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Food Safety and Imports

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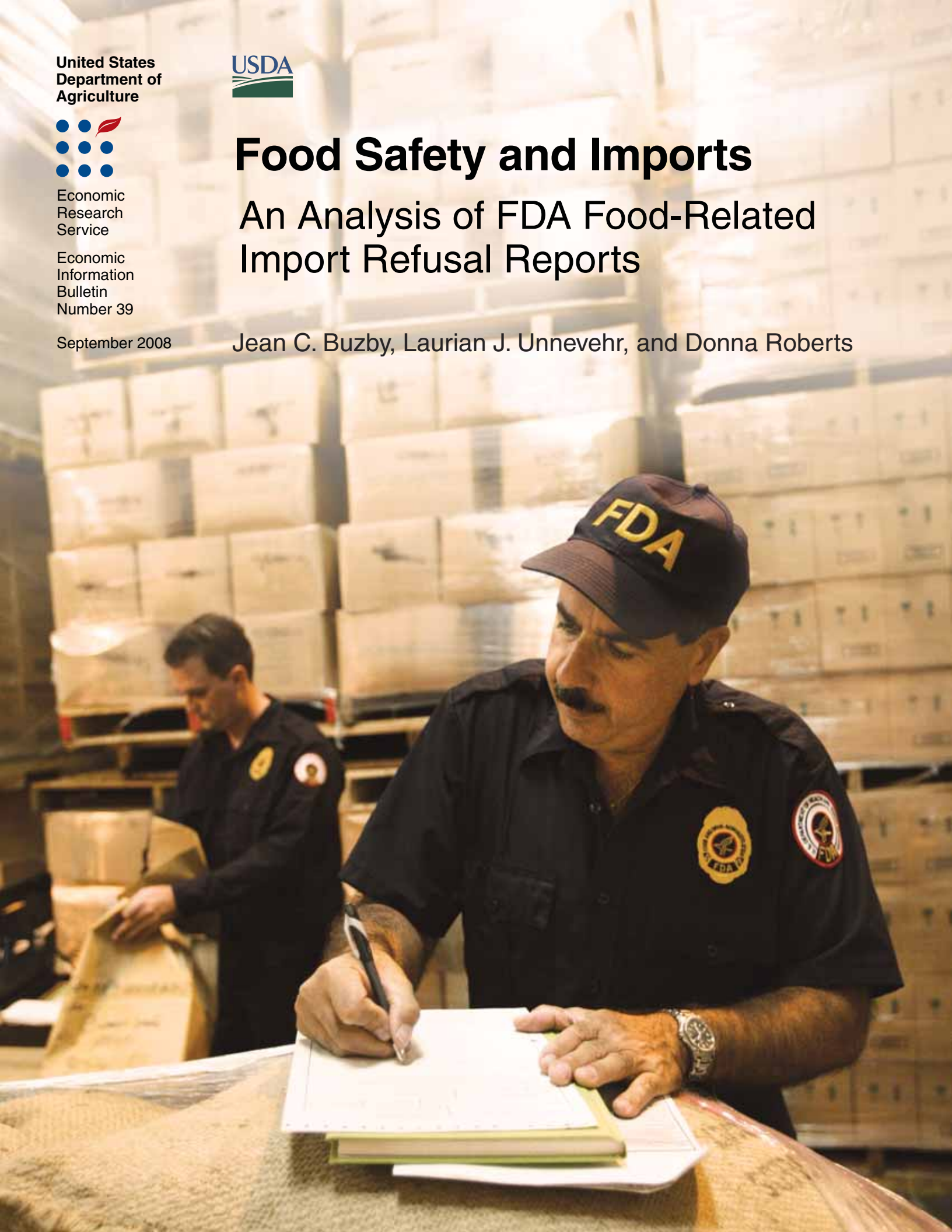
Jean C. Buzby, Laurian J. Unnevehr, and Donna Roberts



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An Analysis of FDA Food-Related Import Refusal Reports

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Abstract

This report examines U.S. Food and Drug Administration (FDA) data on refusals of food offered for importation into the United States from 1998 to 2004. Although the data do not necessarily reflect the distribution of risk in foods, the study found that import refusals highlight food safety problems that appear to recur in trade and where the FDA has focused its import alerts, examinations (e.g., sampling), and other monitoring efforts. The data show some food industries and types of violations are consistent sources of problems both over time and in comparison with previous studies of more limited data. The three food industry groups with the most violations were vegetables (20.6 percent of total violations), fishery and seafood (20.1 percent), and fruits (11.7 percent). Violations observed over the entire time period include sanitary issues in seafood and fruit products, unsafe pesticide residues in vegetables, and unregistered processes for canned food products in all three industries.

Keywords: Adulteration, food imports, Food and Drug Administration (FDA), food safety, misbranding, labeling, refusal, shipment, violation

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Summary

Interest in the safety of imported foods has increased over time, not only because the volume of food imports is increasing in the United States, but because the imported share of the total U.S. food consumption is also rising, particularly for perishable, minimally processed foods. Food safety concerns about food imports may have far-reaching implications—reducing demand for certain imported products, altering international food trade patterns, and limiting access to U.S. markets for some foreign exporters.

What Is the Issue?

Data limitations constrain what is known about the safety of imported foods. As a first step to understanding this issue better, ERS researchers analyzed U.S. Food and Drug Administration (FDA) refusals of food import shipments for 1998-2004 by food industry group and by type of violation. Here, the term *violations* refers to products that appear to violate one or more of the laws enforced by FDA, such as those dealing with adulterated or misbranded products.

What Did the Study Find?

The study revealed recurring food safety risks and other problems (e.g., inadequate labeling) in certain types of imported foods. The findings, however, do not indicate the actual level or distribution of food safety risk that imports may pose to American consumers because FDA's process for selecting shipments for inspection or other administrative actions is not random. Instead, FDA relies on risk-based criteria to guide its actions, including data on products and manufacturers with a history of violating U.S. import regulations. In essence, import refusals highlight food safety problems that appear to recur in trade and where the FDA has focused its import alerts and monitoring efforts.

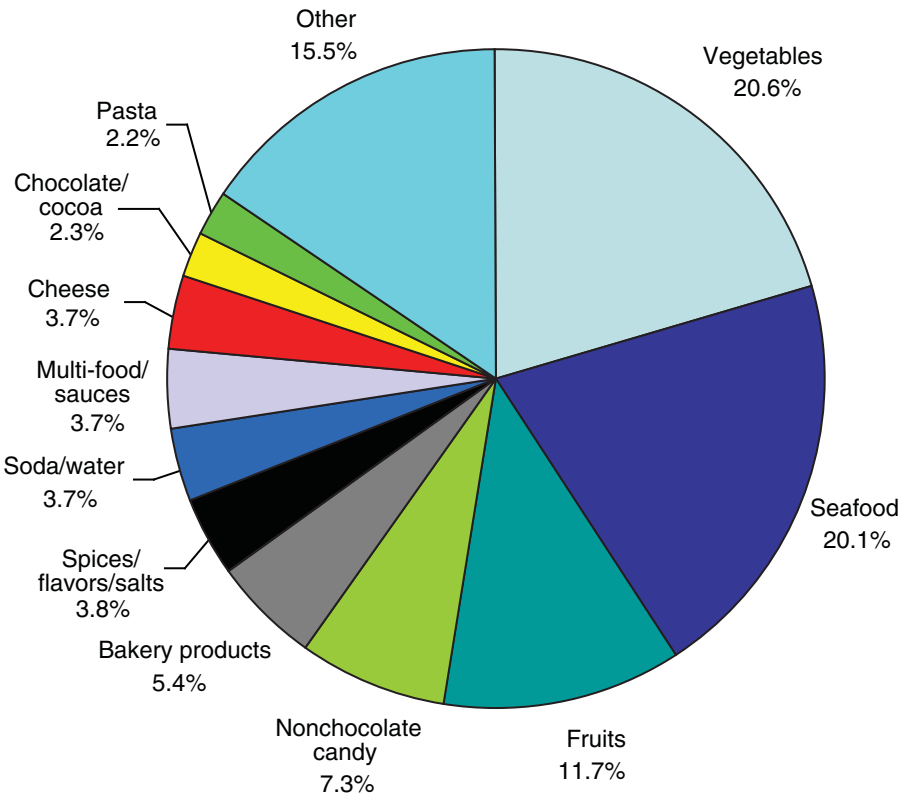
The top imported food categories refused due to food safety and other violations under FDA law were:

1. Vegetables and vegetable products (accounting for 20.6 percent of total violations);
2. Fishery and seafood products (20.1 percent); and
3. Fruits and fruit products (11.7 percent).

An examination of violations in these three categories reveals that refusals for sanitary violations in seafood and fruit products, pesticide violations in vegetables, and unregistered processes for canned food products in all three categories were persistent over time (fig. 1).

Of the 70,369 violations reported from 1998 to 2004, 33 percent were for *misbranding* or the lack of appropriate labeling and 65 percent were for *adulteration* or safety and packaging integrity problems (e.g., leaky containers/swollen cans may suggest the presence of microbial growth). Adulteration violations pose a wide range of food safety risks, from less severe risks, such as an insect in cooked soup, to immediate risks to human

Figure 1
FDA import violations by food industry, 1998-2004



Source: ERS calculations using FDA Food-Related Import Refusal Reports, 1998-2004.

health, like botulism in canned food. The data indicate that the most common adulteration violations were for the appearance of filth in a food product and for failure to file information or register a specified process. When specific pathogens were identified in import refusals, they tended to be found in food products typically associated with such risks (e.g., *Listeria* in cheese and cheese products).

How Was the Study Conducted?

Researchers analyzed FDA Import Refusal Reports (IRR) for food shipments refused entry into U.S. commerce between 1998 and 2004. Tabulations were created of refusals by industry group and FDA violation code (e.g., type of violation). Adulteration violations were examined closely, particularly those linked to pathogen contamination.

Introduction

Global food trade is expanding due to improvements in transportation, infrastructure, marketing networks and consumer demand. Trade is also increasing due to global increases in per capita income and population. Along with growth in international food trade, food safety has become progressively important to industry, consumers, and policymakers, particularly in developed countries. Policymakers are experiencing more pressure to guard or enhance the safety of their nations' food supplies. The globalization of the food supply means new food safety risks can be introduced into countries (e.g., emerging bacteria), previously controlled risks can be re-introduced into countries (e.g., cholera), and contaminated food can be spread across greater geographic areas, causing illness worldwide. Food safety concerns may reduce demand for certain products, alter international food trade patterns, and limit market access for some exporters.

In the United States, food imports made up 16 percent of all foods consumed in 2004 (table 1). Import shares are higher for some foods that are often linked to microbial foodborne illness. An analysis of 5,000 foodborne illness outbreaks between 1990 and 2004 found that the food categories linked to most outbreaks (excluding multi-ingredient foods) were seafood, produce, poultry, beef, and eggs (CSPI, 2006). Imported fish and shellfish account for 80 percent of U.S. consumption, while imported fruits and nuts account for 33.9 percent of U.S. consumption (Jerardo, 2004). On the other hand, imported red meat accounts for 10.4 percent of U.S. consumption and imported animal products, as a group, account for 5.6 percent of U.S. consumption.

Table 1

Import share of U.S. food consumption[1]

Food groups	Average 1981-85	Average 1986-90	Average 1991-95	Average 1996-00	2001	2002	2003	2004
				Percent				
Total food consumption	9.2	10.1	11.3	13.4	15.0	14.9	15.3	16.0
Animal products[2]	3.5	3.9	3.8	4.4	5.5	5.3	5.3	5.6
Red meat	6.4	8.1	7.7	7.2	8.9	9.3	9.4	10.4
Dairy products	1.9	1.8	1.9	2.5	3.4	3.0	2.9	3.1
Fish and shellfish	50.9	56.0	56.0	64.4	77.8	77.5	82.1	80.0
Animal fat	1.0	1.6	3.5	—	6.8	5.9	—	—
Crops and products[3]	15.2	16.3	18.1	21.8	25.0	25.0	25.8	27.2
Fruits and nuts	13.4	20.9	27.3	29.7	30.6	33.1	34.5	33.9
Vegetables	4.5	5.8	5.9	8.6	9.6	10.4	10.7	10.9
Vegetable oils	33.1	42.9	45.0	47.4	42.3	39.1	37.4	45.3
Grain products	3.7	6.1	12.5	14.7	16.9	14.0	12.4	13.1
Sweeteners and candy	31.0	16.6	11.0	13.3	10.0	9.4	10.7	11.2

Note: — Indicates data were not available.

