U.S. Food and Drug Administration
Protecting and Promoting Public Health

THE REPORTABLE FOOD REGISTRY: TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION

Fourth Annual Report Data Time Period: September 8, 2012 – September 7, 2013

CONTENTS

A. INTRODUCTION

The Reportable Food Registry (RFR or the Registry) was established by Section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), which amended the Food, Drug, and Cosmetic Act (FD&C Act) by creating a new Section 417, Reportable Food Registry [21 U.S.C. 350f]. It required FDA to establish an electronic portal to which reports about instances of reportable food must be submitted to FDA within 24 hours by responsible parties and to which reports may be submitted by public health officials.

A reportable food is an article of food/feed for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

This is the fourth Reportable Food Registry Annual Report, covering the period September 8, 2012 to September 7, 2013. The first, second, and third Reportable Food Registry Annual Reports presented FDA's experience with the RFR from the opening of the Reportable Food electronic portal on September 8, 2009 until September 7, 2012.

The RFR covers all human and animal food/feed (including pet food) regulated by FDA except infant formula and dietary supplements for which FDA has other mandatory reporting systems. The RFR does not accept submissions regarding drugs or other medical products, reports about products under the exclusive jurisdiction of the U.S. Department of Agriculture, or reports from consumers.

The congressionally identified purpose of the Registry is to provide a reliable mechanism to track patterns of food and feed adulteration to support efforts by FDA to target limited inspection resources to protect the public health. The FDA Food Safety Modernization Act (FSMA) included Section 211, which amends Section 417 of the FD&C Act in relevant part to provide that:

- FDA may require a responsible party to submit to FDA consumer-oriented information regarding a reportable food. This critical information must include a description of the article of food; affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient for the consumer to identify the article of food; contact information for the responsible party; and, any other information FDA determines is necessary to enable a consumer to accurately identify whether such consumer possesses the reportable food. Fruits and vegetables that are raw agricultural commodities are exempted from this requirement.
- FDA is required to prepare the critical information as a standardized one-page summary and publish the one-page summary on FDA.gov in a format that grocery stores can easily print for purposes for consumer notification.
- A Grocery store that is part of a chain of establishments with 15 or more physical locations and has sold a reportable food that is the subject of a one-page critical information summary published on FDA.gov is required to notify consumers by prominently displaying the one-page summary or information from such summary within 24 hours of its FDA web posting and maintain the display for 14 days.

Implementation of the FSMA amendments to section 417 of the FD&C Act will give the RFR a greater role in informing the public about the sale of reportable foods in chain grocery stores. FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) on March 26, 2014 to solicit comments, data, and information to assist the agency in implementing the FSMA amendments. The ANPRM will be open for a 75-day comment period and all interested parties are invited to comment through June 9, 2014. A Constituent Update explaining the

ANPRM can be accessed using this web link and additional information on commenting on the ANPRM is available in the online Federal Register Notice: Advance Notice of Proposed Rulemaking: Implementation of the Food and Drug Administration Food Safety Modernization Act Amendments to the Reportable Food Registry Provisions of the Federal Food, Drug, and Cosmetic Act.
NOTE: Definitions for certain specialized terms used in this report are hyperlinked to the list of definitions in Section K.

B. Executive Summary

Key Findings

Although the number of entries in Year 4 increased to 1269 from 1095 in Year 3, Year 1 continues to have the highest number of entries (2240) due to *Salmonella* in a very widely used ingredient, Hydrolyzed Vegetable Protein (HVP), which resulted in 1071 reports.

Highlighted below are events that resulted in the submission of the greatest number of reports during Year 4:

- *Salmonella* Bredeney in widely distributed peanut butter (related to a human illness outbreak investigation), resulting in 207 subsequent entries, i.e., reports resulting from a primary report
- *Listeria monocytogenes* in imported smoked salmon, resulting in 80 subsequent entries
- *E. coli* O121 in various frozen foods resulting in 69 subsequent entries (related to a human illness outbreak investigation)

See Section E for further information on the comparison of Year 4 entries with previous years.

Table 1: Comparison of Years 1, 2, 3 and 4 RFR Total Submissions and Entries

Report Category	Year 1	Year 2	Year 3	Year 4
Total Submissions	**2600**	**1153**	**1471**	**1534**
Nonreportable submissions	(360)	(271)	(376)	(265)
Total Entries	**2240**	**882**	**1095**	**1269**
Primary (Industry and Voluntary) Entries	229	225	224	202
Subsequent Entries (Upstream and Downstream)	1872	483	609	849
Amended Entries	139	174	262	218

Observed Changes

Primary Entries Decrease: 202 primary entries decreased in Year 4, down from 224 primary entries in Year 3.

Undeclared Allergens Reports Increase: 88 primary reports in Year 4, up from 85 primary reports in Year 3. Undeclared Allergen reports have steadily increased since RFR inception, representing 30% of reports in Year 1 and rising to just under 44% of reports in Year 4 (Table 6). The Bakery commodity continues to account for the most reports relating to Undeclared Allergens for all four years.

Produce- Raw Agricultural Commodities (RAC) and Produce- Fresh Cut Reports Decrease: 10 primary reports in Year 4 for Produce- RAC, down from 33 primary reports in Year 3. 13 primary reports in Year 4 for Produce- Fresh Cut, down from 23 primary reports in Year 3.

Animal Food/Feed (including pet food) Reports Increase: 30 primary reports in Year 4, up from 19 reports in Year 3. Animal Food/Feed (including pet food) reports represented the most frequently reported commodity in Year 4, as well as the majority of *Salmonella*-related reports.

FDA INITIATIVES

- **Advance Notice of Proposed Rulemaking:** FDA published an Advance Notice of Proposed Rulemaking in March 2014 to solicit comments, data, and information to assist the Agency in implementing Section 211 of the FDA Food Safety Modernization Act (FSMA), which added new provisions to the Reportable Food Registry (RFR) requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

- **Proposed Rules under FSMA:** FDA has issued seven proposed rules under FSMA since early 2013: Sanitary Transportation for Human and Animal Food, Focused Mitigation Strategies to Protect Food Against Intentional Adulteration, Preventive Controls for Human Food, Preventive Controls for Animal Food, Standards for Produce Safety, Foreign Supplier Verification Program, and Third Party Certification.

- **Guidance Documents Issued:** FDA published new or revised guidance documents to assist industry and regulators relating to the prevention and control of reportable foods.

- **Article Published in *Food Safety Magazine* to Educate Industry:** **"Learning from FDA Food Allergen Recalls and Reportable Foods"** provides a summary of RFR and recall data in reference to the increasing issues experienced with undeclared allergens in order to explain the nature of the problems that led to these reportable foods and recalls, which foods were most often affected, and the allergens that were most often involved.

- **RFR Submissions Triggered Follow-up Investigations that Resulted in**:
  - Six firms being placed on Import Alert.
  - One Import Bulletin to increase surveillance by FDA investigators at ports of entry of products that were the subject of RFR submissions.

- **FDA Draft Risk Profile on Spices**: describes the nature and extent of public health risk posed by consumption of spices and provides information for use in the development of plans to reduce or prevent illness from spices contaminated by microbial pathogens and/or filth.

INDUSTRY INITIATIVES

- **New Guidance on Environmental Monitoring and Control of *Listeria* for the Fresh Produce Industry:** A guidance document was published by the United Fresh Produce Association with the intention of reducing the risk of *Listeria monocytogenes* in fresh and fresh-cut produce.

- **New Allergen Resources for the Baking Industry:** The American Bakers Association published an online list of resources in April 2013 to assist in the identification and management of potential food allergens.

C. CONTINUED OUTREACH

ONLINE RESOURCES

FDA updated the main RFR Web page with useful RFR information and resources for all audiences:

- Training Video: explains RFR reporting requirements and how to access the Safety Reporting Portal to submit a reportable food report. It is closed-captioned in Arabic, Chinese, French, Japanese, Korean, Portuguese, English, and Spanish.
- RFR At A Glance
- Previously published RFR Annual Reports
- 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)
- Constituent Update explaining the March 2014 publication of an Advance Notice of Proposed Rulemaking: Implementation of the Food and Drug Administration Food Safety Modernization Act Amendments to the Reportable Food Registry Provisions of the Federal Food, Drug, and Cosmetic Act

FDA RFR PRESENTATIONS

FDA continues to provide RFR presentations, webinars, and briefings to food industry groups, state and local regulators, FDA headquarters and field staff, officials of other federal agencies, international trade organizations, and officials from foreign countries. The presentations explain the RFR; RFR requirements; and include information about the Safety Reporting Portal (SRP), the Department of Health and Human Services web site that streamlines the process of reporting product safety issues.

