FDA Foods and Veterinary Medicine Program

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

Third Annual Report:
September 8, 2011 – September 7, 2012

This is the third annual report that measures our success in receiving early warning on problems with food and feed. The Reportable Food Registry (RFR) has already proven itself an invaluable tool to help prevent contaminated food from reaching the public.

By providing early warning about potential public-health risks from reportable foods, the Registry increases the speed with which the FDA, its state- and local-level partners, and industry can remove hazards from the marketplace.

The RFR data also is providing valuable data to help meet requirements under the Food Safety Modernization Act. For example, we can use the data 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 data are also being used to help target inspections, plan work, identify and prioritize risks and develop guidance for industry. The FDA will continue working closely with the food and feed industries to enhance this important and beneficial tool.

Michael R. Taylor
Deputy Commissioner for Foods and Veterinary Medicine

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 third Reportable Food Registry Annual Report, covering the period September 8, 2011 to September 7, 2012. The first and second 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, 2011.

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 Congressional intent for the Registry is to help FDA better protect public health by tracking patterns of food and feed adulteration and targeting inspection resources. After two years of operation, a critical evaluation of the data being collected by the RFR was undertaken to ensure that the most useful information was being collected in support of the program's objectives. As a result of this evaluation, enhancements were made to the Safety Reporting Portal (SRP) Rationale Questionnaire (RQ) (the electronic form used to submit an RFR report) by adding 14 new data elements. These additions improve the quality of information received and help support agency initiatives that are data-driven, including those required under the Food Safety Modernization Act (FSMA).

In June 2012, these data elements were implemented as voluntary input to allow users to become familiar with the changes to the SRP. On Sept 8, 2012, the new data elements became mandatory input and will provide a full data set for analysis in Year 4.

The new data will increase FDA's ability to track patterns of adulteration in human food and animal food/feed (including pet food). The targeted information will be used in conjunction with other data to plan and prioritize inspections and regulatory activities. FDA believes that this new information will prove extremely valuable and is highlighting four of the data elements below and the reason for their inclusion:

- *The reason the food has been determined to be reportable (agent)* will enable FDA to accurately identify the problem with the product. For example, *Salmonella*, *Listeria monocytogenes*, and Undeclared Allergens represent the most commonly reported hazards to the RFR and are now easily displayed using a checklist on the portal.

- *A description of the root cause of the reportable food* will provide information on how a particular problem potentially occurred and help to identify food safety preventive controls and action plans.

- *A brief description of the corrective actions taken to avoid repeating reportable food events* will ensure that appropriate corrective actions are taken to prevent future instances of reportable foods, whenever possible, such as training of employees or implementing improved manufacturing controls.

- *The commodity type of the reportable food* will enrich data tracking abilities and provide categorization of products by their commodity types within the context of the RFR Commodity Definitions document. The RFR group will continue outreach on differences in commodity types to improve collection of this information from responsible parties.

A Constituent Update explaining all the new data elements is available. (The entire RFR Rationale Questionnaire can also be viewed by accessing the SRP at www.safetyreporting.hhs.gov.)

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

B. Executive Summary

Key Findings

Although the number of entries in Year 3 increased to 1095 from 882 in Year 2, 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 3:

- *Listeria monocytogenes* in widely distributed fresh cut onions, which resulted in 136 subsequent entries;
- *Salmonella* Braenderup in imported mangoes, resulting in 104 subsequent entries; (related to a human illness outbreak investigation);
- Undeclared milk in a nationally distributed snack bar, resulting in 43 subsequent entries.

See Section E for further information on the comparison of Year 3 entries with previous years.

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

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

Observed Changes

Amended Reports Increase: Year 3 yielded 262 reports, up from 139 reports in Year 1. The 88% increase indicates that more facilities are submitting amended reports, which contain additional information to correct or complete a primary or subsequent report. Amended reports may include updates about company investigations of problems and efforts to correct the causes.

Spices and Seasonings Reports Decrease: 8 primary reports in Year 3, down from 25 primary reports in Year 2. Out of the total, 5 of these reports concerned *Salmonella* in Y3 compared to 23 in Y2.

Produce- Fresh Cut Reports Increase: 23 primary reports in Year 3, up from 9 primary reports in Year 2. Produce- Fresh Cut and Produce- RAC were the most frequently reported commodities in Year 3.

Undeclared Allergens Reports Increase: 85 primary reports in Year 3, up from 75 in Year 2. The Bakery commodity continues to account for the most reports relating to Undeclared Allergens for all three years.

NOTABLE OUTCOMES

In three instances reportable food submissions alerted FDA to potential public health issues early and helped the agency to quickly act to keep potentially harmful products out of the retail marketplace or to remove those already in the marketplace:

- A voluntary report was submitted by the Michigan Department of Agriculture and Rural Development (MDARD) notifying FDA and state counterparts about a positive test result for *Salmonella* Infantis contamination in a nationally distributed dog food product. Public health agencies are not required to submit reports but can do so voluntarily. Through collaboration with state and federal public health officials, FDA's review of consumer complaints, and FDA and state testing, some brands of dry pet food produced by a single manufacturing facility in South Carolina were linked to 53 human *Salmonella* illnesses. Seventeen different major brand names were recalled and 13 subsequent RFR reports were received relating to this reportable food. For further information, see Investigation of Multistate Outbreak of Human Infections Linked to Dry Pet Food.