[1]Computed from units of weight, weight equivalents, or content weight. Some food consumption estimates are reduced by waste, but import weights are not.

[2]Includes poultry meats, eggs, animal fats, and carcass weight equivalent of imported live feeder animals.

[3]Includes coffee, cocoa, tea, spices, wine, and beer. Fruit and vegetable imports include juices and other processed products.

Source: U.S. Department of Agriculture and U.S. Census Bureau.

The FDA has food safety oversight of all domestic and imported foods, except for the meat, poultry, and processed egg products that are regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) (see box, "Food Safety Oversight in the United States"). FDA data were used in this analysis because they cover the vast majority of food imports and potential food safety issues.[1]

This study uses newly available data from FDA Import Refusal Reports (IRR) from 1998 through 2004.[2] IRR data include only those shipments[3] ultimately refused entry into U.S. commerce, and thus are a better indicator of potential violations in food imports than the previously reported detention data. For each refusal, FDA reports the violation or charge codes, which document the reasons for refusal (Appendix A provides more detail about violation codes).

In this report, we provide an analysis of food imports refused entry into U.S. commerce by the FDA for what appear to be food safety violations and other reasons (e.g., labeling issues). Our primary goals were to identify what the FDA import refusal data represent, which sanitary issues and other violations were most common, how such violations were distributed among different industry groups, and which violations were most persistent over time. This analysis provides insight into which FDA-regulated food imports face recurring and important problems in meeting food safety requirements for entry into U.S. markets. The scope of the report does not include the imported meat, poultry, and processed egg products regulated by FSIS (see box, "Food Safety Oversight in the United States").

[1]FSIS follows different procedures for monitoring the safety of food imports under its jurisdiction, thus comparable data are not available. ERS plans to analyze data from FSIS' Automated Import Inspection System in a separate analysis. ERS analyzed the FDA data first because FDA data have the broadest coverage of all types of food imports and may reflect a broader range of potential food safety issues. As previously mentioned, FSIS import data are only for meat, poultry, and processed egg products.

[2] Previous studies used detention data, which reflect shipments where FDA issued Notice of Detention actions. A large share of the detained shipments are not ultimately refused entry (i.e., admission) into the United States, but are eventually released into trade. The data did not provide information on the ultimate administrative outcome for each shipment.

[3] We use the term *shipment* for each of the *entry lines* in the FDA refusal data. An entry line is a unique shipment or lot of a particular food by a particular shipper offered for admission into U.S. commerce at a particular place in time.

Food Safety Oversight in the United States

In the United States, there are three main regulatory agencies with Federal jurisdiction over food and food ingredients:

- **Food Safety and Inspection Service (FSIS)** within the U.S. Department of Agriculture (USDA) ensures the safety of all domestic and imported meat (except game and exotic meats), poultry, and processed egg products.

- **Food and Drug Administration (FDA)** within the Department of Health and Human Services (DHHS) has in its purview all domestic and imported foods marketed in interstate commerce as well as game and exotic meats (e.g., kangaroo, quail, and duck), food additives, animal feed, and veterinary drugs. As noted above, the exception is for meat, poultry, and processed egg products regulated by FSIS. FDA-regulated meat and poultry products include products that contain less than 2 percent cooked or 3 percent raw meat by volume. FDA allows FDA-regulated meat, poultry, or egg products only from an approved source.

- **Environmental Protection Agency (EPA)** licenses pesticide products and establishes maximum allowable limits (tolerances) for pesticide residues in food and animal feed. (FDA and FSIS enforce pesticide tolerances for the commodities under their jurisdiction.) In addition, EPA manages regulatory and research programs related to water- and foodborne toxic chemicals such as dioxin (President's Council on Food Safety, 2001).

The food safety efforts of these agencies are supported by a number of other government organizations, including State, tribal, and local governments. FDA is responsible for all import inspections except for meat, poultry, and processed egg products, which fall under FSIS jurisdiction. Responsibility for particular food groups is often shared among agencies. For example, for fruits and vegetables, EPA and USDA share pesticide regulation responsibilities, while FDA handles import inspections.

The FDA's mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws designed to protect consumer health, safety, and welfare (FDA, March 17, 1999). These laws apply equally to domestic and imported products. All food under FDA jurisdiction, as defined in the FD&C and related Acts, is subject to examination by FDA when it is being imported or offered for import into the United States. Imported foods must be pure, wholesome, safe to eat, produced under sanitary conditions, and contain informative and truthful labeling in English.

FDA Import Refusal Reports Data

We analyzed FDA data for import shipments from 1998 to 2004 that were ultimately refused entry into U.S. markets.[4] FDA routinely posts 12 recent months of Import Refusal Reports (IRR) on its Web site (see www.fda.gov/ora/oasis/ora_ref_cntry.html). We obtained more comprehensive data for 1998-2004 food shipment refusals through an interagency request to FDA with the agreement that the data would not be shared without FDA consent. Others, such as Food & Water Watch (2007), have obtained IRR data by submitting a Freedom of Information Act request to FDA. The FDA generates IRR reports from data collected by its Operational and Administrative System for Import Support (OASIS). OASIS is a computer-based system that processes import requests for FDA-regulated shipments of foreign origin that seek to enter U.S. commerce (FDA, Oct. 28, 2004). The FDA also uses OASIS to make admissibility determinations. Appendix B provides information on the general procedures for the FDA's import program.

In the IRR, each shipment or refused entry may have multiple records, depending on the number of violations associated with it. Each record represents one charge or violation and generally includes data specifying the entry number, country of origin for the shipper and the manufacturer, industry code, product code description (e.g., shrimp and prawns, peas), importer's product description, corrected product description, violation code, and narrative text. Our focus is on violations since they provide specific information about potential food safety issues and risks. For shipments with more than one violation, the data did not indicate which, if any, of the violations were most critical in triggering FDA refusals. Consequently, our analysis could not pair each shipment with a primary violation.[5]

Note that each violation or refusal of a shipment does not necessarily mean that there was a violative product, but rather that the product appeared to be violative in FDA's judgment. According to England (2000):

> Section 801(a) of the Food, Drug, and Cosmetic act, "gives the authority to FDA to refuse admission of any article that 'appears' to be in violation" of one of the laws enforced by FDA. "The significance of the appearance standard under FDA law is that the Government is NOT required to prove an ACTUAL VIOLATION of law or the regulations has occurred. Rather, the FDA must be able to show that there exists an 'appearance' of a violation to refuse admission of goods. The appearance of a violation may arise by the examination of physical samples, a field examination, review of entry documents, or based upon the history of prior violative shipments made from the same shipper."

Role of Import Alerts in the Data

Many of the refusals in the IRR data are the result of FDA import alerts. These import alerts communicate guidance to FDA field offices. They can be informational, such as to identify and disseminate import information on violative trends and problems to FDA field personnel. They can also call for intensified surveillance of a particular food product from a particular

[4] In a small proportion of cases, shipments were recorded as "refused" because FDA considered there to be a violation, yet the importer chose to re-export the shipment to a third country (e.g., rather than pay to have it tested or otherwise verified to be in compliance with laws enforced by FDA).

[5] Prior to the analysis, data consistency was evaluated by comparing industry group (identified by the industry code) with accompanying text for the product description, importer product description, and corrected product description. When the FDA provided a corrected product description that differed from the original product or importer product descriptions, we corrected the description used in our analysis. That is, we used the FDA changes and not the data submitted by the filer. We deleted violations with inconsistent product descriptions and those for which we had insufficient information to make corrections (e.g., a violation that had a product description for a seafood item, an importer product description for fresh fruit, and no corrected product description to clarify if the item was really seafood, fruit, or something else). We deleted a small number of violations for nonfood uses, such as betel nut cigarettes, cosmetic products, massage oils, and medicine samples, as well as duplicate records. We also identified records with the same entry number that were refused for the same violation on different dates and deleted the record with the older date. In total, we culled 1,089 violations, leaving 70,369 violations in the sample.

country. In some instances, an alert places a grower/product on detention without physical examination (DWPE) (FDA, March 17, 1999). This means subsequent shipments will be refused entry into U.S. commerce unless the importer presents evidence (via testing or other means) to FDA proving the item can overcome the appearance of a violation (FDA, Feb. 1, 2008; FDA, CFSAN, Feb./March 2002). This procedure is based on past history and/or other information indicating the product may be violative or when violative findings for a grower/shipper are of a nature that suggests future shipments from that grower/shipper may also be in violation (FDA, CFSAN, Feb./ March 2002).

The purpose of import alerts are to:

1. Prevent products that appear to be violative from coming into the country, based on factual evidence;
2. Free up Agency resources to look at other commodities of high-risk; and
3. Place the responsibility of importing products that are in compliance with the law back on the importer.

The agency cannot inspect each shipment, but instead relies on risk-based criteria to choose which shipments to examine (e.g., sampling, label review) and which food safety and other problems to post as import alerts. These examinations and import alerts may lead to import refusals. Therefore, IRR are not a result of a random sample. The IRR reflect the FDA's criteria for shipments to examine, refusals as a result of FDA's import alerts, and other factors, such as newly identified issues in food imports. In essence, to an important yet unquantifiable extent, IRR data reveal where the FDA has focused its efforts (e.g., developing and disseminating specific import alerts) and/or resources (e.g., choosing shipments to examine) in response to identified problems.

We identified this connection between import alerts and refusals in two ways. First, an examination of FDA import alerts posted on the FDA Web site on July 23, 2007, showed that FDA industry groups with the most import alerts are basically the same groups with the most refusals in the 1998-2004 IRR data (see Appendix B). This is an imperfect comparison, because there is no way to identify which import alerts would have been in effect at any particular time during the timeframe of our sample (1998 to 2004). Second, the narrative text variable in refusal data provides comments for roughly 70 percent of all observations, and import alerts are frequently mentioned. There is no guarantee, however, that an import alert would have been specified in the text comment each time an alert was associated with a particular shipment. Thus, while a connection between import alerts and refusals seems to exist, Kendall (2007) reported that it is not possible to determine definitively whether an import refusal was caused by a particular import alert solely from the IRR data. Therefore, we cannot determine the volume or share of violations or refusals linked to import alerts or DWPE.

Limitations of the IRR Data

To interpret the IRR data, it is important to understand the limitations of the data:

- FDA inspections cover a small percent of food import entries (about 1 percent in FY2000 (GAO, Oct. 10, 2001)). The FDA sampled 2.1 percent or less of seafood shipments for sensory examination or laboratory inspection between 2003 and 2006 (Food & Water Watch, 2007). We do not have precise numbers on the percent of food shipments inspected by the FDA or data on the other food industry groups for the other years covered in the sample.
- The IRR data are not a result of a random sampling of imports. For example, as discussed, the IRR tend to reflect those growers, shippers, or commodities identified by FDA through their import alert system as more likely to be in violation.
- IRR data do not provide information on the total number of food shipments offered to FDA for admission (i.e., entries) into U.S. commerce for the years covered in our sample. We cannot, therefore, calculate the share of shipments refused entry.
- FDA data on shipment quantity/weight are inappropriate to calculate either the total amount or volume of food products rejected by FDA for entry into U.S. commerce or to calculate the share of refusals out of total imports. The data are incomplete. For example, a shipment could be declared in pounds, gallons, or count (e.g., 50 jars, 100 cartons), precluding meaningful aggregations.[6]

In spite of these limitations, the IRR data provide the best available information on the problems that occur in food imports in terms of meeting standards for entry into U.S. markets. The subsample of IRR observations categorized as *adulteration* (e.g., sanitation, safety, and packaging integrity problems such as swollen or leaky containers) provide a partial view of the food vehicle and safety problems in imports that appear to pose food safety risks to human health. The recurrence of particular violations over time shows where food imports have persistent failures in meeting U.S. standards.

