming Codex meetings.

The Codex meeting attendees may include industry and trade organizations who serve as non-governmental organizations (NGOs) representing food companies around the world. The trade association representatives may monitor and participate in the work of Codex Committees and Codex task forces. Participation could include providing input to electronic working groups or providing data relevant to food safety issues. For example, to support the technological need for food additives, the food industry works with the JECFA experts to detail out processing systems.

Safe food benefits everyone. The technical and scientific data from industry is relevant to building safe food systems. Bringing together industry and government provides opportunity to develop strategic interventions and builds support to enforce food regulations.

## Regulatory Authorities in the Food Safety Modernization Act (FSMA) That Apply to Imported Food Safety (by Neal Fortin)

### *FSMA and New, Science-Based, Preventive Controls*

> *Prevention of foodborne illness, not reaction to problems, is now the guiding principle of our food safety law -- with the primary responsibility for prevention resting squarely on the shoulders of food producers and processors* (FDA 2011).

FSMA created a new paradigm for the regulation of imported foods regulated by FDA. FSMA shifts the focus of US food law from reacting to food safety problems to prevention. This preventive responsibility applies equally to foreign and domestic

food producers and processors. This preventive framework is built on risk-based preventive controls and produce safety standards.

## *Mandatory Risk-Based Preventive Controls*

All FDA-regulated food companies must implement hazard analysis and preventive controls unless specifically exempt. Exemptions include juice and seafood whose suppliers are in compliance with HACCP regulations, food imported for research and evaluation purposes, food imported for personal consumption, alcoholic beverages, food imported for future export (outside of the United States), and products subject to low-acid canned food requirements. All food facilities, including foreign facilities for food imported into the United States, must implement a written hazard analysis and risk-based preventive control plan (21 U.S.C. 350g). The FSMA hazard analysis and preventive control plan (HAPCP) is essentially an enhanced HACCP system. FSMA HAPCP is slightly broader because the plan requires identification and control of hazards generally, not just critical control points (CCPs). In short, FSMA requires establishment of science-based mitigation strategies to prepare and protect the food supply chain against intentional contamination at vulnerable points (Food, Drug, and Cosmetic Act § 420).

## *Mandatory Produce Safety Standards*

FSMA directs FDA to work with the USDA to create "science-based minimum standards for the safe production and harvesting" of fruits and vegetables for which FDA has determined such standards will minimize the risk of "serious adverse health consequences." The rules must consider naturally-occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (such as compost), hygiene, packaging, temperature controls, animals in the growing area, and water (21 U.S.C. § 350h).

FDA's proposed produce rule covers all fruits and vegetables except those rarely consumed raw, produced for personal consumption, or destined for commercial processing that will reduce microorganisms of public health concern. The rule is based on science and risk analysis and therefore focuses on areas of risk, including but not limited to:

- Agricultural water
- Biological soil amendments
- Health and hygiene
- Domesticated and wild animals
- Equipment, tools, and buildings

## *The Regulatory "Tool Kit" for Imported Foods*

The mandatory risk-based preventive controls and produce safety standards provide the preventive framework for the safety of imported (and domestic) food. To ensure implementation of these preventive standards, FSMA provides a new "regulatory tool kit" for imported foods, consisting of the following elements:

1. Foreign supplier verification programs (FSMA sec. 301)
2. Voluntary qualified importer program (sec. 302)
3. Mandatory certification (sec. 303)
4. Enhancements to prior notice (sec. 304)
5. Building capacity of foreign governments (sec. 305)
6. Improved enforcement authorities (sec. 306)
7. Accreditation of third-party auditors (sec. 307)

The scope of this chapter does not permit covering all of the above elements and is limited to salient points.

## *Definition of an Importer*

The definition of an "importer" is important because the term determines responsibility and liability. The importer is a person in the United States who has purchased the food being offered for import. If there is no US owner at the time of entry, the importer is the US consignee. If there is no US owner or consignee at the time of entry, the importer is the US agent or representative of the foreign owner or consignee.

## *Foreign Supplier Verification Programs (FSVPs, FSMA sec. 301)*

Importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies. The requirements vary based on the type of food product, the category of importer (e.g., very small), the nature of the hazard identified in the food, and who is to control the hazard. Primarily, verification is based on controlling the hazards that are reasonably likely to occur.

Importers must perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as required of domestic food producers. In general, importers would need to conduct the following activities as part of their FSVPs:

- Compliance status review of foods and suppliers
- Hazard analysis

- Supplier verification activities
- Corrective actions (if necessary)
- Periodic reassessment of the FSVP
- Importer identification at entry
- Record/keeping

### *Compliance Status Review*

The importer reviews the compliance status of the food and the potential foreign supplier before importing the food and follows up with periodic review afterward. At a minimum, the review needs to include any FDA warning letters, import alerts, and requirements for certification issued by FDA under sec. 801(q) of the Food, Drug, and Cosmetic Act (FD&C Act).

### *Hazard Analysis*

The importer analyzes the hazards associated with each imported food. The hazard analysis is used to identify the hazards that are reasonably likely to occur for each type of food imported and evaluate the severity of the illness or injury if such a hazard were to occur.