- A California onion processor was notified by FDA that the Canadian Food Inspection Agency (CFIA) had tested and found its exported product positive for *Listeria monocytogenes* contamination, resulting in the greatest number of RFR report submissions in Year 3. After FDA's investigation in conjunction with CFIA, one lot of the affected onions that had been distributed to 14 states and Canada was recalled. FDA actively investigated and monitored the event for several months with subsequent visits to the firm implicating additional lots of sliced onions and resulting in two recall expansions. Consequently, potentially dangerous products were removed from the marketplace, human illnesses were avoided, and the public was informed of the possible *Listeria monocytogenes* contamination of the product. Before production resumed, FDA worked collaboratively with the firm, and preventive measures were established to prevent future occurrences of contamination. No associated illnesses were reported.

- A manufacturer received a consumer complaint of a severe allergic reaction to its snack bar product and submitted a report to RFR. After investigation and analysis, a chocolate ingredient, used in the production of the snack bars, was found by the manufacturer to contain high levels of undeclared milk protein. People who are allergic to milk run a risk of having serious, even life-threatening, reactions if they consume such products. The product was quickly recalled, and the responsible party implemented new procedures to ensure that all allergen information provided by ingredient suppliers is carried over to product labels. This reportable food was distributed nationwide and resulted in 43 Registry entries. There were no additional allergic reactions reported to FDA.

FDA INITIATIVES

- **Proposed Rules under FSMA:** In January 2013, FDA issued two proposed rules under the Food Safety Modernization Act: Preventive Controls for Human Food and Standards for Produce Safety. 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.

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

- **New Data Elements Added to RFR Reporting Form**: After two years of operation, an evaluation of the quality of information being received into the RFR was conducted. As a result of this analysis, new data elements were added and are detailed in the Introduction section of this report above.

- **RFR submissions triggered follow-up investigations that resulted in**:
  - Five firms being placed on Import Alert.
  - Four Import Bulletins to increase surveillance by FDA investigators at ports of entry of products that were the subject of RFR submissions.

- **Risk Profile on Spices** (not yet released as of publication of this report): describes the nature and extent of public health risk posed by consumption of spices.

- **Letter to Cantaloupe Industry**: promotes food safety of cantaloupes and adoption of best practices.

- **Updated Internal Inspection Guidance:** An updated internal inspection guidance was issued that provides instruction to FDA district and state regulatory agency officials who follow-up on reportable food reports.

INDUSTRY INITIATIVES

- **New Industry Cantaloupes and Netted Melons Guidance Intended to Decrease Future RFR Entries**: A working group of industry, academic, and regulatory experts published the "National Commodity-Specific Food Safety for Cantaloupes and Netted Melons" online guidance in February 2013 to offer a framework for ensuring food safety in cantaloupe production.

- **Industry Guidance for Spices and Seasonings:** A guidance document was published by the American Spice Trade Association in March 2011 with the intention of reducing the risk of product contamination with *Salmonella*.

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.
- Voluntary Submission Video: Demonstrates program requirements and ease of use of the Safety Reporting Portal (SRP) for public health officials (voluntary reporters).
- Updated RFR At A Glance (AAG) is detailed in Section K.
- Constituent Update issued in June 2012 explaining addition of new data elements to the electronic portal.

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 Program Requirements and Data," International Dairy Show, September 2011
- "Regulatory Update," Grocery Manufacturers Association (GMA) Stakeholder Meeting, October 2011
- "International Post" meeting was conducted with FDA staff world-wide focusing on RFR program requirements for registered foreign facilities, available resources, and annual data reports, February 2012
- "Food Safety Modernization Act (FSMA) RFR Updates and Requests for Information," Make Our Food Safe Coalition Stakeholder Meeting, March 2012
- "Second Annual Report Publication," Food Safety Summit (FSS) Conference, April 2012
- "RFR Annual Report Data Update," United Fresh Annual Meeting, April 2012
- "RFR Key Findings," Association of Food and Drug Officials (AFDO), June 2012
- "Maneuvering the RFR," International Association for Food Protection (IAFP) Symposium, July 2012
- "FDA Risk Profile: Pathogens and Filth in Spices," American Spice Trade Association (ASTA) Regulatory and Legislative Workshop, October 2012
- "RFR Second Annual Report and FSMA," American Spice Trade Association (ASTA) Regulatory and Legislative Workshop, October 2012
- Over the course of the year, various stakeholder sessions were conducted to identify knowledge gaps and determine ways to enhance RFR reporting and information quality. The added data elements are highlighted in FDA Improves the Reportable Food Registry by Adding New Data Elements.

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 1095 Registry entries, representing primary, subsequent, and amended reports, during Year 3.

There was a much higher number of Registry entries for Year 1 (2240) than for Years 2 (882) and 3 (1095). 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 3:

- *Listeria monocytogenes* in widely distributed fresh cut onions, resulting in 136 subsequent entries, i.e., reports resulting from a primary report.
- *Salmonella* Braenderup in imported mangoes, resulting in 104 subsequent entries; (related to a human illness outbreak investigation).
- Undeclared milk in a nationally distributed snack bar resulting in 43 subsequent entries.