- "FSMA and RFR Overview," New York Summer Fancy Food Show, June 2013
- "Reportable Food Registry Program," Puerto Rico Food Industry Marketing and Distribution Association, June 2013
- "RFR Program and FSMA Updates." Make Our Food Safe Coalition, June 2013
- "RFR Overview," New Hampshire Department of Health and Human Services Food Protection Meeting, June 2013
- "Reportable Food Registry," International Association for Food Protection (IAFP) Symposium, July 2013
- "Food Safety Modernization Act (FSMA) RFR Updates and Requests for Information," Make Our Food Safe Coalition Stakeholder Meeting, June 2013
- "Reportable Food Registry," Public Affairs Specialists and Small Business Representatives Food Industry Outreach Training, August 2013
- "Reportable Food Registry Refresher," FDA Recalls Training Monthly Meeting, August 2013
- "Reportable Food Registry," Utah Department of Agriculture and Foods (UDAF), September 2013
- "Reportable Food Registry," Shellfish Steering Committee, November 2013
- "Reportable Food Registry Program," Annual Puerto Rican Bakery Convention, October 2013
- "FSMA and RFR Overview," First International Korean Trade Conference, November 2013
- "Reportable Food Registry Program," Puerto Rico Food Industry Forum, November 2013
- "Reportable Food Registry," Alcohol and Tobacco Tax and Trade/FDA Monthly Meeting, November 2013
- "RFR Overview," Alcohol and Tobacco and Trade Tax Meeting, November 2013
- "Who is Watching Your Food," New York Lawyers Association Public Health Forum, April 2014
- "FDA Emergency Response(s) and RFR Overview" Pennsylvania Department of Health, March 2014

RFR ASSISTANCE

To respond to industry concerns and questions regarding the RFR, there are two email contact points:

- The RFR Help Center at RFRSupport@fda.hhs.gov answers questions about RFR policies, procedures, and interpretations.
- The SRP Service Desk at Support.srp@jbsinternational.com answers technical and computer-related questions about the SRP, which includes the RFR.

D. COLLABORATIVE REVIEW OF RFR SUBMISSIONS AND NOTIFICATIONS

When a reportable food report is submitted to the Safety Reporting Portal, it is sent to the FDA Risk Control Review (RCR) team for review. The RCR team includes the following FDA organizations: the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Veterinary Medicine (CVM), the Office of Emergency Operations (OEO), and the Office of Regulatory Affairs (ORA). In addition, the FDA District Office for the geographic area from which the report originated receives a copy and participates in the review. Appropriate regulatory commissioned officials in the state or states involved are automatically notified of any reportable food reports that pertain to their jurisdictions. Immediate sharing of reportable food report information allows for rapid collaboration and coordination between FDA field offices and state officials.

Each report is reviewed by the RCR team to assess whether the subject food or feed meets the definition of a reportable food, and to identify appropriate follow-up actions. All reports are then referred to the appropriate FDA personnel for follow-up ("Risk Control Review (RCR) Process for Assessing Reportable Food Reports").

For reports that FDA considers to meet the definition of reportable food, a District Office investigator is assigned to contact the firm or individual submitting the report to obtain additional information if necessary. The District Office investigator may visit the firm to conduct a follow-up investigation. When necessary, District Offices advise the responsible party to notify the immediate previous supplier(s) of materials and/or the immediate subsequent recipient(s) of a reportable food and provide to the supplier/recipient the initial reporter's Individual Case Safety Report (ICSR) number.

If information submitted indicates that the subject food or feed may have been intentionally adulterated, FDA immediately sends a copy of the report to the Department of Homeland Security. If the subject food is under the exclusive jurisdiction of the USDA, a copy of the report is sent to USDA. If a submission involves a food or feed or an ingredient imported into the United States, FDA contacts the competent authority in the country of origin.

E. KEY FINDINGS

As shown in Table 2, there were 1269 Registry entries, representing primary, subsequent, and amended reports, during Year 4.

Registry entries for Year 1 (2240) were much higher than for other years. This is largely attributable to *Salmonella* Tennessee contamination of a widely used flavor enhancer, Hydrolyzed Vegetable Protein (HVP), which resulted in 1071 Registry entries during Year 1.

Highlighted below are events resulting in the greatest number of reports submitted during Year 4:

- *Salmonella* Bredeney in widely distributed peanut butter (related to a human illness outbreak investigation), resulting in 207 subsequent entries, i.e., reports resulting from a primary report
- *Listeria monocytogenes* in imported smoked salmon, resulting in 80 subsequent entries
- *E. coli* O121 in various frozen food products resulting in 69 subsequent entries (related to a human illness outbreak investigation)

Table 2: Monthly Registry Entries Years 1, 2, 3 and 4

Period	Year 1	Year 2	Year 3	Year 4
September 8–30	37	45	48	197
October	92	48	133	279
November	236	54	75	151
December	50	109	133	76
January	159	75	78	101
February	144	76	44	53
March	1117	68	53	53
April	61	66	55	119
May	68	137	93	67
June	71	42	28	37
July	71	31	164	61
August	117	98	156	46
September 1–7	17	33	35	29
Total	**2240**	**882**	**1095**	**1269**

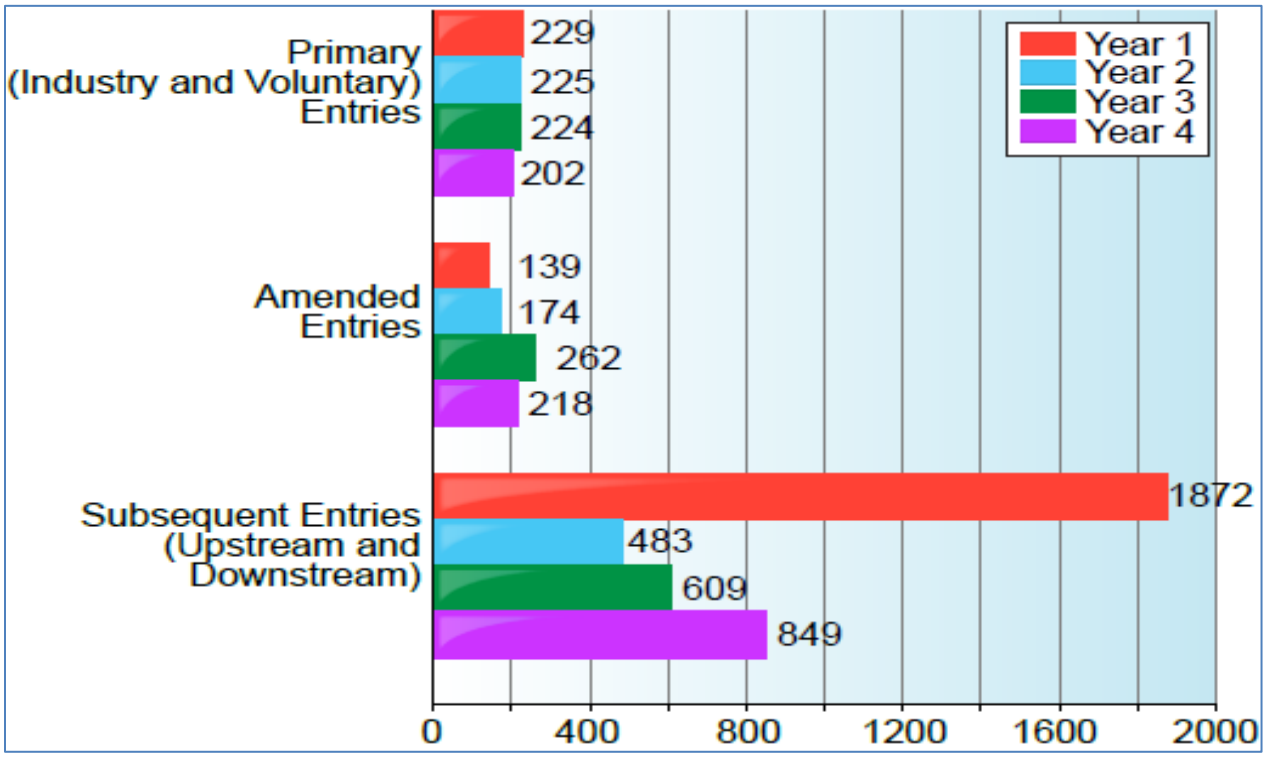
Of the 1269 Year 4 RFR entries, 202 were primary reports (200 of these were mandatory industry reports and two were voluntary reports submitted by state and federal regulatory officials); 849 were subsequent reports as a result of primary reports; and 218 were amended reports, updating previously submitted primary or subsequent reports, as shown in Figure 1 below.