[6] Quantity is not a required data element for filing an entry for an FDA-regulated commodity.

Analysis of the IRR Data

Import Shipments Refused by the FDA

During 1998-2004, we found that 49,448 shipments were refused entry into U.S. markets by FDA (table 2). There were roughly twice as many refused shipments in each of the last 3 years of the data than in each of the previous 4 years. Some of this growth may reflect the strengthening of the reporting system in later years, such as greater use of the OASIS electronic entry submission system, processing, and admissibility determinations (before OASIS, paper submissions were required for all shipments). It also reflects the increased volume of food shipments. FDA's *Food Protection Plan* estimated that in FY2007, there were 9.5 million food entries (i.e., shipments of food), up from around 3 million in FY1997 (FDA, Nov. 2007, p. 8).[7]

The top food categories with the highest shares of both refused shipments and violations were vegetables and vegetable products (accounting for 20.6 percent of total violations), fishery and seafood products (20.1 percent), and fruits and fruit products (11.7 percent). These three groups were consistent in having the greatest number of refusals from 1998 to 2004. They were also the top industry groups for FDA import detentions in 1999 (Unnevehr, 2000).

Refused shipments often had more than one violation. The 49,448 refused shipments reflected a total of 70,369 violations or an average of 1.4 violations per refused shipment. There appeared to be little variation of average violations by industry group. Average violations ranged from 1.26 violations per refused shipment of alcoholic beverages to 1.98 violations per refused shipment of vegetable protein products (table 2).

Adulteration, Misbranding, and Other Violations

The FDA separates most import violations into two main categories: adulteration and misbranding. As defined in the Food, Drug, and Cosmetic Act, the term *adulteration* involves the content of a product, such as the addition of a substance that makes it inferior, impure, or not genuine (FDA, March 17, 1999). For our purposes, *adulteration* deals with safety, packaging integrity, or sanitation (Caswell and Wang, 2001). *Misbranding* includes untruthful or misleading statements on labels and labeling and includes products missing appropriate labeling or packaging. According to FDA, many of the misbranding issues may have arisen from products that were analyzed for sanitary issues (e.g., foodborne pathogens).

The severity of the risk posed by shipments charged with misbranding and adulteration varies. For example, a misbranding violation from a nonstandard nutrient label may not pose health risks, whereas a misbranding violation for undeclared sulfites may pose risks to sulfite-sensitive consumers. Similarly, adulteration violations for obvious rat filth in raw produce may pose higher health risks than the same circumstance in cooked produce, although both are unacceptable.

Of all import violations from 1998 to 2004, we calculate that 65 percent were for adulteration, 33 percent were for misbranding, and 2 percent were for

[7] The *Food Protection Plan* defines an import line or "entry line" as "each portion of an import shipment that is listed as a separate item on an entry document." Items in an import entry having different tariff descriptions must be listed separately. According to an FDA official, the volume of shipments of both food and nonfood reached 5.05 million in 1998 and 11.62 million in 2004, a 130-percent increase over this period (Kendall, 2007). In 2006, the estimated food and nonfood volume of shipments rose to almost 15 million (Kendall, 2007).

Table 2

Shipments refused for importation by FDA, 1998-2004

FDA industry group	Shipments refused per year							Total shipments	Total violations	Avg. violations per entry line
	1998	1999	2000	2001	2002	2003	2004			
Vegetables and vegetable products	1,308	1,002	665	1,076	2,399	2,053	2,566	11,069	14,463	1.31
Fishery and seafood products	1,412	713	581	1,168	2,444	2,293	2,405	11,016	14,109	1.28
Fruits and fruit products	859	675	418	652	1,070	957	1,057	5,688	8,263	1.45
Candy w/out chocolate/special/gum	439	616	305	238	67	619	575	3,459	5,132	1.48
Bakery products/dough/mix/icing	168	230	164	186	457	429	602	2,236	3,814	1.71
Spices, flavors, and salts	149	137	137	180	410	425	463	1,901	2,709	1.43
Soft drinks and water	54	66	124	151	303	388	327	1,413	2,622	1.86
Multi-food dinner/gravy/sauce/special	155	99	72	129	447	514	389	1,805	2,620	1.45
Cheese and cheese products	72	95	39	341	394	461	521	1,923	2,586	1.34
Chocolate and cocoa products	44	50	60	148	212	162	151	827	1,605	1.94
Macaroni and noodle products	144	60	74	63	426	234	144	1,145	1,535	1.34
Milk/butter/dried milk products	35	31	62	148	260	261	194	991	1,357	1.37
Nuts and edible seeds	86	111	49	91	139	162	138	776	1,101	1.42
Snack food items	68	42	36	46	126	105	232	655	1,092	1.67
Beverage bases/concentrate/nectar	42	54	40	69	127	133	113	578	998	1.73
Whole grain/milled grain prod/starch	101	65	78	60	192	97	129	722	987	1.37
Dressings and condiments	27	24	39	48	145	165	138	586	975	1.66
Soup	56	25	29	71	205	112	91	589	911	1.55
Gelatin/pudding mix/pie filling	30	41	73	32	100	40	38	354	658	1.86
Coffee and tea	30	47	11	63	102	57	83	393	601	1.53
Food sweeteners (nutritive)	12	19	12	17	84	90	65	299	494	1.65
Vegetable oils	17	21	22	27	43	43	51	224	395	1.76
Cereal prep/breakfast food	27	17	16	16	36	44	36	192	347	1.81
Baby food products	0	0	0	12	37	17	68	134	246	1.84
Ice cream products	5	3	7	7	15	34	20	91	147	1.62
Alcoholic beverages	13	1	5	5	7	8	61	100	126	1.26
Vegetable protein products	2	1	2	18	28	5	4	60	119	1.98
Meat, meat products, and poultry[1]	3	5	1	7	22	17	27	82	114	1.39
Eggs and egg products	1	6	18	5	2	8	25	65	103	1.58
Filled milk/imitation milk products[2]	0	3	1	4	8	16	11	43	84	1.95
Prepared salad products	1	4	2	4	5	5	11	32	56	1.75
Total	5,360	4,263	3,142	5,082	10,912	9,954	10,735	49,448	70,369	N/A

[1]Meats have very few refusals, presumably due to the pre-certification of inspection systems in exporting countries carried out by USDA/FSIS and mandated by U.S. food safety legislation specific to meat and poultry and because the data only cover FDA-regulated meat and poultry products (see box, “Food Safety Oversight in the United States,” p. 3).

[2]Filled milk is skim milk that has been reconstituted with fats from nondairy sources, such as palm oil or coconut oil.

Source: ERS calculations using FDA Import Refusal Reports, 1998-2004.

"other violations"[8] (table 3). Three types of violations accounted for over 53 percent of all adulteration violations. The most common adulteration violation was filth, which is defined as an article that "appears to consist in whole or in part of a filthy, putrid, or decomposed substance or is otherwise unfit for food" (FILTHY,[9] 24.1 percent). The second most common adulteration violation occurred when the manufacturer of a low-acid canned food or an acidified food had not filed information on its scheduled process (NO PROCESS, 17.9 percent).[10] The third most common adulteration violation occurred when the manufacturer was not registered as a low-acid canned food or acidified food manufacturer. In this case, the processing plant had not received a Food Canning Establishment number (NEEDS FCE, 11.5 percent). According to the FDA, both of the latter two violations for unregistered processes are considered adulteration because of the potential risk to public health. Cooking and other processing procedures for low-acid canned foods are particularly important to minimize risk from botulism. The lack of process registration does not, in and of itself, indicate a contaminated product.

Three types of violations accounted for over half of all misbranding violations. These violations occurred when the article's labeling failed to bear the required nutritional information (NUTRIT LBL, 23.8 percent), did not list the common name for each ingredient (LIST INGRE, 15.2 percent), or was not written in English (NO ENGLISH, 11.2 percent). The fruits and fruit products group had the highest number of misbranding violations. Two examples of misbranding for fruits occurred when tamarind paste was missing a nutrition label or when prune jam contained saccharin and its label failed to bear the required warning statement.

Pathogen, Chemical, and Other Adulteration Violations

Adulteration violations were examined in depth, as we believe they were more likely to be associated with food safety risks than misbranding or "other violations." Three subcategories of adulteration violations were created to increase our understanding of potential food safety problems (table 3):

1. Pathogens, such as *Salmonella*, and their toxins, such as mycotoxins;
2. Chemical contamination with pesticides or unapproved additives; and
3. "Other sanitary violations" including filthy or decomposed appearance and unregistered processes for canned food products that the FDA considers to pose safety violations.[11]

Of the 45,941 adulteration violations found, those for pathogens comprised 15.3 percent (10 percent of all violations), chemical contamination totaled 25 percent (16 percent of all violations), and other sanitary violations made up 59.7 percent (39 percent of all violations). Fishery and seafood products had the most violations for pathogen adulteration. The vegetables and vegetable products group had the most violations for chemical contamination. The vegetables and the fisheries groups had the most "other sanitary violations."

Salmonella was the most common violation for a pathogen adulterant, accounting for 63 percent of pathogen violations. Unsafe coloring was the most common chemical contamination violation, accounting for 45.6 percent

[8] These include violations the FDA tags as importation restricted; forbidden or restricted in sale; unsanitary manufacturing, processing, or packaging; nonstandard; prohibition without permit; or unspecified.

[9] All capitalized terms are FDA shorthand code for import violations and are defined in Appendix A.

[10] Acid or acidified foods have an equilibrium pH of 4.6 or below. According to the Code of Federal Regulations (21 CFR, section 108.25), a commercial processor engaged in processing acidified foods shall, not later than 60 days after registration and before packing any new product, provide the FDA information on the scheduled processes including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for each acidified food in each container size.

[11] We classified pathogen violations as those for aflatoxin, histamine, *Listeria, Salmonella, Shigella*, and for two catch-all categories of violations (e.g., BACTERIA, DISEASED). Chemical violations included CHLORAMP, COL ADDED, COUMARIN, CYCLAMATE, DIOXIN, DULCIN, EXCESS SUL, FLUOROCARB, NEW VET DR, ALCOHOL, PESTICIDE, PESTICIDES, POIS CHLOR, UNSAFE ADD, UNSAFE COL, and VETDRUGRES. "Other sanitary violations" included the remaining reasons listed in Appendix A.

