



# **The US Food Import System: Issues, Processes and Proposals**

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*Disclaimer*

This document is intended for use as a guide to the US food import system, and is not intended for use in the importation of food or food products.

## *Introduction*

Food is a heavily traded international commodity. In 2005, global agricultural trade was valued at \$852 billion dollars (World Trade Organization, 2006) with imports of food into the United States alone averaging more than 10% growth each year (Dohlman & Gehlhar, 2007). In the decade prior to FY 2006, the value of food imports into the United States doubled, reaching a record high of \$64 billion dollars<sup>1</sup>. As of August 2007, the total value of food imported into the United States was \$70.5 billion, with estimates for FY 2008 of \$75 billion (Collins, 2007). This translates into over nine million entries into the United States of imported food and food-related products annually (Lutter, 2006) passing through one of more than 300 entry points which include ports, border crossings, and postal facilities (Leavitt & Connor, 2007).

Imported foods now make up an estimated 10 to 13% of the US diet (Jerardo, 2003; Milano, 2007; Smith De Waal, 2007). The growth in imports of food to the United States is based on a number of factors, including short term changes in the domestic food supply, changes in diet, seasonal availability of foods, the exchange rate, tariff changes, the robustness of the US economy (Jerardo, 2003), and consumer preferences for specific food products. The greatest increase in food commodities between 1998 and 2006 was in confections, beer, wine, fruit, and vegetables (Dohlman & Gehlhar, 2007).

In spite of this increase in international commerce of foods, recalls of food products imported into the US are not a new phenomenon. Indeed, several well-known outbreaks of foodborne illness attributed to imported food products occurred during the last decade. These included disease outbreaks caused by the consumption of Guatemalan raspberries contaminated by *Cyclospora* in 1996 (Calvin, Flores & Foster, 2003), outbreaks of Hepatitis A due to contaminated

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<sup>1</sup> This is an increase in agricultural and seafood products of 32.9 metric tons in calendar year 1996 to 46.7 metric tons in 2006 (Becker, 2007).

strawberries from Mexico in 1997 (Centers for Disease Control, 1997) and Mexican green onions in 2003 (Calvin, Avendano, & Schwentesius, 2004); and outbreaks of Salmonellosis in 1997, 2000, 2001 and 2002 as the result of handling and eating Mexican cantaloupes contaminated by *Salmonella* (Centers for Disease Control, 2002; Mohle-Boetani et al., 1999). The CDC estimates that every year 76 million Americans fall ill with a foodborne illness, of these 325,000 are hospitalized. Five thousands Americans every year die from a foodborne illness (Mead et al., 1999).

Until recently however, issues regarding the safety of imported food have had little permanent effect on the market for imported foods in the United States. Yet, in 2007 a number of high profile recalls raised American's awareness of issues related to the safety of a variety of products imported into the US. Parents became concerned as the result of the recall of tens of thousands of toys produced overseas because they contained unacceptable levels of lead (Mattel, 2007). Several brands of pet food were recalled because some of the ingredients imported from China used to make the foods were contaminated with the chemical melamine, which subsequently sickened and killed many cats and dogs<sup>2</sup>. The FDA seized all farm-raised seafood imported from China because of the suspicion that they contained unapproved drug residues (Becker, 2007). The FDA also issued an advisory to avoid several brands of toothpaste made in China due to their contamination with diethylene glycol (Food and Drug Administration, 2007a).

American consumers, legislators, and the media, already primed by the high-profile recalls of US-produced bagged spinach in the autumn of 2006, and of Peter Pan™ peanut butter early in 2007; began to call for action by the US government to address concerns relating to the safety of imported foods<sup>3</sup>. Unfortunately, while there is a great deal of interest in food imports and their safety, the information required to understand the relevant issues is not only widely dispersed among

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<sup>2</sup> See <http://www.fda.gov/oc/opacom/hottopics/petfood.html> for complete coverage of the pet food recalls.

<sup>3</sup> The Interagency Working Group on Import Safety was created by Executive Order on July 18, 2007 to evaluate existing import procedures (The White House, 2007).

the federal agencies that share responsibility for the food imports system, but complex in its specifics regarding the process of regulating the import of foods. As such, there is no easily understood primer devoted to the subject. Therefore, in response to questions by consumers, journalists, and legislators about the issues related to the importation of food into the United States, and the regulatory structure designed to ensure their safety, this paper provides a review of the issues and processes and proposals for importing food and the current proposals for ensuring its safety under discussion by the federal government.

#### *Responsibilities and relevant enabling legislation*

There are several organizations and key agreements that set the standards for regulations regarding the safety of food and food products internationally. The World Trade Organization's Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement) serve as guides to international trade regarding food safety, animal and plant health safety, and product standards. Both the SPS Agreement and the TBT Agreement define the Codex Alimentarius Commission<sup>4</sup> as the relevant standard-setting organization for food. Founded in 1963, the Commission serves as the "global reference point for consumers, food producers and processors, national food control agencies and the international food trade" (Food and Agriculture Organization, 2005). Its role is to harmonize food standards across countries, ensure their global implementation, and facilitate international trade. The Commission's 176 member countries have developed more than 200 standards for processed, semi-processed or unprocessed foods, for hygienic/technological practice, set maximum levels for pesticide residues, evaluated food additives and veterinary drugs, and specified multiple guidelines

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<sup>4</sup> The World Trade Organization's (WTO) and the Food and Agriculture Organization's (FAO) joint commission on international food standards.

for contaminants; with the expressed goal that these codes provide value for national food control or enforcement authorities (Food and Agriculture Organization, 2000).

The World Organization for Animal Health (OIE; formerly the Office International des Epizooties) is responsible for international standards on animal health. Comprised of 169 Member Countries and Territories (as of May 2007), the OIE mandate is to control the international spread of infectious animal diseases and improve animal health worldwide (World Organization for Animal Health, 2007).

### **Missions of the World Organization for Animal Health**

- To ensure transparency in the global animal disease situation.
- To collect, analyze and disseminate veterinary scientific information.
- To provide expertise and encourage international solidarity in the control of animal diseases.
- Within its mandate under the WTO SPS Agreement, to safeguard world trade by publishing health standards for international trade in animals and animal products.
- To improve the legal framework and resources of national veterinary services.
- To provide a better guarantee of food of animal origin and to promote animal welfare through a science-based approach  
(World Trade Organization, undated a).

At the national level, the responsibility for ensuring the safety of the American food supply is shared among multiple agencies that collectively administer at least 35 laws (Shames, 2007).

