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FDA Refusals of Imported Food Products by Country and Category, 2005–2013

John Bovay

United States Department of Agriculture

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FDA Refusals of Imported Food Products by Country and Category, 2005–2013

John Bovay

Abstract

This report analyzes food import shipments that were refused entry into the United States by the U.S. Food and Drug Administration (FDA) from 2005 to 2013 and assesses patterns in import refusals. It highlights which products are most often found in violation, identifies the most common types of violations, and discusses country-product patterns of note and changes in import refusal patterns over time. The industry group with the most shipments refused over 2005-13 was fishery and seafood products, with 20.5 percent of refused shipments. This was followed by vegetables/vegetable products (16.1 percent) and fruit/fruit products (10.5 percent). The share of refusals for fishery/seafood products was slightly higher over 2005-2013 than over 1998-2004, while the shares for vegetables and fruit both decreased. The share of refusals for spices, flavors, and salts increased substantially, with more than one-third of refusals originating from India. Sanitary violations were the most common reason for a shipment refusal in both fishery/seafood products and fruit/fruit products, whereas pesticide residues were the most common violation for vegetables. FDA inspectors target certain firms or product categories that are prone to greater risks, so records do not represent a random sample of all U.S. food imports.

Keywords: U.S. Food and Drug Administration, food safety, food imports, inspections, refusals, adulteration, misbranding, Import Alerts

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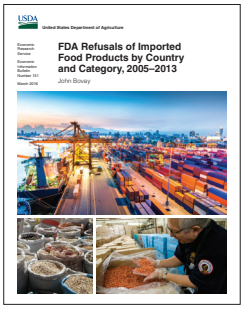

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FDA Refusals of Imported Food Products by Country and Category, 2005–2013

John Bovay

What Is the Issue?

The U.S. Food and Drug Administration (FDA) is responsible for overseeing the safety of most food sold in the United States, including food imported from foreign countries. FDA has the resources to inspect only a handful of foreign facilities, and physically examines less than 1 percent of shipments offered for import. FDA uses a risk-based prediction algorithm to prioritize inspections. To better understand the countries and products that pose the greatest risk for U.S. consumers, ERS researchers have analyzed FDA import refusal patterns. This report reviews import refusal patterns over 2005-13 for a variety of subgroups (e.g., product categories, violations) while paying special attention to shipments from the three exporting countries with the most shipments refused (Mexico, India, and China). For many countries, the most commonly refused products are correlated with the most commonly exported products.

What Did the Study Find?

The number of food shipments refused by FDA inspectors has remained relatively stable, despite an increasing volume of food imports over 2005-13. Thus, the number of shipments refused declined relative to the volume of imports. This decline may reflect improvements in compliance with U.S. laws among foreign producers and importers, or it may reflect FDA's limited resources and capacity to inspect, detain, and refuse imported food. This is difficult to determine because FDA does not randomly sample import shipments for inspection. Instead, FDA uses a risk-based prediction algorithm to determine whether shipments should be inspected in the field or a laboratory, and also relies on *Import Alerts*, which provide guidance on firms and products that meet the criteria for detention without physical examination and require the importer to produce evidence that no violation is present, before the shipment may enter general commerce.

The following food product categories accounted for the majority of shipments refused:

1. Fishery and seafood products (20.5 percent of all refusals);
2. Vegetables and vegetable products (16.1 percent);
3. Fruit and fruit products (10.5 percent);

ERS is a primary source of economic research and analysis from the U.S. Department of Agriculture, providing timely information on economic and policy issues related to agriculture, food, the environment, and rural America.

4. Spices, flavors, and salts (7.7 percent); and
5. Candy without chocolate and chewing gum (7.2 percent).

For both fishery/seafood products and fruit/fruit products, the most common reason for a shipment to be refused was sanitary violations or, specifically, "filth." Vegetables/vegetable products were most commonly refused because of unsafe pesticide residues. The most common violation for spices, flavors, and salts was the presence of *Salmonella* bacteria. The use of an unsafe color additive was the most common violation for non-chocolate candies and gum.

Of the 142,679 violations reported, 57 percent were for adulteration (i.e., a problem relating to safety issues, packaging integrity, or sanitation), and 41 percent were for misbranding, which may include untruthful or misleading labels or labels that lack English. Although adulteration generally poses a greater risk to human health than misbranding, improper labeling, such as a failure to identify an allergen, may lead to illness and fatalities in some cases.

The countries with the most food shipments refused by FDA—Mexico, India, and China—have distinct sets of product categories (vegetables, spices, and seafood, respectively) that have been subject to the most refusals. The persistence of the same problems, year after year, in food import shipments indicates that FDA's inspection regime has not completely deterred producers and importers from offering food shipments for import that violate U.S. laws. Overall, the patterns of refused import shipments correlate with the volumes of imports (of various product categories and from various countries), but data are unavailable to perform a more precise analysis of this relationship.

How Was the Study Conducted?

ERS researchers analyzed FDA data on food shipments offered for import into the United States and refused entry over 2005–2013. Researchers tabulated refusals by country, industry group, and type of violation, and assessed patterns in refusals. Patterns in adulteration violations and violations for pathogen and toxin adulteration were examined closely because of their clear links to foodborne illness in humans. Special attention is given to persistent patterns in import refusals for shipments from Mexico, India, and China, the three countries with the most shipments refused over the period of analysis.

The nonrandom nature of FDA sampling means that researchers cannot draw inferences about the relative safety of food produced in various countries or the relative risk of certain food products. Instead, the conclusions drawn in this report highlight FDA refusals that reveal recurring patterns of import violations in food products, which have repeatedly attracted the attention of FDA inspectors.

FDA Refusals of Imported Food Products by Country and Category, 2005–2013

Introduction

The imperfect provision of safe food is a major problem internationally. Around the world, more than 2,000 children die every day from diarrheal disease—much of which is caused by contaminated food (Centers for Disease Control and Prevention, 2013). In the United States, about 3,000 people die each year from all foodborne illnesses (USDA-Food Safety and Inspection Service, 2013). But with the share of imported food consumed in the United States continuing to rise, many have expressed concern about the safety of these imports. As Jerardo (2015b) reports, the share of food and beverages imported, by weight, in the United States rose from around 11 percent in 1990 to 17 percent in 2009. For certain categories, growth in imports has been even stronger: by weight, seafood imports grew from 56 percent to 85 percent over 1990-2009, fruit and nut imports grew from 28 to 39 percent, and vegetable imports grew from 3 to 18 percent. The total volume of import shipments for food categories under the jurisdiction of FDA was over 61 million tons in 2014 (Jerardo, 2015a).

Produce (i.e., vegetables and fruits) and seafood are the food categories most frequently linked to foodborne illness outbreaks among FDA-regulated commodities (Painter et al., 2013),[1] so the surge in imports of these product categories are of special concern, as echoed by media commentators such as Philpott (2012) and *The New York Times* editorial board (2013).

The U.S. Food and Drug Administration (FDA) oversees the safety of most seafood and all fresh and processed produce in the United States, among other products (see box, "Federal Food Safety Oversight"), and inspects imports at the port of entry for signs of adulteration or misbranding. All imports refused entry are reported in the OASIS (Operational and Administrative System for Import Support) database, which includes information on all refused imports, as well as other data that FDA uses in determining whether to inspect a given shipment. FDA makes an abstract of specific data fields in the OASIS database available to the public on its website; this abstract is known as the Import Refusal Report.[2]

This report analyzes the food imports refused entry into the United States from 2005 to 2013. It identifies patterns in FDA import refusals by product category and by violation category, which

[1]See box, "Federal Food Safety Oversight," for details on the regulatory authorities of FDA and USDA's Food Safety and Inspection Service.

[2]Through an interagency request to FDA, ERS obtained a subset of the OASIS with a few additional variables (importer's product description, corrected product description, and additional narrative remarks on the reason for refusal) not disclosed in the Import Refusal Report, for all FDA import refusals from 2005 to 2013. As a condition for using this data set, ERS researchers agreed not to share the data without FDA consent. See Appendix for additional information on FDA's import inspection program.

Federal Food Safety Oversight

The U.S. Food and Drug Administration (FDA) was founded in 1862 as the Division of Chemistry within the newly created U.S. Department of Agriculture (USDA). In 1906, Congress passed two separate acts that, respectively, charged one branch of USDA with inspecting meat, and the predecessor of FDA with ensuring the safety of all other foods. Thus, both the USDA–Food Safety and Inspection Service (FSIS) and FDA regulate the safety of food in the United States today, with jurisdiction largely divided according to the roles established by the 1906 legislation. (FDA is now part of the U.S. Department of Health and Human Services.) FSIS inspects most meat, poultry, and processed egg products (FDA, 2014b), and, as a result of the 2008 Farm Bill, has been responsible for the inspection of the Siluriformes order (including catfish) since March 1, 2016 (USDA-FSIS, 2015b). FDA is responsible for ensuring the safety of all other domestic and imported foods marketed in interstate commerce, food additives, animal feed, and veterinary drugs. In addition, FDA is responsible for inspecting the safety of sandwiches (made in central facilities for off-site consumption) and certain products that contain a small amount of meat and poultry (by volume), as well as game and exotic meats (including alligator, rabbit, and quail). Both FSIS and FDA require that producing facilities register with their respective agencies in order to supply meat, poultry, or egg products for interstate commerce.