Table 3

FDA import refusals for adulteration or misbranding violations, 1998-2004

	Adulteration								Misbranding		
	Pathogens		Chemical		Other		Total				Total
FDA Industry Group	Number	% of total	Number	% of total	Number	% of total	Number	% of total	Number	% of total	violations[1] Number
Vegetables and vegetable products	189	1	4,236	29	7,874	54	12,299	85	2,115	15	14,463
Fishery and seafood products	3,743	27	471	3	7,458	53	11,672	83	1,979	14	14,109
Fruits and fruit products	438	5	1,828	22	3,480	42	5,746	70	2,499	30	8,263
Candy w/out chocolate/ special/gum	133	3	1,901	37	711	14	2,745	53	2,378	46	5,132
Bakery products/ dough/mix/icing	52	1	747	20	589	15	1,388	36	2,421	63	3,814
Spices, flavors, and salts	743	27	279	10	707	26	1,729	64	976	36	2,709
Soft drinks and water	1	0	486	19	539	21	1,026	39	1,595	61	2,622
Multi-food dinner/ gravy/sauce/special	246	9	74	3	1,574	60	1,894	72	721	28	2,620
Cheese and cheese products	1,136	44	19	1	364	14	1,519	59	807	31	2,586
Chocolate and cocoa products	34	2	185	12	103	6	322	20	1,282	80	1,605
Macaroni and noodle products	4	0	47	3	616	40	667	43	866	56	1,535
Milk/butter/dried milk products	6	0	3	0	442	33	451	33	394	29	1,357
Nuts and edible seeds	185	17	195	18	274	25	654	59	443	40	1,101
Snack food items	58	5	222	20	80	7	360	33	732	67	1,092
Beverage bases, concentrate, nectar	3	0	197	20	339	34	539	54	459	46	998
Whole grain/ milled grain prod/starch	9	1	73	7	494	50	576	58	411	42	987
Dressings and condiments	2	0	44	5	583	60	629	65	345	35	975
Soup	3	0	4	0	470	52	477	52	411	45	911
Gelatin/pudding mix/pie filling	1	0	203	31	76	12	280	43	375	57	658
Coffee and tea	2	0	11	2	178	30	191	32	409	68	601
Food sweeteners (nutritive)	1	0	95	19	57	12	153	31	341	69	494
Vegetable oils	2	1	64	16	33	8	99	25	295	75	395
Cereal prep/breakfast food	2	1	27	8	44	13	73	21	274	79	347
Baby food products	0	0	4	2	49	20	53	22	190	77	246
Ice cream products	5	3	49	33	14	10	68	46	79	54	147
Alcoholic beverages	0	0	5	4	14	11	19	15	107	85	126
Vegetable protein products	1	1	1	1	55	46	57	48	62	52	119
Meat, meat products, and poultry[2]	37	32	1	1	39	34	77	68	36	32	114
Eggs and egg products	18	17	1	1	68	66	87	84	15	15	103
Filled milk/imitation milk products[3]	0	0	1	1	50	60	51	61	32	38	84
Prepared salad products	0	0	0	0	40	71	40	71	16	29	56
Total	7,054	10	11,473	16	27,414	39	45,941	65	23,065	33	70,369

[1]Total violations are for adulteration, misbranding, and 1,356 “other violations” not shown here (i.e., less than 2 percent of total violations), such as items forbidden or restricted in sale.

[2]Meats have very few refusals, presumably due to the pre-certification of inspection systems in exporting countries carried out by USDA/FSIS and mandated by the U.S. food safety legislation specific to meat and poultry and because these refusals only include FDA-regulated meat and poultry products (see box, “Food Safety Oversight in the United States,” p. 3).

[3]Filled milk is skim milk that has been reconstituted with fats from nondairy sources, such as palm oil or coconut oil.

Source: ERS calculations using FDA Import Refusal Reports, 1998-2004.

of chemical contamination violations. FILTHY is the most common violation code in "other sanitary violations," accounting for 40.4 percent of these violations. Two unregistered processes for low-acid canned foods or acidified foods (previously mentioned) combined accounted for another 49.3 percent of the "other adulterations" (e.g., NEEDS FCE and NO PROCESS). Thus, adulteration violations tend to be concentrated in particular violation codes.

Pathogen Adulteration Violations

Pathogens pose clearly identifiable risks to human health, and we examine next which pathogens are most important in violations and on particular food vehicles. The 7,054 adulteration violations classified as pathogens are broken down in table 4. Note that food safety risks to human health from these pathogens vary and some of these risks are avoidable with safe food handling procedures.

Salmonella was the most common pathogen adulteration violation, accounting for 63 percent of the total number of pathogen adulteration violations. *Salmonella* is a naturally occurring pathogen sometimes found in a wide variety of live fish, animals, and birds, both domestically and internationally. *Listeria* ranked second with 24.8 percent. Five violations equaled 4 percent or less of the total: histamine, aflatoxin, *Shigella*, a general group for bacteria (i.e., BACTERIA), and another general category for shipments that appear to be, in whole or part, the product of a diseased animal or from an animal which died by means other than slaughter (i.e., DISEASED).[12] Although the violation "diseased" is not a pathogen, the illness may have been associated with a pathogen so we analyzed this violation here.

Unlike other pathogen violations centered on a relatively small number of industry groups, *Salmonella* was dispersed over two dozen FDA industry groups and hundreds of product descriptions, representing specific foods. This dispersion is not unique to food imports, as *Salmonella* is commonly

Table 4
Frequency of pathogen adulteration violations, 1998-2004

Charge	Frequency	Percent
Salmonella	4,445	63.0
Listeria	1,746	24.8
Histamine	282	4.0
Bacteria (general)[1]	280	4.0
Aflatoxin	241	3.4
Shigella	48	0.7
Diseased[2]	12	0.2
Total[3]	7,054	100

[1]The text comments for "bacteria" violations frequently listed the name of a single pathogen, such as *Listeria monocytogenes, E. coli, Salmonella, Vibrio cholerae, Staphylococcus aureus, Staphylococcal enterotoxin, Clostridium botulinum,* Norwalk virus*, Enterobacter sakazakii,* and *Bacillus cereus*, or more general terms like bacteria or coliforms.

[2]Although the violation "diseased" is not a pathogen, the illness may have been associated with a pathogen so we analyzed these violations here. For this violation, the FDA found that the food appeared "to be, in whole or in part, the product of a diseased animal or of an animal which died by means other than slaughter."

[3]Percent of total does not equal 100 due to rounding.

Source: ERS calculations using FDA Import Refusal Reports, 1998-2004.

[12]Note that some pathogens do not have specific violation codes, although they are mentioned in the data. For example, there is no violation code for *Clostridium botulinum*, yet the text variable for an observation mentioned import alert 16-74, which is due to *Clostridium botulinum* (the organism that causes botulism) in salt-cured, air-dried, uneviscerated fish. The lack of a violation code reflects the low probability of occurrence.

found in many foods. Table 5 illustrates the 4,445 *Salmonella* violations; 3,007 were for fishery and seafood products (67.6 percent), 739 were for spices, flavors, and salts (16.6 percent), 139 were for vegetables and vegetable products (3.1 percent), 131 were for fruits and fruit products (2.9 percent), and 100 were for nuts and edible seeds (2.2 percent).

Out of 1,746 violations for *Listeria*, 49.6 percent of the violations were for cheese and cheese products, 21.6 percent for fishery and seafood products, 15.5 percent for fruits and fruit products, and 12.9 percent for multi-food dinners, gravies, and sauces group (table 6).

All 282 histamine violations were for fishery and seafood products. Of these, 131 were for tuna and 112 were associated with mahi-mahi (i.e., dolphin fish). Histamine is a naturally occurring toxin that can accumulate in certain types of seafood and has been linked to scrombroid poisoning outbreaks in the United States.

Table 5
***Salmonella* violations, by FDA industry group, 1998-2004**

FDA industry group	Number	Percent of total
Fishery and seafood products	3,007	67.65
Spices, flavors, and salts	739	16.63
Vegetables and vegetable products	139	3.13
Fruits and fruit products	131	2.95
Nuts and edible seeds	100	2.25
Cheese and cheese products	97	2.18
Snack food items	56	1.26
Bakery products/dough/mix/icing	34	0.76
Meat, meat products, and poultry[1]	33	0.74
Candy w/out chocolate/special/gum	30	0.67
Chocolate and cocoa products	27	0.61
Eggs and egg products	14	0.31
Whole grain/milled grain prod/starch	9	0.20
Multi-food dinner/gravy/sauce/special	8	0.18
Macaroni and noodle products	4	0.09
Beverage bases/concentrate/nectar	3	0.07
Soup	3	0.07
Cereal prep/breakfast food	2	0.04
Coffee and tea	2	0.04
Dressings and condiments	2	0.04
Food sweeteners (nutritive)	1	0.02
Gelatin/pudding mix/pie filling	1	0.02
Ice cream products	1	0.02
Milk/butter/dried milk products	1	0.02
Vegetable protein products	1	0.02
Total[2]	4,445	100

[1]Meats have very few refusals, presumably due to the pre-certification of inspection systems in exporting countries carried out by USDA/FSIS and mandated by the U.S. food safety legislation specific to meat and poultry and because the data only cover FDA-regulated products (see box, "Food Safety Oversight in the United States," p. 3).

[2]Percent total may not equal 100 due to rounding.

Source: ERS calculations using FDA Import Refusal Reports, 1998-2004.

Table 6
***Listeria* violations, by FDA industry group, 1998-2004**

FDA industry group	Number	Percent of total
Cheese and cheese products	866	49.6
Fishery and seafood products	377	21.6
Fruits and fruit products	270	15.5
Multi-food dinner/gravy/sauce/special	226	12.9
Ice cream products	4	0.2
Milk/butter/dried milk products	2	0.1
Vegetables and vegetable products	1	0.1
Total	1,746	100

Source: ERS calculations using FDA Import Refusal Reports, 1998-2004.

Shigella was the only other pathogen with its own violation code in the sample. Of the 48 violations for *Shigella*, 37 were for vegetables and vegetable products, and 11 were for fruits and fruit products. Of the vegetable violations, 31 were for celery, largely in response to an import alert calling for a DWPE for shipments from listed manufacturers, shippers, and growers due to historical problems (see Appendix C).

There were 280 violations for the general group of bacteria (i.e., BACTERIA), 61.8 percent of which were linked to cheese and cheese products and 26.8 percent linked to fishery and seafood products. The text comments for these observations frequently listed the name of a single pathogen or their toxins, such as *Listeria monocytogenes, E. coli, Salmonella, Vibrio cholerae, Staphylococcus aureus, Staphylococcal enterotoxin, Clostridium botulinum,* Norwalk virus, *Enterobacter sakazakii*,[13] and *Bacillus cereus*, or more general terms like bacteria or coliforms. Alkaline phosphatase was mentioned occasionally in the same comment with *E. coli.* Alkaline phosphatase is an enzyme produced by bacteria, and its presence in bovine milk indicates that milk has not been properly pasteurized.

[13]*Enterobacter sakazakii* can cause meningitis and septicemia. Most cases involved infants, perhaps due to powdered milk-based infant formulas contaminated with this pathogen (FDA, Aug. 2002).

Aflatoxin (a specific type of mycotoxin) is a carcinogenic byproduct of mold infestations in food crops. Of the 241 violations for aflatoxin, 42.7 percent were for the nonchocolate candy group and 32.4 percent were for nuts and edible seeds. Many of the nonchocolate candy products contained the nuts and seeds susceptible to aflatoxin contamination.

In summary, the pathogens identified in import refusal violations were found in food vehicles typically associated with such risks. More information about import alerts associated with specific pathogens is found in Appendix C.

Most Common Violations by FDA Food Industry Group

Table 7 presents the most common violation for each industry group, with industry groups ranked by total number of violations. Vegetables and vegetable products have the largest total number of violations; unsafe pesticide residues were the most cited reason. Violations include chemical residues not registered in the United States or residues that exceed tolerance levels set by the U.S. Environmental Protection Agency. The FDA provides addi-

Table 7

Most common violations, by FDA industry group, 1998-2004

FDA industry group	Total violations	Most common violations	No. of most common violations	Percent of most common violations
	Number		*Number*	*Percent*
Vegetables and vegetable products	14,463	Unsafe pesticides	3,846	26.6
Fishery and seafood products	14,109	Filthy	4,406	31.2
Fruits and fruit products	8,263	Filthy	1,960	23.7
Candy w/out chocolate/special/gum	5,132	Unsafe color	1,872	36.5
Bakery products/dough/mix/icing	3,814	Unsafe color	717	18.8
Spices, flavors, and salts	2,709	*Salmonella*	739	27.3
Soft drinks and water	2,622	Unsafe color	468	17.8
Multi-food dinner/gravy/sauce/special	2,620	Manufacturer not properly registered	488	18.6
Cheese and cheese products	2,586	*Listeria*	866	33.5
Chocolate and cocoa products	1,605	Inadequate nutrition label	366	22.8
Macaroni and noodle products	1,535	Filthy	320	20.8
Milk/butter/dried milk products	1,357	Lack of valid import milk permit	499	36.8
Nuts and edible seeds[1]	1,101	Did not file scheduled process	118	10.7
Snack food items	1,092	Unsafe color	216	19.8
Beverage bases/concentrate/nectar	998	Unsafe color	196	19.6
Whole grain/milled grain prod/starch	987	Filthy	305	30.9
Dressings and condiments	975	Did not file scheduled process	315	32.3
Soup	911	Did not file scheduled process	240	26.3
Gelatin/pudding mix/pie filling	658	Unsafe color	199	30.2
Coffee and tea	601	Label not in English	107	17.8
Food sweeteners (nutritive)	494	Inadequate nutrition label	79	16.0
Vegetable oils	395	Inadequate nutrition label	78	19.7
Cereal prep/breakfast food	347	Inadequate nutrition label	73	21.0
Baby food products	246	Inadequate nutrition label	65	26.4
Ice cream products	147	Unsafe color	48	32.7
Alcoholic beverages	126	Inadequate labeling	56	44.4
Vegetable protein products	119	Did not file scheduled process	41	34.5
Meat, meat products, and poultry[2]	114	*Salmonella*	33	28.9
Eggs and egg products	103	Did not file scheduled process	34	33.0
Filled milk/imitation milk products[3]	84	Tie for the most common charge	124	28.6
Prepared salad products	56	Did not file scheduled process	20	35.7
Annual total	70,369	N/A	N/A	N/A

Note: N/A means not applicable.