### *Supplier Verification*

The importer conducts activities that provide adequate assurances that the hazards identified as reasonably likely to occur are adequately controlled. Verification activities could include onsite auditing of foreign suppliers, periodic or lot-by-lot sampling and testing of food, periodic review of foreign supplier food safety records, or other appropriate risk-based procedures (Fig. 22.2). Verification activities applicable to all FSVPs, regardless of identified hazards, include maintaining a written list of foreign suppliers from which food is imported, as well as establishing—and following—adequate written procedures for conducting verification activities.

### *Corrective Actions*

The importer reviews complaints he or she receives concerning the foods imported, investigates the cause or causes of adulteration or misbranding as needed, takes appropriate corrective actions, and revises the FSVPs when necessary.

**Fig. 22.2** Consumer safety officers open refused boxes of bean curds at an FDA import destruction site in 2011 (*Source*: News21.com and Kyle Bruggerman, via Creative Commons) (http://www.flickr.com/photos/50436974@N04/6110870452/in/photolist-aiZNTo-aiX1WK-7HgKXW-aiX1uZ-aiZNQQ-aiZNLL-aiZPg5-ajyACx-aiZNVu-aiX1K8-aiZP6Y-ajyAvM-bXMhqj-82FPnZ-a7tfyd-9tVaWp-fqz4Nt-7K9h7F-7KdbHm-7KdbF1-7KdbKC-7KdbQw-em5cSx-hZz3tB-dCZoum-dCTYLe-7CpjSo-atsXky-d9prSQ-d9prVA-bmTwRa-7HcRnM-d9prML-d9prQL-d9prEU-d9prCb-d9prHL-kvHHMn-9rdUrg-fQgcA5-9Yo9Qd-ckiH2b-fpuZR5-8RuZxv-9JFMdT-9JJAc5-9JFLRr-85jVFH-9JFMiP-9JJA4Q-893TYD)

## *Periodic Reassessment*

The importer must reassess the FSVPs within 3 years of establishing the FSVP or within 3 years of the last assessment. In addition, an importer must reassess the effectiveness of the FSVP sooner if the importer becomes aware of new information about potential hazards associated with the food.

## *Importer Identification*

Importers would be required to obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number for their company and ensure that the DUNS number is provided electronically when filing for entry with Customs and Border Protection.

### *Record/Keeping*

The importer must keep certain records, including those that document compliance status reviews, hazard analyses, foreign supplier verification activities, investigations and corrective actions, and FSVP reassessments.

### *Mandatory Certification (Sec. 303)*

In certain circumstances, FDA may use certifications from accredited auditors in determining whether to admit imported food into the United States that the FDA has determined to pose a food safety risk. Certifications may also be used in determining whether an importer is eligible for expedited review and entry of food.

### *Capacity-Building (Sec. 305)*

FSMA recognizes that domestic food safety depends in part on food safety in other countries. The statute directs FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their food industries for countries that export food to the United States. Training of foreign governments and food producers on US requirements for safe food is a part of capacity-building. Other components may include data sharing, mutual recognition of inspection reports, and harmonization with requirements under Codex Alimentarius (FDA 2013).

The US government has already engaged in capacity-building around the world as part of its commitment to WTO. As part of WTO, "Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members" (WTO 2014b).

### *Accreditation of Third-Party Auditors (Sec. 307)*

FSMA directs FDA to establish a program for the accreditation of third-party auditors for foreign food facilities. Under this program, FDA would recognize accreditation bodies, which would in turn accredit third-party auditors to, among other things, conduct food safety audits and issue certifications for foreign facilities and food under specified programs. Accredited third-party audits and certification will be central to a global system for efficiently ensuring the safety of FDA-regulated food.

Certifications are issued by accredited third-party auditors for two purposes under FSMA. Section 302 of FSMA authorizes the voluntary qualified importer program (VQIP), which provides for expedited review and entry of food into the United States. In order to participate in VQIP, importers must import food from certified facilities. Section 303 of FSMA gives FDA authority to require certification as a condition of entry for certain foods that FDA has determined to pose a food safety risk under Sec. 801(q) of the FD&C Act. An accredited third-party auditor may provide such certifications.

## *Inspection and Compliance*

Preventive control standards improve food safety only to the extent that producers and processors comply with the standards. Therefore, FSMA increases FDA oversight for compliance with these requirements. One of the foremost of these compliance tools is expanded records access. FDA will have authority to access the required written food safety plans, and the records firms are required to keep documenting implementation of their plans. These records are to be kept for not less than 2 years, and the records must be made available "promptly" to a duly authorized agent of FDA upon request (FD&C Act § 418(g) & (h)). FDA also has expanded authority to access records for foods where there is a reasonable belief that the food is adulterated and may cause serious adverse health consequences (FSMA § 101 amending FD&C Act § 414(a)). An importer must keep records of importer verification for not less than 2 years.