As Figure 1 shows, the number of primary reports for all years was similar except for Year 4 where a decrease in primary entries was observed.

Amended reports, additional information supplied by an industry or voluntary submitter to correct or complete a primary or subsequent report, can be considered to be a measure of the efforts of responsible parties to thoroughly investigate a reportable food incident and to determine and correct the root cause of the problem.

FDA recognizes that increased amended report submissions are an important development in the evolution of the RFR and would like to thank and encourage responsible parties in their continuing efforts to update information via amended report submission at the SRP.

Figure1: RFR Entries by Report Type



As Table 3 shows, the 202 primary RFR entries in Year 4 included 172 entries for Human Food, and 30 entries concerning Animal Food/Feed (including pet food).

Table 3: Distribution of Primary RFR Entries by Human Food and Animal Food/Feed (including pet food)

Time Period	Human Food	Animal Food/Feed (including pet food)	Total
Year 1	201	28	229
Year 2	206	19	225
Year 3	205	19	224
Year 4	172	30	202

The 202 primary RFR entries in Year 4 involved 23 commodities as shown in Table 4 below. Further information about these observations is presented in Section H.

Table 4: Distribution of Primary RFR Entries by Commodity
RFR Commodity Definitions

Commodities	Year 1	Year 2	Year 3	Year 4
Acidified/Low Acid Canned Food (LACF)	2	2	2	1
Animal Food/Feed	28	19	19	30
Bakery	16	20	18	22
Beverages	3	2	1	1
Breakfast Cereals	2	0	3	1
Chocolate/Confections/Candy	8	7	12	11
Dairy	18	16	20	10
Dressings/Sauces/Gravies	6	8	5	6
Egg	2	2	2	0
Frozen Foods	9	11	3	10
Fruit and Vegetable Products	12	9	5	3
Game Meats	1	0	0	0
Meal Replacement/Nutritional Food and Beverages	6	2	5	4
Multiple Products	4	1	2	2
Nuts/Nut Products/Seed Products	16	16	13	15
Oil/Margarine	1	0	0	0
Other	0	0	0	0
Pasta	0	1	2	1
Prepared Foods	11	14	9	12
Produce - Fresh Cut	13	9	23	13
Produce – RAC	14	27	33	10
Seafood	17	18	17	19
Snack Foods	7	9	7	10
Soup	4	0	6	2
Spices and Seasonings	17	25	8	12
Stabilizers/Emulsifiers/Flavors/Colors/Texture Enhancers	8	5	5	6
Sweeteners	0	0	0	0
Whole & Milled Grains and Flours	4	2	4	1
Total	**229**	**225**	**224**	**202**

Table 5 shows 202 primary (industry and voluntary) RFR entries tabulated by their food safety hazards for Year 4 during the reporting period from September 8, 2012, to September 7, 2013.

Table 5: Distribution of Primary RFR Entries by Commodity and Hazard- Year 4

Commodity	*Drug Contamination*	*E. coli*	Foreign Object	*Listeria monocytogenes*	Nutrient Imbalance	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Uneviscerated Fish	Total	%
Acidified/Low Acid Canned Foods (LACF)								1			1	0.50
Animal Food/Feed	4		1		6	1	18				30	14.85
Bakery				1				21			22	10.89
Beverages								1			1	0.50
Breakfast Cereals								1			1	0.50
Chocolate/Confections/Candy								11			11	5.45
Dairy		1		4				5			10	4.95
Dressings/Sauces/Gravies								6			6	2.97
Frozen Foods		1				1		8			10	4.95
Fruit and Vegetable Products				1			1		1		3	1.49
Meal Replacement/Nutritional Food and Beverages								4			4	1.98
Multiple Products								2			2	0.99
Nuts/Nut Products/Seed Products				2			11	2			15	7.43
Pasta								1			1	0.50
Prepared Foods				4				8			12	5.94
Produce - Fresh Cut		2		7			4				13	6.44
Produce – RAC				3			7				10	4.95
Seafood				12		1	2	2	1	1	19	9.41
Snack Foods								10			10	4.95
Soup								2			2	0.99
Spices and Seasonings							10	2			12	5.94
Stabilizers/Emulsifiers/ Flavors/Colors/Texture Enhancers				1			4	1			6	2.97
Whole & Milled Grains and Flours							1				1	0.50
Total	4	4	1	35	6	3	58	88	2	1	202	
Percentage	1.98	1.98	0.50	17.33	2.97	1.49	28.71	43.56	0.99	0.50		100.00

NOTE: Due to rounding, the combined sum may not total 100%.There were zero entries in Year 4 for Egg, Game Meats, Oil/Margarine, Sweeteners, and Other commodity types. For Years 1-3 "Distribution of Primary RFR Entries by Commodity and Hazard" *values, see* ***The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration Second Annual Report: September 8, 2010 - September 7, 2012*****.**

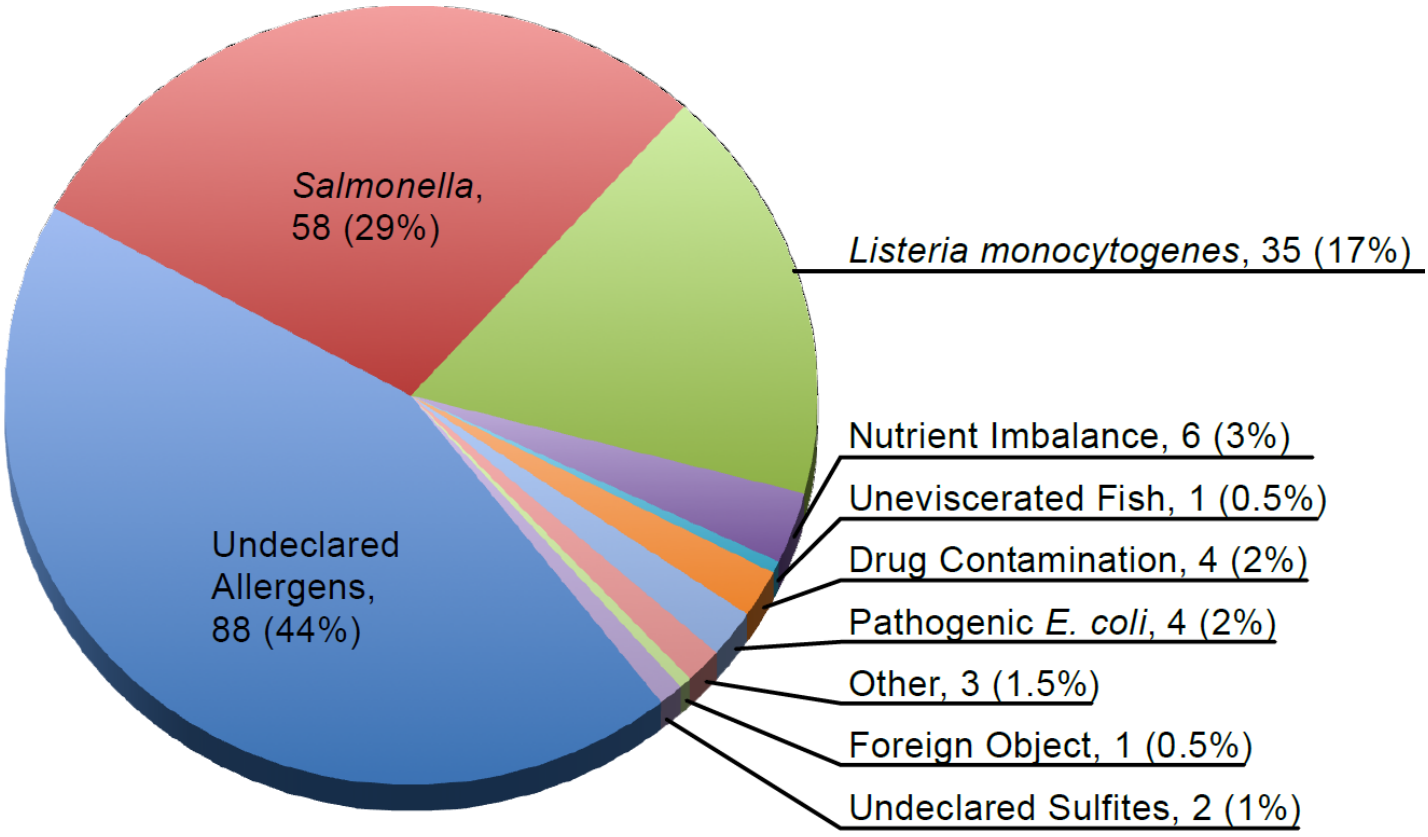
The 202 primary (industry and voluntary) RFR entries for Year 4 include a total of ten food safety hazards: Drug Contamination 1.98%; Pathogenic *E. coli* 1.98% (including 1 primary entry for *E. coli* O157:H7); Foreign Object 0.50%; *Listeria monocytogenes* 17.33%; Nutrient Imbalance 2.97%; Other 1.49%; *Salmonella* 28.71%; Undeclared Allergens 43.56%; Undeclared Sulfites 0.99%; and Uneviscerated Fish 0.50%.

