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General Interest

An Analysis of Food Recalls in the United States, 2002–2023

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ABSTRACT

This article evaluates and summarizes Food and Beverages (F&B) recalls managed or mandated by the U.S. Food and Drug Administration (FDA) over the past 20 years: the database includes over 35,000 recalls. For recall classification purposes, the causes were separated into 2 overall categories consisting of **product contaminants** or **processing issues**. The **product contaminants** category was further separated into 5 groups: allergens, biological contaminants, chemical contaminants, foreign objects, and undeclared food colors. The **processing issues** category was separated into 6 groups: cGMP issues, HACCP issues, manufacturing issues, mislabeling or misbranding, refrigeration issues, and under-processing. **Product contaminants** accounted for 91% of the F&B recalls, while **processing issues** accounted for the remaining 9%. Two groups accounted for about 76% of the recalls: biological contamination and allergens. The FDA classifies recalls by the potential severity of the health impact. Over half of the F&B recalls were Class I recalls, and biological contamination and allergens accounted for 96% of those recalls. *Listeria monocytogenes* was the largest cause of all of the recalls accounting for 7,844 recalls: 22% of the total recalls and 45% of the biological contamination recalls. *Salmonella* serovars were responsible for 6,597 recalls, including 18% of the total recalls and 38% of the biological recalls. *Listeria* and *Salmonella* serovars together resulted in 40% of all of the F&B recalls.

This article evaluates and summarizes Food and Beverages (F&B) recalls managed or mandated by the U.S. Food and Drug Administration (FDA) over the past 20 years. The scope of the review does not include F&B recalls overseen by the U.S. Department of Agriculture (USDA). While the FDA is responsible for most of the F&B products marketed in the U.S., the USDA regulates foods composed of meat, poultry, Siluriformes (catfish), and some egg products (USDA, 2023). The USDA also regulates the labeling standards for organic foods (USDA, 2024).

Food law in the United States. Dunkelberger (1995) offers a thorough history of the Food, Drug and Cosmetic Act (FDCA), Good Manufacturing Practices (GMPs), and Hazard Analysis and Critical Control Points (HACCP) programs. The Food Safety Modernization Act (FSMA) is the overarching law that covers all food regulated by the FDA. FSMA was passed in 2011 and includes risk-based current Good Manufacturing Practices (cGMPs) for both humans and pets. Seafood and juice are excluded from portions of the FSMA regulation only when preexisting regulations are already in place. For example, Seafood HACCP and Juice HACCP preempt FSMA's Preventive Controls Rule, while seafood and juice products are subject to FSMA's Sanitary Transport Rule and Intentional Adulteration Rule, among other rules (FDA, 2017; FDA, 2021d). After FSMA was passed, a new cGMP (21CFR§117) for humans was codified (Fed. Reg., 2015).

The FDA regulations for food safety include controls for acidified and low-acid canned foods, color additives, dietary supplements, food ingredients and packaging, foodborne illness, food labeling and nutrition, infant formula, pesticides and chemical contaminants, and seafood and juice HACCP (University of Maryland Extension, 2023; FDA, 2024f).

The FDA regulates both finished dietary supplement products and dietary ingredients; however, it regulates them under a different set of regulations than those covering conventional foods. The Dietary Supplement Health and Education Act was passed in 1994 (U.S. Congress, 1994). The current Good Manufacturing Practice for dietary supplements is 21CFR§111, under Subchapter B – Food for Human Consumption, so the FDA considers dietary supplements as food (FDA, 2011).

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Food safety control and compliance with regulations are the foundation of a successful food safety culture and are crucial in maintaining **food safety**, **food quality**, and **protection of consumers**. A key component of the food safety, quality, and consumer protection program implemented by the FDA involves the monitoring and management of food adulteration, which includes the process of managing food recalls.

Food is considered adulterated and subject to recall if it, the food, meets any of the following criteria:

1. "If it contains a harmful substance and a potential food safety risk."
2. "If it contains an added harmful substance that cannot be reasonably avoided and exceeds permissible tolerance levels."
3. "If it includes a substance intentionally added to the food but not approved by a regulatory agency."
4. "If it has been handled under unsanitary conditions that may lead to contamination with substances that may pose safety threats." (Smartsense, 2023).

Food safety culture. Despite being a relatively recent development, an emphasis on ***food safety culture*** is and has been vital in preventing recalls and other food safety incidents. Food producers must develop and cultivate strong food safety cultures throughout their facilities and supply chains, surpassing mere compliance with minimum requirements (FDA, 2021c). Frank Yannis, former Deputy Commissioner for Food Policy and Response with the FDA, summarized the foundation of a food safety culture as "patterned ways of thought and behavior … it's the idea that food safety is a belief that all consumers matter, that we care about their safety and the safety of their friends and families" (FDA, 2019).

New era of smarter food safety. The FDA announced the blueprint for the New Era of Smarter Food Safety (NESFS) in July 2020 and published it in 2021. NESFS is focused on 4 key elements: (1) Tech-enabled Traceability; (2) Smarter Tools and Approaches for Prevention and Outbreak Response; (3) New Business Models and Retail Modernization; and (4) Food Safety Culture. It is hoped that those four elements, working together, will "create a safer and more digital, traceable food system." (FDA, 2021c). This initiative aims to minimize recalls and enhance their management. While not legally binding, this document delineates the FDA's standards and should be adhered to in conjunction with FDA regulations pertaining to food safety.

Food recall groups. This study focuses on the cause analysis of the recall groups. The existing FDA F&B database includes over 35,000 recalls for the past 20 years. The large number of recalls for adulterated foods can be grouped in multiple ways. The two major categories for recall classifications are **product contaminants** and **processing issues**. The causes of two major categories for recall classifications were further separated into a total of 11 groups. The product contaminants groups are allergens, biological contaminants, chemical contaminants, foreign objects, and undeclared food colors. The processing issues groups are cGMP, HACCP, manufacturing issues, mislabeling or misbranding, refrigeration issues, and under-processing.

Allergens. True food allergies may produce harmful immune responses in humans to specific components of certain foods. Typically, these immune reactions are triggered by naturally occurring proteins present in the foods (Taylor & Hefle, 2001). The Food Allergen Labeling and Consumer Protection Act (FALCPA) lists 8 primary allergenic foods: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. Sesame was added as a ninth allergen in food in 2023 (U.S. Congress, 2021).

Food allergies and other food sensitivities are adverse reactions to foods and differ in different individuals. These food-related illnesses affect a subset of individuals in the population and most consumers can eat the same foods with no ill effects (Taylor and Hefle, 2001). The Centers for Disease Control estimates that 6.2% of adults and 5.8% of children have a food allergy (CDC, 2023).

Recalls for allergens are caused by cross-contact during processing at the final processing plant because of the inadvertent addition of the wrong ingredient(s) or because the wrong label was applied to the finished product. Such errors may occur in the factory through human error. They may also occur at the supplier level and be spread further down the supply chain; thus, one error at a supplier can impact multiple companies. The risk of supplier error is evidence of the need for a robust supplier approval program in addition to internal allergen control plans, as supplier errors can quickly lead to far-reaching impacts across the industry.

Compliance policy guideline (CPG) 555.250 (FDA, 2023e) is a statement of federal policy for **labeling** and preventing cross-contact of common food allergens. An extensive amount of literature has been published on how to clean food preparation areas in order to prevent cross-contact and correctly label food products for allergens. These publications include allergen-control checklists for the food industry (Deibel et al., 1997; Jackson et al., 2008). Additionally, the FDA published Chapter 11: Food Allergen Program in the Hazard Analysis and Risk-Based Preventive Controls (HARPC) for Human Food: Draft Guidance for Industry which has guidance for establishing a Food Allergen Program as part of a Food Safety Plan (FDA, 2024b).

Biological contamination. The presence of some severe biological contaminants such as the bacteria *Listeria monocytogenes* and *Salmonella* serovars are not allowed at any level in food products. The food processing area also has zero tolerance for these bacteria that are known to cause illness and even death. Any presence of these pathogens on or in the food or food contact surfaces is considered adulteration and can force a recall (FDA, 1995b, 2008, 2010a).

It is important to note that for some segments of the food industry, namely agriculture, biological contamination may be introduced to the food in the field. Bacteria such as *L. monocytogenes* are ubiquitous in the environment, and there have been well-publicized recalls related to pathogenic *Escherichia coli* in agricultural water (FDA, 2023). This is not to say that these segments should be treated differently than the rest of the food industry, but to acknowledge that some factories face significant challenges due to the presence of pathogens in their incoming raw materials: these factories potentially introduce pathogens into their processing environments daily. Thus, maintaining a sanitary environment is an ongoing challenge. Facilities that produce food without a kill step must develop robust environmental field- and plant-wide monitoring programs that are routinely challenged and reassessed. Corrective and preventive actions must be documented. Sanitary design must be part of all equipment reviews and approvals. Biological contamination may be due to human error, but it may also be introduced with the food. No matter the source, the facility must educate employees on the risks of biological contamination and stress the importance of following sanitation procedures.

Many bacteria have allowable levels in food products, and some produce toxins. The presence of these bacterial toxins is strictly prohibited. For example, up to 10^4 CFU/gm of *Staphylococcus aureus* cells is allowed in milk and fish (FDA, 2010a, 2022), but the presence of *S. aureus* enterotoxin is prohibited in the same food groups and is considered adulteration.

To assist the industry in development of robust Food Safety Plans that comply with FDA expectations, the FDA created an Appendix entitled "Known or Reasonably Foreseeable Hazards ("Potential Hazards")" in the document Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. This appendix includes Tables 1A–P which identify the biological hazards the FDA considers known or reasonably foreseeable in specific food categories (FDA 2024c). The tables should be used by factories to identify potential hazards associated with the ingredients they use and the foods they produce.

In CPG 527.300, the FDA lists multiple bacterial pathogens and enterotoxins that are potential hazards in dairy products. These are *Salmonella* species, Shiga toxin-producing *Escherichia coli* (STEC), and

other enterohemorrhagic *E. coli*, *Campylobacter jejuni*, *Yersinia enterocolitica,* vegetative cells of *Clostridium botulinum, Clostridium botulinum* toxin, *Staphylococcus* enterotoxin, and *Bacillus cereus* enterotoxin (FDA, 2010a).

Histamine, the result of the decarboxylation of free histidine is considered to be a sign of decomposition in seafood (DeBeer et al., 2021). About 148 species of bacteria are capable of forming histamine, but there is no regulation concerning allowable levels of histamine-forming bacteria (HFB) in foods (DeBeer and Bell, 2024). The FDA has set a limit on the amount of histamine in tuna-like fish. Histamine higher than the Defect Action Level (DAL) of 50 ppm indicates decomposition and is considered adulteration, while histamine levels above the Action Level (AL) of 500 ppm may be a threat to human health (CPG 540.525) (FDA, 2021b). The DAL of 50 ppm for histamine provides a 10-fold safety buffer. The growth of histamine-forming bacteria and subsequent formation of histamine takes place because the seafood is not chilled rapidly after capture: failure to control histamine formation results from human error (DeBeer et al., 2021).