## *Some Points About Compliance*

Food law in the United States puts the responsibility for food safety clearly on the shoulders of the manufacturer and seller of that food. Ultimately, this responsibility is the best reason for implementing a systematic risk-control plan. Complying mechanically with government regulations will not bring about the degree of confidence or safety that comes from a sincere commitment by management to systematically implement the highest degree of food safety.

Supervision must also ensure that records are properly maintained. "If it isn't documented, then it didn't happen" is a good refrain to remember. Documentation has never been more important for demonstrating compliance. This documentation can also be essential in any litigation involving injury from a food safety problem. Further, one of the best ways to prevent foodborne illness liability is to prevent the incidence of illness.

## How Inspection Methods Adapt in Order to Account for the Globalization of the US Food Supply

Although the benefits are widely acknowledged, the adoption of HACCP was slow for many reasons (Fortin 2003). The benefits are real, but tend to be long-term benefits. On the other hand, the burden of responsibility is immediate and requires change. The change for industry is apparent, but changes in the philosophy and approach to inspections are also necessary.

Rather than a cat-and-mouse inspection for sanitation violations, the FPP performing inspections must seek to understand the risk-control *systems*, review the record/keeping documentation, and assess whether the food safety systems are functioning properly. This approach adds a new responsibility to both food facility managers and FPPs.

Regulatory policy must make enforcement a priority for cases involving incomplete, false, or deceptive records.

## Conclusion

Due to significant changes in food technology and the globalization of food trade, there is a growing interest in governments working across national borders to ensure safe food. As a result, most countries are in the process of updating and/or modernizing their food systems by devoting more resources to prevention and capacity-building (i.e., laboratories, training inspectors). In the United States, domestic food safety must take into consideration the international context of food regulations, particularly Codex Alimentarius standards and World Trade Organization obligations. By working across international organizations and national agencies, it is possible to harmonize food safety systems and drive science-based regulations. There is a new regulatory "tool kit" for inspectors of importers and imported food. A key component is the foreign supplier verification programs (FSVPs). Importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies. A new paradigm of regulation and inspection exists for US food importers. Importers must perform risk-based safety verification of each food imported and each supplier, including a hazard analysis of the food and record/keeping of the specific verification activities for each supplier.

## Take-Home Message

Today's food industry and FPPs must be cognizant of the increasingly global nature of food supply chains. Fortunately, the new imported food paradigm provides powerful tools to ensure the safety of those supply chains. However, this approach will take a change in one's mindset of ensuring the effectiveness of systems and record/keeping for risk-based, preventive controls.

## Activity

Fill in the Blank with the Appropriate Answer

1. The international standard for food safety regulation is the _____.
2. Independent scientific advisors to the UN FAO/WHO on food additives and contaminates specifications are provided by the _____.
3. Governments that belong to the _____ have a forum to learn of other governments' food safety measures and ensure that science-based regulations are being put into place.
4. Under FSMA, food importers have a responsibility to _____ that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.

## Discussion Question

5. How do HACCP-style inspection techniques apply to inspections of food importers?

## References

Food and Agriculture Organization of the United Nations (2014a) Food safety and quality. Chemical risks and JECFA. http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/. Accessed 16 Dec 2014

Food and Agriculture Organization of the United Nations (2014b) Food safety and quality. Microbial risks and JEMRA. http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/. Accessed 16 Dec 2014

Fortin ND (2003) The hang-up with HACCP. Food Drug Law J 58:565–593

U.S. Department of Agriculture, Economic Research Service (2014) Overview. http://www.ers.usda.gov/data-products/us-food-imports.aspx. Accessed 16 Dec 2014

U.S. Department of Health & Human Services (2013) Import safety: status of FDA's screening efforts at the border. Statement by Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, Food and Drug Administration before the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, U.S. House of Representatives. http://www.hhs.gov/asl/testify/2011/04/t20110413a.html. Accessed 16 Dec 2014

U.S. Food and Drug Administration (2011) The FDA Food Safety Modernization Act: putting ideas into action. Michael R. Taylor, Deputy Commissioner for Foods, Food and Drug Administration. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/ucm241192.htm. Accessed 16 Dec 2014

U.S. Food and Drug Administration (2013) FDA's International Food Safety Capacity-Building Plan. http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341440.pdf. Accessed 16 Dec 2014

World Health Organization (2014a) Food safety. Joint FAO/WHO Meeting on Pesticide Residues (JMPR). http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/. Accessed 16 Dec 2014

World Trade Organization (2014b) The WTO Agreement on the application of Sanitary and Phytosanitary Measures (SPS Agreement). http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm. Accessed 16 Dec 2014

## Additional Resources

Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 301 *et seq.*), Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended

Fortin ND (2009) Food regulation: law, science, policy, and practice. Wiley, Hoboken

## Answers

1. Codex Alimentarius
2. Joint Expert Committee on Food Additives (JECFA)
3. World Trade Organization (WTO)
4. Verify
5. The participant should be able to explain how the HACCP inspection focuses on the risk-control systems via review of record/keeping and documentation, and, similarly, the inspector of a food importer must review record/keeping and documentation to assess the hazard analysis, foreign supplier verification activities, and so forth.