Figure 2 shows the distribution of food safety hazards for Year 4. This was quite similar to previous years with some exceptions: Year 4 showed an increase in Undeclared Allergens related reports for human food. Also, there was a decrease in *Listeria monocytogenes, E. coli* O157:H7, and Uneviscerated Fish related reports between Years 3 and 4.

Table 6: Distribution of Primary RFR Entries by the Three Most Frequently Reported Food Safety Hazards by Year

Hazard	Year 1	Year 2	Year 3	Year 4
Salmonella	37.6%(86)	38.2%(86)	28.1%(63)	28.7%(58)
Listeria monocytogenes	14.4%(33)	17.8%(40)	21.4%(48)	17.3%(35)
Undeclared Allergens	30.1%(69)	38.3%(75)	37.9%(85)	43.6%(88)
Percentage (No. of entries)	**82.1%(188)**	**94.3%(201)**	**87.4%(196)**	**89.6%(181)**

Figure 2: Distribution of Primary RFR Entries by Food Safety Hazard, Year 4



Years 1-3 Pie Charts can be accessed in The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration Second Annual Report: September 8, 2010 - September 7, 2012.

F. FDA Initiatives

FDA studies RFR entries for signals of larger systemic food safety issues that may be affecting a commodity, a region, or an entire industry. Early detection enables FDA to thoroughly investigate existing or emerging issues and then implement focused regulatory strategies to mitigate or eliminate the concern before it becomes a major problem or a foodborne illness outbreak. Such regulatory initiatives assist FDA in focusing limited resources on eliminating the sources of food safety problems. For example, RFR data can be used to identify hazards associated with products for which we have not previously made such an association and thus identify foods for which preventive controls may be needed. The initiatives relating to the RFR's fourth year of operation are summarized below.

Advance Notice of Proposed Rulemaking

FDA published an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register on March 26, 2014 to solicit comments, data, and information (with a 75 day open comment period) to assist FDA in implementing the Food Safety Modernization Act (FSMA), which added new provisions to the RFR requirements of the Federal Food, Drug, and Cosmetic act (the FD&C Act).

Under the new provisions, FDA may require a responsible party to submit "consumer-oriented" information regarding certain reportable foods, including information necessary to enable a consumer to accurately identify whether the consumer is in possession of that reportable food. In addition, FSMA directs FDA to use such "consumer-oriented" information to create one-page summaries that would be posted on FDA's website in a format that can be easily printed for the purposes of consumer notification. Further, a grocery store that is part of a chain with 15 or more physical locations that sold a reportable food that is the subject of an FDA one-page summary, would be required to prominently display the one-page FDA summary, or information from the summary, within 24 hours of FDA's web posting. Grocery stores would also be required to maintain the display of the information for 14 days.

FDA is seeking input on topics including:

1. Consumer-Oriented Information Submissions and Consumer Notifications
2. Grocery Stores
3. Posting Consumer Notifications
4. Other Issues

Submissions to the RFR can provide early warning to FDA about potential serious public health risks and increase the speed with which the Agency and its partners at the state and local levels investigate and take appropriate action, including ensuring that reportable foods are removed from commerce when necessary. The congressionally identified purpose of the RFR program is to provide a reliable mechanism to track patterns of adulteration in food to support efforts by FDA to target limited inspection resources to protect the public health (Public Law 110-085, section 1005(a)(4)). The ANPRM solicits comments, data, and information to assist the Agency in implementing and enforcing the FSMA amendments to the RFR requirements of the FD&C Act. In addition, the document provides background information, including previously submitted public comments and notable discussion points from the FDA FSMA RFR working-group and a description of the current FDA RFR and recall program roles and practices. Also, the ANPRM notes that there may be potential public health impacts if consumer notifications for reportable foods do not include information on certain FDA regulated food products, based on statutory exemptions, particularly if the public believes that such consumer notifications are meant to encompass all food products regulated by FDA. The ANPRM requests comments or other

information on whether consumer notifications should advise consumers that such notifications do not cover certain foods.

Overall, implementation of the FSMA amendments to section 417 of the FD&C Act will give the RFR a greater role in informing the public about the sale of reportable foods in chain grocery stores. FDA anticipates that information from stakeholders and the public regarding the issues identified in the ANPRM will significantly assist the Agency in developing requirements to implement section 417 of FD&C Act and efficiently enforce such requirements. All interested parties are invited to comment using docket number FDA-2013-N-0590.

PROPOSED REGULATIONS

FDA's proposed rules, when implemented, would help address many of the food safety problems evidenced by RFR data by establishing the foundation of a central framework for the modern food safety system envisioned by Congress in the FDA Food Safety Modernization Act:

- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration. This proposed rule on food defense would require domestic and foreign facilities to address vulnerable processes in their operations to prevent acts on the food supply intended to cause large-scale public harm and would require the largest food businesses to have a written food defense plan that addresses significant vulnerabilities in a food operation.

- Sanitary Transportation of Human and Animal Food. This proposed rule would require those who transport food to use sanitary transportation practices to ensure the safety of food and would help maintain the safety of both human and animal food during transportation by establishing criteria, e.g., conditions and practices, training and record keeping, for the sanitary transportation of food.

- Preventive Controls for Human Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. This proposed rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. This action is intended to prevent foodborne pathogens or other hazards in foods from getting into the food supply.

- Preventive Controls for Animal Food: Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Food For Animals. This proposed rule would apply to domestic and imported food for animals, including pet food, animal feed, and raw materials and ingredients. Facilities that manufacture, process, pack, or hold food for animals would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions would be taken to correct problems that arise. In addition, the proposed rule would also establish certain Current Good Manufacturing Practices (CGMPs) that specifically address animal food facilities.

- Produce: Standards for the Growing, Harvesting, Packing, and Holding of produce for Human Consumption. The proposed rule would set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards.

- Foreign Supplier Verification Program for Importers of Food for Humans and Animals. This proposed rule would require importers to perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of domestic food producers.

- Accreditation of Third Party Auditors. This proposed rule would establish a program for accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals that they produce.

GUIDANCE

FDA also published new or revised guidance documents to assist industry and regulators relating to reportable foods:

- Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Fifth Edition): Published in December 2012, this guidance was developed to answer frequently asked questions relating to the registration requirements of section 415 of the FD&C Act (21 U.S.C. 350d) that requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with FDA.

- Guidance for Industry: What You Need To Know About Registration of Food Facilities; Small Entity Compliance Guide: Published in December 2012, this guidance was created to inform domestic and foreign food facilities about new and existing food facility registration requirements. Registration pertains only to facilities that manufacture/process, pack, or hold food, as defined in 21 CFR 1.227, for consumption by humans or animals in the U.S.

- Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access): Published in July 2013, this document provides draft guidance to egg producers on certain provisions contained in FDA's July 9, 2009, final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation" (74 FR 33030, codified at 21 CFR part 118), concerning the management of production systems that provide laying hens with access to the outdoors.

- Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages: Published in January 2014, this guidance will help dietary supplement and beverage manufacturers and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage. In addition, this guidance describes the factors that distinguish liquid products that are dietary supplements from those that are conventional foods and further reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the FD&C Act regarding their respective ingredients and labeling.

ARTICLE: LEARNING FROM FDA FOOD ALLERGEN RECALLS AND REPORTABLE FOODS

The presence of unlabeled allergens presents a significant health hazard for food allergic consumers and allergen recalls represent an economic burden for industry and a resource need for FDA. In order for FDA and the food industry to be able to develop practical approaches to reducing the number of food allergen reportable foods and recalls, and thereby reducing the risk of illness to allergic consumers, it is important to understand the nature of the problems that lead to these issues, the foods that are most often affected, and the allergens that are most often involved.