The U.S. Environmental Protection Agency (EPA) establishes standards for the use of pesticides and acceptable levels of pesticide residues in food and animal feed (EPA, 2013). FDA and FSIS enforce the residue standards for the commodities under their respective jurisdictions. The food safety efforts of FSIS, FDA, and EPA are also supported by various State, tribal, and local government entities.

FDA has the authority to inspect all food in categories under its jurisdiction at the point of entry into the United States, but has the resources to physically inspect less than 1 percent of all regulated food imports into the United States (FDA, 2014a). Thus, FDA inspectors must use a risk-based prediction algorithm to target shipments posing a greater risk to human health or more likely to be in violation of U.S. laws. Among the factors accounted for by FDA's current algorithm are inherent product risks, history of field examinations and lab analyses associated with a firm or product, and results of facility inspections (FDA, 2014e). FDA performs its border inspections in coordination with Customs and Border Protection (CBP), an agency of the Department of Homeland Security (FDA, 2009). FSIS also works with CBP to inspect food shipments under its jurisdiction (FSIS, 2015a).

may help Federal inspectors, especially as FDA begins to inspect foreign facilities for the first time as part of implementing the Food Safety Modernization Act. The report also provides updated information about the product-country pairs that have repeatedly raised concerns for FDA inspectors and have been refused. The most commonly refused products from various countries tend to reflect the most commonly exported products from those countries. The research shows that problems with adulterated and misbranded food import shipments persist, despite FDA's vigilant deterrence and detection efforts. However, as the total volume of imported food has risen, the share of shipments refused has declined. This decline may reflect improvements in compliance with U.S. laws among foreign producers and importers, or it may reflect FDA's limited resources and capacity to inspect, detain, and refuse imported food.

This report updates the results of Buzby and colleagues (2008), who analyzed similar data for 1998-2004. It reviews variations in import refusal patterns across years for a variety of subgroups (e.g., product categories, violations) and examines patterns in import refusals for the three most commonly refused producing countries and product categories.

Several other studies have used FDA Import Refusal Reports data in other contexts. Buzby and Roberts (2011) showed that lower income countries were subjected to more import refusals per dollar of exports to the United States, and that vegetables/vegetable products had more refused shipments per dollar of imports than fishery/seafood products or fruit/fruit products. They also showed that poorer countries were more likely to have sanitary, *Salmonella*, and pesticide adulteration violations than high-income countries, which tended to have more recordkeeping and information violations. Gale and Buzby (2009) focused particularly on FDA refusals of food shipments from China and found recurring problems with filth, unsafe additives, labeling, and veterinary drug residues in fish and seafood. Baylis and colleagues (2009) found that newer exporting countries face fewer import refusals, which is to be expected given the use of FDA's risk-based inspection targeting systems (PREDICT and OASIS). The same article also suggests that lobbying by U.S. companies in a given industry may increase import refusals for that industry. Tran and colleagues (2011) used a gravity model to examine FDA import refusals of crustaceans from six Asian countries; veterinary drug residues accounted for 24 percent of crustacean refusals in 2003 but just 3 percent by 2010. They showed that tighter standards for residues of chloramphenicol (a veterinary drug) would most adversely affect the leading exporters of crustaceans.

Data on Import Refusals

This report uses a complete set of FDA data on import shipments that were refused entry into U.S. markets from 2005 to 2013. In the OASIS data set, FDA records all shipments that have been refused entry, detailing date of submission, product description, country of origin, manufacturer address, declared value of shipment, and one or more violation codes with accompanying narrative remarks. The richness and completeness of this data set allows insights into the problems with food shipments offered for import into the United States.

The "narrative remarks" text explains (with more detail than a charge code) why a shipment was refused. Often, this text cites an Import Alert associated with the shipment. FDA regularly issues Import Alerts pertaining to a particular importer, manufacturer, or country-commodity pair. In most cases, Import Alerts inform FDA field staff that the agency has sufficient evidence to allow for detention without physical examination (DWPE). Products are subject to DWPE based upon past violations, which means that future imports of the product are detained at the port of entry unless the importer can provide evidence (via testing or other means) to FDA proving that the shipment is not in violation (FDA, 2013a). (See Appendix for more details on Import Alerts.)

Import Alerts are not the only criteria that may trigger increased surveillance of a particular importer, producer, or commodity, but they do indicate that FDA is focusing on certain products. At least 16,682 of the 87,552 shipments refused over 2005-2013 (19.1 percent) had an Import Alert listed in the "narrative text" accompanying the entry.[3] Additional import refusals may have been based on Import Alerts, but do not have an Import Alert listed in the narrative text.

Since FDA has neither the personnel nor the funding to physically inspect more than 1 percent of all shipments (FDA, 2014a), it targets inspections for the sake of efficiency and as a deterrence mechanism. Thus, the OASIS data are not a representative sample of all food shipments offered for import in violation of FDA laws, and conclusions such as "X country ships the most unsafe food" or "Y food is most likely to be adulterated" are unsound. Instead, this report analyzes *patterns* in the shipments of food both inspected and refused by FDA, which are predicated on FDA's targeting algorithms and its priorities in using limited resources to reduce the probability that harmful food products enter the United States. The patterns identified in this report highlight the most frequently detected problems in shipments of FDA-regulated food. They allow insights into the types of food products and the countries that have frequently been under FDA scrutiny and often found to have adulteration or misbranding violations. The persistence of the same problems, year after year, in food import shipments suggests that FDA's inspection regime may not have been completely successful in deterring producers and importers from offering food shipments that violate U.S. laws.

All entries in the OASIS data set are coded with a standardized product description generated using dropdown menus (4,045 descriptions are used in the period of our analysis). Each entry also contains an "importer's description," and some have "corrected descriptions." However, inspection of the OASIS data set reveals that thousands of entries are likely to be improperly coded: the standardized product description matches neither the importer's description nor

[3]In some cases, an Import Alert may be mentioned in the narrative text, but misspelling or unusual formatting prevents us from identifying a shipment as being associated with an Import Alert. Thus, all estimates of shipments associated with Import Alerts are conservative.

the corrected description (supplied by FDA).[4] Because all inconsistencies cannot be resolved, this report assumes that the errors in assignment of product descriptions are uncorrelated and that the data set allows unbiased estimates of the patterns in FDA import refusals. The data used in this analysis comprise the complete record of food shipments refused for importation by FDA over 2005-2013, so all empirical evidence presented in this report should be considered as evidence of patterns in import refusals but not as evidence of the relative safety of food produced in foreign countries.

[4]For example, one entry from 2013 has the standardized product description coded as "Coconut Pudding (Pie Filling) Mix (Not Custard)," while the importer's description is "Sweet Red Mung Beans" and there is no corrected description. Others are less obviously wrong: "Fresh Chinese Okra" is miscoded as "Okra" in multiple entries (the two plants are from different botanical orders); and the importer's description often gives foreign-language names for products, making cross-referencing difficult. It is impossible to know whether the importer's description or the coded product description was incorrect in these ambiguous cases, and to identify and remove all obviously inconsistent entries would not guarantee that all entries are correctly identified. Inspecting several hundred randomly drawn observations (of the 87,552) shows that at least 2 percent of those were improperly coded, with another 2 percent problematic. The true number of miscoded entries may, of course, be higher or lower.

Patterns in FDA Import Refusals

From 2005 to 2013, FDA refused the entry of 87,552 shipments of food into the United States after determining that the shipments violated or appeared to violate one or more U.S. laws. The annual number of shipments refused remained relatively stable throughout the period, despite an increasing volume of FDA-regulated food imports over that time. Thus, the number of shipments refused declined relative to the volume of imports. This decline may reflect improved compliance with U.S. laws by foreign producers and importers, or it may reflect FDA's limited capacity to inspect, detain, and refuse imported food.

Industries with most frequent import refusals

Two industries (i.e., product categories) were responsible for more than one-third of all import shipments refused over 2005–2013. Fishery and seafood products had the most refused shipments each year from 2008 through 2013, and accounted for 20.5 percent of all shipments refused over the period (table 1). Vegetables and vegetable products had the most refused shipments in 2005-07, and accounted for 17.7 percent of refusals overall.

