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

THE REPORTABLE FOOD REGISTRY: A FIVE YEAR OVERVIEW OF TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION

September 8, 2009 – September 7, 2014

CONTENTS

Contents

A. Executive Summary

Key Findings

Highlighted below are events that resulted in the submission of the greatest number of reports during Year 5:

- *Listeria monocytogenes* in a ready to eat salad product, resulting in 180 subsequent entries
- *Listeria monocytogenes* in stone fruits, including peaches, resulting in 43 subsequent entries (related to a human illness outbreak investigation)
- Undeclared milk in frozen popsicles resulting in 27 subsequent entries

See Section E for further information on the comparison of Year 5 entries with previous years.

Observed Changes

Undeclared Allergen Reports Increase: 95 primary reports in Year 5, up from 88 primary reports in Year 4. Undeclared allergen reports have steadily increased since RFR inception, representing 30% of reports in Year 1 and rising to 47% of reports in Year 5 (Table 6). The Bakery commodity accounted for the most reports related to undeclared allergens for all five years.

Dairy Reports Increase: 24 primary reports in Year 5, up from 10 primary reports in Year 4. Half of the dairy reports concerned undeclared allergens in Year 5.

Seafood Reports Decrease: 7 primary reports in Year 5, down from 19 primary reports in Year 4. The largest decrease was seen in *Listeria monocytogenes* related seafood reports.

Animal Food/Feed (including pet food) Reports Decrease: 18 primary reports in Year 5, down from 30 reports in Year 4. *Salmonella* related animal food/feed reports displayed the largest decrease.

FDA Initiatives

- **Safety Reporting Portal Enhancements:** new features have been added to the RFR IT system to increase user functionality.
- **Final Rules under FSMA:** FDA has issued the following rules related to food safety:
  - Sanitary Transportation of Human and Animal Food
  - Accredited Third-Party Certification
  - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption
  - Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food
  - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

- **Guidance Documents Issued:** FDA published new or revised guidance documents to assist industry and regulators relating to food safety:

    - Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition)
    - Draft Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3)
    - Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls

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

INDUSTRY INITIATIVES OVER THE PAST FIVE YEARS

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

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

- **Spices and Seasonings Good Manufacturing Practice (GMP) Guidance:** The American Spice Trade Association (ASTA) published GMP guidance as well as Principles of Physical Cleaning guidance to help ensure the production of clean, safe spice for consumers.

- **Cantaloupes and Netted Melons Guidance**: Developed by a broad, national coalition of industry stakeholders and government representatives, the "National Commodity-Specific Food Safety for Cantaloupes and Netted Melons" working group published online guidance to help ensure food safety in cantaloupe production.

B. 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 fifth Reportable Food Registry Annual Report, covering the new time period September 8, 2013 to September 7, 2014. Previous 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, 2013.

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. For example, FDA utilizes the information provided to RFR in conjunction with other data to identify key commodity risk points to target public health initiatives including planning and prioritization of inspections, developing guidance, generating sampling assignments, issuing import alerts, and other activities.

NOTE: Definitions for certain specialized terms used in this report are hyperlinked to the list of definitions in Section K.

C. 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.

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.

D. Continued Outreach

Online Resources

The main RFR Web page contains 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)

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.

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.

E. KEY FINDINGS

Highlighted below are events resulting in the greatest number of reports submitted during Year 5:

- *Listeria monocytogenes* in a ready to eat salad product, resulting in 180 subsequent entries
- *Listeria monocytogenes* in stone fruits, including peaches, resulting in 43 subsequent entries (related to a human illness outbreak investigation)
- Undeclared milk in frozen popsicles resulting in 27 subsequent entries

Table 1: Comparison of RFR Total Submissions and Entries, by Year

Report Category	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Total Submissions	**2600**	**1153**	**1471**	**1534**	**1157**	**7915**
Nonreportable submissions	(360)	(271)	(376)	(265)	(248)	(1520)
Total Entries	**2240**	**882**	**1095**	**1269**	**909**	**6395**
Primary (Industry and Voluntary) Entries	229	225	224	202	201	1081
Subsequent Entries (Upstream and Downstream)	1872	483	609	849	464	4277
Amended Entries	139	174	262	218	244	1037

As shown in Table 2, there were 909 Registry entries, representing primary, subsequent, and amended reports, during Year 5.

Table 2: Monthly Registry Entries by Year

Period	Year 1	Year 2	Year 3	Year 4	Year 5	Total
September 8–30	37	45	48	197	62	389
October	92	48	133	279	178	730
November	236	54	75	151	99	615
December	50	109	133	76	17	385
January	159	75	78	101	34	447
February	144	76	44	53	34	351
March	1117	68	53	53	104	1395
April	61	66	55	119	63	364
May	68	137	93	67	89	454
June	71	42	28	37	80	258
July	71	31	164	61	78	405
August	117	98	156	46	63	480
September 1–7	17	33	35	29	8	122
Total	**2240**	**882**	**1095**	**1269**	**909**	**6395**

Of the 909 Year 5 RFR entries, 201 were mandatory primary reports submitted by industry; 464 were subsequent reports as a result of primary reports; and 244 were amended reports, updating previously submitted primary or subsequent reports, as shown in Figure 1 below.