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

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

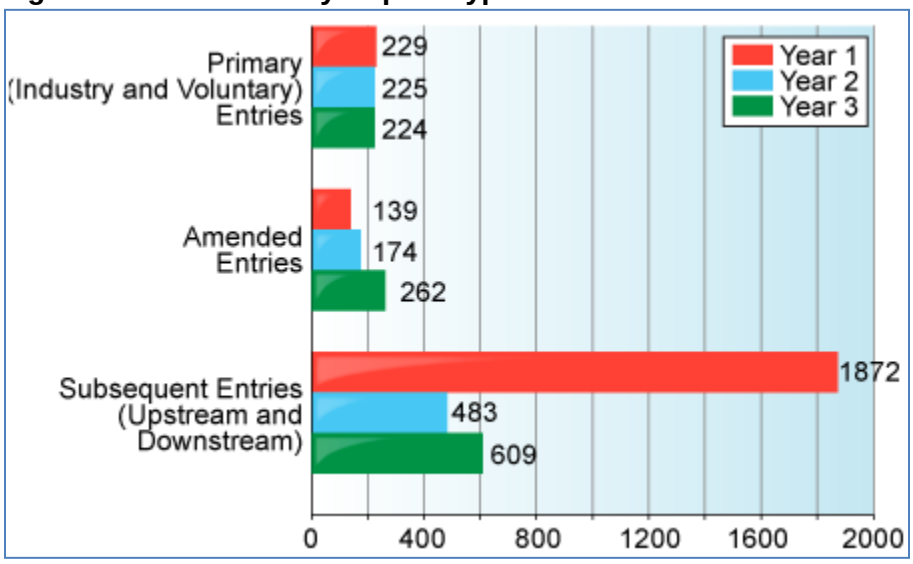
Of the 1095 Year 3 RFR entries, 224 were primary reports (221 of these were mandatory industry reports and 3 were voluntary reports submitted by state regulatory officials); 609 were subsequent reports as a result of primary reports; and 262 were amended reports, updating previously submitted primary or subsequent reports, as shown in Figure 1 below.

As Figure 1 shows, the number of primary reports for all 3 years was similar. There was an increase in the number of amended reports in Year 3; 262 compared to 174 in Year 2 and 139 in Year 1, representing an overall 88% increase since the program began.

Amended reports, additional information supplied by an industry or voluntary submitter to correct or complete a primary or subsequent report, are 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 responsible parties for their continuing efforts to update information at the SRP.

Figure1: RFR Entries by Report Type



As Table 3 shows, the 224 primary RFR entries in Year 3 included 205 for Human Food, and 19 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

The 224 primary RFR entries in Year 3 involved 24 commodities as shown in Table 4 below. There were increases by an amount of 5 entries or more between Year 2 and Year 3 for: (1) Produce-Fresh Cut, (2) Soup, (3) Produce—Raw Agricultural Commodities (Produce—RAC), and (4) Chocolate/Confections/Candy commodities. There was a decrease of 5 entries or more between Year 2 and Year 3 in the (1) Spices and Seasonings, (2) Frozen Foods, and (3) Prepared Foods commodities. Further information about these observations is presented in Section I.

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

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

Table 5 shows 224 primary (industry and voluntary) RFR entries tabulated by their food safety hazards, for Year 3, the reporting period from September 8, 2011, to September 7, 2012.

Table 5: Distribution of Primary RFR Entries by Commodity and Hazard- Year 3

Commodity	Drug Contamination	*E. coli* O157:H7	Foreign Object	*Listeria monocytogenes*	Nutrient Imbalance	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Uneviscerated Fish	Total	%
Acidified/Low Acid Canned Foods (LACF)						1		1			2	0.89%
Animal Food/Feed	4		1		8	1	5				19	8.50%
Bakery								18			18	8.04%
Beverages								1			1	0.45%
Breakfast Cereals							1	2			3	1.34%
Chocolate/ Confections/ Candy							1	11			12	5.36%
Dairy				11			2	7			20	8.92%
Dressings/ Sauces/ Gravies								5			5	2.23%
Egg				2							2	0.89%
Frozen Foods				1				2			3	1.34%
Fruit and Vegetable Products							4		1		5	2.23%
Game Meats											0	0.00%
Meal Replacement/ Nutritional Food and Beverages							2	3			5	2.23%
Multiple Products								2			2	0.89%
Nuts/Nut Products/ Seed Products		1					8	4			13	5.80%
Oil/Margarine											0	0.00%
Pasta								2			2	0.89%
Prepared Foods				5				4			9	4.02%
Produce - Fresh Cut		2		15			6				23	10.27%
Produce – RAC		1		10			22				33	14.73%
Seafood				4		1	1	5		6	17	7.59%
Snack Foods								7			7	3.13%
Soup						1		5			6	2.23%
Spices and Seasonings							5	3			8	3.57%
Stabilizers/ Emulsifiers/ Flavors/ Colors/ Texture Enhancers							5				5	2.23%
Sweeteners												0.00%
Whole & Milled Grains and Flours							1	3			4	1.79%
Total	4	4	1	48	8	4	63	85	1	6	224	
Percentage	1.79%	1.79%	0.45%	21.4%	3.57%	1.79%	28.1%	37.9%	0.45%	2.68%		100%