[1]One observation in the nuts and edible seeds group did not specify the violation.

[2]Meats have very few refusals, presumably due to the pre-certification of inspection systems in exporting countries carried out by USDA/FSIS and mandated by the U.S. food safety legislation specific to meat and poultry and because the data only cover FDA-regulated meat and poultry products (see box, “Food Safety Oversight in the United States,” p. 3).

[3]There was a tie for the most common charge for this group between: (1) manufacturer of a low-acid canned food or an acidified food failed to file information on its scheduled process (NO PROCESS) and (2) the manufacturer was not registered as a low-acid canned food or acidified food manufacturer.

Source: ERS calculations using FDA Import Refusal Reports, 1998-2004.

tional information about the nature of pesticide residue violations in domestic and imported produce for 2002 and 2003 (FDA, 2002; FDA, 2003). In both 2002 and 2003, more violations occurred in imported produce for unregistered pesticide residues than for violative residues that exceed U.S. tolerance levels. Unregistered chemicals may or may not pose health risks; they may be unregistered because they are not used in American production and thus vendors have not submitted data to support registration.

In fishery and seafood products and fruits and fruit products, the industry groups with the second and third largest numbers of total violations, filthy was the most common violation. Unsafe coloring was the most common violation for candy (excluding chocolate and gum), bakery products, and soft drinks. These most common violations reflect in part the nature of the products in different industry groups, including degree of processing.

Pathogens posing more immediate risks to human health appear as the most common reason for industry groups with far fewer violations. *Salmonella* contamination was the most common violation for the meat group and the spices, flavors, and salts group. Meat, poultry, and their miscellaneous products have very few FDA import refusals since inspection and certification of most of these products are under FSIS jurisdiction (see box, "Food Safety Oversight in the United States," p. 3). *Listeria* contamination was the most common violation for cheese and cheese products.

The most common violation for many other industry groups occurred when the manufacturer failed to file information on their scheduled process, when the article was filthy, an unsafe coloring was used, or when the article did not have the required nutritional information on its label.

The persistence of certain violations over time provides insight into which food safety issues are recurring. Table 8 shows the top three violations from 1998 to 2004 for the three industry groups with the greatest total violations. The top three reasons are consistent for vegetables and vegetable products and account for over half of all violations every year. Unsafe pesticide residues and process violations are the most persistent violations for this industry group. Fishery and seafood product violations are also consistent over time, with filthy, *Salmonella*, and process violations accounting for over half of all violations each year. Fruits and fruit product violations occurred most frequently due to a filthy designation, but the second and third most common reasons varied. Unsafe pesticide residues, processing violations, and inadequate nutrition labeling are most important from 2002 to 2004, while the relative importance of violations due to unsafe coloring and additives has diminished.

The persistence of the same top violations in the IRR data through 2004 suggests that there may be unresolved food safety management issues surrounding the wholesomeness of fishery and seafood products and fruit products, as well as unsafe pesticide residues and processing violations in horticultural products (both vegetables and fruits). Sanitary issues in seafood and pesticide issues in vegetables were also identified in previous studies as areas of concern in food imports. In addition to these previously identified issues, failure to file information on scheduled processes was also a significant reason for refusals.

Table 8

Three most common violations for the top three food groups refused in FDA import refusal data, 1998-2004

FDA industry group	1998	1999	2000	2001	2002	2003	2004	1998-04 Total
Vegetables and vegetable products								
Total violations	1,559	1,273	837	1,444	3,232	2,857	3,261	14,463
Most common violation	Filthy	Pesticides	Pesticides	Pesticides	Pesticides	No process	Pesticides	
Number	456	279	237	413	1,076	740	960	
Percent of total	29.3%	21.9%	28.3%	28.6%	33.3%	25.9%	29.4%	
2nd most common violation	Pesticides	No process	No process	No Process	No process	Pesticides	No process	
Number	339	267	192	340	764	550	738	
Percent of total	21.7%	21.0%	22.9%	23.6%	23.6%	19.3%	22.6%	
3rd most common violation	No process	Filthy	Filthy	Needs FCE	Needs FCE	Needs FCE	Filthy	
Number	311	235	119	266	480	458	575	
Percent of total	20.0%	18.5%	14.2%	18.4%	14.8%	16.0%	17.6%	
Fishery and seafood products								
Total violations	1,679	868	733	1,442	3,116	3,070	3,199	14,107
Most common violation	Filthy	Filthy	Filthy	Filthy	Filthy	Filthy	Filthy	
Number	619	265	230	521	857	853	1,061	
Percent of total	36.9%	30.5%	31.4%	36.1%	27.5%	27.8%	33.2%	
2nd most common violation	*Salmonella*	*Salmonella*	*Salmonella*	*Salmonella*	*Salmonella*	*Salmonella*	*Salmonella*	
Number	397	167	190	323	590	566	774	
Percent of total	23.7%	19.2%	25.9%	22.4%	18.9%	18.4%	24.2%	
3rd most common violation	No process	No process	No process	No process	Insanitary	No process	No process	
Number	123	75	69	108	313	277	217	
Percent of total	7.3%	8.6%	9.4%	7.5%	10.0%	9.0%	6.8%	
Fruits and fruit products								
Total violations	1,182	884	591	1,037	1,662	1,411	1,496	8,263
Most common violation	Filthy	Filthy	Filthy	Filthy	Filthy	Filthy	Filthy	
Number	338	335	133	207	299	319	329	
Percent of total	28.6%	37.9%	22.5%	20.0%	18.0%	22.6%	22.0%	
2nd most common violation	*Listeria*	Unsafe col	Nutrit lbl	Nutrit lbl	Pesticides	Pesticides	No process	
Number	132	86	63	118	160	52	192	
Percent of total	11.2%	9.7%	10.7%	11.4%	9.6%	10.8%	12.8%	
3rd most common violation	Unsafe add	Unsafe add	Unsafe add	No process	Nutrit lbl	Nutrit lbl	Needs FCE	
Number	132	80	42	99	147	151	183	
Percent of total	11.2%	9.1%	7.1%	9.6%	8.8%	10.7%	12.2%	

Source: ERS calculations using FDA Import Refusal Reports, 1998-2004.

Discussion

Our primary goals were to identify what the FDA import refusal data represent, which sanitary issues and other violations were most common, how such violations were distributed among different industry groups, and which violations were most persistent over time.

The IRR data have a number of limitations, thus inferences from data must be made with caution. Nevertheless, the IRR provide insight into food safety problems in food imports. And because the data span a 7-year time frame, the analysis also provides insight into where persistent failures in food safety management potentially appear in international food production, processing, and trade. The sampling strategies by the FDA and other agencies are designed to focus enforcement and inspection efforts on areas that have the highest probability of risk (Ahmed, 1991). Import refusals highlight food safety problems that appear to recur in trade (i.e., the FDA thought they would be a problem and they are) and where the FDA has focused its import alerts and monitoring efforts.

The IRR from 1998 to 2004 show consistency in the food industries and violation types that occur both over time and in comparison with previous studies of more limited detention data. We found that the three food groups with the most violations during 1998-2004 were vegetables and vegetable products (20.6 percent of total violations), fishery and seafood products (20.1 percent), and fruits and fruit products (11.7 percent). Of the 70,369 violations, 65 percent were for adulteration and 33 percent were for misbranding. The most common adulteration violations were for the appearance of filth in a food product or for failures to file information or register a specified process. When specific pathogens were identified in import refusals, they tended to be found in food products typically associated with such risks. An examination of violations in the top three industry groups revealed that refusals for sanitary violations in seafood and fruits, pesticide violations in vegetables, and unregistered processes in all three industries were persistent over time.

Future Analysis

For FDA-regulated food products, ERS plans to examine the relationship between import refusals and the volume of trade and type of exporter (i.e., level of economic development), and the relationship between types of violations, country of origin, and product characteristics. A future study will analyze violations within fruits and vegetables, since vegetable, seafood, and fruit groups were the three product categories with the most import violations from 1998 to 2004. We did not consider further investigation of seafood, since seafood import detentions were previously investigated in detail by Allshouse et al. (2003).

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APPENDIX A

Subset of FDA's Violation Code Translation[1]

Reason: ADDED BULK
Section: 402(b)(4), 801(a)(3); ADULTERATION
Charge: The food appears to have a substance added to, mixed, or packed with it so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Reason: AFLATOXIN
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain mycotoxin, a poisonous and deleterious substance which may render it injurious to health.

Reason: AGR RX
Section: 801(d)(1),(2); IMPORTATION RESTRICTED
Charge: The article appears to be a prescription drug manufactured in the United States and offered for import by other than the manufacturer and reimportation does not appear to have been authorized by the Secretary for use in a medical [text missing]

Reason: ALCOHOL
Section: 402(d)(2), 801(a)(3); ADULTERATION
Charge: The article appears to be a confectionary that bears or contains alcohol in excess of 1/2 of 1% by volume derived solely from the use of flavoring extracts.

Reason: BACTERIA
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain a poisonous and deleterious substance which may render it injurious to health. Contains [text missing]

Reason: BUTTER
Section: 402(e), 801(a)(3); ADULTERATION
Charge: The article appears to be oleo/margarine or butter with raw materials consisting in whole or in part of a filthy, putrid, or decomposed substance or the article is otherwise unfit for food.

Reason: CHLORAMP
Section: 402(a)(2)(C)(i), 801(a)(3); ADULTERATION
Charge: The article appears to contain a food additive, namely chloramphenicol, that is unsafe within the meaning of 21 U.S.C. 348.

Reason: COL ADDED
Section: 501(a)(4)(A), 801(a)(3); ADULTERATION
Charge: The article appears to bear or contain, for the purpose of coloring only, a color additive which is unsafe within the meaning of Section 721(a).

[1]In our analysis, we classified LACK NOTIF as an adulteration because the term "adulterated" was used in the charge statement. We combined violations for FILTH and FILTHY and combined PESTICIDE and PESTICIDES.

Reason: COLOR LBLG
Section: 602(e), 801(a)(3); MISBRANDING
Charge: The color additive appears to not have its packaging and labeling in conformity with such requirements as issued under section 721.

Reason: COLOR LBLG
Section: 403(k), 801(a)(3); MISBRANDING
Charge: The article appears to contain an artificial coloring and it fails to bear labeling stating that fact.

Reason: CONTAINER
Section: 402(a)(6), 801(a)(3); ADULTERATION
Charge: The container appears to be composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health.

Reason: CONTAINER
Section: 601(d), 801(a)(3); ADULTERATION
Charge: The container appears to be composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health.

