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Research Paper

Recalls Associated with Food Allergens and Gluten in FDA-Regulated Foods from Fiscal Years 2013 to 2019

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ABSTRACT

Allergens are one of the leading causes of food recalls in the US. The Food and Drug Administration (FDA) enforces requirements relating to major food allergens (MFAs) and gluten-free labeling to ensure food safety for allergic and celiac patients, respectively. Violative foods are subject to recalls. In this study, recall data for FDA-regulated foods were analyzed for fiscal years (FYs) 2013–2019 to identify trends and root causes associated with 1471 food allergen and gluten recalls. Of the 1471 recalls, 1415 recalls were due to MFAs, 34 recalls were due to gluten-free labeling violation and 23 recalls involved other allergens. Recalls due to MFAs overall increased during the study period with a peak incidence in FY 2017. MFA recall health hazard classifications were assessed as Class I (51.2%), Class II (45.5%), and Class III (3.3%). A majority of MFA recalls involved one allergen (78.8%). Milk was the most common MFA involved in MFA recalls (37.5%), followed by soy (22.5%) and tree nuts (21.6%). Almond, anchovy, and shrimp were the most common allergens recalled within the MFA groups of tree nuts, fish, and Crustacean shellfish, respectively. About 97% of MFA recalls involved one product category and among them, the category of 'bakery products, dough, bakery mixes and icings' ranked first (367 recalls), followed by the category of 'chocolate and cocoa products' (120 recalls). Labeling-associated errors accounted for 71.1% of MFA recalls with known root causes (914 out of 1286). It is important for the industry to develop and implement appropriate allergen controls to reduce the number of MFA recalls.

Food allergies impact millions of US consumers and are a public health concern. Food allergens are components of food, typically protein, which can trigger an immune-mediated allergic reaction in sensitive individuals. Some allergic reactions can result in anaphylaxis, a serious and life-threatening adverse health consequence. While promising prevention and therapeutic strategies are being developed, food allergies currently cannot be cured. Also, while risk assessments of food challenge data have identified doses of allergen exposure that may not pose significant hazard to the majority of the allergic population, "safe" allergen thresholds below which no reactions are possible have not been defined (Allen et al., 2014; Remington et al., 2020; Taylor et al., 2014). Thus, to prevent potentially life-threatening reactions from allergen exposures, allergic consumers and their caregivers rely on food product label information about food allergens to avoid food allergen hazards.

With few exceptions, general labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) require that all foods used as ingredients in food products be listed by the common or usual name of the food ingredient on the product label. There are more specific labeling requirements for foods defined as major food allergens (MFAs). The Food and Drug Administration (FDA) enforces these requirements. Violative products are subject to FDA compliance actions, including product recalls. The FD&C Act defines MFAs as milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame (effective date for sesame was January 1, 2023). Key requirements for MFA labeling include that the source of the MFA be listed in cases in which the common or usual name of the ingredient does not include the MFA source and cases in which the MFA is used in ingredients with collective terms (e.g., natural flavor, artificial color) or is an incidental additive. Manufacturers can label the MFA in the ingredient list or a separate "Contains" statement. If a "Contains" statement is used, all MFAs in the product need to be listed and not just MFAs not already identified in the ingredient list.

In addition to MFA labeling requirements, there are also food allergen manufacturing requirements. For example, the 2015 "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based

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Preventive Controls for Human Food" rule (21 Code of Federal Regulations (CFR) Part 117; referred as the CGMP and PC rule hereafter) includes requirements to ensure MFAs are properly labeled and to prevent or significantly minimize allergen cross-contact. Juice and seafood processors would control food allergen hazard under their respective HACCP programs. Some manufacturers voluntarily use allergen advisory statements (also known as precautionary allergen labeling), to convey the potential of unintended allergen presence due to cross-contact. Various types of advisory statements are currently used on food packages but not all statements signify the same degree of risk to consumers to avoid consuming product (Holleman et al., 2021). It has been FDA's policy that, if allergen advisory statements are used, they must be truthful and not misleading and cannot be used in lieu of current good manufacturing practices.

Additionally, FDA has established "gluten-free" labeling requirements in 21 CFR 101.91 (FDA, 2013, 2020). "Gluten-free" is a voluntary claim that can be used by food manufacturers on food labels if they meet all the requirements of the regulations. To be in compliance, food bearing a gluten-free claim should not contain a gluten-containing grain, an ingredient derived from gluten-containing grain and not processed to removed gluten, an ingredient derived from gluten-containing grain and processed to removed gluten but its use results in 20 ppm or more gluten in the food, or any unavoidable presence resulting in 20 ppm or more gluten in the food. There are additional labeling requirements in the regulation for gluten-free compliant foods containing low levels of wheat allergen and certain record requirements for fermented or hydrolyzed foods.

A violative food (e.g., adulterated or misbranded food that does not comply with requirements of the FD&C Act and its implementing regulations) can sometimes enter the food supply and pose food safety concerns for consumers. Such foods are often recalled to protect public health. Certain violative foods, including foods with MFA hazards, that meet Class I health hazard criteria (i.e., associated with the reasonable probability of serious adverse health consequences or death) are "reportable foods" and are reported to FDA via the Reportable Food Registry (RFR) electronic portal (https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry).

About one-third of food product concerns reported in the US through the RFR involve MFAs. Other evidence suggests that violative foods due to allergens are an important cause of food recalls globally. Among the food safety incidences from Canada, European Union, the United Kingdom, and the US in the years 2008–2018, allergens ranked first (46%) followed by microbiological hazards (40%) (Soon et al., 2020). Also, allergens were responsible for 27.4% of USDA and FDA-regulated food recalls for the years 2004–2013 (Page, 2018).