Twenty-eight House and Senate Committees provide oversight of these statutes. Primary oversight in the House is through the Agriculture Committee and the Commerce Committee. In the Senate, the Agriculture, Nutrition and Forestry Committee; and the Labor and Human Resources Committee provide primary oversight. The joint House and Senate Agriculture, Rural Development and Related Agencies Appropriation Subcommittee also oversees food safety statutes. Additionally,

there are over 50 interagency agreements to govern the combined food safety oversight responsibilities of the various agencies. The federal system is supplemented by the states, which have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products (Robinson, 2004).

However, while the task of ensuring the safety of the American food supply is distributed among a number of legislative committees and government agencies<sup>5</sup>, as a consequence of both their levels of funding and staffing primary responsibility for regulation of food imports is shared by the Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA) (Congressional Research Service, 2007).

### **Federal Agencies involved in Oversight of Food**

Department of Health and Human Services

- Food and Drug Administration
- Centers for Disease Control

United States Department of Agriculture

- Food Safety and Inspection Service
- Animal and Plant Health Inspection
- Agricultural Marketing Service
- Agricultural Research Service
- Grain Inspection, Packers and

Stockyards Administration

- Economic Research Service
- National Agricultural Statistics Service
- Cooperative State Research, Education,

Extension Service

U.S. Customs Service

Department of Commerce

National Marine Fisheries Service

Environmental Protection Agency

Federal Trade Commission

Department of the Treasury

Department of Homeland Security

(Robinson. 2005)

The philosophy of the US food safety system is described as being “based on strong, flexible, and science-based federal and state laws and industry’s legal responsibility to produce safe foods” (Food and Drug Administration & United States Department of Agriculture, 2000).

However, an historical analysis of the legislation regulating the importation of food into the US would likely suggest that food imports laws have developed primarily in response to food crises, rather than as the result of a thoughtful planned approach to food safety. Rooted in century-old

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<sup>5</sup> In February of 2003, the Agricultural Quarantine Inspection (AQI) program, formerly under the aegis of the Animal and Plant Health Inspection Service (APHIS) was moved to the Department of Homeland Security.

legislation (the 1906 Meat Inspections Act and the 1906 Pure Food and Drugs Act), and in spite of amendments due to improvements in science and under the pressure of social change, the majority of the regulations that govern the system have been in place since the 1950's or before (Taylor, Glavin, Morris & Woteki, 2003). The intervention-focused strategy, based on point-in-time assessment at the border (Zhang, 2007), has been described by the General Accounting Office (Dyckman, 2002) as a “patchwork structure that hampers efforts to adequately address existing and emerging food safety issues, whether those risks involve inadvertent or deliberate contamination.”

The key laws establishing the current American food safety system--the 1906 Meat Inspection Act and the 1906 Pure Food and Drugs Act--were similar in their emphasis on unadulterated food, but different in their implementation. The Meat Inspection Act focused on in-plant inspections by government inspectors, while the Pure Food and Drug Act focused on sampling of foods to uncover violations. Both acts were guided by five principles: that foods must be safe and wholesome to be marketed, that regulatory decisions need to be based in science, that enforcement is a government responsibility, that compliance is mandatory for companies involved in the production, marketing, sale or import of food; and that the regulatory process should be transparent to the public.

Since the initial acts were established, a number of amendments have enhanced or extended the oversight of food. In 1938, the Pure Food and Drug Act was substantially revised and subsequently renamed the Food, Drug, and Cosmetic Act (FD&C). Food amendments to the FD&C included, among others, the Pesticide Amendment (1954), the Food Additives Amendment (1958), and the Color Additive Amendments (1960) (Food and Drug Administration, 2008). In 1967, the Meat Inspection Act was amended to the Wholesome Meat Act. The Poultry Products Inspection Act of 1957, which had been amended by the Poultry Products Inspection Act of 1968, was merged with the Wholesome Meat Act and managed under the aegis of the Consumer and

Marketing Service of USDA's Agricultural Research Service. In 1972 responsibility for meat and poultry inspections was transferred to the Animal and Plant Health Inspection Service (APHIS) in 1972. The Food Safety and Quality Service took over responsibility for inspections in 1977, and in 1981 was renamed as the Food Safety and Inspection Service (United States Department of Agriculture & Food Safety and Inspection Service, 2006). Changes in responsibility and administration in both the FDA and the USDA were brought about due to shortcomings in the original language and scope of the acts, as well as changes required due to developments in the manufacture and processing of foods.

**Examples of legislation that control the importation of food into the US.**

**FDA**

- Food, Drug and Cosmetic Act (Section 801)
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002
- Infant Formula Act
- Federal Import Milk Act 1927
- Sanitary Food Transportation Act
- Nutrition Labeling and Education Act
- Dietary Supplement Health and Education Act of 1994
- Food Quality Protection Act
- Food and Drug Administration Modernization Act
- Food Allergen Labeling and Consumer Protection Act
- Federal Trade Commission Act
- Filled Milk Act
- Public Health Service Act
- Fair Packaging and Labeling Act

**USDA**

- Federal Meat Inspection Act
- Poultry Inspection Act
- Egg Products Inspection Act
- Animal Health Protection Act
- Animal Welfare Act
- Agricultural Marketing Act
- Perishable Commodities Trading Act
- Tariff Act of 1930
- North American Free Trade Act
- Plant Protection Act
- Organic Food Production Act

One of the most significant improvements in ensuring food safety was the incorporation in 1973 of Hazard Analysis Critical Control Point (HACCP) principles into the FDA Good Manufacturing Practices regulations for acidified and low acid canned foods. Developed in response to poisonings resulting from botulism in canned foods, HACCP is guided by seven principles. The intent of exercising these principles is to “engineer safety into the food from the very beginning of the production process” (Entis, 2007). The FDA subsequently mandated HACCP regulations for fish and seafood products in 1995, and for juice processing and packaging in 2001.

### **Hazard Analysis and Critical Control Points Principles**

- Conduct a hazard analysis.
- Determine the critical control points.
  - Establish critical limits.
  - Establish monitoring procedures.
  - Establish corrective actions.
  - Establish verification procedures.
- Establish record-keeping and documentation procedures

(Food and Drug Administration, United States Department of Agriculture & NACMCF, 1997).

In 1998, the USDA, through the Food Safety and Inspection Service (FSIS), mandated HACCP for meat and poultry plants. To further ensure the safety of food products produced in meat and poultry plants, the HACCP rules extended the original reliance on organoleptic (sight/smell/touch) inspections to that of a focus on the prevention of foodborne illness by the application of science-based controls at critical steps of the production process (Committee to Ensure Safe Food from Production to Consumption, 1998). These regulations have been described as the “most significant change in regulatory philosophy in the history of the inspection programs” (United States Department of Agriculture & Food Safety and Inspection Service, 2006).