FDA prepared an article, published in April 2014 in *Food Safety Magazine*, to address some of the trends and emerging issues evidenced by RFR and recall data. Specifically, unlabeled allergens continue to be the

leading cause of recalls and a leading cause of reportable foods for FDA regulated foods. In addition, Undeclared Allergen-related reportable food reports have steadily increased since inception of the RFR program, representing 30.1% of reports in Year 1 and rising to 43.6% of reports in Year 4 (Table 6).

RFR entries in Year 4 triggered follow-up investigations by FDA that resulted in Import Alerts and Import Bulletins.

IMPORT ALERTS

- *Salmonella* in red pepper from a facility in Thailand
- *Listeria monocytogenes* in smoked salmon from a facility in Chile
- *Salmonella* in tomatoes from a facility in Mexico
- *Listeria monocytogenes* in cheese from a facility in France
- *Listeria monocytogenes* in herring from a facility in Ukraine
- *Salmonella* in tahini from a facility in Turkey

IMPORT BULLETINS

- Undeclared eggs in dough from facilities in Canada

FDA RISK PROFILE

Draft Risk Profile on Pathogens and Filth in Spices: In October 2013, FDA made available for public comment a draft risk profile to identify the most commonly occurring microbial and filth hazards in spices and describe the nature and extent of public health risk posed by the consumption of spices. The draft risk profile also evaluates current mitigation and control options, and provides information for FDA and industry to use in the development of plans to reduce or prevent illness from spices contaminated by microbial pathogens and/or filth.

The objectives of the risk profile are to:

1. describe the nature and extent of the public health risk posed by consumption of spices in the United States by identifying the most commonly occurring microbial hazards and filth in spice;
2. describe and evaluate current mitigation and control options designed to reduce the public health risk posed by consumption of contaminated spices in the United States;
3. identify potential additional mitigation and control options; and
4. identify critical data gaps and research needs.

Selected FDA research studies included in the Draft Risk Profile:

- J.M. Van Doren, R.J. Blodgett, R. Pouillot, A. Westerman, D. Kleinmeier, G.C. Ziobro, Y. Ma, T.S. Hammack, V. Gill, M.F. Muckenfuss, L. Fabbri, “Prevalence, level and distribution of *Salmonella* in shipments of imported capsicum and sesame seed spice offered for entry to the United States: Observations and modeling results,” Food Microbiology, 36: 149-610 (2013).

- J. M. Van Doren, D. Kleinmeier, T. S. Hammack, A. Westerman. “Prevalence, serotype diversity, and antimicrobial resistance of *Salmonella* in shipments of imported spice offered for entry to the United States, FY2007-FY2009,” Food Microbiology. Available online Oct 17, 2012.

- S. E. Keller, J. M. Van Doren, E. M. Grasso, and L. A. Halik. "Growth and survival of *Salmonella* in ground black pepper (*Piper nigrum*)," Food Microbiology, 34(1): 182-188 (2013). Available online 12/2012.

- J.M. Van Doren, K. P. Neil, M. Parish, L. Gieraltowski, L.H. Gould, and K.L. Gombas. "Foodborne illness outbreaks from microbial contaminants in spices, 1973-2010," Food Microbiology online, accepted 4/2013.

G. INDUSTRY INITIATIVES

Since the RFR electronic portal opened, changes have occurred in areas of the food industry regulated by FDA related to either the RFR's reporting requirements or the information resulting from reports to the portal. The Year 3 RFR report provided details about the Clean, Safe Spices and Seasonings Guidance from the American Spice Trade Association (ASTA) and the Cantaloupes and Netted Melons Guidance, produced by a national coalition of industry and government stakeholders, to reduce the risk of contamination with *Salmonella* and other pathogens, as well as highlighted some industry hosted webinars for training and education. Following are some updated industry related initiatives in Year 4:

- **Guidance on Environmental Monitoring and Control of *Listeria* for the Fresh Produce Industry:** The United Fresh Produce Association published guidance in 2013 to reduce the risk of *Listeria monocytogenes* contamination in fresh and fresh-cut produce, including field and field packing, packinghouse, and other produce handling operations including re-pack, value-added and transport/distribution to retail/foodservice.

- **Allergen Resources for the Baking Industry:** The American Bakers Association published an online list of resources in April 2013, including legislation and best practices from leading organizations in the baking and food industry to assist bakers, both large and small, in the identification and management of potential food allergens.

- **Industry Seminars:**
  - ASTA and the Joint Institute for Food Safety and Applied Nutrition(JIFSAN) hosted a "Supply Chain Management for Spices" workshop in May 2013 to detail ways to implement monitoring programs in spices and seasonings.

  - International Association for Food Protection (IAFP) provided a "Persistent and Ongoing Food Allergen Challenges: Labeling, Detection and Control" session in July 2013 to provide an overview of international food allergen labeling requirements and best practices to detect and control food allergens.

H. Issues Identified by RFR Entries

The Congressional intent of the RFR, as stated in Section 1005 of the Food and Drug Administration Amendments Act of 2007, which created the Registry, is to help FDA better protect public health by tracking patterns of food and feed adulteration and targeting inspection resources.

Salmonella

Overall, the 58 primary reports for *Salmonella* in Year 4 remained similar to the 63 primary reports in Year 3.

Data from the fourth year of operation of the RFR indicates that Animal Food/Feed (including pet food) accounts for the majority of *Salmonella*-related reports. This commodity also represents the largest increase in *Salmonella*-related reports from 6.4% of reports in Year 3 to 31% of reports in Year 4.

The largest decrease in *Salmonella* was observed in the Produce- RAC commodity, with a total of seven primary entries in Year 4 compared to 22 in Year 3, representing a 22.8% decrease between these years. This decline is likely due to cessation of a surveillance sampling program that targeted Produce- RAC and Produce-Fresh Cut commodities for pathogen testing.

As indicated in the descriptions of industry and regulatory initiatives, respectively, in Sections F and G, FDA is working with industry to identify controls to reduce *Salmonella* contamination.

Table 7: Distribution of *Salmonella* Primary RFR Entries By Commodity

Commodity	Year 1		Year 2		Year 3		Year 4	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Animal Food/Feed	13	15.1%	8	9.3%	4	6.4%	18	31.0%
Bakery	1	1.1%	0	0.0%	0	0.0%	0	0.0%
Beverages	1	1.1%	1	1.1%	0	0.0%	0	0.0%
Breakfast Cereals	1	1.1%	0	0.0%	1	1.6%	0	0.0%
Chocolate/Confections/Candy	1	1.1%	0	0.0%	1	1.6%	0	0.0%
Dairy	1	1.1%	3	3.4%	3	4.8%	0	0.0%
Egg	1	1.1%	0	0.0%	0	0.0%	0	0.0%
Frozen Foods	3	3.4%	1	1.1%	0	0.0%	0	0.0%
Fruit and Vegetable Products	1	1.1%	6	6.9%	4	6.4%	1	1.7%
Meal Replacement/Nutritional Food and Beverages	5	5.8%	1	1.1%	2	3.2%	0	0.0%
Multiple Products	1	1.1%	0	0.0%	0	0.0%	0	0.0%
Nuts/Nut Products/Seed Products	12	13.9%	11	12.7%	8	12.7%	11	19.0%
Prepared Foods	0	0.0%	1	1.1%	0	0.0%	0	0.0%
Produce - Fresh Cut	5	5.8%	2	2.3%	6	9.5%	4	6.9%
Produce – RAC	14	16.2%	25	29.0%	22	34.9%	7	12.1%
Seafood	0	0.0%	0	0.0%	1	1.6%	2	3.4%
Snack Foods	1	1.1%	0	0.0%	0	0.0%	0	0.0%
Spices and Seasonings	16	18.6%	23	26.7%	5	7.9%	10	17.2%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	6	6.9%	3	3.4%	5	7.9%	4	6.9%
Whole & Milled Grains and Flours	3	3.4%	1	1.1%	1	1.6%	1	1.7%
Total	**86**	**100%**	**86**	**100%**	**63**	**100%**	**58**	**100%**

NOTE: Due to rounding, the combined sum may not total 100%.The following eight commodities had zero entries related to *Salmonella* hazards for all Years: Acidified/Low Acid Canned Food (LACF), Dressing/Sauces/Gravies, Oil/Margarine, Pasta, Soup, Other, Sweeteners, and Game Meats.