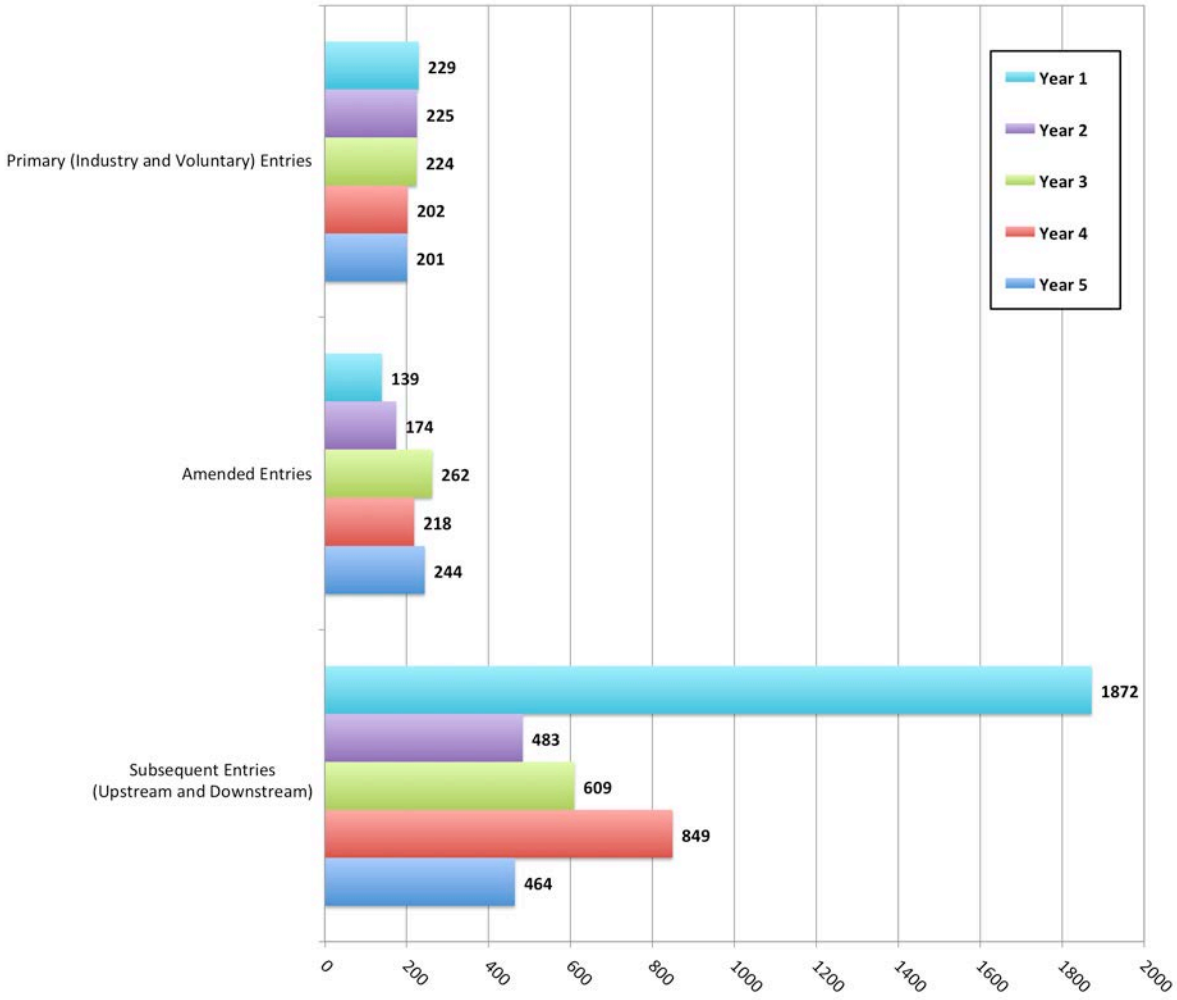
As Figure 1 shows, the number of primary reports for all years was similar except for Years 4 and 5 where decreases in primary entries were observed when compared to Years 1 through 3.

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.

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.

Figure 1: RFR Entries by Report Type and Year



As Table 3 shows, the 201 primary RFR entries in Year 5 included 183 entries for human food, and 18 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) and Year

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
Year 5	183	18	201
Total	**967**	**114**	**1081**

The 201 primary RFR entries in Year 5 involved 23 commodities as shown in Table 4 below. Further information about these observations is presented in Section F.

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

Commodities	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Acidified/Low Acid Canned Food (LACF)	2	2	2	1	0	7
Animal Food/Feed	28	19	19	30	18	114
Bakery	16	20	18	22	23	99
Beverages	3	2	1	1	4	11
Breakfast Cereals	2	0	3	1	2	8
Chocolate/Confections/Candy	8	7	12	11	16	54
Dairy	18	16	20	10	24	88
Dressings/Sauces/Gravies	6	8	5	6	6	31
Egg	2	2	2	0	0	6
Frozen Foods	9	11	3	10	12	45
Fruit and Vegetable Products	12	9	5	3	5	34
Game Meats	1	0	0	0	0	1
Meal Replacement/Nutritional Food and Beverages	6	2	5	4	2	19
Multiple Products	4	1	2	2	2	11
Nuts/Nut Products/Seed Products	16	16	13	15	10	70
Oil/Margarine	1	0	0	0	0	1
Other	0	0	0	0	0	0
Pasta	0	1	2	1	2	6
Prepared Foods	11	14	9	12	17	63
Produce - Fresh Cut	13	9	23	13	11	69
Produce – RAC	14	27	33	10	14	98
Seafood	17	18	17	19	7	78
Snack Foods	7	9	7	10	4	37
Soup	4	0	6	2	2	14
Spices and Seasonings	17	25	8	12	12	74
Stabilizers/Emulsifiers/Flavors/Colors/Texture Enhancers	8	5	5	6	6	30
Sweeteners	0	0	0	0	1	1
Whole & Milled Grains and Flours	4	2	4	1	1	12
Total	**229**	**225**	**224**	**202**	**201**	**1081**

Table 5 shows 201 primary RFR entries tabulated by their food safety hazards for Year 5 during the reporting period from September 8, 2013, to September 7, 2014.