### *Regulating imported foods*

The USDA and FDA are both charged with inspecting domestic and imported food products. In 2006 the USDA was responsible for inspecting 4.3 billion pounds of meat, poultry, and egg products (approximately 20% of imported food items). In 2007, the FDA inspected approximately 16 million import shipments, of which about 9.5 million were food-shipments (Food and Drug Administration, 2007b). While the USDA and FDA both play critical roles in protecting the integrity of the food supply, the process by which each agency regulates imported foods is somewhat different.

*USDA Regulation and Inspections System.* The USDA is responsible for overseeing the safety of food products that make up 20% of both the domestic and foreign food supply (Dingell, 2007). Within the USDA, the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) are the two main agencies charged with the responsibility for the regulation of food imports. Other agencies within the USDA with roles in the regulation of food imports include the Agricultural Marketing Service (AMS), which is responsible for the grading and certification of certain fruits and vegetables, and the Foreign Agricultural Service (FAS), which is responsible for trade agreements.

The Animal and Plant Health Inspection Service (APHIS) is responsible for ensuring the safety of plant and animal health. More specifically, it manages control and prevention programs that protect the United States against entry of diseases and foreign pests, and regulates the safety of genetically modified foods. APHIS is responsible for the protection of US agriculture by controlling the importation of animals and plant products, and has jurisdiction over live animals, animal-derived materials, plants, plant products, genetically engineered products, and microorganisms. Its regulatory authority is vested in the Animal Health Protection Act, the Animal Welfare Act, and the Plant Protection Act. For AMS, authority is vested in the Agricultural Marketing Act, the Perishable

Agricultural Commodities Act, and the Organic Food Production Act. For FAS it is the Tariff Act of 1930 and the North American Free Trade Agreement.

APHIS works closely with the OIE in setting the standards for the promotion of international trade. Import standards for live animals, and certain animal and plant products differ according to product and the country of origin. Using information from the OIE (World Organization for Animal Health) on the disease status of animals in countries around the world, APHIS makes the determination whether or not the country is eligible to import into the United States. At importation, livestock and poultry require health certifications issued by an official of the country of origin, demonstrating that the animals are disease free (Foreign Agricultural Service, 1999).

FSIS is responsible for ensuring that imported meat, meat food products, poultry, and egg products (except for shelled eggs, which are under the aegis of the FDA) adhere to U.S. food safety regulations. Regulatory authority for the FSIS is provided under the Federal Meat Inspection Act (1906), the Poultry Products Inspection Act (1957), and the Egg Products Inspection Act (1970).

USDA controls the import of meats from cattle, sheep, goats, swine, horses or other equines, ratites (e.g., ostrich, emu), chickens, turkeys, ducks, geese, and guineas. FDA is responsible for monitoring the importation of bison, rabbit, deer, game, wild animals, wild birds, products containing less than 2% cooked meat, 3% or less raw meat, less than 2% cooked poultry meat, and products not considered part of the meat industry (e.g., hamburgers in a bun).

FSIS ensures that the products under its jurisdiction are inspected and safe *before* they enter the food supply (Rawson & Vogt, 1998) by requiring equivalency in the food safety systems of importing

countries. To import meat, poultry, and egg products into the United States a country needs to demonstrate that their food safety and inspection program is equivalent to that of the US. Once a system is deemed equivalent, FSIS relies on the importing country's inspection agencies to certify that facilities meet (and maintain) the requirements for equivalency<sup>6</sup>. FSIS has certified 33 countries as eligible to import meat, poultry or egg products into the US (Food Safety and Inspection Service, 2008).

**Countries approved by the USDA for import of meat and poultry.**

Argentina, Australia, Austria, Belgium, Belize, Brazil, Canada, Chile, Costa Rica, Czech Republic, Denmark, Dominican Republic, El Salvador, England and Wales, Finland, France, Germany (Federal Republic), Guatemala, Honduras, Hungary, Iceland, Ireland (Eire), Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Northern Ireland, Norway, Paraguay, Poland, Republic of China, (Taiwan), Republic of Croatia, Republic of Slovenia, Romania, San Marino, Scotland, Slovakia, Spain, Sweden, Switzerland, Uruguay, Venezuela, Yugoslavia have all been certified by FSIS as eligible to import meat products into the US.

Australia (ratites only), Canada, France, Great Britain, Hong Kong, Israel, Mexico, New Zealand and China may export poultry to the US.

Canada and the Netherlands may export egg products to the US.

Once equivalency has been determined and approval received from FSIS, FSIS verifies maintenance of import status by document analysis, on-site audits, and continuous inspections of products at the port of entry. However, it is the importing country's responsibility to certify "individual exporting establishments to FSIS and for providing annual re-certification documentation" (United States Department of Agriculture, undated a). Periodic review of the country's laws and regulations, annual in-country audits which evaluate process and regulatory

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<sup>6</sup> Equivalency of imported meat, poultry and eggs is defined by the USDA as equal in terms of level of protection, not identical in terms of actual processes (United States Department of Agriculture, undated b).

control, and port of entry reinspections (random sampling<sup>7</sup> at entry and inspection at the US processing facility) are used to determine maintenance of equivalency. Failures during reinspection result in increased sampling of future shipments.

If it is determined that the country's system fails to maintain equivalency requirements, or if a product is found to be harmful to human or animal health, that country's eligibility can be suspended. FSIS may suspend imports if an emergency sanitary measure is implemented by FSIS to address a hazard that is so severe that no product can enter the marketplace from a foreign establishment until the control is in place, if an exporting country does not provide satisfactory documentation of an equivalent sanitary measure, or if a system audit reveals that an exporting country is not implementing a public health sanitary measure in the manner that FSIS initially determined to be equivalent (Smith DeWaal, 2007). However, the country is given the opportunity to improve their inspection systems to meet U.S. standards or remedy the situation in order to regain eligibility.

While a country may be determined eligible to export to the United States, 100% of products under the import authority of the USDA must be approved by a visual inspection and examination of labels, certificates and counts. According to Markheim and Walsh (2008, 4), "Seventy four import inspectors stationed at 33 major ports inspect cargo at roughly 135 import inspection centers," as well as may undergo reinspection at the site of entry. In 2004, the USDA reinspected 3.8 billion pounds, or approximately 1.7 million metric tons, of imported meat, poultry and processed egg products from 33 countries (Swacina, 2004). In FY 2006, the USDA reinspected approximately 15% (USDA, 2006) of all imports based on random statistical sampling. Sampling methodologies may include microbial, drug or chemical analysis, physical examination, or food

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<sup>7</sup> FSIS noted that "A new system for random selection of shipments was implemented in the fall of 2002. Shipments are reinspected at a frequency that provides a 95 percent confidence level that any problem affecting the safety or wholesomeness of the product will be identified by FSIS inspectors" (United States Department of Agriculture, undated b).

chemistry analysis. In the first quarter of FY 2007, USDA reinspected 11.8% of imported goods, under its jurisdiction, rejecting 2.7 million pounds of food (Smith De Waal, 2007).