Understanding the incidence and root causes of food allergen-related recalls can help identify practices, trends/patterns, or other information that are contributing to recalls so that effective measures can be instituted to prevent them. This information may also be used to evaluate the impact of new regulations on the allergen landscape. Gendel and Zhu (2013) previously evaluated FDA-regulated food allergen recalls for fiscal year (FY) 2007–2012, a period soon after implementation of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), and found a large and growing recall problem. The main root cause identified was some failure of label controls in 67% of cases. A number of regulations, including the gluten-free rule and CGMP and PC rules, have been implemented since 2012. The current study was aimed to further continue the evaluation of incidences and root causes of FDA-regulated food allergen recalls as well as gluten recalls for FY 2013–2019.

Materials and methods

All information relating to a recall event is collected and captured by the FDA in an information technology (IT) application called Recall Enterprise System (RES). Each recall event is assigned a RES ID with the appropriate 'reason for recall' selected from a predefined list. A recall event (referred to as a recall hereafter) is a firm's recall of one or more products. A web intelligence tool at FDA, Online Reporting Analysis Decision Support System (ORADSS), was used to build a query to search food allergen and gluten recalls from RES database files.

The scope of this study was to identify and analyze recalls associated with MFAs, gluten and other allergenic foods initiated from FY 2013 to 2019 (October 1, 2012 to September 30, 2019) and compare relative incidences, root causes, and other factors. The RES database was searched for recalls that had at least one of the following predefined 'reason for recalls': labeling/undeclared allergen, labeling/FALCPA violation, labeling/allergen cross-contact, labeling/undeclared nonallergenic ingredient, misc. labeling. Recalls do not include market withdrawals, and therefore, market withdrawals were excluded from the search. A subset of recalls identified by the search involved violations for undeclared sulfites or colors subject to batch certification by FDA (e.g., FD&C Yellow No. 5, FD&C Yellow No. 6) that are required to be specifically listed as they may cause allergic-type reactions in sensitive consumers. Since these latter substances are additives and not defined food allergens, they were not included within the study scope, and this information was not analyzed further. Further, other recalls which were not related to allergens were also considered outside study scope and excluded from further analysis. In some cases, a single root cause problem or incident can lead to multiple recalls. For example, allergen cross-contact occurring at an ingredient supplier facility might result in multiple products being recalled from several downstream manufacturers. These cases would lead to multiple recalls from the original root problem or incident and potentially skew the analysis of root causes. Recalls from the ORADSS search were manually screened to identify if the recall was a primary recall, i.e., a recall where the violation initially occurred. Downstream recalls related to or resulting from expansion of the primary recall were identified and excluded from further analysis.

Recalls identified by the search and within study scope were subsequently grouped into recalls due to MFAs, gluten, or other. When the recall was due to gluten-free misbranding violations, the category 'gluten' was used for such recall. The 'other' category involved misbranding violations for certain allergenic foods [e.g., sesame (prior to January 1, 2023), molluscan shellfish, etc.] that are not MFAs subject to MFA requirements but nonetheless are subject to FDA's general labeling requirements. Some of the foods implicated in the others category are priority allergens in other parts of the world and can pose an allergen hazard for a segment of the population (Gendel, 2012; Remington et al., 2020). Recall information such as the number and type of food allergens or gluten involved in the recall and category of recalled products was collected and analyzed. Major food allergens were subcategorized into individual eight MFAs (sesame excluded as it was not an MFA during the study period). When a recall involved multiple types or species from the same food allergen group (tree nuts, fish, Crustacean, and other), the number of allergens was considered one allergen for that group. For example, a recall involving almond and walnut allergens was considered a recall with one allergen type – tree nuts; whereas a recall involving almond and milk allergens was considered a recall with two allergen types – tree nuts and milk.

Recalls could involve a single product or multiple products from one or more food categories. Each product implicated in a recall was categorized based on the most appropriate FDA industry code (https://www.fda.gov/industry/import-program-resources/product-codes-and-product-code-builder). For example, cake would be categorized under FDA industry code of 03 - bakery products, dough, bakery mixes, and icings.

Every recall requires a health hazard evaluation (HHE) and recall classification. Recalls are classified by the FDA into three Classes (I, II, and III) to indicate the relative degree of health hazard presented

by the product being recalled. The violative product resulting in Class I recalls poses a reasonable probability of serious adverse health consequences or death, whereas those in Class II recalls pose a remote probability of serious adverse health consequences or temporary/reversible adverse health consequences. A Class III recall occurs when a violative product is not likely to cause adverse health consequences. Each product involved in a recall is classified individually into Class I, II, or III representing the highest to lowest health hazard. Therefore, if a recall involves multiple products, the recall may have different hazard classifications associated with the various products. For such recalls with multiple products and different hazard classifications, the highest health hazard classification associated with that recall was used for further analysis. For example, if a recall involves two products, with one classified as Class II and another as Class III hazard, the recall was identified as Class II for further analysis.

Additional recall information was collected such as RES ID, recall initiation date, reason for recall, recall classification, mode of discovery, and root cause. For certain additional recall information, other FDA internal documents, public press releases, or RFR data were queried to obtain recall-specific information. In some instances, recall-specific information, such as mode of discovery and root cause, was not clearly described and could not be readily determined by review of information available to FDA.