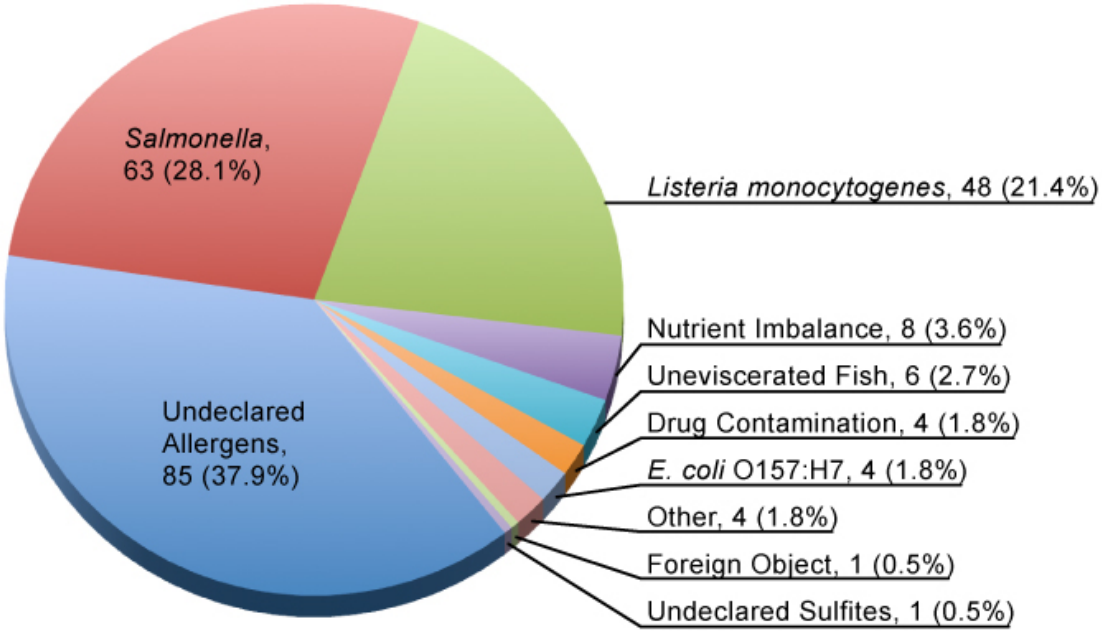
NOTE: Due to rounding, the combined sum may not total 100%.

For Year 1 and Year 2* "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, 2011].

The 224 primary (industry and voluntary) RFR entries for Year 3 include a total of ten food safety hazards: Drug Contamination 1.8%; *E. coli* O157:H7 1.8%; Foreign Object 0.5%; *Listeria monocytogenes* 21.4%; Nutrient Imbalance 3.6%; Other 1.8%; *Salmonella* 28.1%; Undeclared Allergens 37.9%; Undeclared Sulfites 0.5%; and Uneviscerated Fish 2.7%.

Figure 2 shows the distribution of food safety hazards for Year 3; this was quite similar to Years 1 and 2 with some exceptions: Year 3 showed a decrease in *Salmonella* reports and there were no reports for excessive urea hazards. In addition, Drug Contamination emerged as a hazard in the animal feed/food commodity and there was an increase in Undeclared Allergens reports for human food.

Figure 2: Distribution of Primary RFR Entries by Food Safety Hazard, Year 3



Year 1 and Year 2 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, 2011].

F. Notable Outcomes

Salmonella Infantis in Dog Food

A voluntary report, which can be provided by a public health official, was submitted by the Michigan Department of Agriculture and Rural Development (MDARD) notifying FDA and state counterparts about a positive test result *for Salmonella* Infantis contamination in a nationally distributed dog food product. Through collaboration with state and federal public health officials, FDA's review of consumer complaints and FDA and state testing, some brands of dry pet food produced by a single manufacturing facility in South Carolina were linked to 53 human *Salmonella* illnesses. Seventeen different major brand names were recalled and 13 subsequent RFR reports were received relating to this reportable food. For further information, see Investigation of Multistate Outbreak of Human Infections Linked to Dry Pet Food.

Listeria monocytogenes in Fresh Cut Onions

A California onion processor was notified by FDA that the Canadian Food Inspection Agency (CFIA) had tested and found its exported product positive for *Listeria monocytogenes* contamination. After FDA's investigation in conjunction with CFIA, one lot of the affected onions that had been distributed to 14 states and Canada was recalled. FDA actively investigated and monitored the event for several months with subsequent visits to the firm implicating additional lots of sliced onions and resulting in two recall expansions. Consequently, potentially dangerous products were removed from the marketplace, human illnesses were avoided, and the public was informed of the possible *Listeria monocytogenes* contamination of the product. Before production resumed, FDA worked collaboratively with the firm, and preventive measures were established to prevent future occurrences of contamination. No associated illnesses were reported.

Undeclared Milk in Chocolate Ingredient

A manufacturer received a consumer complaint of a severe allergic reaction to its snack bar product and submitted a report to RFR. After investigation and analysis, a chocolate ingredient used in the production of the snack bars was found to contain high levels of undeclared milk protein. People who are allergic to milk run a risk of having serious, even life threatening, reactions if they consume such products. The product was quickly recalled and the responsible party implemented new procedures to ensure that all allergen information provided by ingredient suppliers is carried over to product labels. This reportable food was distributed nationwide and resulted in 43 Registry entries. There were no additional allergic reactions reported to FDA.

G. 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. The initiatives relating to the RFR's third year of operation are summarized below.

Proposed Regulations

FDA's proposed rules on Preventive Controls for Human Food and Produce Safety were published in January 2013 to address many of the problems evidenced by the RFR data, especially microbiological contamination. The proposed regulations are the first of several proposed rules that would establish the foundation of and central framework for the modern food safety system envisioned by Congress in the FDA Food Safety Modernization Act (FSMA):

- 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.

- 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.

Guidance

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

- Guidance for Industry: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation: Published in December 2011, this final guidance provides recommendations on the following provisions of the final rule: *Salmonella* Enteritidis (SE) prevention measures; environmental testing for SE; egg testing for SE; sampling methodology for SE; and recordkeeping requirements for the SE prevention plan. The final guidance differs from the draft guidance in that it addresses environmental sampling plans for a variety of poultry house styles, as requested by commenters.

- Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods: Published in March 2012, this guidance addresses testing procedures for Salmonella species (Salmonella spp.) in human foods and direct-human-contact animal foods, and the interpretation of test results, when the presence of Salmonella spp. in the food may render the food injurious to human health.

- Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation : Published in August 2012, this guidance addresses questions regarding the requirements under the rule, including how to determine whether and when producers must comply with the requirements, *Salmonella* enteritidis prevention measures, sampling and testing requirements, facility registration, and enforcement and compliance.

- Guidance for Industry: Necessity of the Use of Food Product Categories in Registration of Food Facilities**:** Updated in October 2012, this guidance provides additional food categories to be included in the food facility registration form as mandatory fields, including food categories that are currently included on the food facility registration form as optional fields. FDA intends to issue three other updated food facility registration guidance documents to provide more information regarding FSMA amendments to the food facility registration requirements of section 415 of the Federal Food, Drug, and Cosmetic Act.

NEW DATA ELEMENTS

FDA incorporated additional RFR data elements in 2012 as part of an effort to improve the program's information gathering capability. By gathering and analyzing the new data, FDA will improve its ability to track patterns of adulteration in human food and animal feed (including pet food) and to target its inspection resources as detailed in the Introduction section of this report above.

RFR entries in Year 3 triggered follow-up investigations by FDA that resulted in Import Alerts and Import Bulletins.

IMPORT ALERTS

- *Salmonella* in tuna from a facility in India
- *Listeria monocytogenes* in snow crab clusters from a facility in China
- Uneviscerated herring from facilities in Ukraine and Canada
- Undeclared sulfites in dried potatoes from a facility in China

IMPORT BULLETINS

- Undeclared milk in chocolate from facilities in Belgium
- *Clostridium botulinum* in canned olives from facilities in Italy
- *Listeria monocytogenes* in cheese from facilities in Canada
- *Salmonella* in soy protein from facilities in China

FDA RISK PROFILE

Risk Profile on Pathogens and Filth in Spices

FDA is finalizing a risk profile to describe the nature and extent of public health risk posed by consumption of spices by identifying the most commonly occurring microbial and filth hazards in spices. The risk profile will also describe and evaluate current mitigation and control options, identify potential additional mitigation and control options and identify research needs and data gaps.

In efforts to share analyzed data as soon as possible, FDA has published the following journal articles while compilation and review of the risk profile continue.

- 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.

Letter to the Cantaloupe Industry

Issued in February 2013, this is the second correspondence from FDA to firms that grow, harvest, sort, pack, process, or ship cantaloupe in efforts to promote and enhance food safety in this commodity. With two recent human illness outbreaks, involving whole and fresh cut cantaloupes contaminated with *Salmonella* and *Listeria monocytogenes* pathogens, collectively sickening over 400 and taking the lives of 36 individuals, it is paramount to follow the principles set forth in the Guide to Minimize Microbial Food Safety Hazards for Fruits and Vegetables and our draft Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Melons and implement best available practices. FDA will continue to work collaboratively with stakeholders in pursuit of our common goal of enhancing food safety and protecting public health.

Updated Internal Inspection Guidance

An updated internal inspection guidance was issued in May 2012 that provides instruction to FDA district and state regulatory agency officials who conduct domestic and foreign inspectional activities to follow up on reportable food reports or determine compliance with the requirements of the Reportable Food Registry, Section 417 of the Food, Drug & Cosmetic Act.

H. 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 2 RFR report provided details about the Spices and Seasonings Guidance from the American Spice Trade Association (ASTA) to reduce the risk of contamination with *Salmonella* and other pathogens, future bakery products guidance, and highlighted some industry hosted webinars for training and education. Following are some updated industry related initiatives in Year 3:

- **Spices and Seasonings Guidance:** The American Spice Trade Association published guidance in March 2011 to reduce the risk of contamination with *Salmonella* highlighting aspects of preventive and processing controls, environmental monitoring, validation of microbial reduction treatment steps, and product testing. In relation to the guidance, ASTA issued a white paper in March 2013 summarizing validation of microbiological reduction treatment processes.

- **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 for ensuring food safety in cantaloupe production.

- **Industry Seminars:**
  - ASTA hosted an "Environmental Monitoring Workshop" in May 2012 to detail ways to implement monitoring programs in accordance with the spices and seasoning guidance cited above.
  - International Association for Food Protection (IAFP) provided a "Food Allergen Labeling: Challenges and Best Practices" session in July 2012 to overview international food allergen labeling requirements and best practices to enhance compliance with food allergens regulations.

I. 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

Data from the third year of operation of the RFR indicates that Produce – RAC accounts for the majority of *Salmonella*-related reports.

The number of primary reports for *Salmonella* decreased to 63 from 86 in both Years 1 and 2. As indicated in the descriptions of FDA and industry initiatives, respectively, in Sections G and H, FDA is working with industry to identify controls to reduce *Salmonella* contamination.

The largest decrease in *Salmonella* was observed in the Spices and Seasonings commodity, with a total of 5 primary entries in Year 3 compared to 23 in Year 2, a difference of 18 primary entries. This decline, in combination with the decrease of 4 entries in the Animal Food/Feed commodity, accounts for the overall 26.7% decrease in *Salmonella*-associated primary entries in Year 3.