The 201 primary (industry) RFR entries for Year 5 include a total of eight food safety hazards: Drug Contamination 1.0%; Pathogenic *E. coli* 1.0% (including 1 primary entry for *E. coli* O157:H7); *Listeria monocytogenes* 18.9%; Nutrient Imbalance 4.0%; Lead 0.5%; *Salmonella* 24.9%; Undeclared Allergens 47.3%; Undeclared Sulfites 2.5%.

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

Commodity	*Drug Contamination*	*E. coli*	*Listeria monocytogenes*	Nutrient Imbalance	Lead	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Total No. (%)
Animal Food/Feed	2	0	2	8	0	6	0	0	18 (9.0%)
Bakery	0	0	0	0	0	0	23	0	23 (11.4%)
Beverages	0	0	0	0	0	1	3	0	4 (2.0%)
Breakfast Cereals	0	0	0	0	0	0	2	0	2 (1.0%)
Chocolate/ Confections/Candy	0	0	0	0	0	1	14	1	16 (8.0%)
Dairy	0	1	5	0	0	5	12	1	24 (11.9%)
Dressings/Sauces/ Gravies	0	0	0	0	0	0	6	0	6 (3.0%)
Frozen Foods	0	0	1	0	0	1	10	0	12 (6.0%)
Fruit and Vegetable Products	0	0	0	0	0	2	1	2	5 (2.5%)
Meal Replacement/Nutritional Food and Beverages	0	0	0	0	0	0	2	0	2 (1.0%)
Multiple Products	0	0	1	0	0	0	1	0	2 (1.0%)
Nuts/Nut Products/Seed Products	0	0	2	0	0	5	2	1	1 (5.0%)
Pasta	0	0	1	0	0	0	1	0	2 (1.0%)
Prepared Foods	0	1	7	0	0	0	9	0	17 (8.5%)
Produce - Fresh Cut	0	0	5	0	0	5	1	0	11 (5.5%)
Produce - RAC	0	0	8	0	0	6	0	0	14 (7.0%)
Seafood	0	0	6	0	0	0	1	0	7 (3.5%)
Snack Foods	0	0	0	0	0	0	4	0	4 (2.0%)
Soup	0	0	0	0	0	0	2	0	2 (1.0%)
Spices and Seasonings	0	0	0	0	1	11	0	0	12 (6.0%)
Stabilizers/Emulsifiers /Flavors/Colors/ Texture Enhancers	0	0	0	0	0	6	0	0	6 (3.0%)
Sweetners	0	0	0	0	0	1	0	0	1 (0.5%)
Whole & Milled Grains and Flours	0	0	0	0	0	0	1	0	1 (0.5%)
Total	**2**	**2**	**38**	**8**	**1**	**50**	**95**	**5**	**201**
Percentage	**1.0**	**1.0**	**18.9**	**4.0**	**0.5**	**24.9**	**47.3**	**2.5**	**100%**

NOTE: Due to rounding, the combined sum may not total 100%.There were zero entries in Year 5 for Acidified/Low Acid Canned Foods (LACF), Egg, Game Meats, Oil/Margarine, and Other commodity types. For Years 1-4 "Distribution of Primary RFR Entries by Commodity and Hazard" *values, see* ***The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration Fourth Annual Report: September 8, 2010 - September 7, 2013****.*

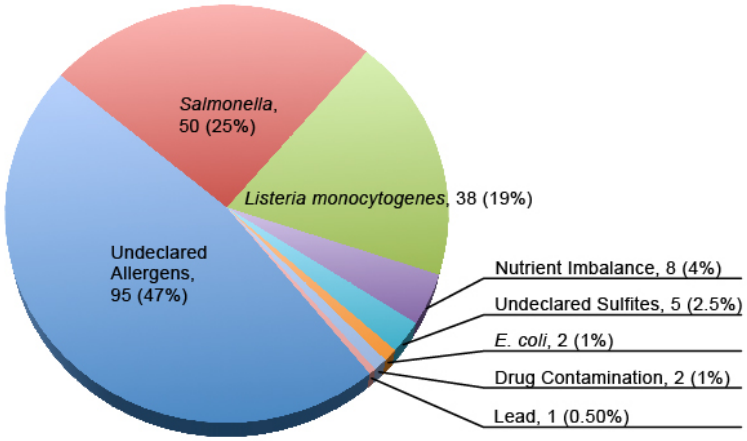
Salmonella, *Listeria monocytogenes,* and Undeclared Allergens hazards have accounted for roughly 88% or 949 out of 1081 total primary entries for all five years.

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

Hazard	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Salmonella	86 (37.6%)	86 (38.2%)	63 (28.1%)	58 (28.7%)	50 (24.9%)	343 (36.1%)
Listeria monocytogenes	33 (14.4%)	40 (17.8%)	48 (21.4%)	35 (17.3%)	38 (19.0%)	194 (20.4%)
Undeclared Allergens	69 (30.1%)	75 (38.3%)	85 (37.9%)	88 (43.6%)	95 (47.0%)	412 (43.4%)
No. of entries (percentage)	**188 (82.1%)**	**201 (94.3%)**	**196 (87.4%)**	**181 (89.6%)**	**183 (90.6%)**	**949 (100%)**

Figure 2 shows the distribution of food safety hazards for Year 5. Years 2 through 5 showed increases in undeclared allergens related reports for human food. Also, there was a small decrease in *Salmonella* related reports between Years 4 and 5.

Figure 2: Distribution of Primary RFR Entries by Food Safety Hazard, Year 5



Years 1-4 Pie Charts can be accessed in The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration Fourth Annual Report: September 8, 2010 - September 7, 2013.

F. 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 50 primary reports for *Salmonella* in Year 5 remained similar to the 58 primary reports observed in Year 4.

Data from the fifth year of operation of the RFR indicates that spices and seasonings account for the majority of *Salmonella*-related reports.