Salmonella serovars are a major concern for whole egg processing facilities. One of the 10 largest recalls in the past 20 years involved whole-shell eggs (thedailymeal, 2015). Eggs and egg products are regulated by both the USDA and the FDA. The USDA regulates egg product processing plants, such as facilities that break and pasteurize eggs, while the FDA regulates whole shell eggs of domestic chickens and egg processing plants which wash, sort, and pack these eggs (Registrar Corp, 2023).

Chemical contamination. Food contaminants of chemical nature can be typically classified into four subgroups: natural toxins, environmental contaminants, agrochemical residues, and food process toxicants, together with intentionally added chemicals (Lebelo et al., 2021).

There are multiple regulations for chemicals that are either prohibited in foods or are approved as food additives. The FDA maintains a database of these chemicals and the CFR sections containing their regulations (FDA, 2023f). For a list of Chemical Contaminants & Pesticides see FDA (2023c), The Environmental Protection Agency regulates the minimum risk level (MRLs) in pesticides (EPA, 2024).

The FDA plans to provide guidance on preventive controls for chemical hazards, in Chapter 12 of the Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food; however, the chapter has not been released to date (FDA, 2024a).

Foreign objects. This F&B recall group includes items such as metal, plastic, wood, dirt, and rocks that do not belong in the food product. Broken screening wire, flakes of metal, or rust or paint from processing equipment were classified in this group. The guidance for foreign objects is provided in CPG 555.425 – Foods, Adulteration Involving Hard or Sharp Foreign Objects (FDA, 2005b). Additionally, the FDA plans to provide guidance on preventive controls for physical hazards, such as foreign material, in Chapter 13 of the Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: however, the chapter has not been released to date (FDA, 2024a).

Agricultural products are at risk of foreign material from the field or harvest location contaminating the food. Fields may be contaminated with foreign material from a variety of sources, e.g., some materials are already present in the field before planting and harvest. When the crop is harvested, these materials may unknowingly be mixed in with the crop. Good Agriculture Practices, field assessments, and inspection during harvest and upon receipt at the facility are the best ways to prevent foreign material from the field ending up in finished product.

Undeclared food colors. Any substance used as a color additive in the U.S. must be authorized by regulations in 21CFR§70, 73, 74, 81, or 82 (FDA, 1977b, 1977c, 1982, 2023a, 2023b). Undeclared colors have caused so many recalls that they have their own classification group separate from other mislabeled products. This separate classification is important because of the potential for undeclared food colors to cause allergen-like reactions (FDA, 2023h).

cGMP issues. cGMPs provide and describe the minimum methods, facilities, equipment, and process controls for producing safe processed foods. GMPs are also known as sanitary controls. The most well-known cGMPs for human foods are in 21CFR§110 (FDA, 1986) and 21CFR§117 (FDA, 2015b); however, cGMPs are included or referenced in at least nine of the other 21CFR series of FDA food regulations (Appendix A). cGMP failures generally result in the production of foods in an unsafe manner, in an unsanitary area, or with unsanitary equipment.

HACCP issues. This group includes juice or seafood products. HACCP Guidances for juice (21CFR120) and seafood (21CFR123) were addressed in the introduction (Fed. Reg., 1995, 2001a). Examples of these recalls in seafood included smoked fish that was not produced under a HACCP plan or Critical Control Point process deviations when the Critical limit was not met or when unpasteurized juice was sold to retailers.

Manufacturing issues. Manufacturing issues include improper methods for packaging, adding and mixing ingredients, processing, or other manufacturing mistakes.

Mislabeling and misbranding. In general, mislabeling refers to errors or omissions on food product labels, while misbranding refers to false or misleading claims or representations about the product. An example of mislabeling is when the product is labeled “gluten-free” but contains gluten. An example of misbranding is if a product is labeled “organic” but does not meet the legal requirements for organic certification (Langel, 2023).

Refrigeration issues. Refrigeration issues include products not cooled quickly enough, as well as products that are in cold storage facilities that had lost refrigeration for an extensive period of time. An example would be refrigerated containers losing power on an oceanic voyage. Although the incidents may be inadvertent, this is still human error by not preventing those maintenance issues from occurring, as are the failures to cool products quickly that need cooling for food safety reasons.

Under-processing. This recall group includes foods that were acidified, pasteurized, dried, or retorted by improperly conducted or incomplete processes. These errors also include improper sealing or seaming of the cans and containers, incomplete or nonexisting process filing, and other process failures. Food processing regulations include 21CFR§108 (Emergency Filing); 21CFR§113, Low-acid Canned Foods (LACF); and 21CFR§114, Acidified Foods (Fed. Reg., 1979a,b,c). The requirements for milk pasteurization are described in 21CFR§133.3 and 21CFR§1240.61 (FDA, 1983, 1992) while juice pasteurization is described in the juice HACCP regulation (Fed. Reg., 2001a).

Frozen, salted, and dried fish that are over 5 in. long must be eviscerated prior to sale per CPG 540.650 to control *C. botulinum* because they are consumed without further preparation such as a cooking kill-step (FDA, 2005a). Thus, noncompliance to the regulations for the control of *C. botulinum* with this product form is also classified as under-processing.

U.S. recall regulations. U.S. regulations classify food recalls into Classes I, II, or III, as determined in 21CFR§7.3 and 21CFR§7.40 (FDA, 2021a). The classification of an issued recall is determined by the FDA using the following criteria:

(i) Class I: A reasonable probability exists that the consumption or exposure to a noncompliant food product will result in severe adverse health effects or death.
(ii) Class II: Consumption or exposure to a noncompliant food product may lead to temporary or medically reversible adverse health effects, or the likelihood of severe adverse health consequences is remote.
(iii) Class III: Consumption or exposure to a noncompliant food product is unlikely to cause adverse health effects.

Prior to the passage of the Food Safety Modernization Act (FSMA) of 2011, the FDA could not mandate a F&B product recall except for

infant formula (FDA, 2016, 2017). After the passage of FSMA, the FDA has the full authority to mandate a recall. However, the FDA strongly prefers that the food processor issues a voluntary recall and manages the recall rather than the FDA mandating a recall and being responsible for the enforcement. Until 2023, there had been only one recall mandated by the FDA, and that was in 2018 for Kratom powder (*Mitragyna speciosa*) contaminated with *Salmonella* serovars that had been linked to a multistate outbreak of Salmonellosis. There have also been two additional recalls that were initially ordered (mandated) by the FDA but were swiftly transitioned to voluntary recalls by the companies involved (FDA, 2018a; Kaur & Ellison, 2018).

Reportable food registry. The Reportable Food Registry (RFR) was established in 2007 under the FDA Amendments Act. This electronic portal enables food processors, manufacturers, packers, warehouses, and others, to report any food released for public distribution that may pose a significant health risk (FDA, 2010b). The RFR officially became the method for the required reporting and notification of the FDA of possible Class I recalls in 2009. When a food-processing company is uncertain about the possible recall classification and reporting requirements to the RFR, guidance, and answers can be obtained from its local FDA Recall Coordinator (FDA, 2010b).

Recall preparedness and handling. A written recall plan is required for all food processing facilities or manufacturing companies. A written plan was recommended earlier in 21CFR§7.59 (FDA, 1977a) but is now mandated as part of a required FSMA food safety plan. FSMA-HARPC requires a Food Safety plan which in turn requires a written recall plan for each food with a potential food safety hazard requiring preventative control (21CFR§117.139) (FDA, 2015b). The written recall plan must include a traceability plan that provides the ability to trace raw materials from the harvester through to the wholesaler or retailer that sells the finished product. To assist the industry in developing a written recall plan, the FDA included Chapter 14: Recall Plan in the Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. This chapter includes a list of resources to help companies develop a recall plan (FDA, 2024d). A written recall plan is also required by a merchant selling raw fruit or vegetables to the general public. In November 2023, the FDA published the final Traceability Rule for certain foods with potential food safety hazards (FDA, 2023g).

The objective for a cause analysis of these F&B recalls is to focus on the pathogens, chemicals, allergens, processing errors, foreign objects, and/or other factors which contributed to these recalls. This analysis of the types and causes of food recalls may help prevent future recalls.

Methodology

The FDA has maintained a database of recalls of different product classifications since October 2002. The product classifications include Animal & Veterinary, Drugs, Food & Beverages, Tobacco, and others (FDA, 2023j). Granular information about these recalls is available through a Freedom of Information Act (FOI) request. FDA data specialists can provide the information formatted in multiple ways based on the request.

The data on recalls for Food & Beverages from 2002 through mid-2023 were requested through an FOI application and were provided by the FDA in an Excel spreadsheet. Each recall has three identifiers: an event number (not unique), an incident number (unique), and a product ID (unique). The event number is for the overall or master recall for a problem for a firm, and the incident number is for the individual product(s) from a company or firm within an event. There can be just one or many recall incident numbers in a single event.

There were over 10,000 F&B recall events and over 35,000 recall incidents for 2002–2023. These recall data were analyzed using search terms and grouped using Microsoft Excel pivot tables. Each recall incident (number) was assessed to determine its cause.

These causes were separated into two major categories for recall classifications which are **product contaminants** and **processing issues**. The product contaminants category was further separated into five groups: Allergens, Biological Contaminants, Chemical Contaminants, Foreign Objects, and Undeclared Food Colors. The processing issues category was further separated into six groups: cGMP, HACCP, Manufacturing Issues, Mislabeling Or Misbranding, Refrigeration Issues, and Under-Processing.

A recall incident may have several potential causes but only a single cause or group was assigned for each incident. An informed judgment call was made to assign each single cause. A single recall event number with multiple incidents may have different causes for each of the different recall incident numbers. For example, recall event numbered 26,507, which included multiple sorbet and gelato items, had three different causes assigned for the seven recall incidents: allergens, undeclared food colors, and mislabeling.

Some groups of recall causes were assigned second and third identifiers. For example, the Biological Contamination group included the further identification of the genus and species of the bacteria responsible for the recalls when possible. The Chemical Contamination group included the presence of chemicals, antibiotics, pesticides, insecticides, sulfites, and others. The Allergens group included the nine major food allergens identified by the FDA and others. Tree-nut allergens were further identified by common name, i.e., almonds, pecans, etc. The Foreign Objects were further identified as metal, plastic, rocks, and others, when possible.

Recalls for elevated histamine levels were assigned to Biological Contamination group because of the microbial origin. Undeclared sulfites/sulfates were assigned to the Chemical Contamination group. The presence of alkaline phosphatase is a general test of nonpasteurization of milk, so the recall incidents for alkaline phosphatase were classified in the under-processing group (CDR Food Lab., 2023). Frozen fish over 5-in long that were not eviscerated (*C. botulinum* danger) were classified as under-processed.

Results

The classifications and causes of all of the 35,548 F&B recall incidents are shown in Table 1. The major classification of **Product Contaminants** accounted for 91% of the recalls, and **Processing Issues** accounted for 9%. By a large margin, Biological Contamination was the leading cause for all F&B recalls during the 20-year review period. Allergens, Foreign Objects, and Chemical Contamination followed with over 1,000 recall incidents in each of these groups. These four recall groups of Product Contamination accounted for 89% of the recalls.