Table 1
Number of shipments in violation, by year and by industry, 2005-2013

Industry	Year									Total shipments refused	Total violations
	2005	2006	2007	2008	2009	2010	2011	2012	2013		
Fishery and seafood products	1,871	1,741	1,765	1,745	1,688	2,101	2,857	2,551	1,661	**17,980**	**23,398**
Vegetables and vegetable products	2,296	1,898	1,770	1,221	1,217	1,342	1,447	1,321	1,618	**14,130**	**19,987**
Fruit and fruit products	799	895	985	739	921	1,106	1,498	1,140	1,099	**9,182**	**15,138**
Spices, flavors, and salts	400	521	636	968	631	1,136	933	857	695	**6,777**	**9,160**
Candy without chocolate/ specialty candy/ chewing gum	681	732	598	815	963	736	698	556	530	**6,309**	**12,261**
Bakery products/ dough/mix/icing	611	509	487	666	762	569	640	658	714	**5,616**	**11,532**
Multi-food dinner/ gravy/sauce/ specialties	304	327	352	520	440	338	275	276	263	**3,095**	**5,842**
Chocolate and cocoa products	155	158	220	696	500	236	299	319	255	**2,838**	**6,245**
Soft drinks and water	285	302	337	452	372	321	273	207	245	**2,794**	**5,697**
Cheese and cheese products	267	199	251	295	255	181	197	466	487	**2,598**	**4,356**
Snack food items	191	279	180	270	280	474	345	262	160	**2,441**	**4,469**
Whole-grain/ milled grain products/starch	117	159	159	128	166	152	256	659	624	**2,420**	**3,284**

— continued

Table 1

Number of shipments in violation, by year and by industry, 2005-2013—continued

Industry	Year									Total shipments refused	Total violations
	2005	2006	2007	2008	2009	2010	2011	2012	2013		
Nuts and edible seeds	154	217	159	107	227	229	206	169	181	**1,649**	**2,608**
Dressings and condiments	142	149	246	198	201	130	135	221	110	**1,532**	**2,949**
Macaroni and noodle products	96	108	86	168	140	187	227	147	153	**1,312**	**2,306**
Coffee and tea	76	81	86	139	123	151	114	202	158	**1,130**	**1,915**
Beverage bases, concentrate, nectar	119	106	91	81	93	135	84	69	88	**866**	**1,835**
Food sweeteners (nutritive)	50	80	77	89	51	92	120	99	113	**771**	**1,422**
Milk/butter/dried milk products	120	92	125	122	89	39	50	47	31	**715**	**1,511**
Vegetable oils	42	40	43	38	46	39	63	68	235	**614**	**985**
Dietary conventional foods/meal replacements	59	66	53	59	71	73	74	95	45	**595**	**1,134**
Gelatin/pudding mix/pie filling	53	47	30	72	62	61	85	59	43	**512**	**1,121**
Soup	42	68	43	62	53	41	50	18	37	**414**	**801**
Cereal preparations/ breakfast food	29	32	20	21	59	41	55	41	26	**324**	**578**
Baby food products	26	15	27	14	5	22	62	12	27	**210**	**617**
Ice cream products	11	14	23	21	36	21	33	20	18	**197**	**448**
Meat, meat products, and poultry	15	18	8	7	8	17	14	17	41	**145**	**229**
Filled milk/ imitation milk products	2	9	2	9	6	86	5	5	4	**128**	**337**
Vegetable protein products	10	4	18	4	20	10	10	11	17	**104**	**222**
Alcoholic beverages	7	4	20	7	5	8	12	1	20	**84**	**171**
Egg and egg products	2	3	0	13	11	3	4	0	3	**39**	**65**
Prepared salad products	9	5	1	6	0	5	0	1	4	**31**	**56**
Total	**9,041**	**8,878**	**8,898**	**9,752**	**9,501**	**10,082**	**11,121**	**10,574**	**9,705**	**87,552**	**142,679**

Note: FDA does not generally inspect meat or poultry products, so only a few observations of meat or poultry appear in the FDA OASIS (Operational and Administrative System for Import Support) data. It is not clear why FDA inspected the meat and poultry products that do appear in this data set.

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS data.

Four other product categories (fruit and fruit products; spices, flavors, and salts; non-chocolate candy and gum; bakery products/dough/mix/icing) each accounted for at least 5 percent of import violations; in total, the top 6 categories accounted for about 69 percent of FDA import refusals. Table 2 presents information about the specific charge codes that accounted for the most violations in the industries with the most import refusals. Pesticides were among the two most common violations for both vegetables/vegetable products and fruit/fruit products; filth[5] was the most common violation in both fishery/seafood products and fruit/fruit products, and the third most common violation in vegetables/vegetable products.

Table 2
Most common violations for selected product categories, 2005-2013

	Year									Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	
Fishery and seafood products										
Filth/filthy	703	582	826	714	888	814	947	944	531	**6,949**
Salmonella	576	462	309	410	406	579	971	619	463	**4,795**
Veterinary drug residue	72	187	232	136	127	195	242	129	114	**1,434**
No information on scheduled process filed	148	111	119	153	184	135	72	118	82	**1,122**
Manufactured under insanitary conditions	222	128	138	105	94	95	312	780	339	**822**
Vegetable and vegetable products										
Pesticides	932	931	844	367	363	401	428	493	812	**4,639**
No information on scheduled process filed	598	476	507	400	376	349	420	301	225	**3,652**
Filth/filthy	524	297	234	148	333	194	160	183	182	**2,255**
Needs food canning establishment number	321	304	350	238	238	210	272	150	126	**2,209**
Fails to bear nutrition label	110	75	112	116	189	159	173	149	136	**1,219**
Fruit and fruit products										
Filthy	261	204	278	236	348	322	201	216	254	**2,320**
Pesticide	107	218	203	78	120	152	236	327	266	**1,707**
Unsafe color additive	75	144	152	90	177	199	148	109	209	**1,303**
No information on scheduled process filed	160	107	175	140	203	117	135	95	98	**1,230**
Fails to bear nutrition label	93	122	130	109	181	221	110	117	101	**1,184**

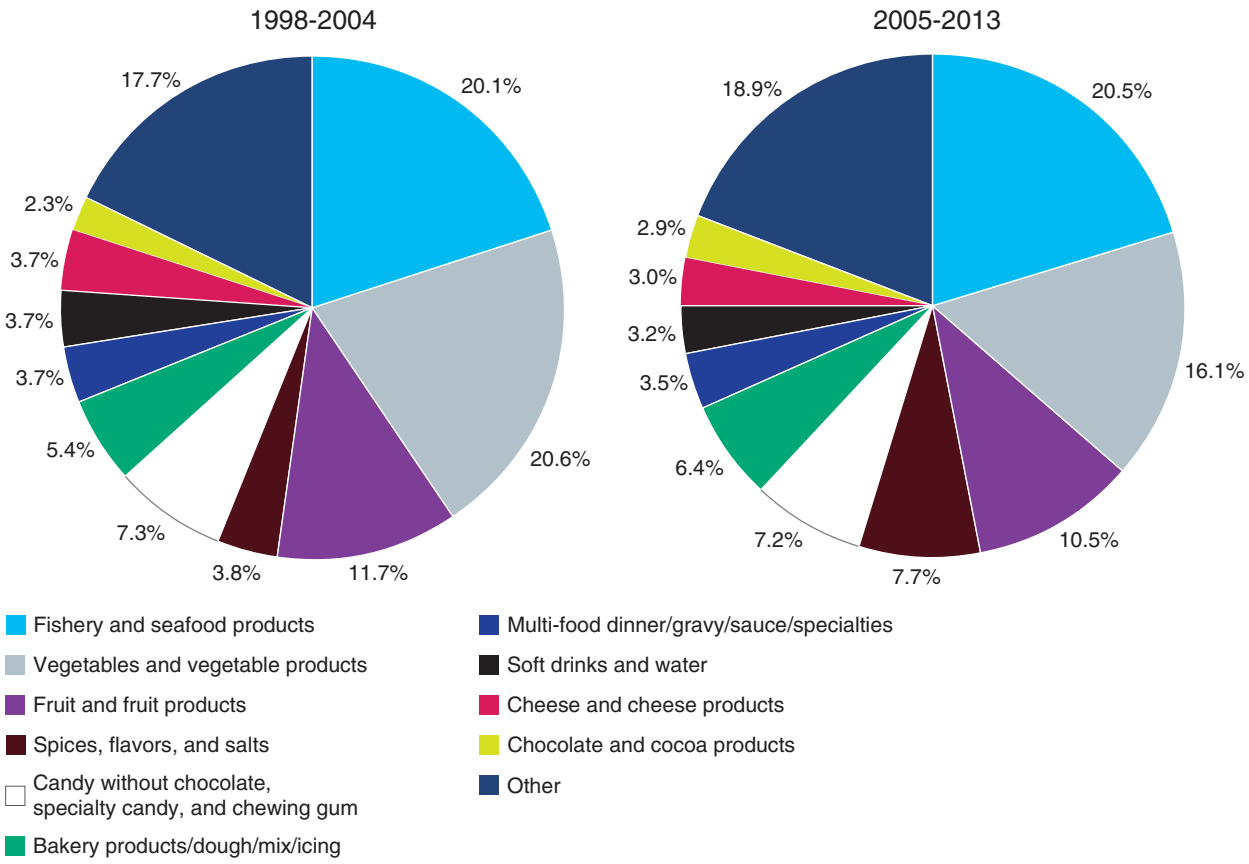
Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

[5]From the FDA's manual on Microanalytical and Filth Analysis (FDA, 2013b): "The terms filth, foreign material, or extraneous material are used interchangeably. The courts define filth in a common sense manner; filth does not have any specialized or technical definition. Filth is any type of matter that obviously does not belong in a food product. Representative examples of filth in food products include but are not limited to rodent excreta, insects, parasites, and extraneous materials such as metal and glass shards."