The largest decrease in *Salmonella* was observed in the animal food/feed (including pet food) commodity, with a total of 6 primary entries in Year 5 compared to 18 entries in Year 4, representing 31% of *Salmonella* entries in Year 4 and decreasing to 11.8% of total *Salmonella* entries in Year 5.

FDA is working with industry to identify controls to reduce *Salmonella* contamination. See sections H and I within this report for more information on industry and regulatory initiatives.

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

Commodity	Year 1 No. (%)	Year 2 No. (%)	Year 3 No. (%)	Year 4 No. (%)	Year 5 No. (%)	Total No. (%)
Animal Food/Feed	13 (15.1%)	8 (9.3%)	4 (6.3%)	18 (31%)	6 (12.0%)	49 (14.3%)
Bakery	1 (1.2%)	0	0	0	0	1 (0.3%)
Beverages	1 (1.2%)	1 (1.2%)	0	0	1 (2.0%)	3 (0.9%)
Breakfast Cereals	1 (1.2%)	0	1 (1.6%)	0	0	2 (0.6%)
Chocolate/Confections/Candy	1 (1.2%)	0	1 (1.6%)	0	1 (2.0%)	3 (0.9%)
Dairy	1 (1.2%)	3 (3.4%)	3 (4.8%)	0	5 (10.0%)	12 (3.5%)
Egg	1 (1.2%)	0	0	0	0	1 (0.3%)
Frozen Foods	3 (3.4%)	1 (1.2%)	0	0	1 (2.0%)	5 (1.5%)
Fruit and Vegetable Products	1 (1.2%)	6 (7.0%)	4 (6.3%)	1 (1.7%)	2 (4.0%)	14 (4.1%)
Meal Replacement/Nutritional Food and Beverages	5 (5.8%)	1 (1.2%)	2 (3.2%)	0	0	8 (2.3%)
Multiple Products	1 (1.2%)	0	0	0	0	1 (0.3%)
Nuts/Nut Products/Seed Products	12 (14.0%)	11 (12.8%)	8 (12.7%)	11 (19.0%)	5 (10.0%)	47 (13.7%)
Prepared Foods	0	1 (1.2%)	0	0	0	1 (0.3%)
Produce - Fresh Cut	5 (5.8%)	2 (2.3%)	6 (9.5%)	4 (6.9%)	5 (10.0%)	22 (6.4%)
Produce - RAC	14 (16.3%)	25 (29%)	22 (34.9%)	7 (12.1%)	6 (12.0%)	74 (21.6%)
Seafood	0	0	1 (1.6%)	2 (3.4%)	0	3 (0.9%)
Snack Foods	1 (1.2%)	0	0	0	0	1 (0.3%)
Spices and Seasonings	16 (18.6%)	23 (26.7%)	5 (7.9%)	10 (17.2%)	11 (22.0%)	65 (19.0%)
Stabilizers/Emulsifiers/Flavors/ Colors/Texture Enhancers	6 (7.0%)	3 (3.5%)	5 (7.9%)	4 (6.9%)	6 (12.0%)	24 (7.0%)
Whole & Milled Grains and Flours	3 (3.5%)	1 (1.2%)	1 (1.6%)	1 (1.7%)	1 (2.0%)	7 (2.0%)
Total	**86**	**86**	**63**	**58**	**50**	**343**

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 38 primary reports in Year 5 for *Listeria monocytogenes* (*Lm*) show a slight increase from the 35 primary reports in Year 4, representing 19.0% of total entries in Year 5.

Produce- RAC accounts for 21.1% of all *Lm* related reports with 8 primary entries followed by prepared foods and produce- fresh cut, with 7 and 6 primary entries, respectively. The largest decrease in *Lm* was observed in the seafood commodity with 6 primary entries in Year 5 compared to 12 primary entries in Year 4.

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

Commodity	Year 1 No. (%)	Year 2 No. (%)	Year 3 No. (%)	Year 4 No. (%)	Year 5 No. (%)	Total No. (%)
Animal Food/Feed (including pet food)	0	0	0	0	2 (5.3%)	2 (1.0%)
Bakery	0	0	0	1 (2.9%)	0	1 (0.5%)
Dairy	8 (24.2%)	7 (17.5%)	11 (22.9%)	4 (11.4%)	5 (13.2%)	35 (18%)
Dressing/Sauces/Gravies	1 (3.0%)	0	0	0	0	1 (0.5%)
Egg	0	2 (5.0%)	2 (4.2%)	0	0	4 (2.1%)
Frozen Foods	3 (9.1%)	1 (2.5%)	1 (2.1%)	0	1 (2.6%)	6 (3.1%)
Fruit and Vegetable Products	2 (6.1%)	2 (5.0%)	0	1 (2.9%)	0	5 (2.6%)
Meal Replacement/Nutritional Food and Beverages	1 (3.0%)	0	0	0	0	1 (0.5%)
Multiple Products	1 (3.0%)	0	0	0	1 (2.6%)	2 (1.0%)
Nuts/Nut Products/Seed Products	1 (3.0%)	0	0	2 (5.7%)	2 (5.3%)	5 (2.6%)
Pasta	0	0	0	0	1 (2.6%)	1 (0.5%)
Prepared Foods	2 (6.1%)	10 (25.0%)	5 (10.4%)	4 (11.4%)	7 (18.4%)	28 (14.4%)
Produce- Fresh Cut	5 (15.2%)	7 (17.5%)	15 (31.3%)	7 (20%)	5 (13.2%)	39 (20.1%)
Produce- RAC	0	2 (5.0%)	10 (20.8%)	3 (8.6%)	8 (21.1%)	23 (11.9%)
Seafood	9 (27.3%)	8 (20.0%)	4 (8.3%)	12 (34.3%)	6 (15.8%)	39 (20.1%)
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	0	1 (2.5%)	0	1 (2.9%)	0	2 (1.0%)
Total	**33**	**40**	**48**	**35**	**38**	**194**

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

UNDECLARED MAJOR FOOD ALLERGENS

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.