The number of reinspections for a specific importer is based on the history of prior shipments. During reinspection, shipments may be rejected if the shipper is from a country not approved to import, if the shipper is from a country not approved to import that item to the US, if the country of origin or manufacturer is not listed, if APHIS has a disease restriction on the location, or the containers have duplicate shipping marks (United States Department of Agriculture & Food Safety and Inspection Service, 2007).

Even if the shipment is not rejected, additional testing may be required. Random testing is performed on approximately 10% of all shipments (James, 2007). The sampling rate for each country in the absence of prior history and problems is based on the amount of goods exported by each location. Since this analysis can take a long time, unless there is a prior history with the company or location or a belief that the product is contaminated the shipment is often released prior to the laboratory results. If an item fails inspection, it must be fixed, exported, converted or destroyed (United States Department of Agriculture & Food Safety and Inspection Service, 2007).

*FDA Regulations and Inspections System.* The Food and Drug Administration (FDA) is charged with the protection of consumer health by assuring the safety of all foods, domestic and imported, except for meat, poultry, and egg products, which are regulated by the USDA. The majority (80%; valued in 2003 at \$49 billion dollars) (Food and Drug Administration, 2007b) of all imported foods fall under the regulatory responsibilities of the FDA for inspection. The very large and growing quantity of imported foods, imported from approximately 189,000 registered foreign facilities (Food and Drug Administration, 2007b), makes ensuring their safety a prodigious task. According to William K. Hubbard, the former FDA Senior Associate Commissioner for Policy and Planning and Legislation (2007), in 2006 the FDA had only 450 inspectors to cover more than 400 ports. (In

2007, Michael Leavitt, the Secretary of Health and Human Services, commented that there were 300 ports of entry (The White House, 2007), while the Subcommittee on Oversight and Investigations (2007) reported to the Committee on Energy and Commerce that there were 326 ports of entry.) These inspectors were responsible for the screening of almost 20 million imports of foods, drugs, and other products, an average of more than 44,000 shipments per inspector. For those products under FDA authority, it is estimated that only 1% of all food that reaches the US border is inspected, and of those only 0.2% undergo laboratory analysis (Barrionuevo, 2007).

The FDA system is less restrictive than the USDA inspection system, and import is on a firm-by-firm basis and not a cooperative basis with the exporting country's government, as with the USDA (Markheim & Walsh, 2008). The regulatory authority of the FDA over imported foods is derived from Section 801 of the Food, Drug, and Cosmetic Act (FD&C), which was passed by Congress in 1938. In 2002, the Public Health Security and Bioterrorism Preparedness and Response Act augmented the requirements for the importation of food under the aegis of the FDA and the USDA. Specifically for the FDA, the Act requires that facilities that manufacture, process, pack or hold food for the US market must be registered with the FDA<sup>8</sup>; prior notice of importation is required for food products to enter the inspection system, and importation facilities must maintain records of immediate previous sources and recipients of foods. Such prior hold requirements are not required of meat, poultry and egg imports under the jurisdiction of the USDA.

The Act also provides the FDA with additional authority for administrative detention, expanded access to records, and the ability to mark refused materials to prevent reimportation. Additional regulatory requirements relating to imported milk, low acid canned foods, acidified foods,

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<sup>8</sup> Farms, facilities regulated by the USDA, facilities where food undergoes further manufacturing/processing, restaurants, retail establishments, fishing vessels that do not engage in processing and non-profit food establishments are exempted from registration requirements (Food and Drug Administration & Center for Food Safety and Applied Nutrition, 2004a).

infant formulas, juice, seafood, dietary supplements, and bottled water extend the authority of the FDA over foodstuffs.

The FDA uses an inspection-based system to ensure the safety of imported foods. Companies that are interested in importing food products that are regulated by the FDA need to thoroughly follow the import procedures, as Section 801 of the FD&C Act gives the FDA authority to refuse entry to any food product that even *appears* to be adulterated<sup>9</sup> or misbranded. Adulteration is defined as problems associated with safety, sanitation, and packaging integrity, while misbranding addresses issues of labeling (Caswell & Wang, 2001). Detention may occur with or without physical inspection, and is generally based on past history and/or information that indicates that the food product violates regulations.

Unlike the USDA's focus on equivalency for establishing the safety of food imports, the FDA relies on an inspection-based system in regulating imported food. As noted previously, the Bioterrorism Act provides the FDA with the authority to detain any food import on the basis of credible evidence that the product poses a risk of ill-health or death to humans or animals.

The FDA import procedures may be divided into two critical steps, entry notification and determination of inspection (Food and Drug Administration & Center for Food Safety and Applied Nutrition, 2004b). The FDA process begins with the requirement for a notice of the shipment to the port of arrival (which may differ from the port of entry, which is the site where Customs clears goods entering the US). The amount of time that notice must be filed prior to shipment varies depending on the method by which the shipment arrives<sup>10</sup>. Without prior notification, the shipment will be refused at the US border. This requirement applies to food that is destined to enter the US

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<sup>9</sup> See FD&C Act 402 (21 U.S.C. §342), (21, U.S.C. §342 d,f,g).

<sup>10</sup> At least 2 hours before arrival by road, at least 4 hours before arrival by air or by rail, at least 8 hours before arrival by water, or before the food is mailed to the United States, if sent by international mail. Notice may not be submitted more than 5 days prior to arrival.

market, as well as foods that are transshipped across the US or intended for use in a US Foreign Trade Zone (Food and Drug Administration, 2004b).

The FDA receives notification that the shipment has arrived via the Custom Agency's Automated Commercial System (ACS), which is forwarded to the FDA's Operational and Administrative System for Import Support (OASIS), which removes 80% of "low risk" imports from field inspection (Nelson, 2007). This system can access information from similar governmental agencies in 17 foreign countries allowing FDA to

receive not only approval, inspection, adverse event, and emergency information for products manufactured in a partner's territory, but also information relating to common regulatory experiences with key third countries (Interagency Working Group on Import Safety, 2007).

Decisions regarding physical inspection (physical examination, wharf examination or sample examination) of a food product are determined on the basis the type of product, FDA priorities<sup>11</sup>, and past history with the importer. If the FDA chooses to not inspect a shipment, Customs is informed, and the shipment is allowed to pass into the US. At this stage, if the FDA believes that the shipment in question poses a threat to health or animals or humans, they may request that Customs hold the materials for up to 24 hours.