Table 6: Distribution of *Salmonella* Primary RFR Entries By Commodity

Commodity	Year 1		Year 2		Year 3	
	Number	Percentage	Number	Percentage	Number	Percentage
Animal Food/Feed	13	15.1%	8	9.3%	5	7.94%
Bakery	1	1.1%	0	0.0%	0	0.00%
Beverages	1	1.1%	1	1.1%	0	0.00%
Breakfast Cereals	1	1.1%	0	0.0%	1	1.59%
Chocolate/Confections/Candy	1	1.1%	0	0.0%	1	1.59%
Dairy	1	1.1%	3	3.4%	2	3.17%
Egg	1	1.1%	0	0.0%	0	0.00%
Frozen Foods	3	3.4%	1	1.1%	0	0.00%
Fruit and Vegetable Products	1	1.1%	6	6.9%	4	6.35%
Meal Replacement/Nutritional Food and Beverages	5	5.8%	1	1.1%	2	3.17%
Multiple Products	1	1.1%	0	0.0%	0	0.00%
Nuts/Nut Products/Seed Products	12	13.9%	11	12.7%	8	12.70%
Prepared Foods	0	0.0%	1	1.1%	0	0.00%
Produce - Fresh Cut	5	5.8%	2	2.3%	6	9.52%
Produce – RAC	14	16.2%	25	29.0%	22	34.92%
Seafood	0	0.0%	0	0.0%	1	1.59%
Snack Foods	1	1.1%	0	0.0%	0	0.00%
Spices and Seasonings	16	18.6%	23	26.7%	5	7.94%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	6	6.9%	3	3.4%	5	7.94%
Whole & Milled Grains and Flours	3	3.4%	1	1.1%	1	1.59%
Total	**86**	**100%**	**86**	**100%**	**63**	100.00%

NOTE: Due to rounding, the combined sum may not total 100%.The following eight commodities had zero entries related to *Salmonella* hazards for Years 1 through 3: Acidified/Low Acid Canned Food (LACF), Dressing/Sauces/Gravies, Oil/Margarine, Pasta, Soup, Other, Sweeteners, and Game Meats.

LISTERIA MONOCYTOGENES

The 48 primary reports in Year 3 for *Listeria monocytogenes* (*Lm*) show a 45% increase over the 33 primary reports in Year 1. Produce- Fresh Cut accounts for about a third of the *Lm* reports with 15 primary entries, mainly for bagged leafy greens and salad products. Dairy was responsible for 11 entries, with various cheese products accounting for 10 of those entries. The 10 entries for the Produce- RAC commodity included 7 entries for different sprouts and 2 for cantaloupes.

Table 7: Distribution of *Listeria monocytogenes* Primary RFR Entries by Commodity

Commodity	Year 1		Year 2		Year 3	
	Number	Percentage	Number	Percentage	Number	Percentage
Dairy	8	24.2%	7	17.5%	11	22.92%
Dressing/Sauces/Gravies	1	3.0%	0	0.0%	0	0.00%
Egg	0	0.0%	2	5.0%	2	4.17%
Frozen Foods	3	9.0%	1	2.5%	1	2.08%
Fruit and Vegetable Products	2	6.0%	2	5.0%	0	0.00%
Meal Replacement/Nutritional Food and Beverages	1	3.0%	0	0.0%	0	0.00%
Multiple Products	1	3.0%	0	0.0%	0	0.00%
Nuts/Nut Products/Seed Products	1	3.0%	0	0.0%	0	0.00%
Prepared Foods	2	6.0%	10	25.0%	5	10.42%
Produce - Fresh Cut	5	15.1%	7	17.5%	15	31.25%
Produce - RAC	0	0.0%	2	5.0%	10	20.83%
Seafood	9	27.2%	8	20.0%	4	8.33%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	0	0.0%	1	2.5%	0	0.00%
Total	**33**	**100%**	**40**	**100%**	**48**	100.00%

NOTE: Due to rounding, the combined sum may not total 100%. The following 15 commodities had zero entries related to *Listeria monocytogenes* hazards for all Years: Acidified/Low Acid Canned Food, Animal Food/Feed, Bakery, 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, which the Act terms “major food allergens.”

Year 3 demonstrated a 23% increase to 85 entries, up from 69 primary entries in Year 1, in the number of primary reports for Undeclared Major Food Allergens, with the Bakery commodity accounting for 18 of the total of 85 entries. Within Bakery, cookies and cakes were the predominantly reported food types. The 11 entries for the Chocolate/Confections/Candy commodity were for products such as chocolate or yogurt coated dried fruits, icings/ganaches, and chocolate candies.

Table 8: Distribution of Undeclared Major Food Allergens Primary RFR Entries by Commodity

Commodity	Year 1		Year 2		Year 3	
	Number	Percentage	Number	Percentage	Number	Percentage
Acidified and Low Acid Canned Foods (LACF)	2	2.9%	2	2.6%	1	1.18%
Animal Food/Feed	N/A	N/A	N/A	N/A	N/A	N/A
Bakery	14	20.2%	20	26.6%	18	21.18%
Beverages	1	1.4%	1	1.3%	1	1.18%
Breakfast Cereals	1	1.4%	0	0.0%	2	2.35%
Chocolate/Confections/Candy	7	10.1%	7	9.3%	11	12.94%
Dairy	8	11.5%	6	8.0%	7	8.24%
Dressing/Sauces/Gravies	5	7.2%	7	9.3%	5	5.88%
Eggs	0	0.0%	0	0.0%	0	0.00%
Frozen Foods	3	4.3%	9	12.0%	2	2.35%
Fruit and Vegetable Products	0	0.0%	0	0.0%	0	0.00%
Game Meat	0	0.0%	0	0.0%	0	0.00%
Meal Replacement/Nutritional Food and Beverages	0	0.0%	1	1.3%	3	3.53%
Multiple Food Products	2	2.9%	1	1.3%	2	2.35%
Nuts/Nut Products/Seed Products	3	4.3%	4	5.3%	4	4.71%
Oil/Margarine	1	1.4%	0	0.0%	0	0.00%
Other	0	0.0%	0	0.0%	0	0.00%
Pasta	0	0.0%	1	1.3%	2	2.35%
Prepared Foods	8	11.5%	3	4.0%	4	4.71%
Produce - Fresh Cut	0	0.0%	0	0.0%	0	0.00%
Produce - RAC	0	0.0%	0	0.0%	0	0.00%
Seafood	1	1.4%	4	5.3%	5	5.88%
Snack Foods	6	8.7%	8	10.6%	7	8.24%
Soup	4	5.8%	0	0.0%	5	5.88%
Spices and Seasonings	1	1.4%	0	0.0%	3	3.53%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	2	2.9%	0	0.0%	0	0.00%
Sweetener	0	0.0%	0	0.0%	0	0.00%
Whole and Milled Grains and Flours	0	0.0%	1	1.3%	3	3.53%
Total	**69**	**100%**	**75**	**100%**	**85**	100.00%