Reason: CONTAINER
Section: 501(a)(3), 801(a)(3); ADULTERATION
Charge: The container appears to be composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health.

Reason: CONTAM CAN
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to be held in a container containing a poisonous or deleterious substance which may render it injurious to health.

Reason: COUMARIN
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to bear or contain Coumarin, a poisonous or deleterious substance, which may render it injurious to health.

Reason: CYCLAMATE
Section: 402(a)(2)(C); 801(a)(3)
Charge: The article appears to bear or contain cyclamate, an unsafe food additive within the meaning of Section 409.

Reason: DIET INGRE
Section: 402(a)(3), 801(a)(3); ADULTERATION
Charge: The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be for use as an ingredient in a dietary supplement and appears to be or may be otherwise unfit for food.

Reason: DIETARY
Section: 403(j), 801(a)(3); MISBRANDING
Charge: The article purports to be or is represented for special dietary uses and its label does not appear to bear the nutritional information required by regulation.

Reason: DIETARYLBL
Section: 403(s)(2)(B), 801(a)(3); MISBRANDING
Charge: The label/labeling of the dietary supplement fails to identify the product by using the term "dietary supplement."

Reason: DIOXIN
Section: 402(a)(1),402(a)(2)(A),402(a)(2)(C)(i),801(a)(3); ADULTERATION
Charge: The article appears to bear or contain dioxins and/or PCB compounds, poisonous or deleterious substances, and/or unapproved food additives, which may render it injurious to health.

Reason: DIRECTIONS
Section: 502(f)(1), 801(a)(3); MISBRANDING
Charge: The article appears to lack adequate directions for use.

Reason: DIRSEXMPT
Section: 502(f)(1), 801(a)(3); MISBRANDING
Charge: The article appears to lack adequate directions for use, and the article does not appear to be exempt from such requirements.

Reason: DISEASED
Section: 402(a)(5), 801(a)(3); ADULTERATION
Charge: The food appears to be, in whole or in part, the product of a diseased animal or of an animal which has died by means other than slaughter.

Reason: DRUG COLOR
Section: 502(m), 801(a)(3); MISBRANDING
Charge: The article appears to be a color additive, the intended use of which is for the purpose of coloring only, and its packaging and labeling do not conform to regulations issued under section 721.

Reason: DRUG GMPS
Section: 501(a)(2)(B), 801(a)(3); ADULTERATION
Charge: It appears that the methods used in or the facilities or controls used for manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing [text missing]

Reason: DRUG NAME
Section: 502(e)(1); 801(a)(3); MISBRANDING
Charge: The article appears to be a drug and fails to bear the proprietary or established name and/or name and quantity of each active ingredient.

Reason: DULCIN
Section: 402(a)(2)(C); 801(a)(3)
Charge: The article appears to bear or contain dulcin, an unsafe food additive within the meaning of Section 409.

Reason: EXCESS SUL
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain excessive sulfites, a poisonous and deleterious substance which may render it injurious to health.

Reason: FALSE
Section: 403(a)(1), 801(a)(3); MISBRANDING
Charge: The labeling appears to be false and misleading in any particular [text missing]

Reason: FALSE
Section: 502(a), 801(a)(3); MISBRANDING
Charge: The labeling for this article appears to be false or misleading in that it fails to reveal a material fact [text missing]

Reason: FALSECAT
Section: 403(t), 801(a)(3)
Charge: The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded because it purports to be or is represented as catfish, but is not a fish classified within the family [text missing]

Reason: FILTH
Section: 601(b), 801(a)(3); ADULTERATION
Charge: The cosmetic appears to consist in whole or in part of a filthy, putrid, or decomposed substance.

Reason: FILTHY
Section: 402(a)(3), 801(a)(3); ADULTERATION
Charge: The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food.

Reason: FLAVR LBLG
Section: 403(k), 801(a)(3); MISBRANDING
Charge: The article appears to contain an artificial flavoring and it fails to bear labeling stating that fact.

Reason: FLUOROCARB
Section: 402(a)(2)(A), 801(a)(3); ADULTERATION
Charge: The article appears to contain chlorofluorocarbons in violation of 21 CFR 2.125.

Reason: FLUOROCARB
Section: 501(a)(5), 801(a)(3); ADULTERATION
Charge: The article appears to be a new animal drug containing chlorofluorocarbons in violation of 21 CFR 2.125.

Reason: FLUOROCARB
Section: 601(a), 801(a)(3); ADULTERATION
Charge: The article appears to contain chlorofluorocarbons in violation of 21 CFR Part 2.125.

Reason: FORBIDDEN
Section: 801(a)(2); FORBIDDEN OR RESTRICTED IN SALE
Charge: The article appears to be forbidden or restricted for sale in the country in which it was produced or from which it was exported.

Reason: FOREIGN OB
Section: 402(a)(3), 801(a)(3); ADULTERATION
Charge: The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance, or is otherwise unfit for food in that it appears to contain foreign objects.

Reason: FRNMFGREG
Section: 502(o), 801(a)(3); MISBRANDING
Charge: The foreign manufacturer has not registered as required by section 510(i)(1).

Reason: HEALTH C
Section: 801(a)(3); 403(r)(1)(A)/(B); MISBRANDING
Charge: The article appears to be misbranded in that the label or labeling bears an unauthorized nutrient content/health claim.

Reason: HISTAMINE
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to bear or contain histamine, a poisonous and deleterious substance in such quantity as ordinarily renders it injurious to health.

Reason: IMBED OBJT
Section: 402(d)(1), 801(a)(3); ADULTERATION
Charge: The article appears to be a confectionary that has partially or completely imbedded therein any nonnutritive object.

Reason: IMITATION
Section: 403(c), 801(a)(3); MISBRANDING
Charge: The article appears to be an imitation of another food, and the label does not bear in type of uniform size and prominence, the word “imitation” and immediately thereafter, the name of the food imitated.

Reason: IMPTRHACCP
Section: 801(a)(3) , 402(a)(4); ADULTERATION
Charge: The food appears to have been prepared, packed, or held under insanitary (sic) conditions, or may have become injurious to health, due to the failure of the importer to provide verification of compliance pursuant to 21 CFR.

Reason: INCONSPICU
Section: 403(f), 801(a)(3); MISBRANDING
Charge: Information required by the Act to be on the label or labeling does not appear to be conspicuous enough as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Reason: INCONSPICU
Section: 502(c), 801(a)(3); MISBRANDING
Charge: Information required by the Act to be on the label or labeling does not appear to be conspicuous enough as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Reason: INSANITARY (sic)
Section: 501(a)(2)(A), 801(a)(3); ADULTERATION
Charge: The article appears to have been prepared, packed, or held under insanitary (sic) conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

Reason: INSANITARY (sic)
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: The article appears to have been prepared, packed, or held under insanitary (sic) conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

Reason: JUICE %
Section: 403(i)(2), 801(a)(3); MISBRANDING
Charge: It appears the food is a beverage containing vegetable or fruit juice and does not bear a statement on the label in appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice.

Reason: LABELING
Section: Section 4(a); 801(a)(3); MISBRANDING
Charge: The article appears in violation of FPLA because of its placement, form, and/or contents statement.

Reason: LACK NOTIF
Section: 301(s)
Charge: Adulterated, 801(a)(3), lack of documentation establishing that the infant formula meets all notification conditions required by 412(c) or 412(d), Prohibited Act, Section 301(s).

Reason: LACKS FIRM
Section: 403(e)(1), 801(a)(3); MISBRANDING
Charge: The food is in package form and appears not to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Reason: LACKS FIRM
Section: 502(b)(1), 801(a)(3); MISBRANDING
Charge: The article is in package form and appears not to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Reason: LACKS N/C
Section: 403(e)(2), 801(a)(3); MISBRANDING
Charge: The food is in package form and appears to not have a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count and no variations or exemptions have been prescribed by [text missing]

Reason: LACKS N/C
Section: 502(b)(2), 801(a)(3); MISBRANDING
Charge: The article is in package form and appears not to have a label containing an accurate statement of the quantity of the contents in terms of weight, measure or numerical count and no variations or exemptions have been [text missing]

Reason: LEAK/SWELL
Section: 402(a)(3), 801(a)(3); ADULTERATION
Charge: The article appears to be held in swollen containers or contains micro leaks.

Reason: LIST INGRE
Section: 403(i)(2), 801(a)(3); MISBRANDING
Charge: It appears the food is fabricated from two or more ingredients and the label does not list the common or usual name of each ingredient.

Reason: *LISTERIA*
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain *Listeria*, a poisonous and deleterious substance which may render it injurious to health.

Reason: MFR INSAN
Section: 801(a)(1); INSANITARY (sic) MANUFACTURING, PROCESSING, OR PACKING
Charge: The article appears to have been manufactured, processed, or packed under insanitary (sic) conditions.

Reason: MFRHACCP
Section: 402(a)(4), 801(a)(3)
Charge: The product appears to have been prepared, packed, or held under insanitary (sic) conditions, or it may be injurious to health, due to failure of the foreign processor to comply with 21 CFR 123.

Reason: NEEDS ACID
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: The food appears to have been prepared, packed, or held under insanitary (sic) conditions, or it may have been rendered injurious to health due to inadequate acidification.

Reason: NEEDS FCE
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: It appears the manufacturer is not registered as a low-acid canned food or acidified food manufacturer pursuant to 21 CFR 108.25(c)(1) or 108.35(c)(1).

Reason: NEW VET DR
Section: 501(a)(5), 801(a)(3); ADULTERATION
Charge: The article appears to be a new animal drug which is unsafe within the meaning of Section 512(a) in that there is not in effect an approval of an application filed with respect to its intended use or uses.

Reason: NO ENGLISH
Section: 403(f), 801(a)(3); MISBRANDING
Charge: Required label or labeling appears to not be written in English per 21 CFR 101.15(c).

Reason: NO ENGLISH
Section: 502(c); 801(a)(3); MISBRANDING
Charge: Required label or labeling appears to not be written in English in violation of 21 C.F.R. 801.15(c)(1).

Reason: NO PERMIT
Section: 1, 2; PROHIBITION WITHOUT PERMIT
Charge: The article of milk or cream is not accompanied by a valid import milk permit, as required by the Federal Import Milk Act (21 U.S.C. 141-149).

Reason: NO PROCESS
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: It appears that the manufacturer has not filed information on its scheduled process as required by 21 CFR 108.25(c)(2) or 108.35(c)(2).

Reason: NON STD
Section: 536(a),(b); NON STANDARD
Charge: It appears that the article fails to comply with applicable standards prescribed under section 534.

Reason: NONNUT SUB
Section: 402(d)(3), 801(a)(3); ADULTERATION
Charge: The article appears to be confectionery and it bears or contains a nonnutritive substance.

Reason: NONRSP-PRC
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: The article appears to have been prepared or packed under insanitary (sic) conditions whereby it may have been rendered injurious to health due to inadequate processing in that the scheduled process filed by the manufacturer [text missing]

Reason: NONRSP-VER
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: The article appears to have been prepared or packed under insanitary (sic) conditions whereby it may have been rendered injurious to health due to inadequate processing in that the scheduled process filed by the manufacturer [text missing]

Reason: NOT LISTED
Section: 502(o), 801(a)(3); MISBRANDING
Charge: It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).

Reason: NUTRIT LBL
Section: 403(q); 801(a)(3); MISBRANDING
Charge: The article appears to be misbranded in that the label or labeling fails to bear the required nutritional information.

Reason: OFF ODOR
Section: 402(a)(3), 801(a)(3); ADULTERATION
Charge: The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food. Contains an off odor.

Reason: OMITTED
Section: 402(b)(1), 801(a)(3); ADULTERATION
Charge: It appears that a valuable constituent of the article has been in whole or in part omitted or abstracted from the article.

Reason: PERSONALRX
Section: 502(a) & (f)(1), 801(a)(3); MISBRANDING
Charge: The article appears to be a drug which requires a prescription from a doctor.