The study used similar categories of mode of discovery (i.e., how the recall problem was identified) and root cause analysis as those identified by Gendel and Zhu (2013). For the root cause analysis, the study included a few additional categories including foreign language (failure to declare one or more allergens in English language), partial allergen declaration (the 'Contains' statement does not list all MFAs or all MFAs are identified in the ingredient list but the 'Contains' statement on the label only identifies a partial list of the MFAs), and positive allergen test (analytical test revealed the presence of allergen). For recalls that fall under the positive allergen test category, information was insufficient to further categorize the recalls into the specific root causes used in this paper (e.g., rework, wrong ingredient); however, for some of these recalls, some information was available to determine the appropriate controls (cross-contact controls, supply chain controls) that could have been used to prevent the recalls. Allergen cross-contact means the unintentional incorporation of a food allergen into a food. Allergen cross-contact can occur due to a variety of reasons. For our analysis, five subcategories of allergen cross-contact root causes were identified: in-process (described by Gendel and Zhu (2013) as an unfinished product was added to the process stream for another product that was not intended to have the same allergen(s)), positive allergen test, rework (described by Gendel and Zhu (2013) as a finished product was added to the process stream for another product that was not intended to have the same allergen (s)), wrong ingredient, and "other" cross-contact. Other cross-contact captured allergen cross-contact issues related to cleaning/sanitation, shared equipment or food contact surface, adjacent line run, unknown reasons, etc. and closely represent the "cross-contact" root cause category used by Gendel and Zhu (2013). In case of multiple root causes due to different allergens and products involved in a recall, the root cause associated with the product of the highest recall classification was used. All of the root causes were further grouped into five broad categories: raw or incoming ingredients, processing or production, labeling and packaging, other, and unknown.

The data were analyzed using SAS. When possible and appropriate, analysis was conducted to be consistent with the previous analysis by Gendel and Zhu (2013) to facilitate comparison of food allergen recalls for FY 2013–2019 with food allergen recalls for FY 2007–2012.

Results

Incidence and classification of food allergen and gluten (FA/G) recalls

The ORADSS search identified a total of 2033 recalls for FY 2013–2019, of which 1705 recalls met criteria for a FA/G issue. A total of 234 recalls determined to be downstream recalls or related recalls associated with a primary recall were removed from the analysis. Thus, a total of 1471 FA/G recalls with unique RES IDs were included in the final analysis. These could be further broken down into recalls primarily involving MFAs (N = 1415; 96.2%), gluten (N = 34; 2.3%), and other potential food allergen hazards that are not MFA (N = 23; 1.6%) (Table 1). One of the FA/G recalls involved both the MFA and other allergens.

FA/G recall numbers by FY during the study period increased from FY 2013 (173 recalls) to a peak in FY 2017 (255 recalls) and were lower in FY 2018 (232 recalls) and FY 2019 (188 recalls). Figure 1 provides the timeline of FA/G recalls and respective classifications (I, II, or III) for FY 2013–2019 including (Fig. 1A) and excluding (Fig. 1B) downstream or related recalls. The highest spike seen in early 2015 (Fig. 1A) represents multiple downstream recalls for violative food products containing cumin with various levels of peanut hazard; this was the single largest recall resulting in various downstream/related recalls involving an MFA over the study period. Among the 1471 FA/G recalls (Fig. 1B), 725 were Class I recalls (49.3%), 696 were Class II recalls (47.3%), and 50 were Class III recalls (3.4%).

Incidence and hazard classification of MFA recalls

In order to allow comparisons with prior 2007–2012 recall analyses *(4)*, we analyzed MFA recalls separately. MFA recalls (N = 1415) increased from FY 2013 (169 recalls) to FY 2017 (244 recalls), fol-

Table 1
Frequency of food allergen and gluten (FA/G) recalls for FY 2013–2019

Allergen category	Allergen	Number of recalls	% of total recalls
Major food allergen (MFA)	-	1415[1]	96.2[3]
	Milk	531	37.5[2]
	Soy	319	22.5[2]
	Tree nut	305	21.6[2]
	Wheat	258	18.2[2]
	Egg	205	14.5[2]
	Peanut	171	12.1[2]
	Fish	55	3.9[2]
	Crustacean shellfish	35	2.5[2]
Gluten	-	34	2.3[3]
Other[4]	-	23	1.6[3]

[1] Total of different MFA recalls in this column is 1879 as some recalls involved more than one MFA.
[2] Percent based on 100% of 1415 total MFA recalls.
[3] Percent based on 100% of 1471 total FA/G recalls
[4] This category represents potential food allergen hazards that are not MFAs