Each recall group was then sorted by the Class of each recall and then ordered by percent of Class I recalls (Table 2). Biological Contamination, Allergens, and Chemical Contamination had the highest percentage of Class I recalls.

Allergens. Classifications of recalls for Allergens are listed in Table 3. Undeclared milk (including whey) accounted for 36% of these allergen recalls and 10% of the F&B recalls. These were followed by eggs, wheat, peanuts, soy, and tree nuts. Tree nuts were further identified and summarized and are listed in Table 4. Almonds, walnuts, and pistachios that were undeclared on the labels accounted for 48% of the tree nut recalls.

Biological contamination. Four species of live mesophilic bacteria were the cause of the four highest numbers of recall incidents for Biological Contamination and made up 90% of the total recalls for Biological Contamination. These bacterial species were *L. monocytogenes, Salmonella* serovars, *E. coli* serovars, and *C. botulinum* (Appendix B). Another 22 species of bacteria and some unnamed bacteria or microbes were included in the remaining 10% of the Biological Contamination recalls.

Table 1
Causes of Food & Beverage recall incidents (2020–2023) grouped by major recall groups and subgroups

Cause	Class I	Class II	Class III	Grand Total	Pct of Total	Pct Major Grp
Product Contaminants						91%
Allergens	4,431	5,260	318	10,009	28%	
Biological Contamination	13,732	3,004	341	17,077	48%	
Chemical Contamination	448	922	493	1863	5%	
Foreign Objects	3	2,295	314	2,612	7%	
Undeclared Food Colors	54	642	88	784	2%	
Processing Issues						9%
cGMP Issues	–	863	28	891	3%	
HACCP Issues	–	93	2	95	0%	
Manufacturing Issues	16	102	22	140	0%	
Mislabeled & Misbranded	109	411	331	851	2%	
Refrigeration Issues	1	736	21	758	2%	
Under-Processed	75	364	29	468	1%	
Recall Totals	18,869	14,692	1,987	35,548	100%	100%
Contaminants	99%	83%	78%			
Processing Issues	1%	17%	22%			

Table 2
Food & Beverage recall causes sorted by percentage of Class I recalls

Cause	**Class I**	**Class II**	**Class III**
Biological Contamination	80%	18%	2%
Allergens	44%	53%	3%
Chemical Contamination	24%	49%	27%
Under-Processed	16%	78%	6%
Mislabeled & Misbranded	13%	48%	39%
Manufacturing Issues	11%	73%	16%
Undeclared Food Colors	7%	82%	11%
Refrigeration Issues		97%	3%
Foreign Objects		88%	12%
HACCP Issues		98%	2%
cGMP Issues		97%	3%

Almost 80% of the recalls for Biological Contamination were identified by the FDA as Class I, while 18% were assigned as Class II, and only 2% as Class III (Table 2). The great variety of reasons for the causes of these recalls is shown in Appendix B. *L. monocytogenes* was the largest single cause, resulting in 7,844 recalls, which is 22% of the total recalls and 46% of the Biological Contamination recalls. *Salmonella* serovars were responsible for 6,597 recalls which is 18% of the total recalls and 38% of the Biological Contamination recalls. These two Biological Contamination causes, *Listeria* and *Salmonella,* together resulted in 40% of all of the F&B recalls.

Chemical contamination. A detailed list of recalls for Chemical Contamination is found in Appendix C. The majority of these recalls were designated as Class II (Table 2). The three most common recalls for Chemical Contamination were for undeclared sulfites (29%), chloramphenicol (13%), and elevated levels of lead (8%).

Table 3
Allergen recall incidents, ordered by type of allergen by total incidents

Allergens	Class I	Class II	Class III	Grand Total	%
Milk	1,568	1,892	111	3,571	36%
Eggs	979	420	6	1,405	14%
Undeclared wheat	240	1,022	44	1,306	13%
Peanuts	671	491	64	1,226	12%
Soy	277	562	44	883	9%
Tree nuts	428	394	25	847	8%
Undeclared allergens	100	277	4	381	4%
Fish	91	118	7	216	2%
Shellfish	59	39	13	111	1%
Sesame	7	32		39	
Allergic reaction	9	3		12	
Mild flushing		8		8	
Grand Total	**4,429**	**5,258**	**318**	**10,005**	
	44%	**53%**	**3%**		

Table 4
Recall incidents for tree nuts by type of nut

Tree nuts	Class I	Class II	Class III	Grand Total	%
Almonds	85	112	8	205	24%
Walnuts	70	50	2	122	14%
Tree nuts (Unspecified)	35	76		111	13%
(blank) (Unnamed)	52	50	5	107	13%
Pistachios	83	3	2	88	10%
Coconut	20	39	4	63	7%
Pecans	30	24	3	57	7%
Cashews	24	27	1	52	6%
Hazelnuts	16	8		24	3%
Pine nuts	6	1		7	1%
Macadamia nuts	3	2		5	
Shea nuts	3			3	
Brazil nuts		2		2	
Chestnuts	1			1	
Grand Total	**428**	**394**	**25**	**847**	

Foreign objects. The recalls for Foreign Objects are shown in Table 5. Metal objects of some type were the primary reason for the recalls, followed by plastic contaminants of some form. All but three

Table 5
Recalls for Foreign Objects, ordered by type of incident and objects

Foreign objects	Class I	Class II	Class III	Grand Total	%
Metal	2	948	155	1105	42%
Plastic		446	54	500	19%
Foreign material	1	451	42	494	19%
Glass		287	8	295	11%
Rubber		47	3	50	2%
Filth		23	22	45	2%
Cloth material		22	1	23	1%
Cans, sharp edges		20		20	1%
Equipment debris		11	9	20	1%
Coding ink		1	14	15	1%
Human fingertip		9	1	10	
Rocks, sand, grit		8	1	9	
Wood		6	2	8	
Ink pen		6		6	
Bird fragments		4		4	
Pieces of food grade packing material		4		4	
Can enamel issues			2	2	
Insoluble particulate		1		1	
Unknown		1		1	
Grand Total	**3**	**2295**	**314**	**2612**	
	0%	**88%**	**12%**		

of the recalls for Foreign Objects recalls were designated as Class II or class III.

Undeclared food colors. The Undeclared Food Color types and combinations of colors were so varied that the recalls were not summarized any further. Recalls for undeclared food colors were primarily Class II recalls (82%), although some 7% were classified as Class I (Table 2). Undeclared Food Colors accounted for 2% of the total F&B recalls.

cGMP recalls. cGMP noncompliance caused only 3% of the total F&B recalls, and most were designated Class II.

HACCP issues. There were fewer than 100 recalls for HACCP issues, all involving juice or seafood products. None of the HACCP issues were designated as Class I recalls, while 98% were Class II and 2% Class III (Appendix D).

Manufacturing issues. Manufacturing Issues caused less than 1% of the total F&B recalls, but 11% of these recalls were classified as Class I and 73% as Class II.

Misbranded & Mislabeled. Misbranded & Mislabeled recalls of F&B products were caused by many different factors. These causes included undeclared ingredients, attachment of the wrong label or brand to the F&B container or carton, unsupported health claims, and others. Recalls in the Mislabeled & Misbranded group had the highest percentage of Class III recalls at 39% and accounted for 2% of the total F&B recalls.

Refrigeration issues. These recalls for this group were classified as 97% Class II and 2% of the total F&B recalls.

Under-processing. There were fewer than 500 recalls for under-processed F&B products (Table 6). Most of these recalls were for sealed products that are subjected to some form of thermal processing such as bottles, cans, or pouches. There were also recalls of frozen, salted fish over 5 in. long that were not eviscerated.

Further comments. Twenty-six (26) recall events with more than 100 recall incidents per event occurred in this 20-year review period. These recall events included 4,775 incidents, and *L. monocytogenes* was involved in 2,285 (~48%) of these recall incidents (Table 7).

Recall incidents per event were tabulated by incidents per event (Table 8). Almost 65% of the recall events involved a single incident, and over 95% of the recall events contained 10 or fewer incidents. Only 0.25% of the recall events contained more than 100 incidents per event, but they accounted for over 13% of the total recalls or incidents! The average number of recall incidents! per event was 3.5.

Two causes of Biological Contamination (*Listeria* and *Salmonella* combined) were responsible for 40% of all of the F&B recalls. The annual recalls for *L. monocytogenes* and *Salmonella* serovars are shown in Figure 1. The *L. monocytogenes* peaks in 2015/2016 represented recalls of contaminated ice cream and fresh vegetable products, and the *Salmonella* peak in 2009 was caused by the recall of contaminated Peanut Corporation of America products.

These recalls for *L. monocytogenes* and *Salmonella* serovars were also evaluated for the types of foods that were contaminated. These details had not been standardized for the recalls database, so additional evaluations were necessary to designate the contaminated food types. The designations of the food types included dried, fresh, processed, or environmental samples, which were then cross-tabulated by product temperature status (ambient, chilled/frozen, or hot) at the time of sale or recall. This information for the foods recalled for *L. monocytogenes* is presented in Table 9 and for the foods recalled for *Salmonella* serovars in Table 10.

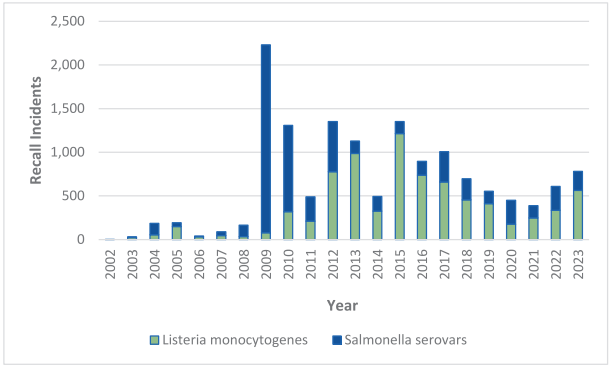

Figure 1. Recall incidents for *Listeria monocytogenes* and *Salmonella* serovars by year.