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.”

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.

Year 5 demonstrated an increase in undeclared major food allergen related reports representing 95 entries or 47.0% of the total primary entries compared to 88 entries or 43.6% of the total primary entries in Year 4 (Table 6).

The bakery commodity accounts for 23 of the total of 88 entries. Within the bakery commodity, the most frequently reported food types were cookies, muffins, and cakes.

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

Commodity	Year 1 No. (%)	Year 2 No. (%)	Year 3 No. (%)	Year 4 No. (%)	Year 5 No. (%)	Total No. (%)
Acidified and Low Acid Canned Foods (LACF)	2 (2.9%)	2 (2.7%)	1 (1.2%)	1 (1.1%)	0	6 (1.5%)
Animal Food/Feed	N/A	N/A	N/A	N/A	N/A	0
Bakery	14 (20.3%)	20 (26.7%)	18 (21.2%)	21 (23.9%)	23 (24.2%)	96 (23.3%)
Beverages	1 (1.4%)	1 (1.3%)	1 (1.2%)	1 (1.1%)	3 (3.2%)	7 (1.7%)
Breakfast Cereals	1 (1.4%)	0	2 (2.4%)	1 (1.1%)	2 (2.1%)	6 (1.5%)
Chocolate/Confections/Candy	7 (10.1%)	7 (9.3%)	11 (12.9%)	11 (12.5%)	14 (14.7%)	50 (12.1%)
Dairy	8 (11.6%)	6 (8%)	7 (8.2%)	5 (5.7%)	12 (12.6%)	38 (9.2%)
Dressing/Sauces/Gravies	5 (7.2%)	7 (9.3%)	5 (5.9%)	6 (6.8%)	6 (6.3%)	29 (7.0%)
Frozen Foods	3 (4.3%)	9 (12.0%)	2 (2.4%)	8 (9.1%)	10 (10.5%)	32 (7.8%)
Fruit and Vegetable Products	0	0	0	0	1 (1.1%)	1 (0.2%)
Meal Replacement/Nutritional Food and Beverages	0	1 (1.3%)	3 (3.5%)	4 (4.5%)	2 (2.1%)	10 (2.4%)
Multiple Food Products	2 (2.9%)	1 (1.3%)	2 (2.4%)	2 (2.3%)	1 (1.1%)	8 (1.9%)
Nuts/Nut Products/Seed Products	3 (4.3%)	4 (5.3%)	4 (4.7%)	2 (2.3%)	2 (2.1%)	15 (3.6%)
Oil/Margarine	1 (1.4%)	0	0	0	0	1 (0.2%)
Pasta	0	1 (1.3%)	2 (2.4%)	1 (1.1%)	1 (1.1%)	5 (1.2%)
Prepared Foods	8 (11.6%)	3 (4%)	4 (4.7%)	8 (9.1%)	9 (9.5%)	32 (7.8%)
Produce- Fresh Cut	0	0	0	0	1 (1.1%)	1 (0.2%)
Seafood	1 (1.4%)	4 (5.3%)	5 (5.9%)	2 (2.3%)	1 (1.1%)	13 (3.2%)
Snack Foods	6 (8.7%)	8 (10.7%)	7 (8.2%)	10 (11.4%)	4 (4.2%)	35 (8.5%)
Soup	4 (5.8%)	0	5 (5.9%)	2 (2.3%)	2 (2.1%)	13 (3.2%)
Spices and Seasonings	1 (1.4%)	0	3 (3.5%)	2 (2.3%)	0	6 (1.5%)
Stabilizers/Emulsifiers/Flavos/ Colors/Texture Enhancers	2 (2.9%)	0	0	1 (1.1%)	0	3 (0.7%)
Sweetners	0	0	0	0	1 (1.1%)	1 (0.2%)
Whole and Milled Grains and Flours	0	1 (1.3%)	3 (3.5%)	0	0	4 (1.0%)
Total	**69**	**75**	**85**	**88**	**95**	**412**

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

Bakery commodities account for the most reports relating to undeclared allergens for all five years (Table 10).

Table 10: Top 3 Commodities with Undeclared Major Food Allergens by Specific Food Allergen in Year 5

Commodity	Egg	Milk	Multiple Food Allergens	Peanut	Soy	Tree Nuts	Total
Bakery	3	7	7	2	1	3	23
Chocolate/Confections/Candy	1	7	2	4	0	0	14
Dairy	5	3	0	1	1	2	12

Undeclared milk remains the most reported specific undeclared major food allergen in Year 5, with 30 primary entries, up from 26 primary entries in Year 4 (Figure 3). Undeclared multiple food allergens decreased from 22 primary entries in Year 4 to 15 primary entries in Year 5. In addition, undeclared egg increased to 15 primary entries, up from 7 primary entries observed in Year 4.