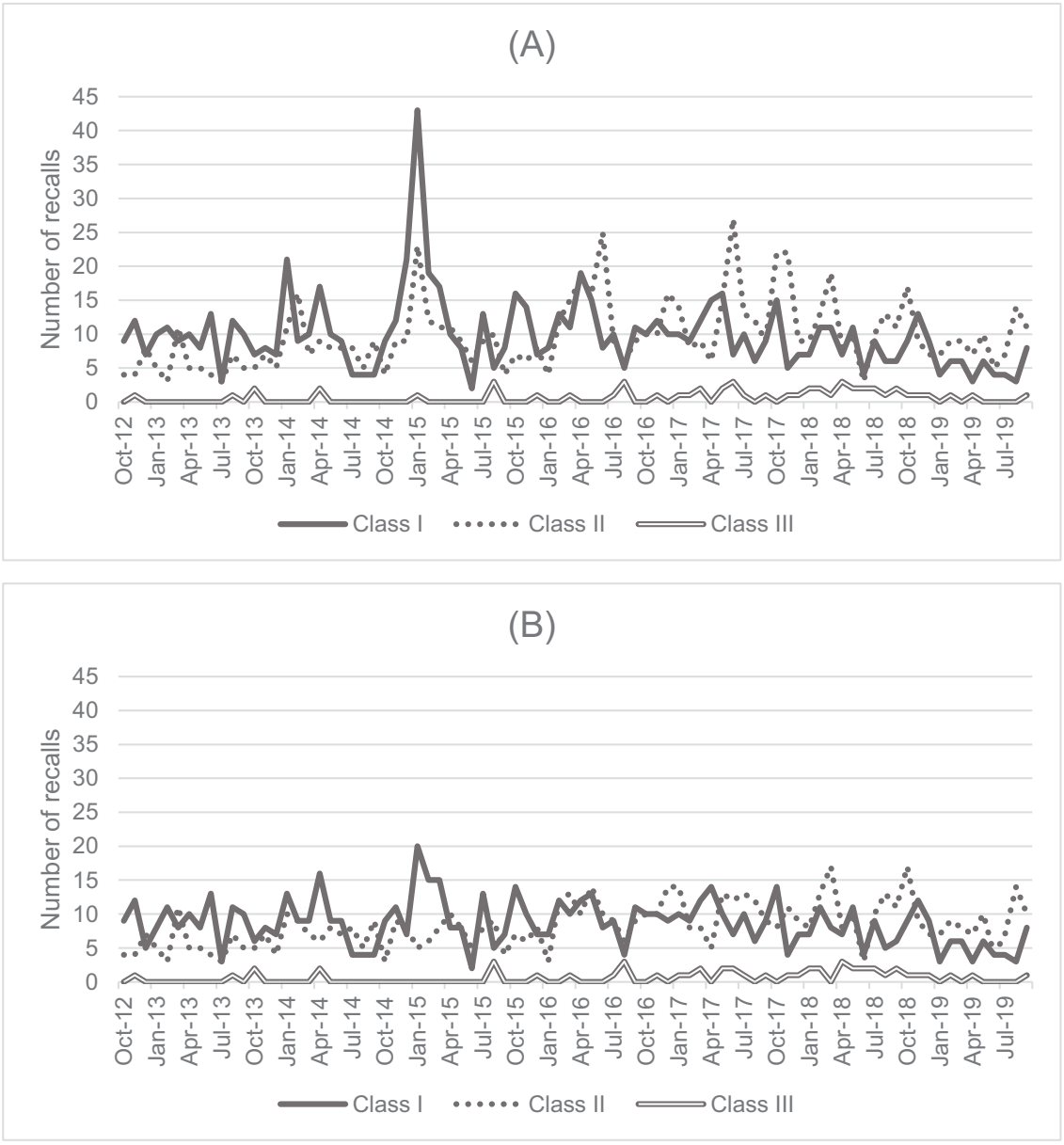

Figure 1. Incidences of food allergen and gluten (FA/G) recalls initiated in FY 2013–2019 and respective classifications (I, II, or III) including (A) and excluding (B) downstream and related recalls. Figure 1B represents primary recall data used for additional analysis.

lowed by a decrease to 226 and 174 recalls for FY 2018 and 2019, respectively (Fig. 2).

Recall hazard classification for MFAs by FY is presented in Figure 3. Over the study period, 51.2% of recalls were Class I, 45.5% were Class II, and 3.3% were Class III. The frequency of Class I MFA recalls was highest during FY 2013–2016 (53.7–63.9% of FY recalls). During FY 2017–2019, a greater frequency of MFA recalls were Class II recall representing 48.0, 51.8, and 55.2% of MFA recalls for FY 2017, 2018, and 2019, respectively.

MFAs, gluten, or other allergen issues involved in recalls

A recall could involve one or multiple food allergens or gluten. There were 1879 instances of MFAs associated with MFA recalls (Table 1). Milk was the leading MFA identified in 531 recalls (37.5%), followed by soy (22.5%), tree nut (21.6%), wheat (18.2%), egg (14.5%), peanut (12.1%), fish (3.9%), and Crustacean shellfish (2.5%). Among MFA recalls, 78.8% (N = 1115) and 13.6% (N = 193) involved one and two MFA, respectively. More than two MFAs were involved in 7.6% of MFA recalls (data not shown).

For 287 out of 305 recalls involving tree nuts, there was information on the type of tree nut involved. Almond was the most frequent cause (100 recalls) followed by walnut (61 recalls), pecan (57 recalls), and coconut (51 recalls). Among 43 of 55 fish allergen recalls with information on specific fish species, anchovy ranked first (30 recalls). Among 28 out of 35 Crustacean shellfish allergen recalls with information on specific species, shrimp was the leading cause (22 recalls).

Of 34 recalls that involved gluten, 17 recalls were due to finding of a gluten ingredient in foods labeled gluten-free and the other 17 were due to cross-contact issues (e.g., finding of gluten >20 ppm in gluten-free product by analytical test). Of the 17 recalls involving gluten ingredient, gluten source was specified as wheat in 9 recalls, barley in 4 recalls, wheat and barley in 1 recall, and unknown in 3 recalls.

Twenty-three recalls involved other food allergen hazard categories. Among these, molluscan shellfish was the most frequently recalled food (6 recalls, of which 4 and 2 recalls involved squid and

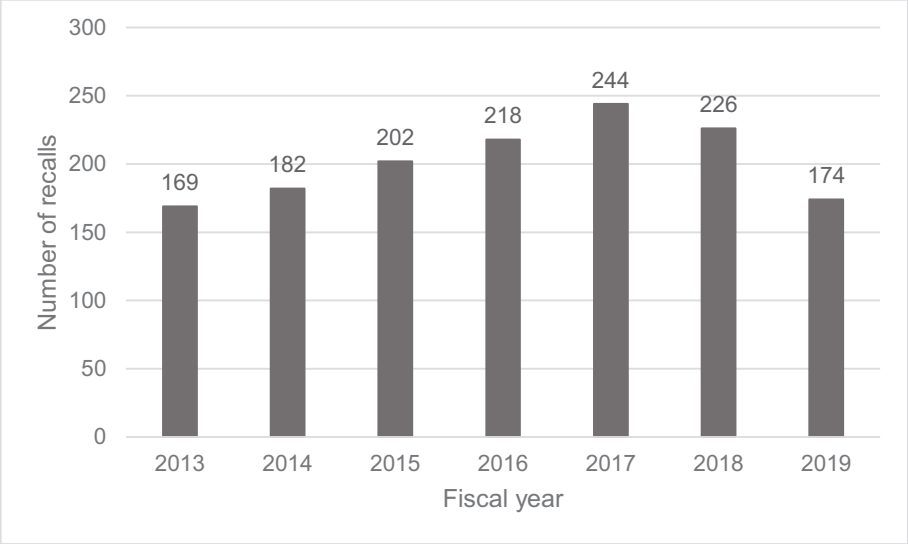

Figure 2. Number of major food allergen (MFA) recalls (N = 1415) initiated in FY 2013–2019.