If the product is selected for inspection, and does not pass analysis, it is refused admission, and the importer is given notice of hearing to offer suggestions as to how the shipment can be brought into compliance, or present evidence that the shipment does not violate import regulations (this includes providing the results of a certified sample analysis that the importer commissioned independently). If, after corrective measures, the shipment is still not in compliance, Customs will destroy or export the shipment.

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<sup>11</sup> FDA priorities include items or countries the FDA has special concerns about at a given time.

### *Consequences of a violation*

Once a shipment is inspected and deemed in violation of import regulations, the USDA, FDA, and Customs have the authority to take several actions. These range from holding or refusing the shipment to referral for criminal investigation (Interagency Working Group on Import Safety, 2007).

Before the USDA inspects a shipment, it must pass through the Automated Import Information System (AIIS). This computer system links FSIS inspectors at all points-of-entry and can assist in analysis of trends and to identify problem companies that export to the United States (Food Safety and Inspection Service, 2002). AIIS information on both shipments and violations can be shared immediately with other inspectors.

Once an import is rejected it can be destroyed in the US, shipped back to its origin, brought into compliance and reinspected, made into animal feed if it can be done in compliance with FDA regulations, or in some cases move sealed through the US for further processing (United States Department of Agriculture & Food Safety and Inspection Service, 2003). Items must be exported, converted, or destroyed within 45 days. A further consequence of a rejected import is greater scrutiny for future imports by facility or country.

For foods under FDA jurisdiction, penalties for violations differ based on the type of violation. Food that is adulterated or misbranded<sup>12</sup> will be denied entry into the US, and will be destroyed if not exported out of the US within 90 days of notice. If a person or company repeatedly attempts to import adulterated food into the US, they may be disbarred from future importing. Disbarment may also occur if proper records are not maintained, knowingly false statements are contained in official documents or paperwork, or if an attempt is made to import food with or for someone who is currently disbarred from importing items into the US.

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<sup>12</sup> See the Federal Food, Drug, and Cosmetic Act Chapter 4 Section 402 explanation of “adulterated” and misbranded.”

### *Bypassing the system*

Despite regulatory barriers, it is possible for unsafe imported food to enter the US food system due to loopholes in the current food import regulations. For example, the use of chemicals, such as carbon monoxide to mask decomposition, can be a means for importers to avoid having food products rejected at entry. Used since the 1990's, carbon monoxide packaging is an FDA-approved method that was given the designation of generally recognized as safe (GRAS) in 2001 (Center for Food Safety and Applied Nutrition, 2002) and in subsequent requests by companies to deem carbon monoxide as not requiring premarket approval as a food additive (Center for Food Safety and Applied Nutrition, 1997).

Another loophole in the system relates to the inability of the FDA to require importers of detained shipments to use FDA approved laboratories for sample testing to prove a food product's compliance with relevant safety regulations. Although the FD&C Act allows the FDA to detain shipments by importers with a history of violations, current import procedures give the importer the right to use private laboratories to test samples of their shipments. When the importer demonstrates through test results provided by these private laboratories that no violation has occurred, the FDA must release the goods, even if an import alert was issued requiring their detention (Dingell, 2007).

Port shopping, or the shipment of goods to ports where the number of inspectors is low, is also a way to avoid inspection. This selective shipping of goods to undermanned ports (FDA inspectors staff about 90 of the nation's more than 300 ports of entry (Burros, 2007) is a means to bypass regulations and inspection. In testimony before the House of Representatives Committee on Energy and Commerce, the Subcommittee on Oversight and Investigations reported that importers had routinely sent seafood to entry ports with less experienced reviewers (Nelson, 2007).

An overreliance by the FDA on OASIS also allows importers to avoid inspection. Due to the high volume of shipments and the low number of inspectors in charge of examining shipments

it is very difficult to enter all the import data into the OASIS database for review. With the implementation of the Bioterrorism Act of 2002, OASIS now receives information from both the Customs and Border and the FDA (Food and Drug Administration, 2004a). According to the FDA field staff, only 20% of food imports are entered into OASIS. It is in this database where import information is reviewed by the authorities for decisions on inspection (Dingell, 2007). Deficiencies in the use of this system make it possible for contaminated shipments to enter the U.S. food supply without being subject to inspection review. Additionally, there is “a lack of connectivity between the US Customs and Border Patrol and US Department of Agriculture’s import inspection data system” (Interagency Working Group on Import Safety, 2007, 9). This makes it possible for imported products that do not comply with US food safety standards to enter the food supply, which is likely a more significant issue for foods controlled by the FDA as opposed to foods overseen by the USDA due to differences in the inspection process and the quantity of foods that each agency must manage, but is an issue nevertheless.

Exporters can also circumvent US food safety standards requirements by shipping products through a country that is eligible to export food to the US, and stating that the intermediate country is the country of origin. Exporters whose products have been refused entry into one port may also attempt to enter their goods through a different port of entry (Interagency Working Group on Import Safety, 2007). Only 20% of imported goods enter the US from companies that export more than 11 shipments per year; one-time exporters account for just under half (45%) of all import shipments to the US (Interagency Working Group on Import Safety, 2007). Exporters that send a small number of shipments to the US each year may be less likely to undergo sampling, unless there had been problems in previous years or there is some other strong indicator to flag the incoming products.

Yet despite the growing concern about the safety of the US food supply following the terrorist attacks of September 11, 2001, the number of active FDA inspectors has been declining since 2003. With import volume nearly doubling since 2003 this has resulted in an inspection rate of less than 1% of all imported foods under FDA control. In testimony before the House Committee on Energy and Commerce it was noted that a typical FDA inspector in San Francisco would have to review 600 food entries, as well as 300 medical device entries, 25 reagent entries, and 25 drug entries in one day, spending less than 30 seconds on most reviews (Nelson, 2007).

This situation is likely due, at least in part, to import volumes rising more quickly than the budget for inspections (Tables 1a, 1b). Between 1996 and 2005, the USDA saw an 87% increase in meat and poultry imports (in millions of pounds). Over the same timeframe, total imported food shipments under FDA control increased 257%, resulting in decreases in import inspections of 10.3% by the USDA, and 0.7% by the FDA. While it would appear from these statistics that the USDA inspection process is at greater risk, FDA inspections were already compromised by the smaller number of inspectors, and the greater volume of imports to be inspected.