Over both 1998-2004 and 2005-13, the top three product categories in violation were fishery/seafood products, vegetables/vegetable products, and fruit/fruit products (fig. 1). Fishery and seafood products became the most refused category beginning in 2008, and both the vegetable and fruit product categories made up a smaller share of import refusals over 2005-2013 than over 1998-2004. Spices, flavors, and salts had more than twice as great a share of all import refusals over 2005-2013 as in the earlier period, which may reflect a significant increase in spice imports, from 304 million kilograms in 1998 to 474 million kg in 2013 (USDA/Foreign Agricultural Service, 2015).

A significant share of U.S. foodborne illnesses are attributed to the product categories most often refused by FDA, based on analysis of foodborne illness data over 1998-2008 by Painter and colleagues (2013). According to that analysis, 41.7 percent of foodborne illnesses were attributed to dairy, eggs, meat and poultry—commodities not routinely inspected by FDA. Vegetables were associated with 34.2 percent of foodborne illnesses over the period, fruit and nuts with 11.7 percent, and seafood ("aquatic animals") with 6.1 percent. The other significant product category in the Painter analysis was grains and beans, associated with 4.5 percent of foodborne illnesses. Patterns of FDA import refusals reflect these broad trends, but with important differences: fishery and seafood products were refused often, relative to the number of illnesses caused, and vegetables refused relatively infrequently. Spices, flavors, and salts are among the product categories often refused by FDA that do not appear in the analysis of Painter and colleagues (2013). These differences may reflect differ-

Figure 1
Vegetable/vegetable products and fruit/fruit products accounted for smaller shares of FDA imported food refusals in 2005-13 than in 1998-2004



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

ences in the safety of imported and domestically produced food, or they may speak to the efficacy of FDA's inspection regime.

Types of violations

FDA sometimes identifies and records more than one violation for a given shipment. Over 2005-13, 30,997 shipments—or 35.4 percent of refused shipments—were found to have more than 1 violation. Of these, the average shipment had 2.78 violations. FDA need not continue inspecting a shipment once a single violation is identified. Thus, the violations recorded in the OASIS data set probably are the violations most easily detected. Even products refused for seemingly innocuous violations like "No English" may pose health risks that are not reflected by the OASIS data, if FDA is less likely to examine them for adulteration problems.

In the OASIS data set, each violation is listed with a charge statement along with a shorthand charge code. Many of these charge statements explicitly list *adulteration* or *misbranding*. Foods that have been adulterated or misbranded are specifically prohibited in interstate commerce by the Federal Food, Drug, & Cosmetic Act (FD&C Act; 21 U.S.C. 331(a), (b), (c), (k)). A food may be considered adulterated under the FD&C Act for poisonous ingredients, unsafe color additives, or filth, which generally constitute a significant threat to consumers' health or safety. Food is typically considered misbranded if it bears a false or misleading label with regard to ingredients, origin/manufacturer, or quality of ingredients.[6] Many foods refused because of misbranding violations do not pose an imminent threat to public health, but others, like violations for undeclared allergens, do. Some violations may be economically motivated, as when producers substitute cheaper ingredients in a product and fail to label this substitution on the package. For example, producers may add maltodextrin (an inexpensive food additive made from starch) to honey, which is safe to consume but nevertheless grounds for refusal as misbranding if it is not labeled accurately, and could be considered fraudulent.

Over 2005-2013, adulteration violations (80,825) accounted for 57 percent of all violations (table 3). Almost all of the remainder (41 percent) were violations for misbranding (58,764), and about 2 percent (3,090) were not easily categorized as either adulteration or misbranding. Over 1998-2004, the share of misbranding violations was lower (33 percent) and the share of adulteration violations higher (65 percent). (Details about all charge statements can be found on FDA's Import Refusal Reports website, under "Violation Code Translations.") Although spices, flavors, and salts ranked sixth for total shipments refused, the category ranked fourth for adulteration violations (figs. 2 and 3).

In all but 2 years from 2005 to 2013, "Filth" (or "Filthy") was the most common charge code, accounting for 20.8 percent of adulteration violations over the entire period and 11.8 percent of all violations. Five other adulteration charges accounted for an additional 63.2 percent of adulteration violations: not filing information on the scheduled processing of low-acid canned foods or acidified foods; *Salmonella*; Unsafe Color Additive; Pesticides; and Needs Food Canning Establishment Number[7] (table 4). FDA considers the latter violations "adulteration" because of the high risk of botulism in low-acid canned foods, even though they do not necessarily indicate contaminated prod-

[6]Under the Food, Drug, and Cosmetics Act, pesticide chemical residues may be considered either misbranding (21 U.S.C. §343(l)) or adulteration (21 U.S.C. §342(a)(2)(B)), depending on whether the residue is considered "unsafe" within 21 U.S.C. §346a. In our analysis, we consider all violations for pesticide residues to be adulteration violations.

[7]That is, a shipment of canned food products is missing a label with the identification number for the canning establishment, issued by FDA.

Table 3

Categories of violation charges, by industry, 2005-2013

	Adulteration				Misbranding	Other violation	Total
	Chemical	Pathogen or toxin	Other	All adulteration			
Fishery and seafood products	2,585	5,883	10,176	18,644	3,440	1,314	**23,398**
Vegetables and vegetable products	6,303	540	8,557	15,400	4,553	34	**19,987**
Fruit and fruit products	3,875	1,023	4,941	9,839	5,187	112	**15,138**
Candy without chocolate/specialty candy/gum	2,994	132	1,475	4,601	7,593	67	**12,261**
Bakery products/ dough/mix/icing	2,204	73	1,555	3,832	7,622	78	**11,532**
Spices, flavors, and salts	1,335	3,793	1,545	6,673	2,457	30	**9,160**
Multi-food dinner/ gravy/sauce/ specialties	288	91	3,316	3,695	2,130	17	**5,842**
Soft drinks and water	1,009	3	1,261	2,273	3,391	33	**5,697**
Chocolate and cocoa products	878	20	208	1,106	5,086	53	**6,245**
Cheese and cheese products	145	771	1,288	2,204	1,145	1,007	**4,356**
Snack food items	949	283	342	1,574	2,869	26	**4,469**
Whole grain/milled grain products/starch	1,342	42	804	2,188	1,088	8	**3,284**
Dressings and condiments	330	12	1,442	1,784	1,158	7	**2,949**
Macaroni and noodle products	203	29	541	773	1,528	5	**2,306**
Nuts and edible seeds	311	739	514	1,564	1,034	10	**2,608**
Beverage bases, concentrate, nectar	309	2	389	700	1,129	6	**1,835**
Milk/butter/dried milk products	48	10	633	691	768	52	**1,511**
Coffee and tea	164	41	494	699	1,129	87	**1,915**
Food sweeteners (nutritive)	284	11	239	534	857	31	**1,422**
Gelatin/pudding mix/pie filling	221	4	154	379	736	6	**1,121**
Dietary conventional foods/meal replacements	63	9	66	138	938	58	**1,134**
Soup	23	11	308	342	451	8	**801**
Vegetable oils	345	0	72	417	560	8	**985**
Cereal preparations/ breakfast food	71	16	50	137	436	5	**578**

— continued

Table 3

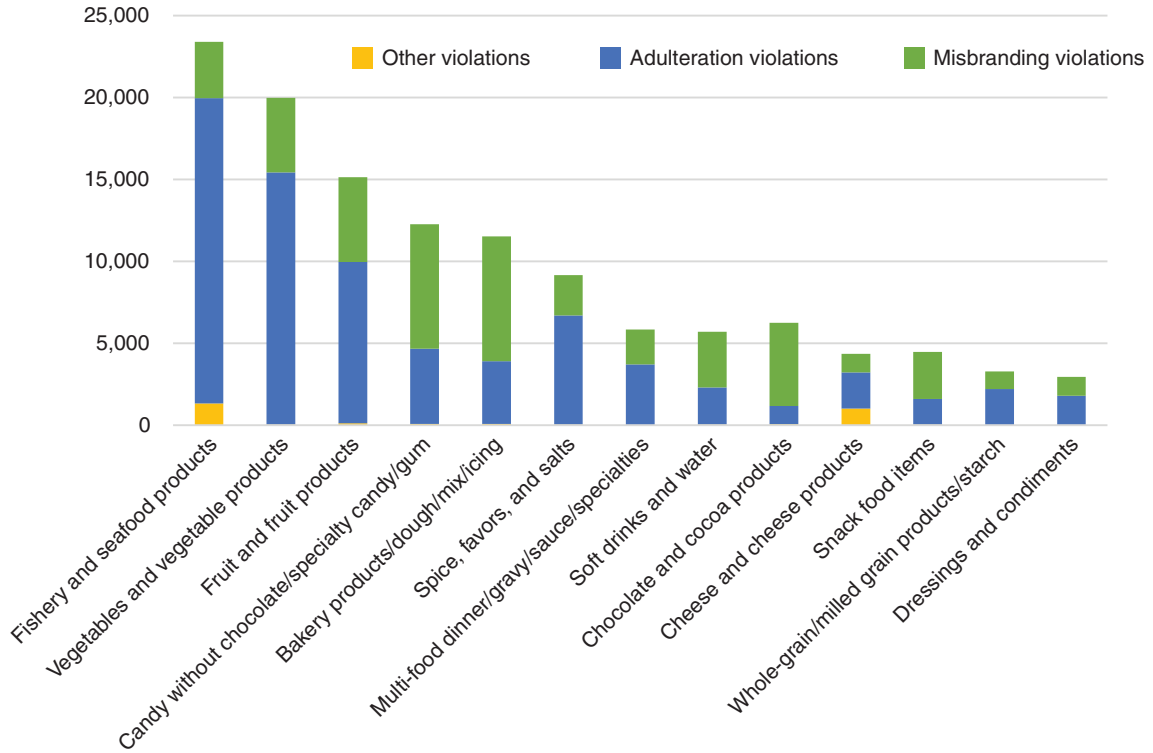
Categories of violation charges, by industry, 2005-2013—continued