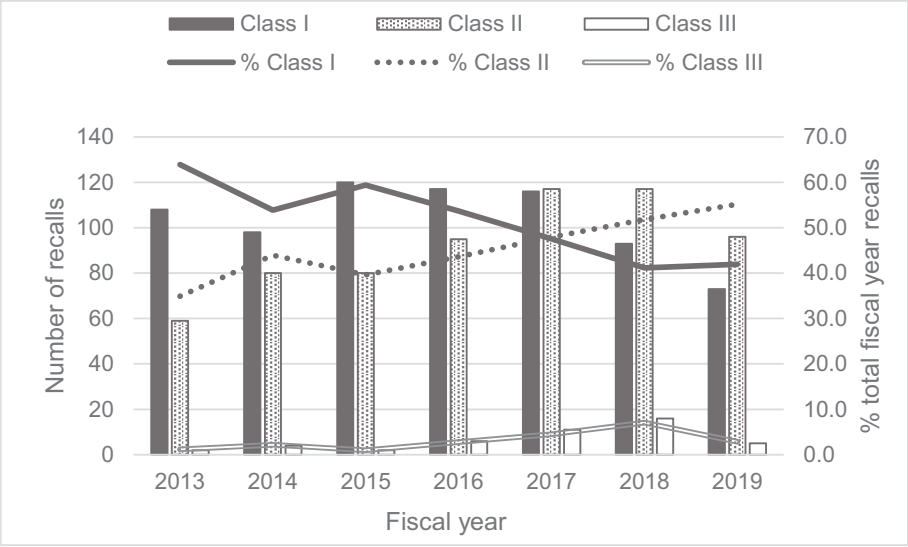

Figure 3. Classification of major food allergen (MFA) recalls (N = 1415) initiated in FY 2013–2019.

oyster, respectively), followed by sesame (5 recalls). Other non-MFAs (such as apple, banana, garlic, celery, etc.) were involved in either 2 or 1 recalls.

Hazard classification of recalls based on MFA cause

Among recalls involving a single MFA cause, milk was the leading cause responsible for 355 out of 1115 recalls (31.8%) followed by tree nuts (20.0%) and soy (12.7%) (Table 2). In total, 48.7% of single MFA cause recalls were Class I, 47.5% were Class II, and 3.8% were Class III recalls (Table 2). Hazard classifications varied depending on the MFA category. The majority of recalls associated with egg (87.2%), Crustacean shellfish (66.7%), peanut (62.7%), and milk (61.4%) resulted in Class I recalls. Tree nut-related recalls were about equally classified as Class I (44.8%) and Class II (50.7%). On the other hand, the majority of recalls associated with soy (69.7%), fish (68.0%), and wheat (94.9%) resulted in Class II recalls. All 34 gluten recalls were Class II recalls, whereas 22 recalls involving only other food allergens were either Class II (18 recalls) or Class III (4 recalls).

Product categories

The great majority (97%) of the FA/G recalls involved only one product category, with multiple product categories involved in only 44 recalls. Among 34 gluten recalls, the most frequently recalled product category was snack food items. In addition, among FA/G recalls, 71.7% of recalls (N = 1055) involved one product and 28.3% (N = 416) involved multiple products.

Among 1415 MFA recalls, 71.5% of recalls (N = 1012) involved one product. The different product categories associated with recalls involving MFAs are presented in Table 3. Multiple product categories were involved in 43 MFA recalls. Among the 1372 MFA recalls with one product category, 'bakery products, dough, bakery mixes, and icings' ranked highest with 367 recalls, followed by 'chocolate and cocoa products' (120 recalls), 'multiple food dinners, gravies, sauces

Table 2
Frequency of recalls involving a single major food allergen (MFA) cause (N = 1115) and respective hazard classification.

Allergen	Number of recalls				% of total recalls
	Class I	Class II	Class III	Total	
Milk	218	129	8	355	31.8
Tree nut	100	113	10	223	20.0
Soy	33	99	10	142	12.7
Peanut	79	42	5	126	11.3
Wheat	0	111	6	117	10.5
Egg	95	13	1	109	9.8
Fish	6	17	2	25	2.2
Crustacean shellfish	12	6	0	18	1.6
Total	543	530	42	1115	100

Table 3
Frequency of major food allergen (MFA) recalls based on product categories involved in the recall. Top five recalled product categories are marked by an asterisk