Table 6
Recalls for Under-Processed items classified as retorted and unretorted product

Under-Processed	Class I	Class II	Class III	Grand Total	NonRetorted	Retorted
Container issues		**116**	**9**	**125**		
Seam or seal defects		62	3	65		65
Swollen containers		33	6	39		39
Leaking containers		21		21		21
Process issues	**75**	**248**	**20**	**343**		
Pasteurization issues	6	83		89	86	
Uneviscerated fish	66	1		67	67	
Under-Processed		46	3	49		49
Process deviations		39		39		39
pH issues		18	5	23	23	
Unapproved process		11		11		11
Undercooked		9		9		9
Nonworking retort thermometer		9		9		9
Elevated water activity		1	7	8	8	
Acidified Food- pH issues		8		8	8	
No process records		6		6		6
Fermentation issues	1	2	2	5	5	
Inadequate pathogens kill step		4		4	4	
No scheduled process		4		4		4
Low water phase salt.	2	1		3		3
Spoilage issues			3	3	3	
Inadequate process control		2		2		2
Clostridium botulinum issues		2		2		2
Unretorted product		2		2		2
Grand Total	**75**	**364**	**29**	**468**	**204**	**261**
	16%	78%	6%			

Table 7
Recall events with over 100 incidents

Recall Event	Cause	Subcategory	Food type	Incident Count	Subtotal
91653	Biological contamination	*L. monocytogenes*	Sandwiches, and other fast foods	404	
70738	Biological contamination	*L. monocytogenes*	Ice cream	286	
66819	Biological contamination	*L. monocytogenes*	Various cut vegetables	255	
66563	Biological contamination	*L. monocytogenes*	Multiple Processed Foods	213	
66677	Biological contamination	*L. monocytogenes*	Fresh processed vegetable foods	213	
81156	Biological contamination	*L. monocytogenes*	Ice cream	172	
63159	Biological contamination	*L. monocytogenes*	Various processed fresh food items	139	
71170	Biological contamination	*L. monocytogenes*	Ice cream	134	
69555	Biological contamination	*L. monocytogenes*	Salads, Sandwiches with UPC codes	121	
70075	Biological contamination	*L. monocytogenes*	Ice-cream, Sorbets	117	
53997	Biological contamination	*L. monocytogenes*	Sushi -Salmon ingredient	116	
70150	Biological contamination	*L. monocytogenes*	Ice cream, Sorbets	115	2,285
74054	cGMP issues	cGMP issues	Dietary supplements	163	
70344	cGMP issues	cGMP issues	Dietary supplements	147	
68421	cGMP issues	cGMP issues	Dietary supplements	118	
68422	cGMP issues	cGMP issues	Dietary supplements	118	
68420	cGMP issues	cGMP issues	Dietary supplements	117	663
77194	Allergens	Milk	Baked goods	369	
77489	Allergens	Milk	Various processed fish items	186	555
83178	Refrigeration issues	Multiple foods	Various processed fresh food items	330	
79663	Refrigeration issues	Multiple foods	Fresh & processed foods	199	529
92423	Biological contamination	*Salmonella* serovars	Batter mix	196	
63257	Biological contamination	*Salmonella* serovars	Processed various nut butters	187	383
77489	Allergens	Undeclared allergens	Dietary supplements	142	142
74890	Biological contamination	*E. coli*	Baked goods	114	114
72083	Mislabeled	Unapproved new drugs	Dietary supplements	104	104
Total					4,775

Table 8
Recall incidents per event, grouped

Incidents per Event Grouped	Events	%	Cum %	Incidents	%	Cum %
1	6,650	%	%	6,650	19%	19%
2–5	2,499	%	%	7,100	20%	39%
6–10	576	6%	%	4,327	12%	51%
11–25	376	4%	%	5,833	16%	67%
26–100	153	1%	1%	6,863	19%	87%
101–500	26			4,775	13%	100%
Total	**10,280**			**35,548**		

Over 60% of the foods recalled for contamination by *L. monocytogenes* were processed in some form, and almost 70% were chilled or frozen products. Over 45% of the food products recalled for contamination by *Salmonella* serovars had been dried, and almost 90% had been stored at ambient temperatures.

All the recall incidents by group by year are shown in Appendix E. No recalls occurred in some years for several of the recall groups, and the total number of recall incidents varied widely by year.

Although the recalled items were not segregated by process type, the recalls for Biological Contamination occurred primarily for fresh, chilled, or frozen food products. The recalls for under-processed foods should have encountered a processing kill step, but did not, while the recalls for Chemical Contamination had many types of preparations.

Discussion

A five-year moving average of F&B recalls is shown in Figure 2. This chart shows an increase in F&B recalls in the initial years of this two-decade analysis. A large number of recalls occurred when FSMA was enacted and implemented in 2011 followed by a decline of F&B recalls in later years of the review period. This trend may indicate that the food processing industry is practicing safer methods and better food safety control.

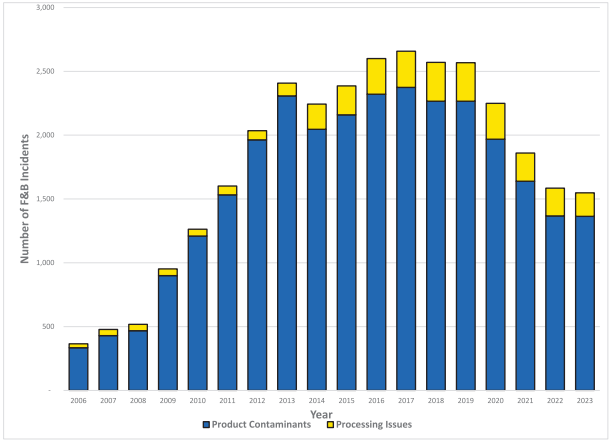

Figure 2. Five-Year Moving Average of F&B Recalls by Major Category.

Biological contamination. Live bacteria in recalled food products suggests that processing areas were not properly cleaned and sanitized or that bacteria were already present in the insufficiently cleaned raw foods, such as contaminated produce. For food products that receive a lethality step, these sources of recalls for Biological Contamination should be considered human or operator error which can be reduced by sanitation of the processing area, a “seek and destroy approach” to environmental monitoring, and control of cross-contact as well as careful assessments of the incoming raw foods. For raw foods that do not receive a lethality step, control of biological contaminants is more complex and may not be due to human error in the factory but from other outside influences like agricultural water and conditions in the harvest field. In these cases, Good Agriculture Practices (GAP), field assessments, and supply chain preventive controls, should be used in addition to sanitation preventive controls, environmental monitoring, and GMPs in the factory.

Allergens. Undeclared milk, eggs, wheat, and peanuts made up 75% of the recalls for Allergens. Soy, tree nuts, and unknown allergens

Table 9
Recalls for *Listeria monocytogenes*: types of food and environmental conditions at time of recall

Type	Ambient	Chilled/frozen	Hot	Grand Total	%
Processed	420	4,390		4,810	61%
Fresh	1,373	1,060		2,433	31%
Dried	303			303	4%
Environmental	298			298	4%
Grand Total	**2,394**	**5,450**		**7,844**	
	31%	**69%**			

Table 10
Recalls for *Salmonella* serovars: types of food and environmental conditions at time of recall

Type	Ambient	Chilled/ frozen	Hot	Grand Total	%
Dried	2,973			2,973	45%
Processed	1,883	683	23	2,589	39%
Fresh	987	49		1,036	16%
Grand Total	**5,843**	**732**	**23**	**6,598**	
	89%	**11%**			

caused another 20%. Fish and shellfish allergens caused only 3% of the Allergen recalls. Of the recalls for tree-nuts, almonds, walnuts, and pistachios had the highest numbers. Tree-nuts are one of the nine identified major food allergens. In assisting the industry to understand the definition of tree-nuts allergies, the FDA created a lengthy list of "other tree nut examples" which is very useful (FDA, 2023k).

Recalls for allergens are caused either by cross-contact in the fields during harvesting or processing at the final processing plant, inadvertent mixing of the wrong ingredient(s), or the wrong label applied to the finished product. All of these failures should be addressed at the factory level in the Allergen Control Program that is part of the Food Safety Plan and in the supply chain through supplier assessments and a Supply-Chain Program Preventive Control.

Recommended controls to reduce or prevent Allergen recalls caused by labeling errors include confirming ingredients against formulas during production, implementing an outgoing merchandise inspection program, comparing the actual labels used with the product specifications, and a rigorous inventory control program. Failures within allergen control programs are generally caused by human error in all these situations.

Foreign objects. Over 90% of the recalls for Foreign Objects were from metal, plastic, foreign materials, and glass found in F&B products. Recalls due to glass contamination are because of a lack of a rigorous glass control policy. Metal and plastic contamination of food products causing recalls for Foreign Objects can result from machine parts breaking and entering the product or package. These processing errors can result from a lack of maintenance or routinely checking machinery for missing or loose parts. Conducting frequent machine inspections and holding all the finished products until inspecting and clearing the processing machinery can help reduce Foreign Objects. Allowing foreign objects into food products and/or allowing these food products to enter the U.S. market is a direct result of human error.

Since suppliers or in the case of agricultural products from the field, may also be sources of foreign material, facilities should perform in-depth investigations into all incidents of the introduction of foreign material. Such investigations should include assessment and analysis of whether the material came from the factory or another source. This information can be used to develop appropriate preventive actions. When combined with other food safety-related programs like supplier assessments, Supply-Chain Preventive Controls, Good Agricultural Practices, and field assessments, the risk of foreign materials coming in with raw materials or ingredients can be mitigated.

Chemical contamination. Undeclared sulfites produced the most recalls in the Chemical Contamination group. Sulfites can cause an allergenic-like reaction in humans but are not an allergen, so they were assigned as Chemical Contamination recalls. Producing F&B products with undeclared sulfites indicates a lack of processing control due to human error.

Chloramphenicol is an antibiotic that has not been approved as a food additive so that any amount detected in food products can result in a recall for Chemical Contamination (FDA, 2023i). Chloramphenicol residues are found in crab meat, honey, and dietary supplements since Chloramphenicol is used to suppress bacterial growth in aquaculture ponds and bee-keeping hives (Rizzo et al., 2020). It enters dietary supplements through the supply chain with an ingredient such as royal jelly from bees. Chloramphenicol can also be in antibiotics on the hands of people hand picking and cleaning crab meat (L. Crawford, pers. comm., 2024). Chloramphenicol in human food and dietary supplements is due to human error.

cGMP issues. Recalls for cGMP issues did not produce Class I recalls but were mostly Class II recalls. The majority of the cGMP recalls were from the dietary supplement industry. The dietary supplement processing sector has its own set of detailed cGMPs, 21CFR§111 (FDA, 2007a). Any such recalls should be considered a human error because the cGMPs are not followed.

Mislabeled & misbranded. Most of the recalls in this group were Class II or Class III (>85%). Again, mislabeling refers to errors or omissions on product labels, while misbranding refers to false or misleading claims or representations about the product (Langel, 2023). These incidents are distinct from allergen mislabeling since allergens are a separate recall group. Human error and loss of labeling control are the causes of these recalls.

Undeclared food colors. The reasons and causes for these recalls are many and varied. Coloring food with natural ingredients to make the food products more appetizing goes back to Egyptian times; however, modern coloring agents can be made from ingredients that are unacceptable as food additives. Federal oversight of food color additives began in the 1880s. The FDA currently requires evidence that the color additive is safe for its intended use in food products (FDA, 2023d). The vast majority of these recalls were classified as Class II or class III (93%) and are the result of human error in the failure to control the addition of the correct food colors to the F&B products.

Refrigeration issues. These recalls were primarily classified as Class II (97%). They often had a large number of incidents per recall event. For example, three of these Refrigeration Issues recall events produced a total of 629 incidents or 83% of the total number of recall incidents for refrigeration issues. Human error is involved in the loss of refrigerated control since probable causes include poor or no inspection of the refrigeration machinery or the absence of monitoring the proper temperature recording devices.