	Adulteration				Misbranding	Other violation	Total
	Chemical	Pathogen or toxin	Other	All adulteration			
Baby food products	6	0	106	112	495	10	**617**
Ice cream products	131	2	9	142	306	0	**448**
Filled milk/imitation milk products	7	0	30	37	296	4	**337**
Meat, meat products, and poultry	10	79	54	143	85	1	**229**
Vegetable protein products	33	9	64	106	107	9	**222**
Alcoholic beverages	22	0	7	29	139	3	**171**
Egg and egg products	8	1	43	52	12	1	**65**
Prepared salad products	0	0	17	17	39	0	**56**
Total	**26,496**	**13,629**	**40,700**	**80,825**	**58,764**	**3,090**	**142,679**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

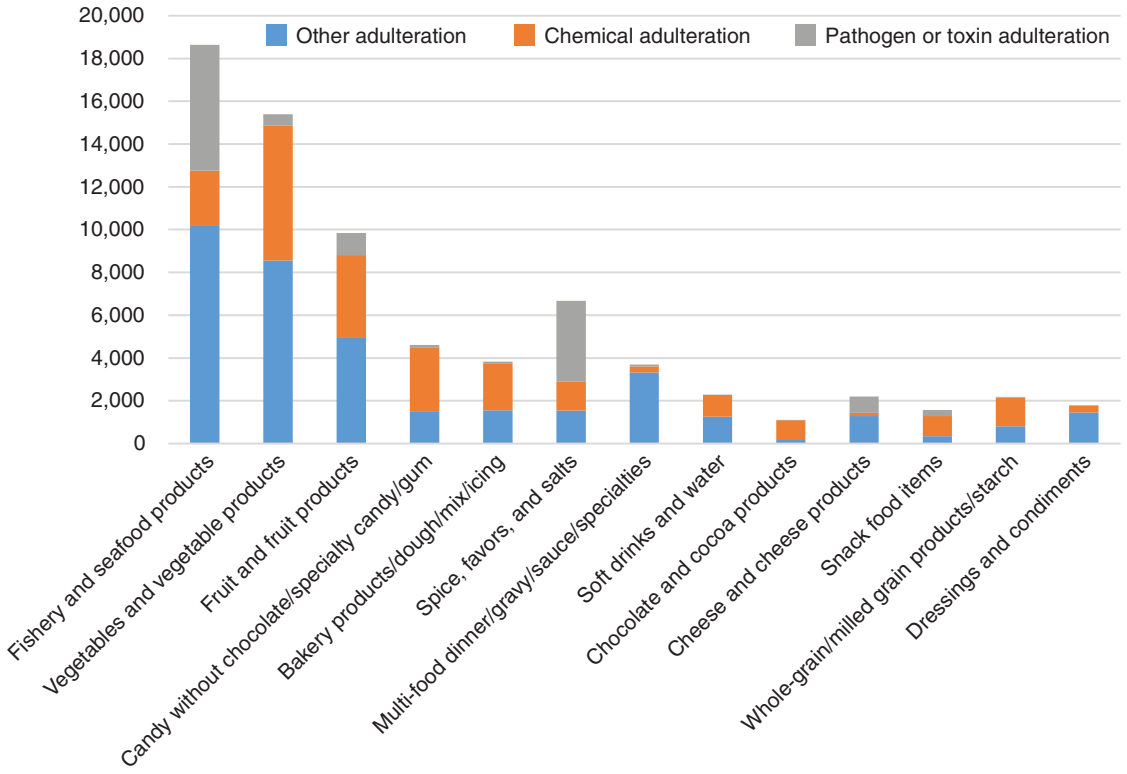
Figure 2

Number of adulteration, misbranding, and other violations, selected industries, 2005-2013



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Figure 3
Number of adulteration violations, selected industries, 2005-2013



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

ucts. Of these common violations, pesticide violations increased, while violations related to food canning establishments decreased, from 2008 to 2013.

The most common violations for misbranding all relate to labeling: lacking a nutrition label (25.0 percent) or ingredients label (14.6 percent); incorrect statement of weight, measure, or numerical count (13.8 percent); and no English (10.1 percent). The incidence of misbranding violations shows no noteworthy trends (table 4).

Because food shipments refused for adulteration are more likely to cause harm to consumers than shipments refused for misbranding, we focus on patterns in adulteration violations and break down adulteration refusals into three subcategories:

1. Pathogens, such as *Salmonella*, and toxins, such as aflatoxins;
2. Chemical contamination (e.g., pesticides, drug residues, or unsafe additives); and
3. "Other sanitary violations" including filthy or decomposed appearance and violations for failure to register processes for canned food products.

Of the 80,825 adulteration violations over 2005–2013, pathogen violations comprised 16.9 percent (9.6 percent of all violations), chemical contamination comprised 32.8 percent (18.6 percent of all violations), and other sanitary violations comprised 50.4 percent (28.5 percent of all violations). Fishery/seafood products were most often cited for adulteration (18,644) and also for adulteration with pathogens or toxins (5,883). Spices, flavors, and salts had the second most violations for adulteration with pathogens or toxins (3,793), and vegetables/vegetable products had the second most violations for all adulteration (8,557).

The industry with the most violations for chemical adulteration over 2005-13 was vegetables/vegetable products, with 73.5 percent of these violations for pesticides. Second most was fruit/fruit products, with 44.1 percent related to pesticides.

Table 4
Most common violations, by charge code and by year, 2005-2013

Charge code or statement	Violation type	Year									Total
		2005	2006	2007	2008	2009	2010	2011	2012	2013	
Filth/filthy	Adulteration	2,121	1,788	1,871	1,615	2,347	1,851	1,692	1,918	1,598	**16,801**
Fails to bear nutrition label	Misbranding	1,035	1,138	1,461	2,248	2,544	1,889	1,669	1,299	1,401	**14,684**
Salmonella	Adulteration	874	965	863	1,357	1,281	1,406	2,161	1,350	1,150	**11,407**
No information on scheduled process filed	Adulteration	1,495	1,356	1,496	1,584	1,515	1,039	1,029	944	705	**11,163**
Unsafe color additive	Adulteration	961	981	1,120	1,234	1,579	1,555	1,334	923	1,097	**10,784**
Pesticides	Adulteration	1,117	1,272	1,194	501	579	830	999	1,678	1,920	**10,090**
No list of ingredients	Misbranding	851	857	794	1,081	1,275	1,088	1,039	818	786	**8,589**
Lacks numerical count label	Misbranding	557	730	917	1,669	1,213	870	827	640	700	**8,123**
Needs food canning establishment number	Adulteration	993	922	1,173	1,207	965	720	688	516	414	**7,598**
No English	Misbranding	518	448	578	572	749	777	903	583	806	**5,934**
Labeling	Misbranding	381	287	324	331	541	386	500	463	428	**3,641**
Does not bear usual name	Misbranding	264	299	307	301	433	328	484	324	462	**3,202**
Lacks firm name	Misbranding	318	250	323	251	423	349	525	341	322	**3,102**
Fails to bear artificial color labeling	Misbranding	236	197	244	363	440	415	452	293	344	**2,984**
Manufactured under insanitary conditions	Adulteration	222	128	138	105	94	95	312	780	339	**2,213**
Insanitary	Adulteration	150	144	89	188	203	270	216	404	310	**1,974**
Unsafe food additive	Adulteration	80	63	206	215	253	215	298	153	235	**1,718**
False or misleading label	Misbranding	119	150	121	135	220	250	215	126	176	**1,512**
Veterinary drug residue	Adulteration	74	187	232	139	130	199	247	135	123	**1,466**
Poisonous	Adulteration	109	67	108	155	137	120	213	226	184	**1,319**
Total		**13,370**	**13,342**	**15,075**	**17,080**	**18,960**	**16,386**	**17,534**	**15,709**	**15,223**	**142,679**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