Reason: PESTICIDE
Section: 402(a)(2)(B), 801(a)(3); ADULTERATION
Charge: The article appears to be a raw agricultural commodity that bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a).

Reason: PESTICIDES
Section: 402(a)(2)(B), 802(a)(B); ADULTERATION
Charge: The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be adulterated because it contains a pesticide chemical, which is in violation of section 402(a)(2)(B). Contains: [text missing]

Reason: POIS CHLOR
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain a poisonous or deleterious substance, namely chloramphenicol, which may render it injurious to health.

Reason: POISONOUS
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain a poisonous or deleterious substance which may render it injurious to health.

Reason: PRESRV LBL
Section: 403(k), 801(a)(3); MISBRANDING
Charge: The article appears to contain a chemical preservative and it fails to bear labeling stating that fact, including its function.

Reason: RX LEGEND
Section: 502(a) & (f)(1), 801(a)(3); MISBRANDING
Charge: The article appears to be a prescription drug without a prescription drug legend as required by Section 503(b)(4).

Reason: SACCHARIN
Section: 403(o); 801(a)(3); MISBRANDING
Charge: The article contains saccharin, a non-nutritive sweetener, and its label or labeling fails to bear the required warning statement.

Reason: SACCHARLBL
Section: 403(i); 803(a)(3); MISBRANDING
Charge: The article contains saccharin, a non-nutritive sweetener, and its label or labeling fails to list it as an added ingredient.

Reason: *SALMONELLA*
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain *Salmonella*, a poisonous and deleterious substance which may render it injurious to health.

Reason: *SHIGELLA*
Section: 402(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to contain *Shigella*, a poisonous and deleterious substance which may render it injurious to health.

Reason: SOAKED/WET
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: The article appears to have been prepared, packed, or held under insanitary (sic) conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health in that it appears to been held [text missing]

Reason: STD FILL
Section: 403(h)(2), 801(a)(3); MISBRANDING
Charge: The article appears to be represented as a food for which a standard of fill of container has been prescribed by regulations as provided by section 401 and it appears it falls below the standard of fill and its label does not so [text missing]

Reason: STD IDENT
Section: 403(g)(1), 801(a)(3); MISBRANDING
Charge: The food appears to be represented as a food for which a definition and standard of identity have been prescribed by regulations as provided by section 401 and the food does not appear to conform to such definition and [text missing]

Reason: STD LABEL
Section: 502(s), 801(a)(3); MISBRANDING
Charge: The article appears to not bear labeling prescribed by the performance standard established under section 514.

Reason: STD NAME
Section: 403(g)(2), 801(a)(3); MISBRANDING
Charge: It appears to be a food for which a definition and standard of identity have been prescribed by regulations under section 401 and appears to not be labeled with the name specified in the definition and standard.

Reason: STD QUALIT
Section: 403(h)(1), 801(a)(3); MISBRANDING
Charge: The article appears to be represented as a food for which a standard of quality has been prescribed by regulation as provided by Sec. 401 and it appears its quality falls below such standard and its label does not so [text missing]

Reason: STERILITY
Section: 501(a)(2)(A), 801(a)(3); ADULTERATION
Charge: The article appears to have been prepared, packed, or held under insanitary (sic) conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

Reason: STERILITY
Section: 501(a)(1), 801(a)(3); ADULTERATION
Charge: The article appears to consist in whole or in part of any filthy, putrid, or decomposed substance.

Reason: SUBSTITUTE
Section: 402(b)(2), 801(a)(3); ADULTERATION
Charge: It appears that a substance has been substituted wholly or in part for one or more of the article's ingredients.

Reason: SUBSTITUTE
Section: 501(d)(2), 801(a)(3); ADULTERATION
Charge: It appears to be a drug that a substance has been substituted wholly or in part.

Reason: SULFITELBL
Section: 403(a)(1), 801(a)(3); MISBRANDING
Charge: The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded because 1) it appears to contain sulfites, but the label fails to declare the presence of sulfites, a fact [text missing]

Reason: TRANSFAT
Section: 403(q), 801(a)(3); MISBRANDING
Charge: The product is misbranded under Section 403(q) because the nutrition label does not provide all of the information required by 21 CFR 101.9(c); specifically, the label does not bear the amount of trans fat [21 CFR 101.9 (c) (2) (ii)].

Reason: UNDER PRC
Section: 402(a)(4), 801(a)(3); ADULTERATION
Charge: The article appears to have inadequate processing in having been prepared, packed, or held under insanitary (sic) conditions whereby it may have been rendered injurious to health.

Reason: UNSAFE ADD
Section: 402(a)(2)(C)(i), 801(a)(3); ADULTERATION
Charge: The article appears to bear or contain a food additive which is unsafe within the meaning of Section 409. Contains [text missing]

Reason: UNSAFE COL
Section: 402(c), 801(a)(3); ADULTERATION
Charge: The article appears to be, or to bear, or contain a color additive which is unsafe within the meaning of Section 721(a).

Reason: UNSAFE COL
Section: 501(a)(4)(B), 801(a)(3); ADULTERATION
Charge: The article appears to be a color additive for the purposes of coloring only in or on drugs or devices and is unsafe within the meaning of Section 721(a).

Reason: UNSAFE SUB
Section: 402(a)(2)(A), 801(a)(3); ADULTERATION
Charge: The article appears to bear or contain a substance which is unsafe within the meaning of Section 406.

Reason: UNSFDIETLB
Section: 402(f)(1)(A), 801(a)(3); ADULTERATION
Charge: The article appears to be a dietary supplement or ingredient that represents a significant or unreasonable risk of illness or injury under customary conditions of use.

Reason: USUAL NAME
Section: 403(i)(1), 801(a)(3); MISBRANDING
Charge: It appears that the label does not bear the common or usual name of the food.

Reason: VETDRUGRES
Section: 402(a)(2)(C)(ii); 801(a)(3); ADULTERATION
Charge: The article appears to contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512. Product contains [text missing]

Reason: VITAMN LBL
Section: 403(a)(2), 801(a)(3); MISBRANDING
Charge: The food appears to be subject to section 411 and its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

Reason: WARNINGS
Section: 502(f)(2), 801(a)(3); MISBRANDING
Charge: It appears to lack adequate warning against use in a pathological condition or by children where it may be dangerous to health or against an unsafe dose, method, administering duration, application, in manner/form, to [text missing]

Reason: WRONG IDEN
Section: 403(b), 801(a)(3); MISBRANDING
Charge: The article appears to be offered for sale under the name of another food.

Reason: YELLOW #5
Section: 402(c), 403(m), 801(a)(3); ADULTERATION, MISBRANDING
Charge: The food appears to bear or contain the color additive FD & C Yellow No. 5, which is not declared on the label per 21 CFR 74.705 under section 721.

Source: This list is a subset of charge codes from the FDA's Violation Code Translation, revised on 05-Dec-2006, 10:01 a.m., www.fda.gov/ora/oasis/ora_oasis_viol.html. The list constitutes the charge codes mentioned in the IRR data sample, as compiled by the authors.

APPENDIX B

General Procedures for the FDA's Import Program

To ensure that the FDA is notified of all regulated products imported into the United States, the importer or his/her representative (i.e., broker or *importer of record*), must file an entry notice and bond with U.S. Customs and Border Protection (CBP) pending a decision regarding the admissibility of the product (FDA, March 17, 1999). FDA inspection and enforcement procedures for imports rely on coordination with Customs with whom the FDA has a longstanding working relationship.

Customs has two general categories of review for foods: formal and informal entries. Formal entries are generally necessary for food imports valued at more than $2,500 and require a broker-facilitated entry whereby the broker posts a bond in case the importer does not follow through on its obligations for any potential duties, taxes, and charges accrued (i.e., the bond is collateral). Informal entries for food shipments include shipments of food products valued at less than $2,500 and include importers with established track records and those who pose relatively low risk (e.g., small shipments of tortillas from Mexico) (Customs, June 29, 2007).

Most food imported into the United States for resale are formal entries, which must first undergo Custom's clearance and FDA review. The FDA is notified by CBP of the entry; FDA then performs an electronic document review to ensure that the shipment contains the necessary information and makes a decision as to the article's admissibility. If the FDA does not wish to examine the entry, the product proceeds into U.S. commerce.

Generally, if FDA decides to examine an entry, an FDA representative will collect a sample from the shipment for evaluation. During an FDA *field examination*, an FDA representative performs a physical, sensory examination on a product for such things as rodent or insect activity, inadequate refrigeration, and label compliance to support a specific decision (FDA, Feb. 8, 2007). This FDA representative may be FDA personnel, contractors hired by FDA, or CBP under a prearranged agreement. The field examination may be conducted on products discharged from vessels onto the wharves (piers); pier sheds; from products in trains, trucks, freezers, and containers at border entry points (i.e., land, air, or sea); or on products set aside for FDA examination (FDA, Feb. 8, 2007).

In addition to catching obvious contamination, a field examination may also uncover an unusual color that might trigger a lab analysis to test for illegal color additives. A label examination is the only valid field examination to determine if the article is in compliance with mandatory labeling requirements, such as required nutrition labeling (FDA, Feb. 8, 2007). Field examinations may not be used for suspected microbiological contamination or for pesticides, industrial chemicals, aflatoxins, and other toxic elements (FDA, Feb. 8, 2007). Lab testing is required to detect the presence of these adulterants. During a field examination, FDA personnel follow FDA's Investigations Operations Manual (FDA, Feb. 8, 2007).

If the examination and analysis indicate the product is in compliance, the shipment may be released into U.S. commerce. If there is a violation, the product will be refused admission. The Food, Drug, and Cosmetic Act, Section 801, directs FDA to refuse admission of any article that "appears" to be in violation of the Act.

When the FDA requests a sample of an article offered for import, the owner or consignee shall hold the shipment and not distribute it until further notice is received regarding the results of the examination. If it appears an article is in violation, the FDA issues a Notice of Detention and Hearing to the owner or consignee specifying a place and period of time whereby the individual may introduce testimony either verbally or in writing.

The importer is provided an opportunity to submit a petition to recondition the product into compliance. The owner or consignee may submit an application to the FDA to relabel or perform other actions to bring the article into compliance or render the article other than a food. An application to relabel or perform other actions to bring the article into compliance must contain a detailed proposal, specifying the time and place where such operations will be carried out and the approximate completion time according to regulation. All petitions to recondition a product are subject to FDA review and approval.

If the product is refused, the importer is required to either re-export or destroy the article under CBP or other approved supervision. If the refused product is not destroyed or re-exported, CBP issues a notice for redelivery to the importer of record. Failure to redeliver the refused product may result in CBP's assessing liquidation damages against the importer's bond.

Import Alerts

Import alerts were developed by the FDA to communicate guidance for import coverage to FDA personnel in field offices, as well as to identify and disseminate import information on problems and violative trends. Import alerts facilitate uniform and effective import coverage. They identify problem commodities and/or shippers, such as those that have met the criteria for DWPE. We performed a rough tabulation of the import alerts posted on the FDA Web site on July 23, 2007. On that date, a total of 127 alerts involving food imports were posted (see http://www.fda.gov/ora/fiars/ora_import_foods.html). Our count excluded food additives, multiple food warehouses, and miscellaneous food items, yet included import alerts for foods in the generic FDA import alert category (No. 99), a catch-all category for items, such as animal drugs, feed and food, medical devices, and items not found in other industry codes. FDA classification and terminology has changed over time, so this count may not perfectly align with terminology used at other points in time. For example, the FDA no longer uses the term "automatic detention," yet the term still appears in several import alerts which we count under the "other" category. Despite the rough nature of this table, it is important to note that 103 out of 127 import alerts called for DWPE (over 81 percent).