LISTERIA MONOCYTOGENES

The 35 primary reports in Year 4 for *Listeria monocytogenes* (*Lm*) show a decrease from the 48 primary reports in Year 3 representing 17.3% of total entries in Year 4 compared to 21.4% of total entries in Year 3 (Table 6).

Seafood accounts for just over a third (34.3%) of the *Lm* reports with 12 primary entries in Year 4, mainly for smoked fishes. Produce- Fresh Cut was responsible for 7 primary entries and included various ready to eat salads or fruits and vegetables. There were 4 primary entries in each of the Prepared Foods and Dairy commodities during Year 4.

Table 8: Distribution of *Listeria monocytogenes* Primary RFR Entries by Commodity

Commodity	Year 1		Year 2		Year 3		Year 4	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Bakery	0	0.0%	0	0.0%	0	0.0%	1	2.9%
Dairy	8	24.2%	7	17.5%	11	22.9%	4	11.4%
Dressing/Sauces/Gravies	1	3.0%	0	0.0%	0	0.0%	0	0.0%
Egg	0	0.0%	2	5.0%	2	4.2%	0	0.0%
Frozen Foods	3	9.0%	1	2.5%	1	2.1%	0	0.0%
Fruit and Vegetable Products	2	6.0%	2	5.0%	0	0.0%	1	2.9%
Meal Replacement/Nutritional Food and Beverages	1	3.0%	0	0.0%	0	0.0%	0	0.0%
Multiple Products	1	3.0%	0	0.0%	0	0.0%	0	0.0%
Nuts/Nut Products/Seed Products	1	3.0%	0	0.0%	0	0.0%	2	5.7%
Prepared Foods	2	6.0%	10	25.0%	5	10.4%	4	11.4%
Produce - Fresh Cut	5	15.1%	7	17.5%	15	31.3%	7	20.0%
Produce - RAC	0	0.0%	2	5.0%	10	20.8%	3	8.6%
Seafood	9	27.2%	8	20.0%	4	8.3%	12	34.3%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	0	0.0%	1	2.5%	0	0.0%	1	2.9%
Total	**33**	**100%**	**40**	**100%**	**48**	**100%**	**35**	**100%**

NOTE: Due to rounding, the combined sum may not total 100%. The following fourteen commodities had zero entries related to *Listeria monocytogenes* hazards for all Years: Acidified/Low Acid Canned Food, Animal Food/Feed, Beverages, Breakfast Cereals, Chocolate/Candy/Confections, Oil/Margarine, Pasta, Snack Foods, Soup, Spices and Seasonings, Other, Sweeteners, Game Meats, and Whole and Milled Grains and Flours.

UNDECLARED MAJOR FOOD ALLERGENS

The Food Allergen Labeling and Consumer Protection Act of 2004 requires that the labels of all packaged foods regulated by FDA declare the presence of any of the eight common food allergens(milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) which the Act terms “major food allergens.”

Year 4 demonstrated an increase in Undeclared Major Food Allergen related reports representing 88 entries or 43.6% of the total primary entries compared to 85 entries or 37.9% of the total primary entries in Year 3 (Table 6).

The Bakery commodity accounts for 21 of the total of 88 entries. Within the Bakery commodity, the most frequently reported food types were cookies, cakes, and mixes.

Table 9: Distribution of Undeclared Major Food Allergens Primary RFR Entries by Commodity

Commodity	Year 1		Year 2		Year 3		Year 4	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acidified and Low Acid Canned Foods (LACF)	2	2.9%	2	2.6%	1	1.2%	1	1.1%
Animal Food/Feed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Bakery	14	20.2%	20	26.6%	18	21.2%	21	23.9%
Beverages	1	1.4%	1	1.3%	1	1.2%	1	1.1%
Breakfast Cereals	1	1.4%	0	0.0%	2	2.4%	1	1.1%
Chocolate/Confections/Candy	7	10.1%	7	9.3%	11	12.9%	11	12.5%
Dairy	8	11.5%	6	8.0%	7	8.2%	5	5.7%
Dressing/Sauces/Gravies	5	7.2%	7	9.3%	5	5.9%	6	6.8%
Frozen Foods	3	4.3%	9	12.0%	2	2.4%	8	9.1%
Meal Replacement/Nutritional Food and Beverages	0	0.0%	1	1.3%	3	3.5%	4	4.5%
Multiple Food Products	2	2.9%	1	1.3%	2	2.4%	2	2.3%
Nuts/Nut Products/Seed Products	3	4.3%	4	5.3%	4	4.7%	2	2.3%
Oil/Margarine	1	1.4%	0	0.0%	0	0.0%	0	0.0%
Pasta	0	0.0%	1	1.3%	2	2.4%	1	1.1%
Prepared Foods	8	11.5%	3	4.0%	4	4.7%	8	9.1%
Seafood	1	1.4%	4	5.3%	5	5.9%	2	2.3%
Snack Foods	6	8.7%	8	10.6%	7	8.2%	10	11.4%
Soup	4	5.8%	0	0.0%	5	5.9%	2	2.3%
Spices and Seasonings	1	1.4%	0	0.0%	3	3.5%	2	2.3%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	2	2.9%	0	0.0%	0	0.0%	1	1.1%
Whole and Milled Grains and Flours	0	0.0%	1	1.3%	3	3.5%	0	0.0%
Total	**69**	**100%**	**75**	**100%**	**85**	**100%**	**88**	**100%**

NOTE: Due to rounding, the combined sum may not total 100%; "N/A" means Not Applicable. The following seven commodities had zero entries related to Undeclared Allergen hazards for all Years: Eggs, Fruit and Vegetable Products, Game Meats, Other, Produce- Fresh Cut, Produce- RAC, and Sweeteners.

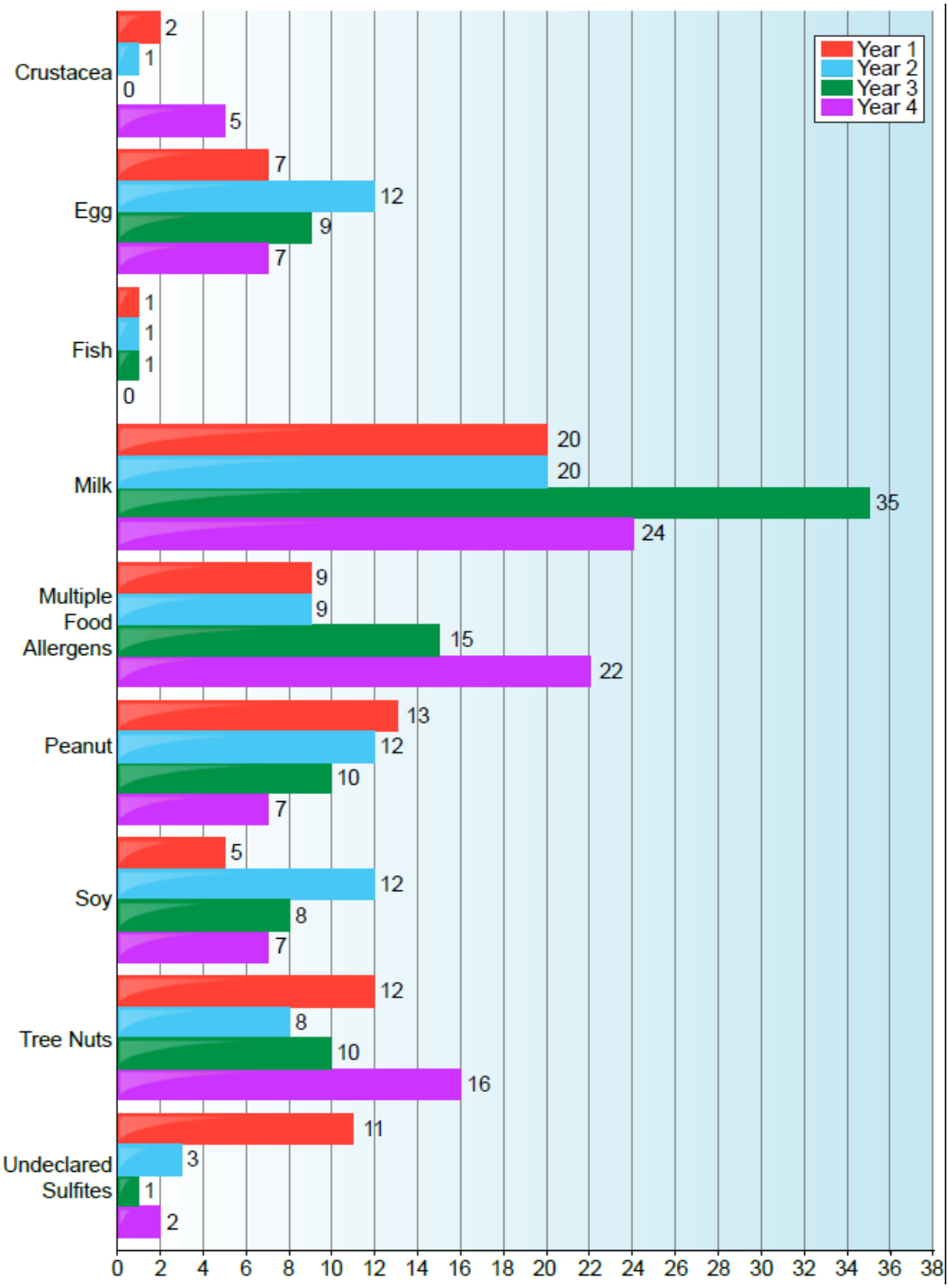
Table 10: Top 3 Commodities with Undeclared Major Food Allergens by Specific Food Allergen in Year 4