Pathogen and toxin adulterations

Pathogens and toxins pose clearly identifiable risks to human health, but the risks of many can be mitigated if food is properly cooked and handled. From 2005 to 2013, *Salmonella* accounted for the vast majority (83.7 percent) of pathogen/toxin adulteration violations up from 63.0 percent over 1998-2004 (table 5). *Salmonella* is a genus of bacteria found in the digestive tracts of mammals and birds; its consumption can cause typhoid fever and other digestive illnesses. *Listeria*, another genus of bacteria, caused the second most import refusals, at 8.5 percent of all pathogen/toxin violations, down from 24.8 percent over 1998-2004. FDA data specifically identify only a handful of pathogens, with 2.1 percent of pathogen/toxin violations listed, generically, as "bacteria."[8]

Fishery/seafood products were most frequently cited as having *Salmonella* violations over 2005-13 (table 6), with 42.0 percent of *Salmonella* violations (down from 67.7 percent over 1998-2004); spices, flavors, and salts followed, with 33.2 percent (up from 16.6 percent over the earlier period). *Salmonella* violations accounted for 25.7 percent of all adulteration violations in fishery and seafood products and 56.8 percent of adulteration violations in spices, flavors, and salts. The share of *Salmonella* violations in fruit and snack food items was also up from 1998 to 2004.

Table 5
Number of violations for pathogen or toxin contamination, by charge code, 2005-2013

	Year									Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	
Salmonella	874	965	863	1,357	1,281	1,406	2,161	1,350	1,150	**11,407**
Listeria	92	166	59	95	138	168	135	179	121	**1,153**
Aflatoxin	37	60	27	24	33	44	51	53	47	**376**
Histamine	46	45	52	35	44	22	33	59	23	**359**
Bacteria	15	19	45	27	28	20	17	26	43	**240**
E. coli O157	0	0	0	0	17	2	6	11	1	**37**
Shigella	2	1	5	6	2	1	3	0	0	**20**
Diseased	0	0	2	2	4	0	0	0	3	**11**
Patulin	2	6	1	0	0	0	1	0	0	**10**
Vibrio	0	0	0	0	0	1	2	1	3	**7**
Hepatitis A	0	6	0	0	0	0	0	0	0	**6**
Biotoxin	2	0	0	0	0	0	0	0	0	**2**
Insanitary BSE	0	0	0	0	0	0	1	0	0	**1**
Total	**1,070**	**1,268**	**1,054**	**1,546**	**1,547**	**1,664**	**2,410**	**1,679**	**1,391**	**13,629**

BSE = Encephalopathy.
Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

[8]FDA recorded no violations with the *E. coli* O157:H7 charge code over 2005-08, and no violations with the *Vibrio* charge code over 2005-09. However, these bacteria were mentioned in hundreds of narrative remarks in earlier years, accompanying a generic "bacteria" charge code.

Table 6

Number of violations for *Salmonella*, by industry, 2005-2013

Industry name	Year									Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	
Fishery and seafood products	576	462	309	410	406	579	971	619	463	**4,795**
Spices, flavors, and salts	188	279	371	686	504	503	486	402	373	**3,792**
Fruit and fruit products	33	67	23	68	13	53	542	134	35	**968**
Vegetables and vegetable products	11	12	25	62	57	88	49	35	156	**495**
Nuts and edible seeds	26	28	43	11	139	78	55	40	49	**469**
Snack food items	1	62	17	20	58	52	8	34	12	**264**
Cheese and cheese products	5	2	31	71	46	7	5	5	3	**175**
Meat, meat products, and poultry	4	7	2	2	6	8	13	13	23	**78**
Candy without chocolate/ specialty candy/chewing gum	13	16	3	0	4	14	0	18	7	**75**
Bakery products/dough/mix/icing	2	5	0	9	4	5	9	16	11	**61**
Multi-food dinner/gravy/sauce/ specialties	1	9	6	2	8	4	9	7	6	**52**
Coffee and tea	4	4	1	4	8	3	5	5	6	**40**
Macaroni and noodle products	0	5	1	3	10	2	3	4	0	**28**
Whole grain/milled grain products/starch	1	5	6	0	4	2	1	5	2	**26**
Cereal preparations/ breakfast food	0	0	1	3	3	2	1	2	1	**13**
Soup	2	0	1	1	5	1	1	0	0	**11**
Food sweeteners (nutritive)	0	0	10	1	0	0	0	0	0	**11**
Chocolate and cocoa products	0	1	6	0	4	0	0	0	0	**11**
Dressings and condiments	4	0	0	0	0	0	0	4	2	**10**
Vegetable protein products	0	0	2	0	0	0	1	6	0	**9**
Dietary conventional foods/ meal replacements	1	1	0	1	2	1	2	0	0	**8**
Milk/butter/dried milk products	1	0	0	2	0	3	0	1	0	**7**
Gelatin/pudding mix/pie filling	1	0	2	1	0	0	0	0	0	**4**
Ice cream products	0	0	2	0	0	0	0	0	0	**2**
Egg and egg products	0	0	0	0	0	1	0	0	0	**1**
Beverage bases, concentrate, nectar	0	0	1	0	0	0	0	0	0	**1**
Soft drinks and water	0	0	0	0	0	0	0	0	1	**1**
Total	**874**	**965**	**863**	**1,357**	**1,281**	**1,406**	**2,161**	**1,350**	**1,150**	**11,407**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

Fishery and seafood products also had the most violations for *Listeria* (table 7), with 59.4 percent over 2005-13, significantly higher than in 1998-2004 (21.6 percent). *Listeria* was also very commonly found in cheese and cheese products, which had 32.0 percent of *Listeria* violations—down from 49.6 percent over 1998-2004. *Listeria* accounted for 16.7 percent of adulteration violations for the cheese and cheese products industry. *Listeria* contamination incidents generally were down significantly from 1998 to 2004.

Histamines are naturally occurring toxins that can accumulate in certain types of seafood and have been linked to scrombroid poisoning outbreaks in the United States. All 359 violations for histamines (table 5) in our data set were for fishery and seafood products.

Aflatoxins are carcinogenic byproducts of mold infestations in food crops. Of the 376 violations for aflatoxins in our data set (table 5), 68.6 percent were in nuts and edible seeds, and 14.0 percent were in non-chocolate candy or gum. Several other product categories also had violations for aflatoxin adulteration.

Of the 240 violations in the generic "bacteria" category, 80.0 percent were in cheese and cheese products and 12.5 percent were in fishery and seafood products. Narrative remarks accompanying these violations often identify more than one bacterial contaminant (many shipments had evidence of both *E. coli* and *Staphylococcus aureus*).

Table 7
Number of violations for *Listeria*, by industry, 2005-2013

	Year									Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	
Fishery and seafood products	48	88	26	54	111	81	104	111	62	**685**
Cheese and cheese products	41	64	29	40	23	51	19	53	49	**369**
Fruit and fruit products	2	5	3	1	1	16	4	4	4	**40**
Multi-food dinner/gravy/sauce/ specialties	1	7	0	0	3	19	1	5	2	**38**
Vegetables and vegetable products	0	0	1	0	0	0	6	6	4	**17**
Nuts and edible seeds	0	1	0	0	0	0	1	0	0	**2**
Milk/butter/dried milk products	0	1	0	0	0	0	0	0	0	**1**
Bakery products/ dough/mix/icing	0	0	0	0	0	1	0	0	0	**1**
Total	**92**	**166**	**59**	**95**	**138**	**168**	**135**	**179**	**121**	**1,153**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

Most common violations by FDA food industry group

Fishery/seafood products had the most import violations over 2005-13, with filth the most common citation in that industry (table 8). Filth was also the most common violation in fruit/fruit products, the industry group with the third most violations.

Table 8
Most common violations, by industry, 2005-2013

	Number of violations	Most common violation (number)
Fishery and seafood products	23,398	Filthy, 6,949
Vegetables and vegetable products	19,987	Pesticides, 5,571
Fruit and fruit products	15,138	Filthy, 2,320
Candy without chocolate/specialty candy/gum	12,261	Unsafe color additive, 2,755
Bakery products/dough/mix/icing	11,532	Lacks nutrition label, 1,955
Spices, flavors, and salts	9,160	*Salmonella*, 3,792
Chocolate and cocoa products	6,245	Lacks nutrition label, 1,645
Multi food dinner/gravy/sauce/specialties	5,842	No information on scheduled process filed, 1,668
Soft drinks and water	5,697	Unsafe color additive, 931
Cheese and cheese products	4,356	Manufactured under insanitary conditions, 1,005
Snack food items	4,469	Unsafe color additive, 870
Whole-grain/milled grain products/starch	3,284	Pesticides, 1,141
Dressings and condiments	2,949	No information on scheduled process filed, 829
Nuts and edible seeds	2,608	*Salmonella*, 469
Macaroni and noodle products	2,306	Filthy, 413
Coffee and tea	1,915	No English, 271
Beverage bases, concentrate, nectar	1,835	Lacks nutrition label, 289
Milk/butter/dried milk products	1,511	No information on scheduled process filed, 299
Food sweeteners (nutritive)	1,422	Lacks nutrition label, 215
Dietary conv food/meal replacements	1,134	Lacks nutrition label, 204
Gelatin/pudding mix/pie filling	1,121	Unsafe color additive, 215
Vegetable oils	985	Pesticides, 194
Soup	801	No information on scheduled process filed, 181
Baby food products	617	Lacks nutrition label, 93
Cereal preparations/breakfast food	578	Lacks nutrition label, 124
Ice cream products	448	Unsafe color additive, 117
Filled milk/imitation milk products	337	Lacks nutrition label, 95
Meat, meat products, and poultry	229	*Salmonella*, 78
Vegetable protein products	222	No information on scheduled process filed, 46
Alcoholic beverages	171	List of ingredients incomplete, 36
Egg and egg products	65	Needs food canning establishment number, 22
Prepared salad products	56	Lacks nutrition label, 20

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

The most common violation cited for vegetables/vegetable products was unsafe pesticide residues. Such violations occur only when the residues exceed the FDA-prescribed tolerance levels in food products or when products contain residues of pesticides that are not registered for use in the United States.