Product categories [Industry code]	Multiple MFA	Crustacean shellfish	Egg	Fish	Milk	Peanut	Soy	Tree nut	Wheat	Total
Bakery Products, dough, bakery mixes, and icings* [03]	83[a]	0	33[a]	1	89[a,b]	22	33[a]	75[a]	31[a]	367
Candy without chocolate, candy specialties, and chewing gum [33]	3	0	4	1	9	4	3	6	1	31
Cereal preparations, breakfast foods [05]	5	0	0	1	5	1	5	20	4	41
Cheese and cheese products [12]	1	0	6	0	4	0	3	2	3	19
Chocolate and cocoa products* [34]	22	0	1	0	42[b]	25[a]	7	20	3	120
Coffee and teas [31]	2	0	0	0	7	1	1	2	0	13
Dietary conventional foods and meal replacements [41]	5	0	0	0	8	3	1	4	0	21
Dressings and condiments [27]	13	0	7	3	10	1	4	2	2	42
Fishery/fishery products [16]	20	8[a]	12	1	9	0	9	1	3	63
Fruit and fruit products [20-22]	2	0	0	0	6	4	0	4	1	17
Ice cream and related* [13]	12	0	5	0	8	20	2	23[b]	2	72
Macaroni and noodle products [04]	3	1	6	2	2	1	3	1	5	24
Milk, butter, and dried milk products [09]	7	0	4	0	6	1	1	8	1	28
Multiple food dinners, gravies, sauces, and specialties (total diet)* [37]	31[b]	2	15	8[a]	20	1	10	11	12	110
Multiple categories	19	0	1	0	6	0	7	4	6	43
Nuts and edible seeds [23]	11	0	0	0	6	16	4	17	8	62
Others[1]	4	1	3	1	18	1	6	3	1	38
Prepared salad products [39]	17	0	4	1	4	1	3	3	7	40
Snack food items (flour, meal, or vegetable base)* [07]	9	0	3	1	45[b]	6	11	6	5	86
Soups [38]	3	2	1	1	6	0	1	2	4	20
Spices, flavors, and salts [28]	4	0	0	0	16	6	4	0	7	37
Vegetable protein products (simulated meats) [18]	0	0	2	0	1	1	4	1	1	10
Vegetable and vegetable products [24-25]	11	3	1	1	8	9	8	8	2	51
Vitamins, minerals, proteins, and unconventional dietary specialties for human and animals [54]	11	1	1	3	19	0	8	0	1	44
Whole grains, milled grain products, and starch [02]	2	0	0	0	1	2	4	0	7	16
Total	300	18	109	25	355	126	142	223	117	1415

[1] Includes all other product categories with less than 10 recalls per category.
[a] Most frequently recalled product category for the specified MFA column.
[b] Most frequently recalled MFA for the top five product categories.

and specialties (total diet)' (110 recalls), 'snack food items' (86 recalls), and 'ice cream and related' (72 recalls).

Milk was the most common allergen hazard for the top four product categories ('bakery products, dough, bakery mixes, and icings'; 'chocolate and cocoa products'; 'multiple food dinners, gravies, sauces and specialties'; and 'snack food items') involved in MFA recalls (Table 3). Tree nut was found to be the top-ranked allergen hazard for the 'ice cream and related' category.

For recalls associated with egg, soy, tree nuts, or wheat, the category of 'bakery products, dough, bakery mixes, and icings' was the most frequently implicated food category (Table 3). For recalls associated with Crustacean shellfish, fish, or peanut, the most frequently implicated food categories were 'fishery/fishery products', 'multiple food dinners, gravies, sauces, and specialties (total diet)', and 'chocolate and cocoa products', respectively (Table 3).

Mode of discovery of MFA recalls

Table 4 provides the frequency of MFA recalls based on the mode of discovery. The majority of the recalls were discovered by "complaint" (27.7%), i.e., problems reported by a customer or others that did not involve adverse reaction. The recalling, manufacturing or the responsible firm discovered the issue in 19.7% of the total MFA recalls analyzed. The FDA and other government agencies (domestic and foreign) identified the issue in 13.6% and 15.2% of total MFA recalls, respectively. Adverse reactions to consumers were reported in 8.8% of total MFA recalls analyzed. Mode of discovery was not identified in FDA's data system for 14.9% of total MFA recalls.

Root causes for MFA recalls

Nineteen different root cause categories were identified for the MFA recalls (Table 5, N = 1415), of which two categories did not have known root cause information (unknown and omission). A total of 1286 MFA recalls (90.9%) had known root cause information. For root cause discussions, the results and percentages are based on either total MFA recalls (N = 1415; Table 5) or MFA recalls with known root cause (N = 1286), as appropriate.

The root causes were further grouped into broader allergen control and source of problem categories. These were selected based on broad

Table 4
Frequency of major food allergen (MFA) recalls (N = 1415) based on their mode of discovery

Discovered by	Description	Number of recalls	% of total recalls
Complaint	Includes complaint from consumer, downstream customer, distributor, or others; did not involve allergic or other adverse reactions	392	27.7
FDA	Includes inspection or other means of discovery by FDA	193	13.6
Firm	Includes recalling firm, manufacturing firm, or responsible firm	279	19.7
Other government	Includes inspection, notification or other means of discovery by State agencies, other federal agencies, or foreign government	215	15.2
Reaction	Includes consumer adverse reaction associated with the consumption of the product	125	8.8
Unknown	mode of discovery not identified based on available information to FDA	211	14.9

Table 5
Frequency and classification of major food allergen (MFA) recalls based on their root causes. Top five root causes are marked by an asterisk

Root cause[1]	Number of recalls				% of total recalls
	Class I	Class II	Class III	Total	
Computer error	35	14	4	53	3.7
Foreign language	6	3	3	12	0.8
In process	15	2	0	17	1.2
Ingredient mislabeled	11	10	0	21	1.5
Knowledge	8	24	2	34	2.4
No carry-through*	104	123	4	231	16.3
No declaration	4	21	0	25	1.8
Not updated	37	18	1	56	4.0
Omission*	58	52	1	111	7.8
Other	35	31	5	71	5.0
Other cross-contact[2]	58	41	2	101	7.1
Partial declaration	12	19	4	35	2.5
Positive allergen test	69	19	0	88	6.2
Rework	9	7	0	16	1.1
Terminology*	23	94	4	121	8.6
Unknown	11	7	0	18	1.3
Wrong ingredient	55	23	1	79	5.6
Wrong label*	92	59	10	161	11.4
Wrong package*	83	77	5	165	11.7
Total	725	644	46	1415	100.0

[1] Root cause associated with the highest class of product recalls used when multiple products with different root cause involved in a recall.
[2] Includes other forms of cross-contact not specified in the Table.

type of allergen controls and/or specific manufacturing areas that could have been implemented to prevent MFA recalls (Table 6). For example, “processing or production” source of problem could potentially be prevented by the implementation of proper allergen cross-contact controls. Of the 1286 MFA recalls with known root causes, source of problem and potential controls that could have prevented the recalls were not identified in 123 recalls and those include 52 out of 88 recalls under the “positive allergen test” root cause and all of the 71 recalls under the “other” root cause. Thus, for discussions on appropriate controls that could have prevented the MFA recalls (Table 6), the results and percentages are based on 1163 MFA recalls (1286 − 123 = 1163).