Under-processed. The causes for recalls for under-processing were also varied. Incorrectly retorted items accounted for more under-processing recalls than all nonretorted items (Table 6). The food safety control failure responsible for recalls due to incorrect retorting and under-processing may include only a small number of recall incidents; however, these recall incidents can involve a broad and complex recall response and result in large financial impacts. Regulations for the thermal processing of food have been issued by the US FDA (21CFR§113) (FDA, 1979), and there are detailed training programs widely used by the industry, such as Better Process Control School. These are essential resources to help companies, and their employees understand the risks and appropriate procedures for making thermally processed foods. The loss of retort control is a critical food safety failure, and human error is the cause of under-processing recalls. The under-processing recalls reviewed in this paper are evidence of the need for a robust training program for employees.

Two of the three events with the most under-processing recall incidents involved improperly pasteurized milk used for ice cream produc-

tion which were both caused by human error. The third of these events involved recalling spoiled yogurt in bloated containers.

Manufacturing issues. The recalls for manufacturing issues included defective packaging or mixed packaging. These recalls also included improper ingredient addition including the addition of the incorrect ingredients or an incorrect amount of the proper ingredients to the food product. The failure to control ingredient addition and causing recalls for manufacturing issues is the result of human error.

HACCP issues. HACCP issues accounted for a relatively low percentage of all of the recalls ($<0.3\%$). Of these HACCP recall incidents, almost 60% involved juice products while the majority of the remainder involved seafood products. The juice HACCP regulations have been in place for 20 years, and the seafood HACCP regulations for almost 25 years. The low number of recalls for HACCP issues suggests that processors of juice and seafood products have a good understanding of HACCP principles and controlling food safety, as well as the ability to implement and comply with the Critical Limits and Critical Control Points required by the HACCP regulations. These recalls were the result of human error.

Canned tuna factories were regulated as low-acid canned foods (LACFs) that included implementing HACCP principles and procedures well before the passage of the 1995 Seafood HACCP regulation, 21CFR§123 (FDA, 1995a). The *E. coli* incident in fast-food hamburgers at the San Diego-based Jack-in-the-Box during 1992 and 1993 and the response to the food safety and human health impacts, greatly illuminated the power of HACCP principles and controls (DOD, 2023). Both Jack-in-the-Box and the canned tuna processor Chicken of the Sea International (COSI) were based in San Diego during the 1990s. Discussions concerning HACCP principles and food safety controls took place between the staff of both companies at that time (J. DeBeer, pers. comm. 2024). COSI had started implementing HACCP-type plans and principles at its canneries by that time and had been checking for histamine in raw tuna for a decade.

Some simplicity underlies the detailed account of the major causes of F&B recalls, e.g., the general knowledge of producing food that is safe for public consumption is well-known: heat it, can it, freeze it, chill it, dry it, fry it, acidify it, or treat it with high pressure, then package and label it correctly (Amit et al., 2017). The specific periods of time or shelf-lives for each F&B product must also be known to ensure that the food, depending on the packaging and storage methods, will be palatable and safe for consumption. Transforming this knowledge of safe food production and handling into practice is **the** critical activity of controlling food safety hazards, producing safe foods, and reducing or eliminating costly and potentially hazardous food recalls. The failure to implement these food safety control practices correctly during the processing of food is the direct consequence of human error.

The people working in the food industry must appreciate that they make food which is eaten by people and animals, and **understand** their role in contributing to food safety. It is the responsibility of company leadership to ensure that employees understand their role in food safety and that they receive appropriate training and instruction on their job tasks and responsibilities.

Safe and compliant foods must be prepared in a clean and sanitary environment. This idea bears repeating. Environmental monitoring of processing areas and production controls is important to ensure sanitary food-contact areas and surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against contamination of food and allergen cross-contact (FDA, 2015b). Useful methods to reduce human errors in manufacturing processed foods are listed by Boye & Godefroy (2011).

Allergens, Undeclared Food Coloring, and Mislabeled & Misbranded groups accounted for 11,645 of the F&B recalls, almost 33% of the total. These recalls are all caused by undeclared or wrongly identified ingredients. *Listeria* and *Salmonella* made up another 40% of the recalls so atleast 75% of the total recalls directly resulted from human error, indicating that the processing area was not necessarily controlled, clean, and sanitary.

"Efforts in *C. botulinum* control should be concentrated on reducing human errors in the delivery of the specified process to containers of food" (Pflug, 2010). This statement about controlling food safety in canned food products can be extended to all food harvesting, processing, and distribution operations. Preventing human errors in handling, processing, packaging, labeling, and distribution isthe key to reducing failures in food products and the resulting recalls. Training employees on the reason behind procedures and educating the supply chain, including raw material suppliers, on the impact their practices have on food safety is essential to help reduce human error.

The foods that need retorting, pasteurization, or acidification need to be processed properly with schedules developed by an LACF process authority. All foods that are chilled or frozen require proper controlled cold storage. Baked goods must be produced properly with potential hazards identified correctly. Raw produce must be watered and harvested under sanitary conditions, meaning that the farms need to be as aware of food safety risks as the food manufacturer.

Herbert (1965), the author of the science fiction story "Dune," wrote: "One does not obtain food-safety-freedom by instinct alone." This speaks to the need for training people on food preparation and safety. The importance of food safety and food safety freedom needs to be understood by food harvesters, handlers, processors, warehouse staff, truck drivers, and retail personnel at all stages of the process chain. This awareness and training is necessary to develop a Food Safety Culture as described by Yiannas (2009) for reducing human errors and food recalls.

Leadership personnel at all levels within an organization must understand that the importance of food safety and its control is critical to prevent food failures and resulting recalls. Leaders must accept this responsibility in ensuring that all foods leaving their facility are safe and have been correctly produced, labeled, and packaged. This importance also includes mid-level or floor-level managers, such as supervisors and lead-people. "Leaders in the middle layers of an organization's hierarchy… wield the most influence on employees' daily experiences, so they play a critical role in company culture" (Yohn, 2021). Senior management may better understand the overall impact of food safety failures and must provide and support mid-level managers with the authority to make decisions that support food safety control throughout the production process since mid-level managers are the people most frequently interacting with and influencing production employees.

A Supplier Verification Program, for both import and domestic production, is critically important to underpinning the production of safe food products. All of the entities involved in the production and sale of food products must have confidence that these early processes in the supply chain were completed properly and in a sanitary manner. Properly identifying and controlling potential hazards is critical to all processes and steps in the production and value chain.

The easiest and best way to control a recall is to prevent it from happening. Ben Frankin is famous for saying "an ounce of prevention is worth a pound of cure" (Asher, 2017). Tech-enabled traceability can make for quicker, more efficient tracking of F&B products to be recalled while helping to prevent further sale of the item, **but it does not prevent the recall**. The keystone to prevention of recalls and producing safe food is to develop a strong **Food Safety Culture** throughout the supply chain, from growing, harvesting, and capturing and then through processing, packaging, labeling, and distribution management.

A common mantra at the J.R. Simplot Company is "Your first loss is your best loss," meaning it is better to identify and address nonconforming product as early in the process as possible (E Blickem, pers. comm. 2024). This attitude and philosophy reminds employees that putting on hold a noncompliant product at the beginning of the process produces a better outcome than implementing an expanding hold

or recall if the affected product is released out of the facility's control. Mid-level managers must embrace this approach to control and eliminate product recalls. Companies that understand the influence of mid-level managers and provide them the education and support to make the right decisions in these situations will have greater success in developing a food safety culture and the prevention or mitigation of food safety incidents and recalls.

Economically motivated adulteration. Very recently, the FDA announced an "Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches" due to the acute toxicity of lead in children and adults (FDA, 2024e). As of March 22, 2024, 136 confirmed cases, 345 probable cases, and 38 suspected cases of elevated lead have been reported from across the United States (CDC, 2024). The median age of those affected is 1-year-old children (FDA, 2024e). Through product sampling and onsite investigations, the FDA determined the source of the elevated lead and chromium to be cinnamon added as an ingredient to the applesauce pouches which were manufactured by several companies (FDA, 2024e). The Codex Alimentarius Committee on Contaminants in Foods has proposed a limit of 2.5 parts per million (ppm) for lead in bark spices (such as cinnamon) (CODEX, 2022). The FDA's sampling found 5,110 ppm and 2,270 ppm of lead in two samples of cinnamon sourced from a company in Ecuador (FDA, 2024e).

Although the FDA's investigation into the incident is ongoing, these findings are important to the entire food industry. According to the FDA, the contamination appears to be in the supply chain and intentional (Brown and Hill, 2024). Although the cinnamon supplier was not a direct distributor into the United States, instead it supplied the ingredient to another company with distribution within the United States (FDA, 2024e). As evidenced by the recall trends reviewed in this paper, intentional or economically motived contamination is not commonplace within the United States food industry. This incident is a poignant example of the importance of **ALL** Supplier Verifications and ingredient traceability. Companies must have robust supplier verification programs, which go beyond their direct suppliers to all levels within the supply chain and must ensure that the suppliers of their direct suppliers are inspected and verified rigorously.

Conclusions

Modern human society has the knowledge and ability to hunt, fish, grow, harvest, process, produce, and market safe foods. Executing safe food handling practices at all stages of the process in the primary issue to maintaining food safety and preventing recalls. The food handling processes must be designed to be safe and controllable. Training and frequent review are critical to conducting the food production processes correctly every time. New employees enter the workforce every day, and they require training on how to conduct their actions and responsibilities correctly. Existing employees need routine retraining and education. The training cycle never stops.

The U.S military is the epitome of training and retraining individuals. For example, before sailors are sent to the fleet or marines are sent to the Fleet Marine Force, they pass basic training, advanced infantry training, and/or A and C schools (the same with soldiers and airmen). After that, the objective-based training continues. To be promoted, the service-women or service-men need to pass qualifications and skill-based tests. Knowing the proper process is the objective or goal. An expert trains until he or the student gets the process right, and a Master trains until he or the student cannot get the process wrong (C. DeBeer, pers. comm.).

The Leadership Principles of the United States Marine Corps can be used as a foundation for engaging employees, developing procedures, and implementing training (USMC, 2008). These principles include:

Be technically and tactically proficient,
Know your people and look out for their welfare,
Keep your personnel informed,
Set the example,
Ensure that the task is understood, supervised, and accomplished, and,
Employ your command within its capabilities (USMC, 2008).

Each of these principles can help guide leadership within food production (and many other industries) to create a culture where employees understand the responsibility of their jobs and perform the necessary tasks to ensure the food is safe. Leaders are not only needed at the top levels of an organization, but they must also be found at all levels, so knowledge is shared, and communication is easy. As General C.B. Cates stated, "leaders can be and are made" (USMC, 2008).

A preventive, safe process is critical to manufacturing food and providing sanitary procedures to maintain the cleanliness of the manufacturing areas and keep the food-contact surfaces clean and food safe. Developing an "A" process is imperative." An A process with a C team can still manufacture a safe product that meets the label, but an A team using a C process will run into trouble eventually." (C. DeBeer, pers. comm. 2024) Checklists are crucial for defining an "A" process (Gawande, 2010). "Never trust your memory more than a checklist." (J. Wilson, pers.comm. 2023).