UNDECLARED SULFITES

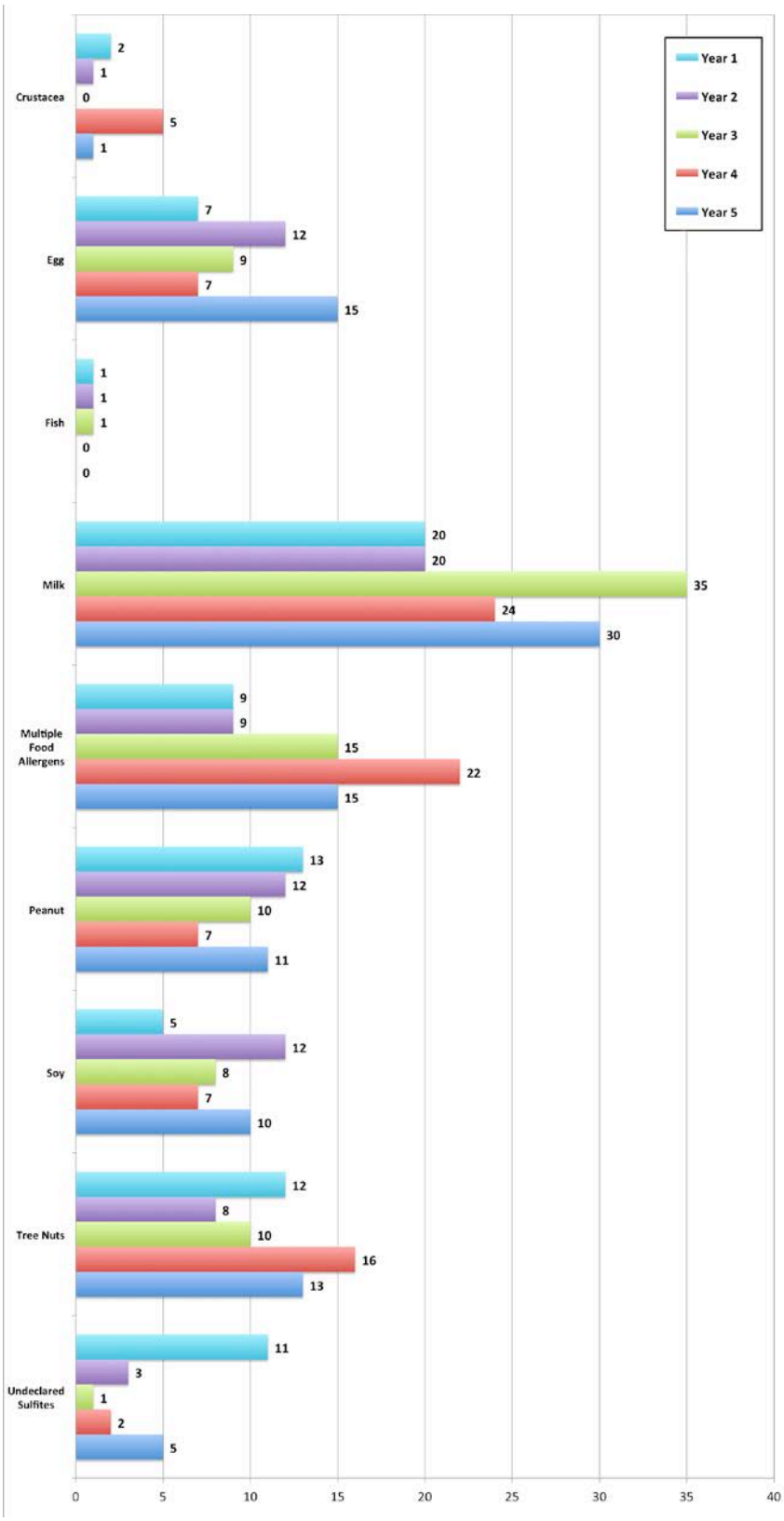
Sulfite-sensitive individuals must avoid the ingredient due to potential health consequences, FDA regulations require that the presence of any sulfiting agent be declared on food labels, as described in 21 CFR Part 101.100 (a) (4).

There were 5 primary entries for Undeclared Sulfites in Fruit and Vegetable and Seafood Products in Year 5.

Table 11: Primary RFR Entries of Undeclared Sulfites by Commodity and Year

Commodity	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Chocolate/Confections/Candy	0	0	0	0	1	1
Dairy	0	0	0	0	1	1
Fruit and Vegetable Products	9	1	1	1	2	14
Nuts	0	0	0	0	1	1
Prepared Foods	1	0	0	0	0	1
Seafood	1	1	0	1	0	3
Snack Foods	0	1	0	0	0	1
Total	**11**	**3**	**1**	**2**	**5**	**22**

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



G. Reports Associated with Imported Foods

Primary RFR entries for foods from international sources remained similar in Year 5 with 37 primary entries, representing 18.4% of the total 201 primary entries, compared to 38 primary entries in Year 4.

The 37 entries in Year 5 encompassed the following five food safety hazards: *Listeria monocytogenes*, *Salmonella*, Undeclared Allergens, Lead, and Undeclared Sulfites distributed across 13 commodities, as shown in Table 12 below.

Table 12: Distribution of Primary RFR Entries Involving Imported Foods by Commodity and Food Safety Hazard, Year 5

Commodity	*Listeria monocytogenes*	Lead	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Total No. (%)
Animal Food/Feed	0	0	1	0	0	1 (2.6%)
Breakfast Cereals	0	0	0	1	0	1 (2.6%)
Chocolate/Confections/Candy	0	0	1	4	1	6 (16.2%)
Dairy	1	0	1	1	0	3 (8.1%)
Dressing/Sauces/ Gravies	0	0	0	1	0	1 (2.6%)
Frozen Foods	0	0	1	2	0	3 (8.1%)
Fruit and Vegetable Products	0	0	1	0	2	3 (8.1%)
Nuts/ Nut Products/Seed Products	0	0	3	0	1	4 (10.8%
Produce- Fresh Cut	0	0	1	0	0	1 (2.6%)
Produce- RAC	0	0	1	0	0	1 (2.6%)
Seafood	3	0	0	0	0	3 (8.1%)
Spices/Seasonings	0	1	6	0	0	7 (18.9%)
Stabilizers, Emulsifiers/Flavors and Colors/ Texture Enhancers	0	0	3	0	0	3 (8.1%)
Total	**4**	**1**	**19**	**9**	**4**	**37**
Percentage	**10.8%**	**2.7%**	**51.4%**	**24.3%**	**10.8%**	**100%**

NOTE: Due to rounding, the combined sum may not total 100%. There were zero entries in Year 5 for the following fifteen commodities: Acidified/Low Acid Canned Foods (LACF), Bakery, Beverages, Egg, Meal Replacement/Nutritional Food and Beverages, Multiple Food Products, Game Meats, Oil/Margarine, Other, Pasta, Prepared Foods, Snack Foods, Soup, Sweeteners, and Whole & Milled Grains and Flour. For Years 1-4 "Distribution of Primary RFR Entries by Commodity and Hazard" *values, see* ***The Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration Fourth Annual Report: September 8, 2010 - September 7, 2013*****.**

Thirty-seven of the 201 primary reports for Year 5 (18.4%) concerned imported foods or ingredients, coming from 24 different countries. When entries for all years are combined, there are 52 different countries represented, as shown in Table 13 below.