NOTE: Due to rounding, the combined sum may not total 100%; “N/A” means Not Applicable.

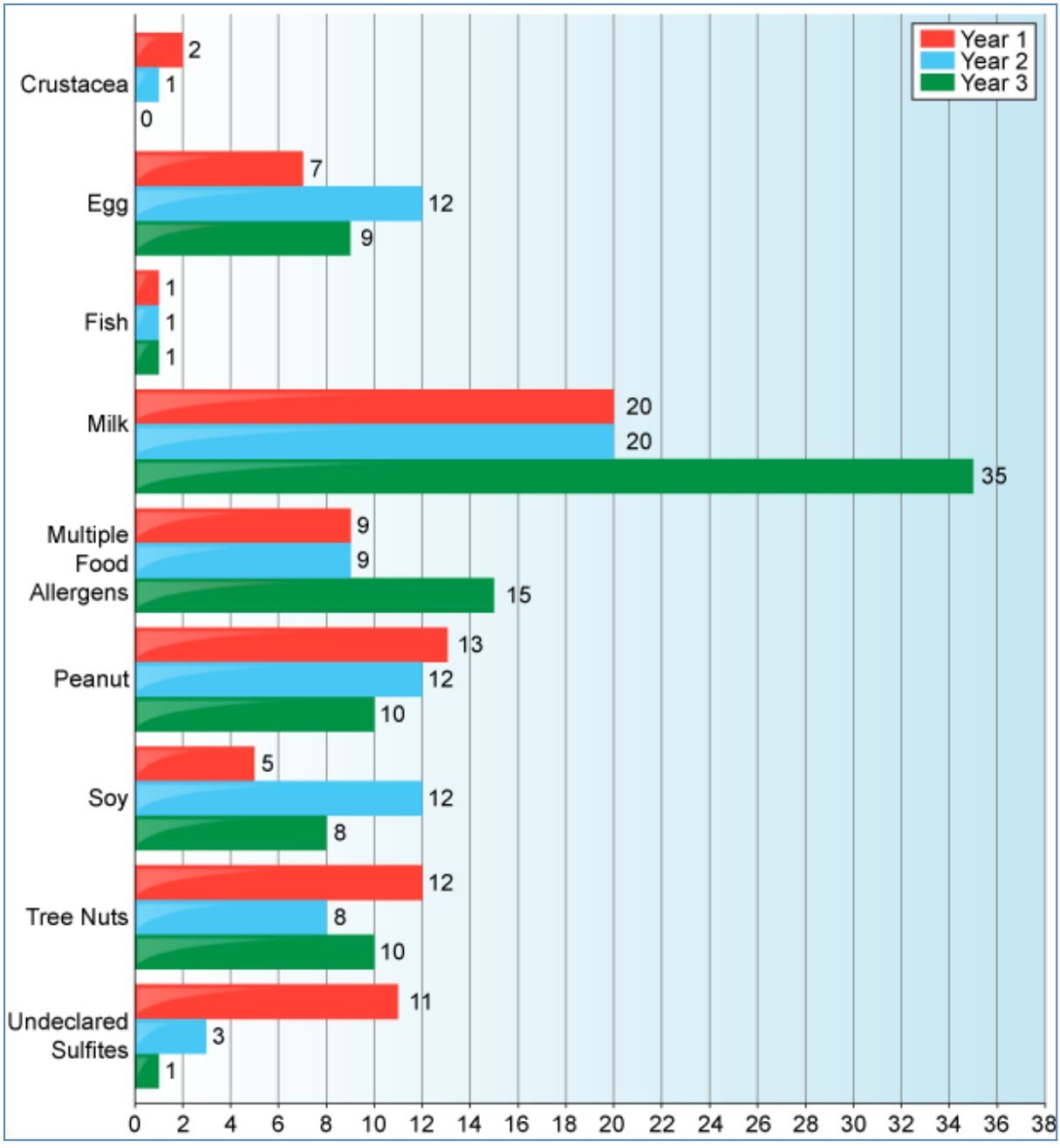
Table 9: Top 3 Commodities with Undeclared Major Food Allergens by Specific Food Allergen in Year 3

The Bakery commodity accounts for the most reports relating to Undeclared Allergens in Year 3.

Commodity	Crustacea	Egg	Fish	Milk	Multiple Food Allergens	Peanut	Soy	Tree Nuts	Total
Bakery	0	4	0	8	2	0	1	3	18
Chocolate/Confections/Candy	0	0	0	5	2	4	0	0	11
Dairy	0	0	0	5	0	1	0	0	6

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 3, with an increase to 35 primary entries, up from 20 primary entries in both Years 1 and 2.



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 10: Primary RFR Entries of Undeclared Sulfites by Commodity

There was a single primary entry for Undeclared Sulfites in Fruit and Vegetable Products in Y3.