The Bakery commodity accounts for the most reports relating to Undeclared Allergens for all four years.

Commodity	Crustacea	Egg	Fish	Milk	Multiple Food Allergens	Peanut	Soy	Tree Nuts	Total
Bakery	0	4	0	5	4	1	0	7	21
Chocolate/Confections/Candy	0	0	0	4	2	2	0	3	11
Dairy	0	0	0	6	1	2	0	1	10

Figure 3: Distribution of Primary RFR Entries by Specific Undeclared Major Allergen and Undeclared Sulfites

Undeclared Milk remains the most reported specific undeclared major food allergen in Year 4, with 24 primary entries, down from 35 primary entries in Year 3. Multiple Food Allergens increased from 15 primary entries in Year 3 to 22 primary entries in Year 4. In addition, Tree Nuts increased to 16 primary entries, up from 10 primary entries observed in Year 3.



UNDECLARED SULFITES

Sulfite-sensitive individuals must avoid the ingredient due to potential health consequences, FDA regulations require that the presence of any sulfiting agent be declared on food labels, as described in 21 CFR Part 101.100 (a) (4).

Table 11: Primary RFR Entries of Undeclared Sulfites by Commodity

There were two primary entries for Undeclared Sulfites in Fruit and Vegetable and Seafood Products in Year 4.

Commodity	Year 1	Year 2	Year 3	Year 4
Fruit and Vegetable Products	9	1	1	1
Prepared Foods	1	0	0	0
Seafood	1	1	0	1
Snack Foods	0	1	0	0
Total	**11**	**3**	**1**	**2**

I. Reports Associated with Imported Foods

Primary RFR entries for foods from international sources decreased in Year 4 to 38 primary entries from 46 primary entries in Year 3.

The 38 entries in Year 4 encompassed the following four food safety hazards: *Listeria monocytogenes*, *Salmonella*, Undeclared Allergens, and Undeclared Sulfites distributed across 11 commodities, as shown in Table 12 below.

Table 12: Distribution of Primary RFR Entries Involving Imported Foods by Commodity and Food Safety Hazard, Year 4

Commodity	*E. coli*	Drug Contamination	Foreign Object	*Listeria monocytogenes*	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Uneviscerated Fish	Total	%
Animal Food/Feed						1				1	2.63
Dairy				2						2	5.26
Dressing/Sauces/ Gravies							1			1	2.63
Frozen Foods							3			3	7.89
Fruit and Vegetable Products				1		1		1		3	7.89
Nuts/ Nut Products/Seed Products						4				4	10.52
Produce - RAC						4				4	10.52
Seafood				6		1				7	18.42
Snack Foods							1			1	2.63
Spices/Seasonings						10				10	26.31
Stabilizers, Emulsifiers/Flavors and Colors/ Texture Enhancers						1	1			2	5.26
Total	0	0	0	9	0	22	6	1	0	38	
Percentage	0.0	0.0	0.0	23.68	0.0	60.50	15.79	2.63	0.0		100

NOTE: Due to rounding, the combined sum may not total 100%. There were zero entries in Year 4 for the following seventeen commodities: Acidified/Low Acid Canned Foods (LACF), Bakery, Beverages, Breakfast Cereals, Chocolate/Confections/Candy, Egg, Meal Replacement/Nutritional Food and Beverages, Multiple Food Products, Game Meats, Oil/Margarine, Other, Pasta, Prepared Foods, Produce- Fresh Cut, Soup, Sweeteners, and Whole & Milled Grands and Flour. For Years 1-3 "Distribution of Primary RFR Entries by Commodity and Hazard" *values, see* ***The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration Second Annual Report: September 8, 2010 - September 7, 2012***.

Thirty-eight of the 202 primary reports for Year 4 (18.8%) concerned imported foods or ingredients, coming from 24 different countries. When entries for all years are combined, there are more than 44 different countries represented, as shown in Table 13 below.

Table 13: Distribution of Primary RFR Entries for Imported Foods by Country of Origin

	Year 1		Year 2		Year 3		Year 4	
Country	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
Afghanistan	1	1.90%	0	0.00%	0	0.00%	0	0.00%
American Samoa	0	0.00%	0	0.00%	1	2.17%	0	0.00%
Australia	0	0.00%	0	0.00%	0	0.00%	1	2.86%
Bulgaria	0	0.00%	0	0.00%	0	0.00%	1	2.86%
Belgium	0	0.00%	0	0.00%	3	6.52%	0	0.00%
Canada	4	7.60%	6	10.70%	8	17.39%	3	8.57%
Chile	0	0.00%	0	0.00%	0	0.00%	1	2.86%
China	13	24.50%	16	28.60%	6	13.04%	4	11.43%
Colombia	0	0.00%	1	1.80%	0	0.00%	0	0.00%
Egypt	0	0.00%	4	7.10%	2	4.35%	2	5.71%
France	0	0.00%	0	0.00%	0	0.00%	1	2.86%
Germany	0	0.00%	0	0.00%	0	0.00%	1	2.86%
Greece	1	1.90%	0	0.00%	1	2.17%	0	0.00%
Guatemala	2	3.80%	0	0.00%	1	2.17%	1	2.86%
India	4	7.50%	7	12.50%	2	4.35%	0	0.00%
Indonesia	1	1.90%	2	3.60%	0	0.00%	2	5.71%
Israel	0	0.00%	1	1.80%	0	0.00%	2	5.71%
Italy	1	1.90%	0	0.00%	1	2.17%	1	2.86%
Japan	0	0.00%	1	1.80%	1	2.17%	1	2.86%
Kenya	0	0.00%	1	1.80%	2	4.35%	1	2.86%
Latvia	0	0.00%	0	0.00%	0	0.00%	1	2.86%
Malawi	1	1.90%	2	3.60%	0	0.00%	0	0.00%
Mexico	5	9.40%	6	10.70%	6	13.04%	4	11.43%
Morocco	0	0.00%	0	0.00%	1	2.17%	0	0.00%
Multiple	1	1.90%	0	0.00%	0	0.00%	0	0.00%
Netherlands	0	0.00%	1	1.80%	1	2.17%	0	0.00%
Nicaragua	1	1.90%	0	0.00%	0	0.00%	0	0.00%
Nigeria	1	1.90%	0	0.00%	0	0.00%	0	0.00%
Norway	1	1.90%	0	0.00%	0	0.00%	1	2.86%
Pakistan	1	1.90%	0	0.00%	0	0.00%	0	0.00%
Peru	0	0.00%	1	1.80%	0	0.00%	0	0.00%
Philippines	0	0.00%	1	1.80%	2	4.35%	0	0.00%
Poland	2	3.80%	0	0.00%	0	0.00%	0	0.00%
Russia	2	3.80%	0	0.00%	1	2.17%	1	2.86%
South Africa	2	3.80%	1	1.80%	0	0.00%	0	0.00%
South Korea	0	0.00%	0	0.00%	1	2.17%	0	0.00%
Sri Lanka	0	0.00%	0	0.00%	0	0.00%	1	2.86%
Taiwan	0	0.00%	0	0.00%	0	0.00%	1	2.86%
Thailand	0	0.00%	1	1.80%	2	4.35%	2	5.71%
Turkey	4	7.50%	0	0.00%	1	2.17%	3	8.57%
Ukraine	0	0.00%	0	0.00%	2	4.35%	1	2.86%
United Kingdom	2	3.80%	1	1.80%	0	0.00%	0	0.00%
Venezuela	1	1.90%	1	1.80%	0	0.00%	0	0.00%
Vietnam	2	3.80%	2	3.60%	1	2.17%	1	2.86%
Total	**53**	**100%**	**56**	**100%**	**46**	**100%**	**38**	**100%**

NOTE: Due to rounding, the combined sum may not total 100%.