Economic adulteration is a particularly insidious form of fraud in that it can cause illness of people such as the current applesauce incident or companion animals such as the melamine incident in 2007 (DeBeer et al., 2023). A Supplier Verification program, both Foreign and Domestic, is so important to address economic adulteration.

Our final word about recalls involves repeating the earlier mantra from J. R. Simplot, "Your first loss in your best loss" (E Blickem, pers.comm. 2024). If you have a potential F&B recall, get control of the situation promptly and deal with it properly.

CRediT authorship contribution statement

John DeBeer: Writing – review & editing, Writing – original draft, Project administration, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Erika Rene Blickem:** Writing – review & editing, Writing – original draft, Conceptualization. **Yadwinder Singh Rana:** Writing – review & editing, Writing – original draft. **Deborah Mona Baumgartel:** Writing – review & editing, Writing – original draft, Methodology. **Jon W. Bell:** Writing – review & editing, Writing – original draft, Conceptualization.

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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The authors have worked in many parts of the seafood sector for many years. This experience includes leading or serving on teams that conducted recalls and participated in the postrecall self-evaluations and risk analysis. They declare no conflicts of interest. There was no funding agency. The authors contributed equally to this manuscript.

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Appendix A

Current Good Manufacturing Practices in the Code of Federal Regulations.

CFR	Food Group	Title	Reference
21CFR§106.5	Infant Formula	Current Good Manufacturing Practice	FDA (2014)
21CFR§110	Human Food	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food	FDA (1986)
21CFR§111	Dietary Supplements	Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	FDA (2007a)
21CFR§113.5	Low-Acid Canned Foods	Current Good Manufacturing Practice	FDA (1979)
21CFR§114.5	Acidified Foods	Current Good Manufacturing Practice	FDA (2015a)
21CFR§117	Human Food	Current Good Manufacturing Practice, Hazard Analysis, and Risk–Based Preventive Controls for Human Food	FDA (2015b)
21CFR§120.5	Juice HACCP	Current Good Manufacturing Practice	FDA (2015c)
21CFR§123.5	Seafood HACCP	Current Good Manufacturing Practice	FDA (1995a)
21CFR§129.1	Bottled Drinking Water	Current Good Manufacturing Practice	FDA (2015d)

Appendix B

Causes for biological contamination recalls.

Biological contamination	Class I	Class II	Class III	Grand Total	%
Listeria monocytogenes	6,906	938		7,844	46%
Salmonella serovars	6,166	428	3	6,597	39%
Escherichia coli	457	174	24	655	4%
Clostridium botulinum	131	217	7	355	2%
Mold		142	84	226	1%
Spoilage issues		102	85	187	1%
Cyclospora cayetanensis		151		151	1%
Microbial contaminant	2	74	16	92	1%
Elevated histamine		77	1	78	
Elevated aflatoxins	1	73	2	76	
Rodents		44	26	70	
Hepatitis A	49	20		69	
Burkholderia cepacia		58		58	
Elevated patulin		54		54	

Appendix B (*continued*)

Biological contamination	Class I	Class II	Class III	Grand Total	%
Insanitary conditions		41	4	45	
Yeast contaminant		24	15	39	
Staphylococcus aureus		30	5	35	
Post-process contamination		34		34	
Norovirus		27	6	33	
Beetles		24	5	29	
Bacillus cereus	1	24		25	
Giardia		24		24	
Coliform levels		15	7	22	
Insect infestation		5	16	21	
Deer feces		18		18	
Bacterial issues		15	2	17	
Food residue		17		17	
Active fermentation	1	14	1	16	
Consumer complaints		16		16	
Enterobacter spp.	1	9		10	
Unapproved source		10		10	
Illness complaint		10		10	
Pseudomonas spp.	1	7	1	9	
Bacterial spoilage		8		8	
Rancid product			8	8	
Pathogen growth		7		7	
Coliforms detected		7		7	
Cronobacter spp.	6	1		7	
Chronic Wasting Disease (CWD)		6		6	
Consent decree issues		6		6	
Candida lusitaniae		5		5	
Klebsiella pneumoniae		5		5	
Stenotrophomonas maltophilia		4		4	
Ingredient quality issues			3	3	
Biological contamination			3	3	
Shipped too early		2	1	3	
Clostridium clostridioforme		3		3	
Illegal Sassafras leaves		1	2	3	
Oysters adulterated		3		3	
Undeclared bovine material			3	3	
Elevated microcystin toxins		3		3	
Fumonisin mycotoxin		3		3	
Human placenta material	1	1		2	
Blood contamination		1	1	2	
Korean shippers delisted		2		2	
Senecio vulgaris		2		2	
Lactobacillus spoilage			2	2	
Cryptosporidium	1	1		2	
No federal inspection		2		2	
Typhoid fever link	2			2	
Acute liver failure	2			2	
Unqualified donor			2	2	
Azaspiracid toxins		2		2	

(*continued on next page*)

Appendix B (*continued*)

Biological contamination	Class I	Class II	Class III	Grand Total	%
Dead worms in product			1	1	
Vibrio parahaemolyticus		1		1	
Closed harvest season, clams		1		1	
Leuconostoc argentinum			1	1	
Bacillus cepacia		1		1	
Failed stability specifications		1		1	
Elevated levels of Vomitoxin		1		1	
Comingled ingredient		1		1	
Acetobacter lovaniensis			1	1	
Violative product			1	1	
Employee food poisoning		1		1	
Elevated hypoglycin, a toxin		1		1	
Streptococcus viridans			1	1	
Clostridium butyricum		1		1	
Unapproved food additive		1		1	
Cronobacter sakazaki		1		1	
Campylobacter	1			1	
Mamey Sapote fruit	1			1	
Paecilomyces variotii		1		1	
Shigella spp.		1		1	
Rejected product released			1	1	
Rhizopus oryzae fungi	1			1	
Grand Total	**13,733 80%**	**3,004 18%**	**341 2%**	**17,078**	

Appendix C

Causes for chemical contamination recalls.

Chemical contamination	Class I	Class II	Class III	Grand Total	%
Undeclared sulfites	337	112	66	515	28%
Chloramphenicol		227		227	12%
Elevated levels of lead	43	97	7	147	8%
Pesticides		28	75	103	6%
Steriods		81		81	4%
PFOA/PFOS			60	60	3%
Cyclamate			49	49	3%
Unapproved antibiotics		43	4	47	3%
Unapproved Picamilon		40		40	2%
Elevated levels of arsenic	15	16	8	39	2%
Herbicides		5	28	33	2%
No Phenylketonuric (PKU) warning		7	24	31	2%
Melamine		31		31	2%
Resin contamination		23		23	1%
Incorrect chemical		3	17	20	1%

Appendix C (*continued*)

Chemical contamination	Class I	Class II	Class III	Grand Total	%
Kratom		20		20	1%
Undeclared HCG			19	19	1%
1,3-Dimethylamylamine	5	13		18	1%
Ammonia		18		18	1%
Undeclared aspartame		1	14	15	1%
Hydroxycut -serious liver issues		14		14	1%
Hordenine		13		13	1%
Undeclared monosodium glutamate		1	11	12	1%
Aldicarb			11	11	1%
Contains isomaltose			11	11	1%
Contaminated with hydrocarbon vapors		11		11	1%
Excessive cadmium	3	7	1	11	1%
Excessive bromate		5	4	9	
Ephedrine	8			8	
Aegeline	7			7	
Androstenedione		7		7	
Contains Acacia rigidula		7		7	
Undeclared antimony		7		7	
Undeclared sulfur dioxide	3	1	3	7	
Nitrofurans		1	5	6	
Azodicarbonamide			6	6	
Glyphosate residues			6	6	
Container can leach lead	5			5	
Contaminated with sanitizers		4	1	5	
Excessive TBHQ		5		5	
Unapproved new drugs		5		5	
Industrial acetic acid			5	5	
Aristolochic acid	4	1		5	
Spermine			4	4	
Undeclared hydroxypropyl methylcellulose (HPMC)		4		4	
Excessive selenium	3		1	4	
Contaminated with cleaning solution		2	2	4	
Lead soldered seams	3	1		4	
Fungicide		1	3	4	
Coltsfoot		3		3	
Nightshade detected		1	2	3	
Metronidazole			3	3	
Coumarin		3		3	
Wrong ingredient	1	2		3	
Ciprofloxacin		3		3	
Undeclared niacin		3		3	
Azoxystrobin			3	3	
Ephedra	6			6	
Contaminated lemongrass		2		2	
Undeclared boron		2		2	
Wrong stabilizer			2	2	
2,6-Dichlorobenzamide			2	2	
Hidden drug ingredient	2			2	
Nonfood grade antifoamer		2		2	
Sodium copper chlorophyllin			2	2	

Appendix C (*continued*)

Chemical contamination	Class I	Class II	Class III	Grand Total	%
Undeclared Agmatine		2		2	
Inhibitory substance was detected.		2		2	
Chlorine wash			2	2	
Unapproved Aegeline		2		2	
Fluvalinate		2		2	
Unapproved Clenbuterol		2		2	
Undeclared Sildenafil	2			2	
DEHP-contaminated clouding agents		2		2	
Organic chemicals		2		2	
Polyfluoroalkyl substances (PFASs)		2		2	
Malachite green			2	2	
Undissolved biotin			1	1	
Elevated morphine		1		1	
Scullcap			1	1	
Chlorine sanitizer		1		1	
Chlorine odor		1		1	
Undeclared methylated anabolic steroid		1		1	
Zeta-cypermethrin			1	1	
Diesel fuel in product			1	1	
Excessive sodium bicarbonate			1	1	
High level of satins	1			1	
Excessive sodium nitrite	1			1	
Undeclared quinine			1	1	
Methanol	1			1	
Elevated levels of cadmium		1		1	
Excessive sulfamethazine			1	1	
Haloxyfop (an herbicide)		1		1	
Mislabeled thiamine hydrochloride			1	1	
Undeclared acesulfame potassium			1	1	
Multiple dietary supplement regulation violations.		1		1	
Chondroitin sulfate out of specification			1	1	
Anabolic steroid		1		1	
Excessive imidacloprid			1	1	
Beta phenyl gamma aminobutyric acid HCL		1		1	
Undeclared sorbic acid			1	1	
Excessive zinc		1		1	
Varying amounts of lubricating oil			1	1	
Fenhexamid			1	1	

Appendix C (*continued*)

Chemical contamination	Class I	Class II	Class III	Grand Total	%
Low potency product			1	1	
Packaging glue			1	1	
Acephate		1		1	
Carbendazim			1	1	
Elevated DHEA		1		1	
Cesium chloride		1		1	
Contaminated with soap			1	1	
Phosphatase residue		1		1	
High level of nitrates		1		1	
Cumene			1	1	
Excessive fluoride		1		1	
Potency of folic acid		1		1	
Hydraulic fluid		1		1	
Change of ingredients		1		1	
Hydroxyethylcellulose.			1	1	
Sanitizing agent			1	1	
Undeclared preservatives			1	1	
Sodium ascorbate.			1	1	
Excessive iodine		1		1	
Formaldehyde		1		1	
Undeclared Splenda			1	1	
Ephedrine	1			1	
Excessive potassium sorbate			1	1	
Chemical residue			1	1	
Wrong drug		1		1	
Subpotency of the alpha lipoic acid			1	1	
Leucomalachite green			1	1	
Sulfathiazole			1	1	
Thiabendazole detected		1		1	
Mebendazole amine			1	1	
Grand Total	**451**	**922**	**493**	**1866**	
Percentage	24%	50%	26%		

Appendix D

Recalls for HACCP issues.