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

J. Reports Associated with Imported Foods

Primary RFR entries for foods from international sources decreased to 46 from 56 in Year 2. The 46 entries encompassed the following 6 food safety hazards: *Listeria monocytogenes*, *Salmonella*, Other (*Clostridium botulinum)*, Uneviscerated Fish, Undeclared Sulfites and Undeclared Allergens, distributed across 14 commodities, as shown in Table 11 below.

Table 11: Distribution of Primary RFR Entries Involving Imported Foods by Commodity and Food Safety Hazard, Year 3 (Click here for previous reporting period tables)

Commodity	Drug Contamination	*E. coli* O157: H7	Foreign Object	*Listeria monocytogenes*	Nutrient Imbalance	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Unevisceratred Fish	Total	%
Acidified / Low Acid Canned Foods (LACF)						1					1	2.17%
Animal Food/Feed											0	0.00%
Bakery								2			2	4.35%
Beverages											0	0.00%
Chocolate/ Confections/Candy							1	2			3	6.52%
Dairy				1			1				2	4.35%
Dressing/Sauces/ Gravies											0	0.00%
Egg											0	0.00%
Frozen Foods											0	0.00%
Fruit and Vegetable Products							2		1		3	6.52%
Meal Replacement/ Nutritional Food and Beverages											0	0.00%
Multiple Food Products								1			1	2.17%
Nuts/ Nut Products/ Seed Products							5	1			6	13.04%
Oil/Margarine											0	0.00%
Pasta											0	0.00%
Prepared Foods											0	0.00%
Produce – Fresh Cut				2							2	4.35%
Produce – RAC							5				5	10.87%
Seafood				3			1	1		6	11	23.91%
Snack Foods								1			1	2.17%
Soup											0	0.00%
Spices/ Seasonings							4				4	8.70%
Stabilizers, Emulsifiers/ Flavors and Colors/ Texture Enhancers							4				4	8.70%
Sweeteners											0	0.00%
Whole & Milled Grains and Flour								1			1	2.17%
Total	0	0	0	6	0	1	23	9	1	6	46	
Percentage	0.0%	0.0%	0.0%	13.0%	0.0%	2.17%	50.0%	19.6%	2.17%	13.0%		100%

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

Forty-six of the 224 primary reports for Year 3 (20%) concerned imported foods or ingredients, coming from 21 different countries. When entries for all years are combined, there are more than 36 different countries represented, as shown in Table 12 below.

Table 12: Distribution of Primary RFR Entries for Imported Foods by Country of Origin

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

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

K. Completed Steps

New Rules

FDA's proposed rules on Preventive Controls for Human Food and Produce Safety were published in January 2013 to address many of the problems evidenced by the RFR data, especially microbiological contamination.

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 (IAFP) Short Symposium with industry entitled "Food Allergen Labeling: Challenges and Best Practices" in July 2012. The session covered labeling requirements and the impact of these requirements on the food industry and consumers. In addition, discussions highlighted international regulations, analysis of FDA's recall database, and supply chain management of allergens.

In December 2012, FDA established a Federal Register Docket requesting data and other information to determine whether the agency can safely establish threshold levels for major food allergens.

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

Updated RFR At A Glance

The RFR At A Glance (AAG) is a handout that summarizes the RFR program and requirements for responsible parties. FDA enhanced the handout for distribution by FDA field investigators in 2013. The updates explain the report identification number and remind responsible parties to submit amended reports as they gather more information during their investigation(s). We would like to highlight the following format and text modifications to the original RFR AAG handout regarding responsible parties:

Responsible Parties:

- A responsible party is not required to submit a reportable food report if ALL of the following three conditions are met:
    - The adulteration originated with the responsible party; AND
    - The responsible party detected the adulteration prior to any transfer to another person of the article of food; AND
    - The responsible party corrected the adulteration or destroyed or caused the destruction of the article of food.

- Will be issued a unique number after report submission, called the Individual Case Safety Report (ICSR) number, that identifies the report and allows FDA to properly link associated reportable food reports in the Registry
- May be required to provide notification to immediate previous sources (suppliers) and immediate subsequent recipients (customers) of the reportable food and share information including the ICSR number, after consultation with FDA
- Must provide amended reports as necessary- for example, FDA understands that it may take more than 24 hours to perform investigation activities and obtain information such as the results of any investigation of the root cause of the adulteration (when applicable) and the disposition of the reportable food

    - As of May 24, 2010, The RFR electronic portal became part of the Department of Human Services' Safety Reporting Portal. The entire set of data elements can be accessed at www.safetyreporting.hhs.gov.

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 produce a web video, similar to the video for mandatory RFR reporters, to explain the process of submitting a voluntary report to the RFR. The video will be available on the RFR web site and is highlighted in Section C of this report.

RFR IMPROVEMENTS REQUIRED BY FSMA

The Food Safety Modernization Act (FSMA) included Section 211, which amends Section 417 of the Federal Food, Drug, and Cosmetic Act (FD & C Act) 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.

- Grocery stores that have 15 or more physical locations and have sold a reportable food that is the subject of a one-page critical information summary published on FDA.gov are 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.

Substantive information gathering and analysis is underway as FDA works to analyze available data and engage stakeholders to better understand the benefits and costs of implementing the provisions in Section 211 of FSMA with minimum disruption of the industry and maximum public health protection. FDA is considering the possibility of issuing an Advance Notice of Proposed Rulemaking to solicit additional input.

L. 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 Drug Contamination, *E. coli* O157:H7, *Listeria monocytogenes*, Nutrient Imbalance, *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.