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

Country	Year 1 No. (%)	Year 2 No. (%)	Year 3 No. (%)	Year 4 No. (%)	Year 5 No. (%)	Total No. (%)
Afghanistan	1 (1.9%)	0	0	0	0	1 (0.4%)
American Samoa	0	0	1 (2.17%)	0	0	1 (0.4%)
Australia	0	0	0	1 (2.86%)	0	1 (0.4%)
Bangladesh	0	0	0	0	1 (2.7%)	1 (0.4%)
Bulgaria	0	0	0	1 (2.86%)	0	1 (0.4%)
Belgium	0	0	3 (6.52%)	0	0	3 (1.3%)
Canada	4 (7.9%)	6 (10.7%)	8 (17.39%)	3 (8.57%)	4 (10.81%)	25 (10.9%)
Chile	0	0	0	1 (2.86%)	0	1 (0.4%)
China	13 (24.5%)	16 (28.6%)	6 (13.04%)	4 (11.43%)	6 (16.22%)	45 (19.6%)
Colombia	0	1 (1.8%)	0	0	1 (2.7%)	2 (0.9%)
Republic of Congo	0	0	0	0	1 (2.7%)	1 (0.4%)
Ecuador	0	0	0	0	1 (2.7%)	1 (0.4%)
Egypt	0	4 (7.1)	2 (4.35%)	2 (5.71%)	0	8 (3.5%)
France	0	0	0	1 (2.86%)	1 (2.7%)	2 (0.9%)
Germany	0	0	0	1 (2.86%)	0	1 (0.4%)
Greece	1 (1.9%)	0	1 (2.17%)	0	0	2 (0.9%)
Guatemala	2 (3.8%)	0	1 (2.17%)	1 (2.86%)	0	4 (1.7%)
India	4 (7.5%)	7 (12.5%)	2 (4.35%)	0	1 (2.7%)	14 (6.1%)
Indonesia	1 (1.9%)	2 (3.6%)	0	2 (5.71%)	0	5 (2.2%)
Israel	0	1 (1.8%)	0	2 (5.71%)	0	3 (1.3%)
Italy	1 (1.9%)	0	1 (2.17%)	1 (2.86%)	2 (5.41%)	5 (2.2%)
Japan	0	1 (1.8%)	1 (2.17%)	1 (2.86%)	0	3 (1.3%)
Kenya	0	1 (1.8%)	2 (4.35%)	1 (2.86%)	0	4 (1.7%)
Latvia	0	0	0	1 (2.86%)	0	1 (0.4%)
Malaysia	0	0	0	0	1 (2.7%)	1 (0.4%)
Malawi	1 (1.9%)	2 (3.6%)	0	0	0	3 (1.3%)
Mexico	5 (9.4%)	6 (10.7%)	6 (13.04%)	4 (11.43%)	1 (2.7%)	22 (9.6%)
Morocco	0	0	1 (2.17%)	0	0	1 (0.4%)
Multiple	1 (1.9%)	0	0	0	0	1 (0.4%)
Netherlands	0	1 (1.8%)	1 (2.17%)	0	2 (5.41%)	4 (1.7%)
Nicaragua	1 (1.9%)	0	0	0	0	1 (0.4%)
Nigeria	1 (1.9%)	0	0	0	0	1 (0.4%)
Norway	1 (1.9%)	0	0	1 (2.86%)	0	2 (0.9%)
Pakistan	1 (1.9%)	0	0	0	0	1 (0.4%)
Peru	0	1 (1.8%)	0	0	2 (5.41%)	3 (1.3%)
Philippines	0	1 (1.8%)	2 (4.35%)	0	0	3 (1.3%)
Poland	2 (3.8%)	0	0	0	0	2 (0.9%)
Russia	2 (3.8%)	0	1 (2.17%)	1 (2.86%)	2 (5.41%)	6 (2.6%)
South Africa	2 (3.8%)	1 (1.8%)	0	0	0	3 (1.3%)
South Korea	0	0	1 (2.17%)	0	2 (5.41%)	3 (1.3%)
Spain	0	0	0	0	1 (2.7%)	1 (0.4%)
Sri Lanka	0	0	0	1 (2.86%)	0	1 (0.4%)
Switzerland	0	0	0	0	1 (2.7%)	1 (0.4%)
Taiwan	0	0	0	1 (2.86%)	0	1 (0.4%)
Thailand	0	1 (1.8%)	2 (4.35%)	2 (5.71%)	1 (2.7%)	6 (2.6%)
Turkey	4 (7.5%)	0	1 (2.17%)	3 (8.57%)	3 (8.11%)	11 (4.8%)
Ukraine	0	0	2 (4.35%)	1 (2.86%)	0	3 (1.3%)
United Kingdom	2 (3.8%)	1 (1.8%)	0	0	0	3 (1.3%)
Venezuela	1 (1.9%)	1 (1.8%)	0	0	0	2 (0.9%)
Vietnam	2 (3.8%)	2 (3.6%)	1 (2.17%)	1 (2.86%)	3 (8.11%)	9 (3.9%)
Total	**53**	**56**	**46**	**38**	**37**	**230**

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

H. 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 fifth year of operation are summarized below.

SAFETY REPORTING PORTAL (SRP) ENHANCEMENTS

FDA completed SRP enhancements for both responsible parties and public health officials entering in RFR reports by adding new functionality related to group access and data file transmission. These new features will allow for collaborative group review and submission of reportable food reports as well as addition and deletion of new group members. These improvements are explained in detail below:

Group Access: The group access feature allows people in the same organization to submit reports for a single report type. In addition, group creation enables people to share their reports with other users in the organization, including editing and submitting other users' draft reports, and creating amended reports for other users' submitted reports. The Group Access system is wholly managed by the user (s) in the group (s), not the FDA or federal government. For more information please visit the SRP online Group Access Frequently Asked Questions (FAQs.)