For 11 of the 32 industry groups, the most common violation was a misbranding violation rather than an adulteration violation. Most of these—for example, in bakery products/dough/mix/icing, chocolate and cocoa products, and food sweeteners (nutritive)—were for lacking a nutrition label (table 8).

Most common violations by exporting country

For the three countries with the most import refusals—Mexico, India, and China—the product categories most commonly refused are correlated with the value of exports to the United States. For example, Mexico is the leading exporter of both vegetables (4.93 billion kg in 2013) and fruit (3.17 billion kg) to the United States (USDA/FAS, 2015). China and India are the leading exporters of seafood (567 million kg) and spices (73.2 million kg), respectively.

The most frequently refused exporting industry in ***Mexico*** was vegetables and vegetable products (30.3 percent of shipments in violation), followed by candy without chocolate and gum (19.3 percent), and fruit and fruit products (15.2 percent). FDA refusals of vegetable/vegetable products from Mexico peaked in 2005, and in none of the top eight product categories did violations peak in 2012 or 2013 (table 9). In 2005, hot and sweet peppers and pepper products (such as sauce) accounted for 63.5 percent of shipments in violation in the vegetable/vegetable products category from Mexico. Over 2005-13, at least 40 percent of vegetable shipments refused from Mexico were associated with an Import Alert; Mexico had more shipments refused in association with Import Alerts (4,331) than any other country, accounting for 35 percent of Mexico's refusals.

Table 9
Shipments refused from Mexico, selected industries, 2005-2013

	Year									Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	
Vegetables and vegetable products	762	485	472	200	340	375	362	233	532	**3,761**
Candy without chocolate/ specialty candy/gum	414	418	213	200	407	244	218	163	124	**2,401**
Fruit and fruit products	192	165	116	89	89	170	649	245	177	**1,892**
Snack food items	24	48	30	57	70	232	159	70	41	**731**
Spices, flavors, and salts	23	15	46	429	30	32	31	20	58	**684**
Cheese and cheese products	28	30	81	46	51	42	63	28	11	**380**
Fishery and seafood products	70	49	31	27	57	42	54	25	21	**376**
Soft drinks and water	36	76	67	18	46	34	11	24	33	**345**
Total	**1,733**	**1,506**	**1,279**	**1,207**	**1,339**	**1,382**	**1,775**	**996**	**1,201**	**12,418**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

In some cases—as with refusals of spices, flavors, and salts from Mexico in 2008—Import Alerts seem to have driven the spike in refusals: 73.2 percent of refused shipments in this category had an Import Alert listed in the report. However, for the most part, peaks and outliers in country-product violation patterns were not strongly correlated with peaks in Import Alerts.

Spices, flavors, and salts accounted for 29.6 percent of the violations for products shipped from ***India*** over 2005-13 (table 10), followed by whole grain/milled grain products/starch (11.9 percent) and bakery products/dough/mix/icing (10.8 percent). Violations in spices, flavors, and salts were especially high from 2010 to 2012, which may indicate increased monitoring of that product category. Whole grain/milled grain products/starch saw a significant uptick in violations in 2012 and 2013, becoming the Indian export category with the most violations in 2013. Most of these violations were for pesticide adulteration. Four industries each had between 4.7 percent and 7.4 percent of India's import violations: snack food items; vegetables/vegetable products; fruit/fruit products; and fishery/seafood products.

Shipments associated with Import Alerts made up at least 41 percent of all shipments of spices, flavors, and salts from India refused by FDA. Across all product categories, Import Alerts were associated with at least 27 percent of refused shipments from India.

In ***China***, the food industries with the most shipments in violation mirrored the industries with the most shipments in violation from all countries. Fishery/seafood product shipments accounted for 32.3 percent of shipments in violation, among products shipped from China; vegetables/vegetable products had 20.9 percent of shipments in violation; and fruit/fruit products had 10.9 percent (table 11). Over the period of analysis, refused fishery/seafood product shipments from China peaked in 2007, while the most violations in both vegetables/vegetable products and bakery products/dough/mix/icing occurred in 2013. Again, these patterns do not necessarily indicate increased problems with food safety of food products from China. Instead, violations

Table 10
Shipments refused from India, selected industries, 2005-2013

	Year									Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	
Spices, flavors, and salts	182	211	288	323	297	610	526	522	309	**3,268**
Whole-grain/milled grain products/starch	45	63	40	35	63	57	140	488	379	**1,310**
Bakery products/ dough/mix/icing	227	162	157	77	129	89	92	139	125	**1,197**
Snack food items	90	182	93	76	101	104	62	60	48	**816**
Vegetables and vegetable products	84	85	86	81	123	89	78	106	64	**796**
Fruit and fruit products	80	95	99	49	92	77	83	80	95	**750**
Fishery and seafood products	87	50	51	19	45	57	128	84	60	**581**
Total	**1,023**	**1,158**	**1,113**	**916**	**1,163**	**1,312**	**1,385**	**1,710**	**1,274**	**11,054**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

Table 11
Shipments refused from China, selected industries, 2005-2013

	Year									Total
	2005	2006	2007	2008	2009	2010	2011	2012	2013	
Fishery and seafood products	157	302	388	203	211	319	383	192	181	**2,336**
Vegetables and vegetable products	247	152	104	106	152	158	144	197	253	**1,513**
Fruit and fruit products	61	73	100	81	106	115	99	91	65	**791**
Bakery products/ dough/mix/icing	16	15	6	73	112	60	77	127	158	**644**
Multi-food dinner/gravy/ sauce/specialties	36	46	29	37	45	30	33	31	53	**340**
Macaroni and noodle products	22	25	21	26	51	40	35	47	33	**300**
Candy without chocolate/ specialty candy/gum	27	13	18	45	43	33	45	24	25	**273**
Total	**670**	**698**	**737**	**780**	**842**	**867**	**940**	**818**	**883**	**7,235**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

and shipments refused by FDA reflect the outcome of a complex system that depends on import volumes and FDA's expectations about the safety of the products offered for import. Import Alerts were associated with 19.6 percent of refused shipments from China.[9]

Table 12 summarizes the number of refused shipments, by major charge code, for the top three refused industries in Mexico, India, and China. Filth and pesticide violations are prevalent across many of these countries and product categories, with filth becoming less commonly cited for products from Mexico over the period of analysis. Pesticides in whole grains/milled grain products/ starches became a major problem in exports from India in 2012-2013 after years without any significant detected problems, likely in part due to increased detection efforts targeting that problem. Veterinary drug residues in fishery/seafood products from China were a major cause of import refusals throughout the period of analysis, peaking in 2006-2007 and 2010-2011.

Other recurring problems with particular products from the same country are apparent from FDA's data set on import refusals. Over 2005-2013, 1,711 shipments of vegetables/vegetable products from the ***Dominican Republic*** were refused—or 12.1 percent of refusals in that category and 76.6 percent of refusals from the Dominican Republic. Refusals of chocolate and cocoa products made up 24.3 percent of refusals from the ***United Kingdom***; refusals from the United Kingdom accounted for 38.5 percent of refusals in that product category. ***France*** was a major source of import refusals in cheese and cheese products (36.8 percent of refusals); of course, France is a major exporter of cheese to the United States, but its shipments made up only 14.1 percent of cheese imports, by value, over the period (USDA/FAS, 2015). ***Indonesia*** and ***Thailand*** were both major sources of import refusals in fishery and seafood products (13.5 percent and 7.1 percent, respectively), but their shares of import refusals were close to their shares of seafood imports (USDA/FAS, 2015).

[9]Import Alerts are inconsistently coded, and these shares represent a conservative estimate of the share of shipments associated with an Import Alert.