No carry-through ranked first among root causes resulting in 231 out of 1415 MFA recalls (16.3%), followed by wrong package (11.7%), wrong label (11.4%), and terminology (8.6%) (Table 5). These top four root causes for MFA recalls were all label-related and together comprised 52.7% (678 out of 1286) of MFA recalls with known root cause. Other label-related root causes for MFA include computer error, foreign language, ingredient mislabeled, knowledge, no declaration, not updated, and partial declaration, which accounted for 18.4% of MFA recalls with known root cause. Overall, allergen label-related errors resulted in 64.6% (N = 914) of total MFA recalls or 71.1% of MFA recalls with known root cause. The root cause of omission is excluded from ‘known’ root cause as it represented situations where one or more allergen was not declared without detailed information on the cause. If all allergen recalls due to omission was caused by labeling error, the overall allergen label-related errors could be 72.4% of total MFA recalls.

Allergen cross-contact resulted in 21.3% (N = 301) of total MFA recalls or 23.4% of MFA recalls with known root cause. It should be noted that for our analysis, we use the definition of “allergen cross-contact” in 21 CFR part 117 (i.e., unintentional incorporation of a food allergen into a food; established in 2015) to categorize food recall root causes. Therefore, in our study, allergen cross-contact includes a broader category of root causes related to various problems in manufacturing practices leading to unintended allergen presence in food products, such as in-process, positive allergen test, rework, and wrong ingredient. The closest category comparable to ‘cross-contact’ from the FY 2007–2012 analysis by Gendel and Zhu (2013) is the “other cross-contact” category in our analysis that included cross-contact due to inadequate sanitation practices. This category represented 7.1% of total MFA recalls which is same as an estimated percentage of total recalls due to cross-contact (52 out of 732 recalls; 7.1%) found by Gendel and Zhu (2013). Another common cause of recalls due to likely allergen cross-contact was a wrong ingredient with unintended allergen presence that was not communicated on the product label (5.6% of total MFA recalls) (Table 5).

Among 1415 MFA recalls, 1163 recalls were identified to have specific root causes and source of problem (excluding omission, other or unknown root causes, and those positive allergen test root cause with no identifiable source of problem), of which 662 recalls belonged to labeling and packaging as source of problem, followed by 307 recalls to raw or incoming ingredients and 194 recalls to processing or production. Based on recalls with known and specific information available on root cause and source of problem, we find that label controls (includes label content controls and label management controls)

Table 6
Identification of allergen control and source of problem categories based on root cause problem for major food allergen (MFA) recalls[1]

Allergen controls	Source of problem	Root cause	Number of recalls	% of total recalls
Cross-contact controls	Processing or production	In process	17	1.5
		Other cross-contact	79	6.8
		Positive allergen test	17	1.5
		Rework	16	1.4
		Wrong ingredient	65	5.6
Total cross-contact controls			*194*	*16.7*
Label content controls	Labeling and packaging	Computer error	53	4.6
		Foreign language	12	1.0
		Knowledge	34	2.9
		No declaration	25	2.2
		Not updated	56	4.8
		Partial declaration	35	3.0
		Terminology	121	10.4
	Raw or incoming ingredients	No carry-through	231	19.9
Total label content controls			*567*	*48.8*
Label management controls	Labeling and packaging	Wrong label	161	13.8
		Wrong package	165	14.2
Total label management controls			*326*	*28.0*
Supply chain controls	Raw or incoming ingredients	Ingredient mislabeled	21	1.8
		Other cross-contact	22	1.9
		Positive allergen test	19	1.6
		Wrong ingredient	14	1.2
Total supply chain controls			*76*	*6.5*
Total allergen controls			1163	100.0

[1] Recalls with omission, other or unknown root causes and those with positive allergen test root cause with no known source of problem were excluded.

could have prevented 893 out of 1163 MFA recalls (76.8%), whereas allergen cross-contact controls and supply chain controls could have prevented 16.7% and 6.5% MFA recalls, respectively (Table 6). If omission represented labeling error and fell under the labeling and packaging source of problem, then label controls could have prevented 78.8% (1004 out of 1274) of recalls with specific root cause and source of problem.

Discussion

Allergens remain a top food safety concern across the world (Soon et al., 2020). Incidences of food allergen or gluten safety problems in packaged food products can sometimes lead to multiple downstream or related recalls (Fig. 1A). A main finding of our study is that overall recall numbers due to allergen hazard problems remain high and labeling errors continue to be the main cause of MFA recalls in the period from FY 2013 to 2019, very similar to results reported from a previous analysis of allergen recall data from FY 2007 to 2012 (Gendel & Zhu, 2013). This again reinforces the importance of following sound allergen preventive controls in food production and management.

Recall data for FY 2013–2019 continued to show some consistent findings from prior recall database analyses. The majority of FA/G recalls (80%) involved a single allergen problem, and the incidence rate of recalls associated with multiple allergens (20%) is similar to other recent datasets which showed 22–24% of recalls involving multiple food allergens (Bucchini et al., 2016; Soon et al., 2020). The percentages for number of MFAs involved in the recalls in our study are similar to those reported by Gendel and Zhu (2013) for FY 2007–2012. Among MFAs, milk remained the most frequently implicated allergen. This finding is consistent with previous findings from the US and other global food allergen recall data analyses in which milk ranked top among allergens involved in 24–40% of food allergen recalls. (Bucchini et al., 2016; Gendel & Zhu, 2013; Soon et al., 2020). Milk was also associated with a majority of recalls by main allergen-related recall product categories (Table 3), similar to FY 2007–2012 data (Gendel & Zhu, 2013). The next most commonly implicated food allergens in the FY 2013–2019 dataset were in order: soy, tree nuts, and wheat. Compared to FY 2007–2012, the order of these foods was different with soy replacing wheat as the second most common allergen cause (Gendel & Zhu, 2013). A possible explanation for this is that our study separated out gluten recalls, which may have comprised (and thus lowered the corresponding number of) some recalls attributed to wheat in the past. However, it is noteworthy that the final rule for voluntary gluten-free labeling was issued in 2013. Thus, a potential reason for a lower relative percentage of wheat recalls compared to FY 2007–2012 may be increasing awareness of wheat gluten source labeling and cross-contact brought on by this regulation.