Neither the USDA nor the FDA has been able to adequately respond to the increased demand for import inspection. In 2003, the majority of expenditures of both the FDA and the USDA related to food safety were for inspection and enforcement of both domestic and imported foods. However, the FDA, which is responsible for inspecting about 80% of the food supply, received only about 25% of federal safety funding (Robinson, 2004). And the monies allocated by FDA towards inspection accounted in 1997 for only 23.5 percent of the total agency budget (Office of Management and Budget, 1998). In 1997 \$203 million of the total FDA budget of \$997 million was spent on food safety issues. The largest share of FDA's budget is devoted to its nonfood drug, cosmetics and medical devices responsibilities (Committee to Ensure Safe Food from Production to Consumption, 1998). And even if there were a corresponding increase in budget allocation, there is

no guarantee that an increase in budget would necessarily result in a concomitant increase in inspections. Between 1996 and 2005, the FDA had a greater percent change in its import inspection budget than the USDA (Tables 1a, 1b), but it still proportionately inspected less incoming food products than the USDA.

An important consideration when looking at budgetary spending of both the USDA and FDA is that imported items may be inspected at the port of entry, as well as during or after processing when mixed with native products. It is possible that some imported foodstuffs are

**Table 1a. USDA regulated imports: 1996 and 2006.**

	<b>1996</b>	<b>2006</b>	<b>Percent change</b>
<b>Meat and poultry imports (billion pounds)</b>	2.3	4.3	87
<b>FSIS total budget (millions)</b>	630 (778*)	928	47 (16*)
<b>Percent meat and poultry physically inspected</b>	20	9.7	

(Becker, 2007b; USDA, 1996; USDA 2005)  
(\*2006 dollars)

**Table 1b. FDA regulated imports: 1996 and 2006.**

	<b>1996</b>	<b>2006</b>	<b>Percent change</b>
<b>Total imported food shipments</b>	2.8	10	257
<b>FDA/CFSAN total budget (millions)</b>	222 (285*)	450	103 (57*)
<b>Percent of shipments physically inspected</b>	1.7	1	

(Becker, 2007b; Department of Health and Human Services, 1996)  
(\*2006 dollars)

undergoing inspection at processing plants, invisibly increasing the level of inspections of imported foods (Committee to Ensure Safe Food from Production to Consumption, 1998; General Accounting Office, 2001). In 1999, the USDA had a budgetary allotment of \$468 million for inspecting slaughterhouses, processing, and import facilities. Of this, only \$7 million went to fund inspections of import/export facilities, however, an additional \$145 million dollars was spent on inspection at domestic processing facilities which might have included the inspection of imported food products destined for further processing (General Accounting Office, 2001). Regardless, there are still concerns that the budgets of the USDA and FDA are not sufficient to allow the agencies to perform a significant number of inspections on imported foods.

#### *Current proposals to reform the import system*

In light of the recent issues in the importation of food and other products into the United States, a number of proposals to reform the food importation system have been developed, and include proposals developed by an umbrella industry organization, by federal legislators, by a White House panel created to address import safety, and by the FDA (See Appendices A and B). These recommendations variably include requirements for the creation of a unified regulatory process under the aegis of a single agency, requirements for stronger food production and inspection standards in other countries, restrictions in the number of ports to which goods can be shipped, and improvements in the processes and methodologies for testing and identifying contaminated food and food products.

The Grocery Manufacturers Association of Food, Beverage and Consumer Product Companies (GMA) proposed the *Four Pillars of Food Safety*. This multi-tiered approach “envisions specific new requirements for the food industry to assure the adequacy of foreign supplier food safety programs, as well as new responsibilities and authorities for FDA in that regard” (Grocery

Manufacturer's Association, 2007, 2) and would require additional investment by industry itself as well as an increase in funding for the FDA. This proposal would result in the establishment of mandatory quality assurance programs for international suppliers, development of a prioritized system of analysis through voluntary import quality assurance programs, expanded and improved capacity for analysis and oversight of foreign food facilities and programs, and an increase in FDA resources for targeting and testing of imports. In February 2008, Dr. Robert Brackett, Senior Vice President and Chief Science and Regulatory Affairs Officer for the GMA provided written testimony on the Four Pillars proposal to the US House of Representatives Committee on Energy and Commerce Oversight and Investigations Subcommittee<sup>13</sup>. In his testimony he called for an increase in FDA funding by \$150 million in FY 2009 to develop the programs and policies as outlined in the GMA proposal to prevent food contamination and ensure food safety.

Multiple bills have been proposed to address food safety. The *Assured Food Safety Act of 2007* (Kaptur, D-OH) would require a certificate of assured safety from the importing country. Both the *Food and Drug Import Safety Act of 2007* (Dingell, D-MI) and the *Imported Food Security Act of 2007* (Durbin, D-IL) would bolster FDA resources as well as require the FDA to implement more rigorous import controls. The *Human and Pet Food Safety Act of 2007* (Durbin, D-IL and DeLauro, D-CT) would require mandatory standards for processing and ingredients as well as more inspections of pet food facilities. The *Safe Food Act of 2007* (Durbin, D-IL and DeLauro, D-CT) would consolidate the FDA, USDA, and several other key agencies into the science-based Food Safety Administration, and modernize the inspection system and reliance on preventative measures and performance standards on-site, as well as provide the authority to audit certified countries, require routine inspections of imports, establish trace back system from point of origin to retail sale,

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<sup>13</sup> See <http://www.gmaonline.org/publicpolicy/temp/Testimony%20of%20Robert%20Brackett.pdf>.

and provide for mandatory recalls from the Food Safety Administration. As of March 2008, all bills have been referred to various Senate committees, but none have been scheduled for discussion<sup>14</sup>.

The Interagency Working Group on Import Safety report, the *Action Plan for Import Safety: A roadmap for continued improvement*<sup>15</sup> recommended an integrated strategy to provide protection by a three-pronged approach which includes the prevention of food contamination by focusing on risks throughout the product life cycle by building safety into the manufacturing and distribution processes, intervention at critical points in the food supply chain with targeted inspections, testing, enhanced risk analysis, and new detection technology to address both unintentional and intentional contamination; and a rapid and more comprehensive response communication system to minimize harm during food-related emergencies.

Required legislative changes include reinspection fees, biannual registrations, access to records during food emergencies, electronic import certificates, and mandatory recalls of contaminated foods (Food and Drug Administration, 2007b). These would allow the FDA to require controls at points of high vulnerability to prevent intentional contamination, a biannual registration of food facilities for approval to export food products into the US, a requirement for import certificates for high-risk products, and empower the FDA to call for mandatory recalls of foods under their control. As a result, the emphasis would shift from an intervention, border-focused strategy to a cost-effective, risk-based approach. Twenty-three US Senators urged the White House to provide additional funding in FY2009 for these changes in a letter submitted to President Bush in December 2007<sup>16</sup>.