- Allows for creation of groups that contain multiple SRP users or email addresses. Group members can collaboratively edit and submit RFR reports. Previously, the system only allowed for one person/email address to register an account on SRP and submit reports.
- Facilitates continuity of operations, for example, when a staff member leaves a particular reporting body there will now be a group of individuals that can access past report submissions and the data will not be lost to that organization.
- Enables easy additions and deletions of users to the created group with no limit to the number of members within a group.

New XML file format available to download or view when a report is submitted: The "Download XML File" button is available on the SRP Report Submission Confirmation page when a user submits a reportable food report. By clicking on the button, the user can download the XML file for the Report that was submitted. More details about the XML file can be found online at SRP XML FAQs webpage.

- Provides an alternative, more structured file type called XML for users to download their submitted report data (in addition to the .pdf format on the report confirmation screen.)
- Allows for easier importation of the report data to any downstream systems, such as external industry systems currently being used to track and communicate reportable food events.

FINAL RULES

FDA's final rules will 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:

- Sanitary Transportation of Human and Animal Food: This rule will help ensure the safety of both human and animal food during transportation by establishing requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food to use sanitary transportation practices.

- Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications: This rule establishes a voluntary program for the accreditation of third-party certification bodies, also known as auditors, to conduct food safety audits and issue certifications of foreign facilities and the foods for humans and animals they produce. These requirements will help ensure the competence and independence of the accreditation bodies and third-party certification bodies participating in the program.

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals: The rule requires that importers perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards.

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food: This rule requires facilities that manufacture, process, pack, or hold human food to have written plans that identify hazards, specify the preventive controls put in place to minimize or prevent those hazards, conduct monitoring, and specify what actions would be taken to correct problems that arise. In addition, the rule includes Current Good Manufacturing Practice requirements.

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals: This rule requires facilities that manufacture, process, pack, or hold food for animals, including pet food and animal feed, to have written plans that identify hazards, specify the preventive controls that will be put in place to minimize or prevent those hazards, conduct monitoring, and specify what actions would be taken to correct problems that arise. In addition, the rule includes Current Good Manufacturing Practice requirements.

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 (Sixth Edition): On October 10, 2003, FDA issued an interim final rule to implement amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) (Pub. L. 107-188). Section 415 of the FD&C Act (21 U.S.C. 350d) 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 by December 12, 2003. This guidance was developed to answer frequently asked questions relating to the registration requirements of section 415.

- Draft Guidance for Industry: Prior Notice of Imported Food Questions and Answers (Edition 3): This guidance document provides a list of questions that frequently have been asked about the requirements of the prior notice regulation, and the answers to those questions. This document is being issued to help the food industry and others comply with the legal requirements established by the Prior Notice rule.

- Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls: this document provides guidance to industry on the implementation of the mandatory food recall provisions of Section 423 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which was added by Section 206 of the FDA Food Safety Modernization Act of 2011 (FSMA).

Import Alerts and Bulletins

RFR entries in Year 5 triggered follow-up investigations by FDA that resulted in Import Alerts and Import Bulletins.

Import Alerts

- Undeclared allergens in salad dressing from a facility in South Korea
- *Listeria monocytogenes* in herring from a facility in Russia
- Undeclared allergens in chocolate from a facility in the Netherlands

Import Bulletins

- Lead in noodles from facilities in India
    - Undeclared milk in chocolate from facilities in Canada

I. Industry Initiatives over the past five years

FDA works closely with industry and publicly shares Reportable Food Registry data relating to tracking and trending of food safety hazards and patterns of adulteration in efforts to help identify risk points to target public health preventive measures. Over the past 5 years, there have been several guidance and resources published related to food safety. Some of these industry resources are highlighted below:

- **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.

- **Spices and Seasonings Guidance:** The American Spice Trade Association (ASTA) published Good Manufacturing Practice (GMP) guidance in April 2015 as well as Principles of Physical Cleaning

guidance that gives an overview of equipment that can be used for the physical cleaning of spices. It is intended to be used with other ASTA guidance to help ensure the production of clean, safe spice for consumers. In addition, ASTA issued a Clean, Safe Spices and Seasoning guidance for reduction of pathogens in spices.

- **Cantaloupes and Netted Melons Guidance**: Developed by a broad, national coalition of industry stakeholders and government representatives, the "National Commodity-Specific Food Safety for Cantaloupes and Netted Melons" working group published online guidance in February 2013 to offer a framework the help ensure food safety in cantaloupe production.

J. Reporting Time Periods Broken Down by Year

Year 1 - September 8, 2009 to September 7, 2010

Year 2 – September 8, 2010 to September 7, 2011

Year 3 - September 8, 2011 to September 7, 2012

Year 4 - September 8, 2012 to September 7, 2013

Year 5 - September 8, 2013 to September 7, 2014

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 – informational documents for FDA field staff concerning significant recurring, new or unusual problems affecting import coverage. They include background data and information about 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 placing a firm and/or product on 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.