HACCP Issues	Class II	Class III	Grand Total
Juice	55		55
Seafood	34		34
Misc	1		1
CCP deviation	3	2	5
Grand Total	**93**	**2**	**95**
	98%	2%	

Appendix E

Recall incidents by group by year.

Year	Allergens	Biological Contamination	Chemical Contamination	Foreign Objects	Undeclared Food Colors	cGMP Issues	HACCP Issues	Manufacturing Issues	Mislabeled & Misbranded	Refrigeration Issues	Under-Processed	Grand Total
2002	1	1	1		2							5
2003	90	52	43	37	90			1	10		5	328
2004	189	216	49	11	71			3	13		3	555
2005	117	238	62	30	81		6	4	41		3	582
2006	116	79	41	26	29			29	16		21	357
2007	177	184	59	36	23		38	4	37	2	6	566
2008	142	211	95	43	15		1	3	9	1	7	527
2009	173	2,367	81	43	31	7			19		9	2,730
2010	456	1,458	59	67	39			4	29		21	2,133
2011	1,034	558	90	119	100	25		2	60	11	53	2,052
2012	710	1,579	59	237	50		17	3	49	8	20	2,732
2013	357	1,293	316	210	50	4		29	71	12	49	2,391
2014	578	638	97	44	31	402	3	7	72	12	24	1,908
2015	973	1,417	59	150	45	149			27	4	24	2,848
2016	846	1,308	130	394	35	199	16	27	128	3	37	3,123
2017	1,375	1,225	150	135	16	9		2	43	3	60	3,018
2018	594	835	110	136	10		1	2	35	206	25	1,954
2019	321	745	73	232	14	17	9	3	29	441	10	1,894
2020	317	632	61	145	3	1	2	5	79	2	10	1,257
2021	327	433	44	246	14	5		4	38	12	52	1,175
2022	534	792	64	134	19	46	2	2	17	15	20	1,645
2023	582	882	54	137	16	27		6	29	26	9	1,768
Grand Total	10,009	17,078	1866	2,612	784	891	95	140	851	758	468	35,548

References

Amit, S. K., Uddin, M., Rahman, R., Islam, S. M., & Khan, M. S. (2017). A review of mechanisms and commercial aspects of food preservation and processing. *Agriculture & Food Security, 6*(1), 1–22. https://doi.org/10.1186/s40066-017-0130-8.

Asher, B. H. (2017). *An ounce of prevention?* Retrieved from https://www.medical.theclinics.com/article/S0025-7125(17)30056-1/fulltext. Accessed December 6, 2023.

Boye, J. I., & Godefroy, S. B. (2011). *Allergen management in the food industry*. John Wiley & Sons. ISBN-13 978-0470227350.

Brown, M., & Hill, M. L. (2024). *Applesauce pouches may have been contaminated on purpose, FDA foods chief says*. Politico. Retrieved from https://www.politico.com/news/2023/12/14/applesauce-pouches-may-have-been-contaminated-on-purpose-fda-foods-chief-says-00131797. Accessed January 24, 2024.

CDC (2023). *More than a quarter of U.S. adults and children have at least one allergy*. Retrieved from https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220126.htm#:~:text=Nearly%201%20in%203%20U.S.,National%20Center%20for%20Health%20Statistics. Accessed July 4, 2023.

CDC (2024). *Lead and chromium poisoning outbreak linked to cinnamon applesauce pouches*. Retrieved from https://www.cdc.gov/lead-prevention/news/outbreak-applesauce-pouches.html. https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html. Accessed January 24July 7, 2024.

CDR Food Lab. (2023). *Alkaline phosphatase (ALP) in cow milk*. Retrieved from https://www.cdrfoodlab.com/cdrfoodlab/analyses/alkaline-phosphatase-milk. Accessed November 28, 2023.

Codex (2022). *Joint FAO/WHO food standards programme codex committee on contaminants in foods*. Retrieved from https://www.fao.org/fao-who-codexalimentarius/sh-proxy/ru/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-15%252FWDs%252Fcf15_07_Add1x.pdf. Accessed January 24, 2024.

DeBeer, J., & Bell, J. W. (2024). A list of histamine-forming bacteria. *Food Protection Trends* (in press).

DeBeer, J., Bell, J. W., Nolte, F., Arcieri, J., & Correa, G. (2021). Histamine limits by country: a survey and review. *Journal of Food Protection, 84*(9), 1610–1628. https://doi.org/10.4315/JFP-21-129.

DeBeer, J., Finke, M., Maxfield, A., Osgood, A. M., Baumgartel, D. M., & Blickem, E. R. (2023). A review of pet food recalls from 2003 through 2022. *Journal of Food Protection*, 100199. https://doi.org/10.1016/j.jfp.2023.100199.

Deibel, K., Trautman, T., DeBoom, T., Sveum, W., Dunaif, G., Scott, V., & Bernard, D. (1997). A comprehensive approach to reducing the risk of allergens in foods. *Journal of Food Protection, 60*, 436–441. https://doi.org/10.4315/0362-028X-60.4.436.

DOD (Department of Defense) (2023). *Crisis communication strategies. Case study: Jack in the Box E. coli crisis*. Retrieved from https://www.ou.edu/deptcomm/dodjcc/groups/02C2/Jack%20in%20the%20Box.htm. Accessed December 21, 2023.

Dunkelberger, E. (1995). The statutory basis for the FDA's food safety assurance programs: from GMP, to emergency permit control, to HACCP. *Food and Drug Law Journal, 50*(3), 357–383.

EPA (2024). *EPA pesticide regulation*. Retrieved from http://npic.orst.edu/reg/epareg.html. Accessed July 4, 2024.

FDA (1977a). *21CFR§7.59. Enforcement policy*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7. Accessed July 7, 2024.

FDA (1977b). *21CFR§70. Color additives*. Retrieved from https://www.eCFR§.gov/current/title-21/chapter-I/subchapter-A/part-70/subpart-A/section-70.3. Accessed May 12, 2023.

FDA (1977c). *21CFR§74. Listing of color additives subject to certification*. Retrieved from https://www.eCFR§.gov/current/title-21/chapter-I/subchapter-A/part-74. Accessed May 12, 2023.

FDA (1979). *21CFR§113.5. Low acid canned foods. Current good manufacturing practice*. Retrieved from https://www.ecfr.gov/current/title-21/section-113.5 Accessed November 29, 2023.

FDA (1982). *21CFR§82. Listing of certified provisionally listed colors and specifications*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-82. Accessed November 29, 2023.

FDA (1983). *21CFR§133.3 definitions – pasteurized milk*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-133/subpart-A/section-133.3. Accessed November 29, 2023.

FDA (1986). *21CFR§110. Human food. Current good manufacturing practice in manufacturing, packing, or holding*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-110. Accessed November 29, 2023.

FDA (1992). *21CFR§1240.61 – Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption*. Retrieved from https://www.eCFR§.gov/current/title-21/chapter-I/subchapter-L/part-1240. Accessed November 27, 2023.

FDA (1995a). *21CFR§123.5 Seafood HACCP. Current good manufacturing practice*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-123. Accessed November 29, 2023.

FDA (1995b). *CPG 555.300 Foods, except dairy products – adulteration with Salmonella*. Retrieved from https://www.fda.gov/media/71946/download. Accessed November 20 2023.

FDA (2005a). *CPG 540.650 Uneviscerated fish products that are salt-cured, dried, or smoked (Revised)*. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-540650-uneviscerated-fish-products-are-salt-cured-dried-or-smoked-revised. Accessed November 16, 2023.

FDA (2005b). *CPG 555.425 Foods, adulteration involving hard or sharp foreign objects*. Available at: https://www.fda.gov/media/71953/download. Accessed 25 February 2023.

FDA (2007a). *21CFR§111. Dietary supplements. Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-111. Accessed November 29, 2023.

FDA (2008). *CPG 555.320 Listeria monocytogenes*. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555320-listeria-monocytogenes. Accessed April 22, 2023.

FDA (2010a). *CPG 527.300 Dairy products – microbial contaminants and alkaline phosphatase activity*. Retrieved from https://www.fda.gov/media/80058/download. Accessed November 23, 2023.

FDA (2010b). *Draft guidance for industry: questions and answers regarding the Reportable Food Registry as established by the Food and Drug Administration Amendments Act of 2007 (Edition 2). Pub. L. 110-085*. Retrieved from https://www.fda.gov/media/79130/download. Accessed September 26, 2022.

FDA (2011) *21 CFR 111 – Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements*. Retrieved from https://www.govinfo.gov/app/details/CFR-2011-title21-vol2/CFR-2011-title21-vol2-part111. Accessed September 6, 2024.

FDA (2014). 21CFR§106.5 Infant Formula. Current good manufacturing practice. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106/subpart-B. Accessed November 29, 2023.

FDA (2015a). *21CFR§114.5. Acidified foods. Current good manufacturing practice*. Retrieved from https://www.ecfr.gov/current/title-21/section-114.5. Accessed November 29, 2023.

FDA (2015b). *21CFR§117. Human food. Current good manufacturing practice, hazard analysis, and risk–based preventive controls for…*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117. Accessed November 29, 2023.

FDA (2015c). *21CFR§120.5. Juice HACCP. Current good manufacturing practice*. Retrieved from https://www.ecfr.gov/current/title-21/section-120.5. Accessed November 29, 2023.

FDA (2015d). *21CFR§129.1 Bottled drinking water. Current good manufacturing practice*. Retrieved from https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-129. Accessed November 29, 2023.

FDA (2016). *21CFR§107- subpart E—infant formula recalls*. Retrieved from https://www.eCFR§.gov/current/title-21/chapter-I/subchapter-B/part-107. Accessed November 17, 2023.

FDA (2017). *Full Text of the Food Safety Modernization Act (FSMA). Improving the reportable food registry*. Retrieved from https://www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma https://www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma#SEC211. Accessed September 26, 2022. July 3, 2024.

FDA (2018a). *FDA orders mandatory recall for kratom products due to risk of Salmonella. Retrieved from FDA orders mandatory recall for kratom products due to risk of Salmonella*. FDA. Accessed May 17, 2024.

FDA (2019). *Remarks on World Food Safety Day: "food safety is everyone's business."* Available at: https://www.fda.gov/news-events/remarks-frank-yiannas-world-food-safety-day-food-safety-everyones-business-united-nations-06072019. Accessed July 3, 2024.