J. Completed Steps

New Rules and Guidance

FDA has published several proposed rules and guidance, including an Advance Notice of Proposed Rulemaking to address Food Safety Modernization Act requirements. FSMA activities will address many of the issues evidenced by the RFR data, including microbiological and physical hazard contamination. Detailed information regarding these efforts can be found in Section F of this report.

Working With Industry

FDA will continue actively working with the food industry in identifying problems and developing solutions. For example, FDA co-convened an International Association for Food Protection Short Symposium with industry entitled "Persistent and Ongoing Food Allergen Challenges: Labeling, Detection and Control" in July 2013. The session covered labeling requirements for the food industry including discussions highlighting regulations, analysis of FDA's recall database, and detection and control of allergens.

Moreover, in December 2012 FDA made available a Federal Register Docket for public comment to gather data and information related to the possibility of conducting a risk assessment related to food allergen thresholds. FDA has completed a detailed analysis of the comments submitted to this docket and is actively assessing the publicly available data in the published scientific literature on levels of sensitivity in the allergic population. Based on these inputs, FDA will use a risk assessment-based approach to determine if the data support establishing practical thresholds for any or all of the major food allergens. FDA will make a draft version of any risk assessment available for public comment before the document and results are finalized.

If safe thresholds can be established, the FDA could:

- more effectively determine the appropriate corrective actions to address unintentional allergen contamination issues;
- better evaluate petitions and notifications for exemptions from allergen labeling;
- better respond to situations where undeclared allergens are found in foods;
- consider how thresholds might be used to improve consumer choices in the marketplace, while protecting sensitive consumers.

In addition, FDA has published the following journal article to share data regarding recalls and reportable foods associated with Undeclared Allergens:

Gendel, Steven M. and Jianmei Zhu. Analysis of U.S. Food and Drug Administration Food Allergen Recalls after Implementation of the Food Allergen Labeling and Consumer Protection Act. *Journal of Food Protection*, Vol. 76, No. 11, 2013, Pages 1933–1938 doi:10.4315/0362-028X.JFP-13-171.

Collaboration with State and Local Regulatory Agencies

Public Law 110-85 states that Federal, State, or local public health officials may submit reports to the FDA. In addition to reminding state and local officials of the availability of the electronic portal, FDA will work with regulatory partners to promote and explain the importance of voluntary report submissions.

K. Terms Used in this Report

Amended Report – additional information supplied by an industry or public health submitter to correct or complete a primary or subsequent report.

Commissioned Official – Section 702 (a) (1) of the FD&C Act authorizes the Secretary of Health and Human Services to commission any health, food, or drug officer or employee of any state, territory, or political subdivision thereof as an officer of the Department, to conduct examinations and investigations for the purposes of the FD&C Act. Commissioned Officials must meet the requirements the state has established to credential its own officials to carry out state government regulatory or enforcement responsibilities, and provide written assurances regarding conflict of interest and prohibited financial interests, and maintain the confidentiality of non-public information provided.

Commodities – in summarizing the statistics generated by reports to the RFR during its first year, FDA has sorted the data by type of report (primary, subsequent, and amended), by food safety hazard, and by commodity. For explanations of the commodity categories used in this report, please go to "Reportable Food Summary Report Definitions." FDA revised the 2nd year "Commodity definitions" to include additional examples for added clarity.

Drug Contamination – a food that contains an unintended drug.

Entries – reportable food submissions that meet the definition of a reportable food and are entered into the Registry.

Excessive Urea – the amount of urea present in feed for an animal species that would cause a serious adverse health consequence or death in that species.

FDA District Offices – FDA's Office of Regulatory Affairs maintains 19 district offices at locations throughout the United States. They are responsible for obtaining compliance with the laws and regulations enforced by FDA, conducting investigations and inspections and collecting samples of foods, drugs, and other commodities for which the Agency has regulatory responsibility, carrying out educational and voluntary compliance programs for FDA-regulated industries, providing assistance to states and localities in emergencies, and conducting consumer affairs and information programs.

Field Assignments – specific instructions and compliance information sent to FDA district offices to address a particular problem relating to FDA-regulated domestic or imported products.

Food Safety Hazards – any biological, chemical, or physical agent that may cause a food/feed to be unsafe for human or animal consumption.

Foreign Objects – objects, typically hard or sharp, that pose physical hazards that can result in injury, e.g. choking, lacerations and perforation of tissues of the mouth, tongue, throat, stomach or intestines. Reportable physical hazards may include, for example, glass, brittle plastic, and metal. For more information concerning foreign objects in human food, see "Adulteration Involving Hard or Sharp Foreign Objects."

ICSR number- stands for the Individual Case Safety Report (ICSR) number and it is the unique number that identifies a report.

Import Alerts – guidance documents for FDA field staff concerning significant recurring, new or unusual problems affecting import coverage. They include background data and guidance for appropriate enforcement action (generally, detention without physical examination) regarding each product and/or problem.

Import Bulletins – generally provide information for FDA field staff on a suspected problem affecting FDA-regulated imported products. Import bulletins generally call for increased surveillance (field examination and/or sample collection) of suspected problem products. The results of that increased surveillance may lead to subjecting a firm and/or product to an import alert.

Industry Report – a mandatory report from a facility that manufactures, processes, packs or holds human food or animal food/feed (including pet food) for consumption in the United States.

Nonreportable Submission – a report concerning a food that the FDA Risk Control Review (RCR) determines does not meet the definition of a reportable food, or does not concern a food regulated by FDA, or is not submitted by a manufacturer, processor, packer or holder of food registered with the FDA as required under Section 415 of the FD&C Act.

Nutrient Imbalance–excessive or deficient nutrient levels or inappropriate proportions of essential nutrients in an animal food that can compromise the health of the intended animal being fed.

Other – food safety hazards other than *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, Uneviscerated Fish, Foreign Objects, Excessive Urea, Undeclared Sulfites, or Undeclared Allergens, for which there were two reports or less during the period of this report. Note: For simplicity, excessive urea was broken out in Y1 tables for this report although only two reports were received regarding this agent in Year 1.

Pathogen – an agent that causes disease. Pathogens of foodborne origin are typically bacteria, parasites and viruses. Reportable food reports involving pathogens submitted to date have included *Salmonella*, *Listeria monocytogenes*, and *E. coli* O157:H7.

Primary Report – the initial report concerning a reportable food from either industry or public health officials, such as federal, state, or local regulators.

Voluntary Report – a voluntary report by a federal, state or local public health official.

Reportable Food – an article of food/feed for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. All foods regulated by FDA are subject to the Reportable Food Registry requirements, with the exception of dietary supplements and infant formula. Other mandatory reporting systems exist for problems with infant formula and dietary supplements.

Reportable Food Registry – an FDA database in which reportable food reports are entered per the "Risk Control Review (RCR) Process for Assessing Reportable Food Reports."

Reportable Food Reports – mandatory reports from industry and voluntary reports from public health officials regarding reportable foods submitted to FDA through the reportable food electronic portal and referred to in this document as "submissions."

Responsible Party – the person who submits the registration information to FDA for a food/feed facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States. The term "person" is defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) as including individuals, partnerships, corporations and associations.

Safety Reporting Portal - a Department of Health and Human Services portal that receives various safety reports including the Reportable Food Registry program.

Submissions – all RFR reports that come through the Safety Reporting Portal, including primary, subsequent, and amended reports.

Subsequent Report – a report by either a supplier (upstream) or a recipient (downstream) of a food/feed (including ingredients) for which a primary report has been submitted. The number of subsequent reports depends on whether the primary report is on a widely used ingredient or a finished food distributed to many different locations.

Undeclared Major Food Allergens – failure to declare on human food labels the presence of any of the eight major human food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) or proteins derived from them.

Undeclared Sulfites – failure to declare on the associated human food label the presence of any sulfiting agent as described in 21 CFR Part 101.100 (a) (4).

Uneviscerated Fish – internal organs not carefully and/or completely removed from fish.