The six building blocks of the proposal stress a risk-based life-cycle approach by building safety procedures into processing and manufacturing, adoption of more effective techniques to

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<sup>14</sup> See [http://www.votesmart.org/resource\\_govt101\\_02.php](http://www.votesmart.org/resource_govt101_02.php) for the process by which a bill becomes a law.

<sup>15</sup> <http://www.importsafety.gov/report/actionplan.pdf>

<sup>16</sup> See <http://www.gmaonline.org/temp/FDAFoodSafetyBudgetLetterDec62007Final.pdf>.

identify risk and more rapid intervention to prevent import of dangerous products, and the creation of a robust, collaborative system to limit exposure of the American public should an unsafe product enter the market (Interagency Working Group on Import Safety, 2007).

**Interagency Working Group proposal building blocks.**

- Advance a common vision.
- Increase accountability, enforcement and deterrence.
- Focus on risks over the life cycle of an imported product.
  - Build interoperable systems.
  - Foster a culture of collaboration.
- Promote technological innovation and new science.

Concurrent with and integrated into the Interagency Working Group report, the FDA released the Food Protection Plan. Following the organizing principles of prevention, intervention and response as outlined in the Interagency Working Group report, the Food Protection Plan recommends building safety into manufacturing and distribution processes, the adoption of more effective techniques for identifying hazards, the coordinated seizure, destruction or preventing dangerous goods from moving past point of entry; and rapid response to limit the potential exposure and harm to the public (Food and Drug Administration, 2007b). As outlined in the Food Operations Plan (Food and Drug Administration, 2007c), the multiyear implementation of the Food Protection Plan will be integrated with the Import Safety Action Plan using resources from FY2008 and FY2009, to “achieve the food defense and food safety priorities in the Food Protection Plan” (Food and Drug Administration, 2007d).

### *Conclusions*

As a result of the well-publicized recalls of both domestic and imported foods, issues of food safety have risen on the public agenda. Increased scrutiny by members of the press, Congress, and consumer groups have revealed a regulatory and inspection system that appears to many to be an underfunded, piecemeal approach to ensuring the safety of the American food supply.

Detractors point to an apparently increasing number of food recalls in recent years, the decline in inspections of foods produced both domestically and abroad, and the lack of resources devoted to keeping up with explosive growth of food imports as evidence of a food safety system that is badly in need of reform.

In contrast, supporters of the current system argue that the number of recalls and the amount of food recalled because of contamination is miniscule relative to the total volume of food produced, imported, and consumed in the United States. This, they suggest, is evidence that the current system works well, and that an increasing number of recalls is largely due to a system that has improved through the use of better science, technology, and information sharing. Indeed, they argue that the United States has “the safest food system in the world.” Opponents to the proposed changes, especially from the global forum, see these changes as protectionist tariffs and strategies masked behind the concern of safe food.

While both sides argue over the state of the current system, it is clear that the demands of a globalizing economy and the increasing expectations of consumers worldwide will continue to place new and increasing pressures on both producers and governments to better ensure the safety of foods coming into and leaving the United States. Indeed, a recent survey suggests that American’s overwhelming (“very confident”) confidence in the food supply has dropped considerably (International Food Information Council, 2007).

As with much of the history of food safety laws, regulations, and procedures promulgated in the United States and abroad, change is likely to arise as the result of consumer demands for “the government to do something.” As such, ultimately it is the pressure of consumer confidence (or lack of confidence) in the safety of the food that is likely to drive any reforms in the current system. The question is whether such reforms will be as the result of a rational reconsideration and reorganization of the entire food safety system, or as the consequence of a more incremental approach to improving the existing system.

*Web links*

World Trade Organization Sanitary and Phytosanitary Measures

[http://www.wto.org/english/tratop\\_e/sps\\_e/sps\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/sps_e.htm)

World Trade Organization Technical Barriers to Trade

[http://www.wto.org/english/tratop\\_e/tbt\\_e/tbt\\_e.htm](http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm)

World Organization for Animal Health

[http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm)

Food and Drug Administration

<http://www.fda.gov/>

United States Department of Agriculture

<http://www.usda.gov/wps/portal/usdahome>

Food Safety and Inspection Service

<http://www.fsis.usda.gov/>

Animal and Plant Health Inspection Service

<http://www.aphis.usda.gov/>

Grocery Manufacturers Association (GMA) Four Pillars of Food Safety

<http://www.gmabrands.com/publicpolicy/foodsafety.cfm>

HR 3610: Food and Drug Import Safety Act of 2007

<http://www.govtrack.us/congress/bill.xpd?bill=h110-3610>

S 1776: Imported Food Security Act of 2007

<http://www.govtrack.us/congress/bill.xpd?bill=s110-1776>

HR 2108 and S 1274: Human and Pet Food Safety Act of 2007

<http://www.govtrack.us/congress/bill.xpd?bill=h110-2108>

<http://www.govtrack.us/congress/bill.xpd?bill=s110-1274>

HR 1148 and SR 653: The Safe Food Act of 2007

<http://www.govtrack.us/congress/bill.xpd?bill=s110-654>

<http://www.govtrack.us/congress/bill.xpd?bill=h110-1148>

HR 2997: Assured Food Safety Act of 2007

<http://www.govtrack.us/congress/bill.xpd?bill=h110-2997>

Interagency Working Group Action Plan for Import Safety

<http://www.importsafety.gov/index.html>

Food and Drug Administration Food Protection Plan

<http://www.fda.gov/oc/initiatives/advance/food.html>

*Appendix A. Proposed legislation to reform the food import system.*

**Safe Food Act of 2007 (Sen. Durbin, D-IL and Rep. DeLauro, D-CT)**

- S 654/HR 1148
- introduced February 15, 2007
- referred to the Committee on Agriculture, Nutrition, and Forestry
- 4 co-sponsors in the Senate; 17 co-sponsors in the House
  - establishes the Food Safety Administration to administer and enforce food safety laws
    - transfers to the Administration all functions related to the administration or enforcement of food safety laws
  - requires a national food safety program based on analysis of hazards
  - establishes standards for processors of food and food establishments
  - establishes a certification system for importers
  - establishes requirements for tracing food and food producing animals from point of origin to retail sale
  - maintains an active surveillance system of food, food products, and epidemiological evidence
  - establishes a sampling system to monitor contaminants in food
  - ranks and analyzes hazards in the food supply
  - establishes a national public education campaign on food safety
  - conducts research relating to food safety