Appendix table

Import alerts posted on the FDA's Web site on July 23, 2007

FDA industry group	DWPE	DWPE and surveillance	DWPE and intensified coverage	DWPE and guidance	Surveillance[1]	Intensified coverage	Guidance	Other[2]	Total alerts
Fishery and seafood products	31	0	0	0	0	1	3	2	37
Fruits and fruit products	10	2	1	0	2	0	0	0	15
Vegetables and vegetable products	9	1	0	0	0	0	0	5	15
FDA catch-all group No. 99[3]	9	0	0	2	0	0	0	0	11
Spices, flavors, and salts	5	1	0	0	0	0	0	0	6
Candy w/out choc/special/gum	4	0	0	0	0	0	0	1	5
Nuts and edible seeds	3	0	1	0	1	0	0	0	5
Cheese and cheese products	3	0	1	0	0	0	0	0	4
Food sweeteners (nutritive)	3	0	0	0	0	0	1	0	4
Meat, meat products, and poultry	1	0	0	0	2	0	0	0	3
Whole grain/milled grain prod/starch	2	0	0	0	0	0	0	0	2
Soft drinks and water	2	0	0	0	0	0	0	0	2
Vegetable oils	1	0	0	0	1	0	0	0	2
Coffee and tea	1	0	0	0	0	0	1	0	2
Multi-food dinner/gravy/sauce/special	1	0	0	0	0	0	0	1	2
Baby food products	1	0	0	0	0	0	0	1	2
Macaroni and noodle products	0	2	0	0	0	0	0	0	2
Dietary conv food/meal replacements	1	0	0	0	0	0	0	0	1
Prepared salad products	1	0	0	0	0	0	0	0	1
Bakery products/dough/mix/icing	1	0	0	0	0	0	0	0	1
Cereal prep/breakfast food	1	0	0	0	0	0	0	0	1
Eggs and egg products	1	0	0	0	0	0	0	0	1
Beverage bases, concentrate, and nectar	1	0	0	0	0	0	0	0	1
Chocolate and cocoa products	0	0	0	0	0	0	0	1	1
Soup	0	0	0	0	0	0	0	1	1
Snack food item	0	0	0	0	0	0	0	0	0
Milk/butter/dried milk products	0	0	0	0	0	0	0	0	0
Ice cream products	0	0	0	0	0	0	0	0	0
Filled milk/imitation milk products	0	0	0	0	0	0	0	0	0
Vegetable protein products	0	0	0	0	0	0	0	0	0
Dressings and condiments	0	0	0	0	0	0	0	0	0
Alcoholic beverages	0	0	0	0	0	0	0	0	0
Gelatin/rennet/pudding mix/pie filling	0	0	0	0	0	0	0	0	0
Total	92	6	3	2	6	1	5	12	127

[1]Includes entry surveillance, increased surveillance, or surveillance.

[2]For example, some still list the outdated term "automatic detention" with no mention of DWPE in the text.

[3]This group (Industry No. 99) is a catch-all group for animal drugs, feed and food, medical devices and others that don't cleanly fit elsewhere. In our tablulations, we only included import alerts for foods, which were usually multiple foods, spanning more than one industry group.

Note: The list of active import alerts is constantly changing. Therefore, this list represents one snapshot in time.

Source: ERS calculations using information from www.fda.gov/ora/fiars/ora_import_alerts.html on July 23, 2007.

Detention Without Physical Examination

When import alerts call for a detention without physical examination (DWPE), this means subsequent entry lines for a grower/product will be refused entry into U.S. commerce unless the importer presents evidence, such as test results, to FDA proving the item meets safety requirements (FDA, CFSAN, Feb./March 2002). This procedure is an administrative act based on past history and/or other information indicating the product may be violative or when violative findings for a grower/shipper are of a nature that suggests future entry lines from that grower/shipper may also be in violation (FDA, CFSAN, Feb./March 2002). DWPE is imposed to protect consumers from potentially contaminated subsequent entry lines until the firm implements

appropriate corrective measures. Occasionally, the FDA identifies products from an entire country or geographic region for DWPE when violative conditions appear to be geographically widespread. Detention recommendations of this breadth are rare and initiated only after other avenues for resolving the problem have been exhausted.

Computerization

To ensure the expeditious handling of imported products, FDA automated its import operations. By combining FDA's Operational and Administrative System for Import Support (OASIS) and CBP's Automated Commercial System (ACS), an FDA reviewer is able to efficiently evaluate and process each import entry. The import filer transmits the required shipment-specific FDA data into the ACS. Within a few minutes, the filer receives notification that either their shipment has been released or the FDA wishes to review it. This system provides the FDA with immediate data on imported products, information on potential problems, and maintains national historic data files to develop profiles on specific products, shippers, and manufacturers. Eventually, all filers processing entries through ACS will provide FDA with information electronically.

In addition to required entry forms, certain products require shippers to present specific information to FDA at time of importation. For example, foreign firms must register and file processing information before shipping any low-acid canned food or acidified low-acid canned food to the United States. The Federal Import Milk Act also requires a permit for milk and cream (including sweetened condensed milk) imported into the United States.

Source: Most of this appendix is an excerpt from the U.S. Food and Drug Administration, Office of Regulatory Affairs, "Import Program System Information," March 17, 1999, www.cfsan.fda./~lrd/imp-info.html. At the time of publication, it was difficult to find adequate documentation of the import process on the FDA Web site. In particular, chapters of the FDA's Web manual, which is also called "Import Program System Information" (www.fda.gov/ora/import/ora_import_system.html), were unavailable because they were under revision. The most up-to-date information can be found in the "Inspection Operations Manual, 2007," which is the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors (www.fda.gov/ora/inspect_ref/iom/). Another important document, "FDA Import Procedures" (www.cfsan.fda.gov/~lrd/import.html) was published in 1996. It is currently being reviewed in light of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which became effective December 12, 2003. For specific information on U.S. Customs procedures, requirements, and forms, see CBP, Dec. 5, 2006. Administrative and legislative changes are always under consideration (CBP, Dec. 5, 2006). Therefore, the information on the import process described is subject to change and should be considered as background only. For detailed, current information, we suggest readers contact the FDA or CBP directly.

Appendix C

Import Alerts and Pathogen Data

Salmonella

Two import alerts were frequently mentioned in association with refusals for *Salmonella* violations for fishery and seafood products. Import alert 16-18 calls for detention without physical examination (DWPE) of all fresh, frozen, and raw shrimp from Bangladesh, Hong Kong, Indonesia, Taiwan, and Thailand due to problems with *Salmonella*, decomposition, and filth (shrimp from India are treated separately in import alert 16-35). Import alert 16-81 calls for DWPE of multiple seafood products from a list of firms and countries that do not readily fit into previously existing import alerts. Import alerts are added, revised, and deleted as deemed necessary by FDA. For example, import alerts 16-56, 16-65, and 16-70 were canceled once they were condensed into import alert 16-81. Some alerts specified in the *Salmonella*-fishery/seafood data calling for DWPE cover all frozen raw fish from Thailand (16-17), specific types of raw molluscan seafood from specific firms and shippers (16-50), and frog legs from specific shippers (16-12).

Of the *Salmonella* violations for spices, flavors, and salts, two commonly mentioned import alerts in the text variable called for DWPE for all shipments of black pepper from India (28-02) and all shipments of whole and cracked black and white pepper from Brazil (28-04). Import alert 99-19 is broad based and covers a wide range of food products found to contain *Salmonella* from specific manufacturers and shippers in multiple countries (excluding black pepper covered in the previously mentioned import alerts 28-02 and 28-04, coconut in import alert 23-12, and seafood under import alerts specifically for seafood). In particular, 99-19 is an extensive 60-page document that lists firms facing DWPE because of historical problems with *Salmonella* in shipments of many types of spices, fruits, vegetables, and exotic meats.

Another broad-based import alert (99-23) was mentioned frequently in the text comments. This alert called for DWPE of raw/fresh and raw/fresh/refrigerated fruits and vegetables due to a history of one or more types of pathogenic contamination. This import alert specifies four OASIS violation codes: those for *Salmonella*, *Shigella*, *E. coli*, and a general category of bacteria. Obviously, there is not a one-to-one link between an import alert and a violation for a pathogen. Also, note that multiple pathogens may be present on a food at the same time. Fresh produce was identified in 1997 as an area of concern in President Clinton's "Food Safety Initiative," and this alert calls for DWPE of specific fruits and vegetables from specific growers, manufacturers, and shippers. For example, DWPE of shipments of cantaloup, green onions, broccoli (Rapini), cilantro, and culantro from particular firms in Costa Rica and Mexico were on the DWPE list due to past problems with *Salmonella*.

Another import alert (22-01) was added as a result of multi-state outbreaks in 2000, 2001, and 2002 from Mexican cantaloup contaminated with *Salmonella*. This import alert calls for DWPE of all fresh, frozen, and processed (including chopped or sliced for salad bars), or frozen cantaloup

from Mexico. The import alert lists a handful of firms exempt from DWPE and lists firms certified as being compliant with good agricultural practices under a 2005 Memorandum of Understanding with Mexico.[1]

[1] The FDA signed a Memorandum of Understanding (MOU) with the Mexican Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA) on Oct. 26, 2005 regarding imports of Mexican cantaloup into the United States (FDA, IA22-01, Aug. 25, 2006). Under this MOU, SENASICA identifies specific Mexican cantaloup firms as being in compliance with their version of FDA's Good Agricultural Practices.

Listeria

Many of the cheese and cheese product refusals provided accompanying text regarding import alerts for DWPE of soft cheese (soft and soft ripened) made from unpasteurized milk from France (12-03) and all other cheese and cheese products (12-10). Another import alert called for DWPE and intensified coverage of St. Jorges brand and all other brands of cheese from the Azores (a Portuguese archipelago), either imported directly or through Canada (12-07). Of the fishery and seafood violations for *Listeria*, many were processed seafood and analogue seafood (i.e., surimi) products under import alert 16-39 since these products are intended to be eaten without further heat treatment or with minimal heating insufficient to destroy *Listeria*, if present. Additionally, there has been an ongoing problem with *Listeria* in avocado products from Mexico since June 1993 when an importer's frozen guacamole was tested by the FDA and found positive for *Listeria* (FDA, IA 21-12, Feb. 3, 2006). Import alerts were initially put in place in 1993 for guacamole and avocado pulp whereby districts may detain, without physical sampling and analysis (i.e., DWPE), avocado products from specific firms. Later, the import alert was expanded to include additional firms and other frozen and refrigerated avocado products.

Histamine

Of the histamine violations, import alert 16-05 for all raw, fresh, or frozen mahi-mahi shipments was commonly mentioned in the text comments. This import alert calls for DWPE on imports from Ecuador and Taiwan and intensified coverage of imports from all countries except Japan (excluding shippers listed as exempt in the import alert). A second import alert (16-105), calls for DWPE of all seafood and seafood products from certain firms, except for select products covered in other import alerts. In particular, this import alert mentioned several firms in Indonesia and Vietnam with a history of problems with histamine and decomposition in tuna shipments.

Shigella

Of the *Shigella* violations, 31 were for celery and appear to be largely in response to import alert 99-23. This import alert calls for a DWPE of over a dozen raw/fresh and raw/fresh/refrigerated fruits and vegetables from listed manufacturers, shippers, and growers due to the presence of pathogen contamination, which may include *Salmonella*, *Shigella*, *E. coli*, or other bacteria. Fresh cantaloup was the most common fruit with the *Shigella* violation code, which fell under import alert 99-23.

"Bacteria"

The majority of import alerts mentioned in the narrative text for violations with the general bacteria violation code (i.e., BACTERIA) have been covered above. Additionally, import alert 16-13 calls for a DWPE on ancho-

vies and anchovy sauce from the Philippines due to historical problems with filth, *E. coli*, and coliforms.

Aflatoxin

Many aflatoxin violations were associated with nuts and nut-containing products, such as nut candy, peanut candy, or snacks with nuts from specific firms in over 20 countries (23-11).

Source: Constructed by the authors using data from the text variable in the FDA Import Refusal Reports, 1998-2004, and information from FDA's Import Alert Retrieval System (FIARS), www.fda.gov/ora/fiars/ora_import_alerts.html.