In this study, based on FDA industry codes, bakery and related products continue to remain an important product category of concern for MFA recalls. The Bakery category also ranked first with 31.5% of total food allergen recalls, followed by Snack (12.1%), Candy (10.0%), Dressing (8.0%), and Dairy (7.9%) for FY 2007–2012, which categorized products based on RFR categories (https://www.fda.gov/media/78732/download) (Gendel & Zhu, 2013). Bucchini et al. (2016) used RFR categories to analyze products recalled due to allergens from various countries/regions and found that overall, the bakery category was most frequently recalled for allergens (20% of total product/allergen combination) in 2011–2014, and is the top-ranked product category for recalls in the databases of European Commission (Rapid Alert System for Food and Feed), US (FDA), and Canada (Canadian Food Inspection Agency).

A shifting trend from Class I to Class II/III recalls for MFA was noted during FY 2007–2012 analysis (Gendel & Zhu, 2013). Our study of FY 2013–2019 data also found the relative percentage of allergen recalls classified as Class I decreased over the study period whereas the relative percentage of Class II recalls appeared to increase. This change did not reflect a general decrease in Class I recalls for allergens (Fig. 3) and was not impacted by a decrease in number of Class I allergen RFR submissions over the study period (https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard). FDA's HHE determination for classifications of recalls is based on available information about the product and considers a number of factors, including the type of hazard and the likelihood of occurrence of the hazard (21 CFR 7.41). We did not further systematically analyze HHE data for the reasons that may have contributed to Class I versus Class II recall determinations.

Compared with previous FY 2007–2012 recall analysis by Gendel and Zhu (2013) of the recalls with known mode of discovery, there was a shift observed from discoveries by government agencies includ-

ing FDA (44.1% of recalls in FY 2007–2012 vs 33.9% in FY 2013–2019) to discovery primarily by complaint (26.8% in FY 2007–2012 vs 32.6% in FY 2013–2019) or by the firm (16.5% in FY 2007–2012 vs 23.2% in FY 2013–2019). However, government agencies (FDA + other government) continued to be the top-ranked mode of discovery, followed by complaint and firm discoveries for both FY 2007–2012 and FY 2013–2019. The proportion of adverse reactions among recalls with known mode of discoveries over the study periods remained relatively constant at 12.6% of recalls in FY 2007–2012 and 10.4% in FY 2013–2019.

Allergen-related errors are the most common cause of label errors and can be responsible for over 90% of recalls due to labeling errors (Soon and Wahab, 2021). Our study found that allergen label-related errors resulted in 64.6% of total MFA recalls (71.1% of MFA recalls with known root cause; Table 5). Despite an increase in number of allergen recalls in FY 2013–2019 as compared to FY 2007–2012, the relative proportion of root cause problems did not vary much. A similar finding of 56% label-related errors was reported by Zurzolo et al. (2020) for allergen recalls by Food Standards Australia New Zealand (FSANZ) for the years 2016–2018. Wrong package and wrong label combined were responsible for 25.3% of recalls with known root cause (excluding omission and unknown) in FY 2013–2019, similar to 26% of MFA recalls with known root cause in FY 2007–2012 (Gendel & Zhu, 2013).

Our study found that allergen cross-contact (including root causes of in-process, other cross-contact, positive allergen test, rework, and wrong ingredient) resulted in 21.3% of total MFA recalls (23.4% of MFA recalls with known root cause). In comparison, Gendel and Zhu (2013) found 15.2% (111 out of 732) of food allergen recalls were due to the root cause of cross-contact, in-process, rework, or wrong ingredient for FY 2007–2012. Cross-contact was responsible for 10% of allergen recalls by FSANZ for 2016–2018 (Zurzolo et al., 2020). One potential contributor to a higher percentage of recalls due to cross-contact in our study is that we also included 88 recalls with positive allergen test result. Among 88 recalls with root cause of positive allergen test, some information was available to identify the source of problem – processing or production (17 recalls) and raw or incoming ingredients (19 recalls) (Table 6). It is possible that not all these 88 recall scenarios represented an unintended allergen cross-contact problem.

Under the preventive controls requirements of the CGMP and PC rule, applicable food facilities are required to implement food allergen controls that includes (1) cross-contact controls to prevent or significantly minimize allergen cross-contact and (2) label controls to ensure allergens are properly labeled on the finished food. Although juice and seafood would follow their respective HACCP programs, their processors would also use a similar approach to control allergen hazard. In this study, we found that 76.8% of MFA recalls with specific root cause and source of problem were likely due to inadequate label controls (Table 6). Among the 893 recalls with labeling-related root causes, adequate label content controls (e.g., measures to ensure proper allergen declaration) could have prevented 567 out of 893 recalls (63.5%), while adequate label management controls (e.g., measures to ensure correct label or package is used) could have prevented the other 326 recalls (36.5%). Similarly, inadequate label controls were a major cause for food allergen recalls in FY 2007–2012, responsible for 67% of recalls with known root causes and 58% of inadequate label controls were linked to label content issue (Gendel & Zhu, 2013). These results suggest that food manufacturers should pay close attention to ensure adequate allergen label controls are in place to protect public safety and prevent food allergen recalls.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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