**Human and Pet Food Safety Act of 2007 (Sen. Durbin, D-IL and Rep. DeLauro, D-CT)**

- S 1274/HR 1208
- introduced May 2, 2007
- referred to the Subcommittee on Health
- 42 co-sponsors in the House; no co-sponsors in the Senate
- Amends the FD&C Act
  - requires immediate notification of location and identity of any food introduced into interstate commerce believed to be in violation of FD&C act
  - provides opportunity for owners of such food to cease distribution, notify all distributing agencies, recall the food and provide notice to consumers and public health officials.
  - authorizes the control and confiscation of such food if actions are not carried out
  - establishes certification and inspection requirements
  - requires specific action to communicate an ongoing recall of human or pet food
  - requires the establishment of
    - processing and ingredient standards for feed, pet food, animal waste, and ingredient definitions
    - updated standards for pet food labeling that includes nutritional information and ingredient information
    - an early warning and surveillance system to identify contaminations of the pet food supply and outbreaks of illness from pet food

### **Imported Food Security Act of 2007 (Sen. Durbin, D-IL)**

- S 1776
- introduced July 12, 2007
- referred to the Committee on Agriculture, Nutrition, and Forestry
- Co-sponsors Brown [D-OH], Casey [D-PA], Dorgan [D-ND], Sessions [R-AL]
- Amends the FD&C Act
  - assess and collect fees on food imported into the United States
  - provide for research on the development of tests of imported food and sampling methodologies
  - establish goals of developing certain tests for specified pathogens or substances
  - establish a certification system for importers
  - authorizes withdrawal of certification of any food if
    - such food is linked to an outbreak of human illness
    - the food safety programs or procedures are no longer equivalent to US
    - there is a refusal to allow US officials to conduct audits and investigations
  - authorizes refusal to import if
    - US audits and inspections are not permitted
    - foreign government or foreign firm does not consent to an investigation when food from that country or firm is linked to a food-borne illness outbreak or is otherwise found to be adulterated or mislabeled
  - provides that any food imported for consumption may be detained, seized, or condemned
  - establishes a transitional food safety import review program.

### **Food and Drug Import Safety Act of 2007 (Dingell, D-MI)**

- Bill HR 3610
- Introduced September 20, 2007; committee hearings held September 26, 2007
- referred to House Energy and Commerce committee and the House Energy and Commerce Subcommittee on Health
- 4 co-sponsors
- Amends the FD&C act
  - provides for research on the development of tests and sampling methodologies for imported food
  - assesses fees on imported food and drugs
  - restricts the importation to ports of entry with a FDA lab
  - requires country of origin labeling
  - requires importers to voluntarily agree to abide by specified guidelines
  - increases civil penalties for the manufacturer or importer of adulterated food
  - reorganizes FDA field laboratories and district offices
  - requires notification for immediate cessation in the distribution of food that may cause serious, adverse health consequences or death
  - subjects all imported food to U.S. food safety standards
  - requires a certification system for a foreign facility seeking to import food

- requires that processed food undergo testing to detect substances that may render the food adulterated
- defines the term "color additive" to include carbon monoxide, unless noted in the label

**Association of Food, Beverage and Consumer Product Companies (GMA) “Four Pillars of Food Safety”**

- multi-tiered approach
  - establishment of mandatory quality assurance programs for international suppliers
  - development of a prioritized system of analysis through voluntary import quality assurance programs
  - expanded and improved capacity for analysis and oversight of foreign food facilities
  - increase in FDA resources for targeting and testing of imports.

**Interagency Working Group on Import Safety *Action Plan for Import Safety***

- integrated strategy would provide protection by the prevention of food contamination, intervention at critical points in the food supply chain, and rapid response to minimize harm
  - allow the FDA to require controls at points of high vulnerability to prevent intentional contamination
  - require biannual registration of food facilities for approval to export food products into the US
  - require import certificates for high-risk products
  - empower the FDA to call for mandatory recalls of foods
- recommends six building blocks to achieve this goal
  - advance a common vision
  - increase accountability, enforcement and deterrence
  - focus on risks over the life cycle of an imported product
  - build interoperable systems
  - foster a culture of collaboration
  - promote technological innovation and new science.

***(NOTE: the Interagency Working Group plan is integrated with the FDA Food Protection Plan)***

**FDA Food Protection Plan**

- Organized around prevention, intervention and response as outlined in the Interagency Working Group report
  - recommends building safety into manufacturing and distribution processes
  - the adoption of more effective techniques for identifying hazards
  - the coordinated seizure, destruction or preventing dangerous goods from moving past point of entry
  - rapid response to limit the potential exposure and harm to the public
- 14 broad recommendations:
  - safety standards: create new and strengthen existing safety standards
  - certification: verify compliance of foreign producers with US safety and security standards through certification
  - good importer practices: promote good importer practices

- penalties: strengthen penalties and take strong enforcement actions to ensure accountability
- foreign collaboration and capacity building: make product safety an important principle of diplomatic relationships with foreign countries
- common mission: harmonize federal government procedures and requirements for processing import shipments
- interoperability: complete a single window interfact for the intraagency, interagency and private sector exchange of information
- information gathering: create an interactive import-safety information network
- new science: expand laboratory capacity and develop rapid test methods
- intellectual property protection: strengthen protection of intellectual property rights
- recall: maximize the effectiveness of product recalls
- federal-state rapid response: maximize federal-state collaboration
- technology: expedite consumer notification of product recalls
- track-and-trace: expand the use of electronic track and trace technologies

*Appendix B. Comparing proposed food safety legislation*

	Unified food safety agency	HACCP program	Import certification/registration	COOL/Trace back	Restrict port of entry	Mandatory recalls	Food standards	Enhanced penalties	Import fees
Safe Food Act of 2007	X	X	X	X		X	X	X	
Human and Pet Food Safety Act of 2007			X			X	X	X	
Imported Food Security Act of 2007			X			*			X
Food and Drug Import Safety Act of 2007			X	X	X	X	X	X	X
GMA Four Pillars		X	X			X			
Interagency Working Group Action Plan			X	X		X	X	X	
FDA Food Protection Plan		X	X	X		X	X	X	X

*\*Provides that any food imported for consumption in the United States may be detained, seized, or condemned.*

	Foreign capacity	Port limits	Research	Seizure of food	Reorganize FDA labs and offices	Rapid response to food issues	Enhanced communication
Safe Food Act of 2007			X	X			
Human and Pet Food Safety Act of 2007				X		X	X
Imported Food Security Act of 2007			X	X			
Food and Drug Import Safety Act of 2007		X	X		X	X	
GMA Four Pillars	X						
Interagency Working Group Action Plan	#		X	X		X	X
FDA Food Protection Plan	X		X	X		X	X

*#Review existing overseas programs...to determine how to improve product safety standards and conduct.*

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