FDA (2021a). *21CFR§7. Enforcement policy*. Retrieved from https://www.eCFR§.gov/current/title-21/chapter-I/subchapter-A/part-7. Accessed September 26, 2022.

FDA (2021b). *CPG 540.525 DRAFT: Scombrotoxin (Histamine)-forming fish and fishery products – decomposition and histamine (CPG 7108.24)*. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-540525-draft-scombrotoxin-histamine-forming-fish-and-fishery-products-decomposition-and. Accessed September 26, 2022.

FDA (2021c). *New era of smarter food safety*. Retrieved from https://www.fda.gov/food/new-era-smarter-food-safety. Accessed August 21, 2023.

FDA (2021d). *Guidance for industry: juice HACCP and the FDA food safety modernization act*. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-haccp-and-fda-food-safety-modernization-act. Accessed August 2, 2024.

FDA (2022). *Fish and fishery products hazards and controls guidance. Table A-1. Limiting conditions for pathogen growth*. Retrieved from https://www.fda.gov/media/80637/download. April 20, 2023.

FDA (2023). *lēf farms recalls "spice" packaged salad greens because of possible health risk*. Retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lef-farms-recalls-spice-packaged-salad-greens-because-possible-health-risk. Accessed August 2, 2024.

FDA (2023a). *21CFR§73. Listing of color additives exempt from certification*. Retrieved from https://www.eCFR§.gov/current/title-21/chapter-I/subchapter-A/part-73. Accessed May 12, 2023.

FDA (2023b). *21CFR§81. General specifications and general restrictions for provisional color additives for use in foods, drugs, and cosmetics*. Retrieved from https://www.eCFR§.gov/current/title-21/chapter-I/subchapter-A/part-81. Accessed May 12, 2023.

FDA (2023c). *Chemical contaminants & pesticides*. Retrieved from https://www.fda.gov/food/chemical-contaminants-pesticides#:~:text=The%20FDA%20helps%20to%20safeguard,when%20detected%20by%20our%20testing. Accessed November 30, 2023.

FDA (2023d). *Color additives in foods*. Retrieved from https://www.fda.gov/food/color-additives-information-consumers/color-additives-foods#:~:text=The%20FDA%

20also%20has%20reported,appropriate%20use%20of%20color%20additives. Accessed December 22, 2023.
FDA (2023e). *CPG 555.250. Statement of policy for labeling and preventing cross-contact of common food allergens*. Retrieved from Accessed December 6, 2023.
FDA (2023f). *Food additive status list*. Retrieved from https://www.fda.gov/food/food-additives-petitions/food-additive-status-list. Accessed November 24, 2023.
FDA (2023g). *FSMA final rule on requirements for additional traceability records for certain foods*. Retrieved from https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods. Accessed November 30, 2023.
FDA (2023h). *How safe are color additives?* Retrieved from https://www.fda.gov/consumers/consumer-updates/how-safe-are-color-additives. https://www.fda.gov/media/102633/download. Accessed November 30, 2023.
FDA (2023i). *Import alert 36-04 for honey and blended syrup due to unsafe drug residues*. Retrieved from https://www.accessdata.fda.gov/cms_ia/importalert_111.html. Accessed December 22, 2023.
FDA (2023j). *Recalls, market withdrawals, & safety alerts*. Retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts. Accessed November 19, 2022.
FDA (2023k). *Section 201(qq) of the Act defines the term "major food allergen" to include "tree nuts." In addition to the three examples provided in section 201(qq) (almonds, pecans, and walnuts), what nuts are considered "tree nuts?"* Retrieved from https://www.fda.gov/industry/fda-basics-industry/section-201qq-act-defines-term-major-food-allergen-include-tree-nuts-addition-three-examples. Accessed January 24, 2024.
FDA (2024a). *Draft guidance for industry: hazard analysis and risk-based preventive controls for human food*. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food. Accessed August 2, 2024.
FDA (2024b). *Hazard analysis and risk-based preventive controls for human food: draft guidance for industry. Chapter 11: Food allergen program*. Retrieved from https://www.fda.gov/media/172318/download?attachment. Accessed August 2, 2024.
FDA (2024c). *Hazard analysis and risk-based preventive controls for human food: draft guidance for industry. Appendix 1: Known or reasonably foreseeable hazards ("potential hazards")*. Retrieved from https://www.fda.gov/media/99581/download. Accessed August 2, 2024.
FDA (2024d). *Hazard analysis and risk-based preventive controls for human food: draft guidance for industry. Chapter 14: Recall plan*. Retrieved from https://www.fda.gov/media/131287/download?attachment. Accessed August 2, 2024.
FDA (2024e). *Investigation of elevated lead & chromium levels: Cinnamon applesauce pouches*. Retrieved from https://www.fda.gov/food/outbreaks-foodborne-illness/investigation-elevated-lead-chromium-levels-cinnamon-applesauce-pouches-november-2023. Accessed January 24, 2024.
FDA (2024f). *What does FDA regulate?* Retrieved from https://www.fda.gov/about-fda/what-we-do/what-does-fda-regulate. Accessed July 4, 2024.
Fed. Reg. (1979a). 44:16204. 21CFR§108. Emergency Permit Control. Available at: https://www.loc.gov/item/fr044053/. Accessed May 22, 2024.
Fed. Reg. (1979b). *44:16215. 21CFR§113. Low acid canned foods*. Available at: https://www.loc.gov/item/fr044053/. Accessed May 22, 2024.
Fed. Reg. (1979c). *44:16235. 21CFR§114. Acidified foods*. Available at: https://www.loc.gov/item/fr044053/. Accessed May 22, 2024.
Fed. Reg. (1995). *60:65096. 21CFR§123. Seafood HACCP regulation*. Available at: https://www.govinfo.gov/content/pkg/FR-1995-12-18/pdf/95-30332.pdf. Accessed 22 May 2021.
Fed. Reg. (2001a). *66:6138-6202. 21CFR§120. Hazard Analysis and Critical Control Point (HAACP); Procedures for the safe and sanitary processing and importing of juice*. Retrieved from https://www.govinfo.gov/app/details/FR-2001-01-19/01-1291. Accessed November 21, 2023.
Fed. Reg. (2015). *80:56145. 21CFR§117. cGMPs- hazard analysis, and risk-based preventive controls for human food*. Retrieved from Available at: https://www.govinfo.gov/content/pkg/FR-2015-09-17/pdf/2015-21920.pdf. https://www.govinfo.gov/app/details/FR-2015-09-17/2015-21920. Accessed May 22July 3, 20212024.
Gawande, A. (2010). *The Checklist Manifesto: How to get things right*. New York: Picador.
Herbert, F. (1965). *DUNE*. Philadelphia, PA: Chilton Book Company.
Jackson, L., Al-Taher, R., Moorman, M., DeVries, J., Tippett, R., Swanson, K., Fu, T., Salter, R., Nunaif, G., Estes, S., Albillos, S., & Gendel, S. (2008). Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-Contact in Food-Processing Operations. *Journal of Food Protection, 71*, 445–458. https://doi.org/10.4315/0362-028X-71.2.445.
Kaur, G. & Ellison, J. P. (2018). *FDA issues first mandatory recall order, exercising FSMA authority over food products containing kratom*. Retrieved from https://www.thefdalawblog.com/2018/04/fda-issues-first-mandatory-recall-order-exercising-fsma-authority-over-food-products-containing-kratom/. Accessed March 15, 2022.
Langel, J. (2023). *Mislabeling vs. misbranding: a practical guide with examples*. https://www.thelangelfirm.com/debt-collection-defense-blog/2023/february/mislabeling-vs-misbranding-a-practical-guide-wit/. Accessed November 23, 2023.
Lebelo, K., Malebo, N., Mochane, M. J., & Masinde, M. (2021). Chemical contamination pathways and the food safety implications along the various stages of food production: a review. *International Journal of Environmental Research and Public Health, 18*(11), 5795.
Pflug, I. J. (2010). Science, practice, and human errors in controlling *Clostridium botulinum* in heat-preserved food in hermetic containers. *Journal of Food Protection, 73*, 993–1002. https://doi.org/10.4315/0362-028X-73.5.993.
Registrar Corp. (2023). *FDA and USDA: who regulates what?* Retrieved from https://www.registrarcorp.com/resources/fda-usda-food-regulations/. Accessed December 4, 2023.
Rizzo, S., Russo, M., Labra, M., Campone, L., & Rastrelli, L. (2020). Determination of chloramphenicol in honey using salting-out assisted liquid-liquid extraction coupled with liquid chromatography-tandem mass spectrometry and validation according to 2002/657 European Commission Decision. *Molecules, 25*(15), 3481. https://doi.org/10.3390/molecules25153481.
Smartsense (2023). *Key federal laws affecting food safety compliance*. Retrieved from https://blog.smartsense.co/federal-laws-food-safety. Accessed November 22, 2023.
Taylor, S. L., & Hefle, S. L. (2001). Food allergies and other food sensitivities. *Food Technology, 55*(9), 68–84.
thedailymeal (2015). *The 10 biggest food recalls in American history*. Retrieved from https://www.thedailymeal.com/eat/10-biggest-food-recalls-american-history-0. Accessed December 4, 2023.
U.S. Congress (1994) *Dietary supplement health and education act of 1994, Public Law 103-417, 103rd congress*. Retrieved from https://ods.od.nih.gov/About/DSHEA_Wording.aspx#sec9. Accessed September 6, 2024.
U.S. Congress (2021). *Food allergen safety, treatment, education and research of 2021, Public Law 117–11*. Retrieved from https://www.congress.gov/117/plaws/publ11/PLAW-117publ11.pdf. Accessed December 4, 2023.
University of Maryland Extension (2023). *Understanding the food safety system*. Retrieved from https://extension.umd.edu/resource/understanding-food-safety-system#:~:text=The%20government%20sets%20the%20standards,state%20regulations%20supersede%20local%20regulations. Accessed November 28, 2023.
USDA (2023). *What-foods-does-the-FDA-regulate regulation, and policy*. Retrieved from https://www.ers.usda.gov/topics/food-safety/markets-regulation-and-policy/#:~:text=USDA%20is%20responsible%20for%20What-foods-does-the-FDA-regulate. Accessed November 15, 2023July 4, 2024.
USDA (2024). *USDA organic*. Retrieved from https://www.usda.gov/topics/organic. Accessed July 4, 2024.
USMC (2008). *RP 0103- Principles of marine corps leadership*. Retrieved from https://www.tecom.marines.mil/Portals/120/Docs/Student%20Materials/CREST%20Manual/RP0103.pdf. Accessed August 2, 2024.
Yiannas, F. (2009). *Food safety culture: creating a behavior-based food safety management system*. Springer, New York. https://doi.org/10.1007/978-0-387-72867-4.
Yohn, D. L. (2021). *Company culture is everyone's responsibility. Harvard business review*. Retrieved from https://hbr.org/2021/02/company-culture-is-everyones-responsibility. Accessed January 24, 2024.