Table 12

Most common violations for selected countries and industries, 2005-2013

Country and industry	Most common violations	Year									Total
		2005	2006	2007	2008	2009	2010	2011	2012	2013	
Mexico											
Vegetables and vegetable products	Pesticides	320	261	279	64	153	195	218	95	325	**1,910**
	Filth/filthy	400	192	137	57	213	104	79	78	68	**1,328**
	Salmonella	0	4	6	49	36	52	19	21	128	**315**
Candy without chocolate/specialty candy/gum	Filth/filthy	221	262	88	99	211	99	31	52	40	**1,103**
	Unsafe color	95	87	75	51	60	60	102	44	37	**611**
	Lacks nutrition label	33	14	17	28	87	45	36	7	12	**279**
Fruit and fruit products	*Salmonella*	33	67	21	20	5	49	535	130	32	**892**
	Filth/filthy	92	41	29	37	37	44	30	35	54	**399**
	Pesticides	22	31	38	8	25	36	60	27	69	**316**
India											
Spices, flavors, and salts	*Salmonella*	104	155	221	204	313	318	327	265	216	**2,123**
	Pesticides	21	4	10	13	17	190	128	161	48	**592**
	Filth/filthy	44	32	55	75	43	66	60	65	46	**486**
Bakery products/ dough/mix/icing	Filth/filthy	43	45	39	36	77	19	51	106	103	**519**
	Unsafe color	173	83	106	26	22	14	17	5	5	**451**
	Lacks nutrition label	33	49	36	23	36	30	18	20	17	**262**
Whole-grain/milled grain products/starch	Pesticides	0	0	1	0	0	0	88	425	321	**835**
	Filth/filthy	35	61	31	16	56	37	33	70	68	**407**
	Lacks nutrition label	4	1	9	12	21	4	11	7	2	**71**
China											
Fishery and seafood products	Veterinary drug residues	21	151	179	88	61	156	160	59	45	**920**
	Filth/filthy	50	68	128	57	85	98	156	57	79	**778**
	Unsafe additive	0	11	59	61	22	89	59	37	32	**370**
Vegetables and vegetable products	Filth/filthy	69	56	43	51	59	53	41	57	89	**518**
	Pesticides	124	20	17	12	19	39	48	73	61	**413**
	No information on scheduled process filed	27	51	30	21	46	20	23	26	27	**271**
Fruit and fruit products	Filth/filthy	34	39	47	27	76	77	29	23	10	**362**
	Unsafe color	15	45	63	22	47	61	44	32	25	**354**
	Fails to list saccharin	7	23	32	11	53	26	12	8	14	**186**

Source: USDA, Economic Research Service, based on U.S. Food and Drug Administration OASIS (Operational and Administrative System for Import Support) data.

Conclusion and Implications

This report provides insights into the industry categories, exporting countries, and violation charge codes most likely to be associated with refusals of food imports by FDA over 2005-2013. Fishery/seafood products, vegetable/vegetable products, and fruit/fruit products were the industries with the most shipments refused over the period, as in 1998-2004. The safety of imported seafood clearly continues to be of significant concern, based on the number of shipments refused by FDA. Spices, flavors, and salts were refused much more often in 2005-2013 than in the earlier period. There were several notable changes in types of violations, particularly with regard to pathogen and toxin adulteration violations. The countries with the most food shipments refused by FDA—Mexico, India, and China—have distinct sets of product categories that have been subject to the most refusals.

Over the next few years, FDA will implement the Food Safety Modernization Act and develop a new regime to inspect foreign food-producing facilities for the first time. FDA officials and cooperating inspection/enforcement agencies might prioritize the countries and products that have posed the greatest problems and inspect foreign facilities accordingly to intercept problems before food shipments reach U.S. ports. In addition to potentially informing FDA and policymakers, this report provides updated information about the recurring problems of adulteration and misbranding in food shipments entering the United States.

However, more research is needed to determine which industries and producing countries pose the greatest risks to U.S. consumers' health. Because FDA inspections of imports are not conducted randomly, but are risk-based and designed as deterrents, additional data (e.g., the value or share of shipments refused for various groups of producers) would be needed for a careful analysis of the risks presented by different producers.

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Appendix: FDA Import Inspection Procedures

The U.S. Customs and Border Protection agency (Customs, or CBP) oversees the safety of all goods imported into the United States (CBP, 2006). Inspection of those articles that are also subject to FDA regulation (as described in the box) is delegated to FDA, and USDA-FSIS inspects food products in categories that it oversees (FDA, 2014c; USDA-FSIS, 2015b). When FDA-regulated products must be reconditioned before import, either FDA or Customs may oversee the reconditioning (FDA, 2014c).

Customs considers all shipments of goods for import with a value of at least $2,500 to be "formal entries" (FDA, 2014c). Formal entries must be accompanied with a bond, for collateral, filed with Customs to cover costs in case a product needs to be redelivered. "Informal entries," which have a customs value of less than $2,500, by contrast, do not require a redelivery bond. Both formal and informal entries may be subject to FDA action (e.g., inspection, detention, or refusal), and all actions are entered into the OASIS database.

Under the Bioterrorism Act of 2002, FDA must receive prior notice of food to be imported into the United States (FDA, 2014c). This prior notice must be submitted electronically to either Customs or FDA, and FDA must receive and confirm this notification 2 to 8 hours before anticipated entry, depending on the mode of transportation. This "prior notice" includes detailed information about the manufacturer, shipper, importer, and product.

FDA may elect to sample or examine any shipments offered for import into the United States (FDA, 2014c). All entries that are not examined, as well as entries examined but without detected violations, are designated "May Proceed" in the OASIS database. (The data set used for this report includes only refused entries, and not all entries in the OASIS database.)

Field examinations of imports are used, essentially, for detection of filth or foreign objects, and other organoleptic inspection (e.g., to detect decomposition) (FDA, 2014d), although FDA field agents may use a portable device that detects heavy metals (FDA, 2014a). Sampling and laboratory examinations, by contrast, can be used to detect microbiological, toxin, or chemical contamination. FDA has at least two mobile labs that can be deployed to various locations to assist with detection efforts (FDA, 2014a).

Decisions to inspect food shipments offered for import using either sampling or field examinations are informed by the FDA's PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting) system, a screening tool that assesses the risks associated with imports (FDA, 2014e). PREDICT has been used in some locations since 2009, and rollout was completed in December 2011 (FDA, 2012). Prior to PREDICT, FDA used a risk-screening component of the OASIS. Among the factors accounted for by PREDICT are inherent product risks, history of field examinations and lab analyses associated with a firm or product, results of facility inspections, data anomalies, and health/economic consequences of foreseeable problems with the given product (FDA, 2014e).

When FDA determines that a product poses serious health risks—because FDA or some other public agency has found, through sampling, a serious violation of FDA regulations—it may issue a recommendation for detention without physical examination (DWPE), accompanied with an Import Alert (FDA, 2013a). When a product is on the DWPE list, the importer must "introduce testimony bearing

on the admissibility" of the shipment in order for individual shipments to be cleared for import. In other words, products on the DWPE list are not automatically refused, but they are refused unless the importer provides such testimony. These DWPE recommendations and Import Alerts may apply to products, countries, manufacturers, packers, shippers, growers, or importers.

As of November 3, 2015, FDA had 130 active Import Alerts for food products (FDA, 2015).[10] Thirteen of these Import Alerts were issued or updated within the prior week, 27 within the prior 30 days, and 57 within the prior 90 days. Thirty Import Alerts had not been updated in at least 3 years.

FDA gives several examples of how and why it may recommend DWPE (FDA, 2013a). These include violations for pesticide residues that exceed an established tolerance or for which no tolerance has been established. Ceramic containers that contain lead or cadmium above the guideline level may generate DWPE recommendations, as may cheeses or ready-to-eat seafood with *Listeria monocytogenes* or *Salmonella*. FDA may recommend DWPE if there is information to indicate that future shipments may violate FDA regulations. These recommendations may be based on a history of violations or information about polluted waters, for example. FDA may also recommend DWPE if agents find at least one sample in violation of FDA regulations, under certain conditions. FDA may also recommend DWPE based on analyses by State or local agencies.

FDA provides guidelines on how firms, products, or countries can be removed from the DWPE list (FDA, 2013a). Shippers are placed on the DWPE list when the FDA cannot identify the manufacturer of products that appear to be in violation. When the shipper does not offer for import any products that appear to be in violation over a 6-month period and the shipper documents efforts to eliminate the violations, FDA may remove the shipper from the DWPE list. Depending on the nature of the violation, ***products*** may be taken off the DWPE list either after a facility inspection or after five consecutive shipments are offered without violation. Similarly, except in the case of fresh produce, if a ***country*** or ***region*** is on the DWPE list, 12 shipments without violation must be offered before FDA may remove the manufacturers or shippers in that country or region from the DWPE list.[11] The criteria are stricter for fresh produce contaminated with pesticides: the country, grower, or importer must present evidence to FDA on how the problem has been addressed.

[10]All of these Import Alerts called for DWPE. In the past, some Import Alerts did not call for DWPE (Buzby and colleagues, 2008).

[11]The 12-shipment threshold also applies to importers, countries, or regions with multiple products on the DWPE list.