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

FDA Foods and Veterinary Medicine Program

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

Second Annual Report:
September 8, 2010 – September 7, 2011

This is the second annual report that measures our success in receiving early warning on problems with food and feed. The Reportable Food Registry 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 increased the speed with which the FDA, its state- and local-level partners, and industry could remove hazards from the marketplace. The Agency also can use the data to target inspections, plan work, identify and prioritize risks and develop guidance for industry on how to strengthen preventive controls.

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

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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 second Reportable Food Registry Annual Report, covering the period September 8, 2010 to September 7, 2011. The first Reportable Food Registry Annual Report presented FDA's experience with the RFR from the opening of the Reportable Food electronic portal on September 8, 2009 until September 7, 2010.

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. With only two years of data, it would be premature to make meaningful statements about trends or patterns. However, data from the RFR has proven extremely useful in a number of very important ways. It has:

- Increased the speed with which FDA and its state and local partners investigate reports and take appropriate follow-up action, including removing reportable foods from commerce when necessary;
- Improved FDA's understanding of how products are distributed through commodity supply chains, increasing FDA's ability to trace reportable foods upstream and downstream;
- Helped FDA and industry identify key commodity risk points and develop guidance for establishing preventive controls;
- Improved coordination among FDA headquarters, FDA field staff, and state and local regulators;
- Provided data for FDA to issue import alerts and import bulletins; and,
- Supplied information to help FDA target inspections, plan work, and identify and prioritize risks.

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

B. Executive Summary

Key Findings

The difference in total reportable entries between Year 1 and Year 2 was the result of three primary reportable entries in year 1 that resulted in 1,284 subsequent reports. These were:

- Undeclared sulfites in widely distributed prepared side dishes, which resulted in 108 subsequent reports;
- *Listeria monocytogenes* in widely distributed cheese spreads, which resulted in 106 subsequent reports; and,
- *Salmonella* in a very widely used ingredient, hydrolyzed vegetable protein (HVP), which resulted in 1070 subsequent reports.

Without these subsequent reports, the total entries for Year 1 would have been 956, or only 74 more than Year 2. After only two years of experience with the RFR, it is not possible to say whether Year 1 was a high year for RFR entries or Year 2 was a low year. (See Section E for further information on the comparison of Year 2 with Year 1).

Table 1: Comparison of Year 1 and Year 2 RFR Total Submissions and Entries

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

Observed Changes

Amended Reports Increase: 174 for Year 2, up from 139 in Year 1. The 25% increase suggests more facilities are informing FDA about their investigations of problems and their efforts to correct the causes.

Animal Feed/Pet Food Reports Decrease: 19 primary reports in Year 2 compared with 28 in Year 1.

Produce Reports Increase: 14 for Year 1 increased to 27 in Year 2. This rise is attributable to the U.S. Department of Agriculture (USDA) sampling program intended to establish current baseline values of contamination against which the effectiveness of new procedures to reduce or eliminate harmful microorganisms in certain fresh fruits and vegetables can be measured.

INDUSTRY INITIATIVES

- **New Industry Guidance Expected to Decrease RFR Entries for Spices and Seasonings:** Although primary reports for *Salmonella* in Spices and Seasonings increased from 16 in Year 1 to 23 in Year 2, new guidance developed by the American Spice Trade Association is expected to have a positive effect on reducing health risks from this commodity group.

- **RFR Entries for Baked Goods Up, New Industry Guidance Expected:** Year 2 data show an increase in primary reports for undeclared allergens in baked goods from 14 in Year 1 to 20 in Year 2. In response to the data from the Year 1 report, one of the nation's largest baking industry trade associations indicated that it would review and enhance its industry guidance on avoiding undeclared allergens in bakery products. This new industry guidance is expected in 2012.

REGULATORY INITIATIVES

- **Notable Outcomes:** In three instances reportable food submissions alerted FDA to potential public health issues early and helped the Agency to quickly ensure that potentially harmful products did not reach the retail marketplace or were quickly removed.

    1. A primary report on frozen breaded seafood products was submitted because the soy flour breading contained undeclared peanut protein. People allergic to peanuts can have serious reactions if they consume such products. Twenty subsequent reports were received on the implicated products. The products were recalled and no adverse events in the U.S. associated with these products have been reported.

    2. A pet treat distribution company submitted a report that their pig ear dog treats were contaminated with *Salmonella*. After FDA's investigation, two lots of the affected pet treats that had been distributed to 18 states were recalled.

    3. A company that had packed and shipped grape tomatoes from a Florida farm submitted a primary report because the tomatoes tested positive for *Salmonella.* The tomatoes, which had been distributed to ten states and Canada, were recalled. Ultimately, there were 64 subsequent reports resulting from the incident. No illnesses associated with these products have been reported.

- FDA published various guidance documents for industry and regulators that address *Salmonella* and other food safety hazards.
- FDA is finalizing a risk profile on pathogens and filth in spices.
- 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.

C. CONTINUING OUTREACH

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 TRAINING VIDEO

A video explaining the RFR reporting requirements and how to access the Safety Reporting Portal to submit an RFR report was completed in 2011. It is closed captioned in Arabic, Chinese, French, Japanese, Korean, Portuguese, and Spanish, and is available via FDA's Reportable Food Registry for Industry web page.

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 882 RFR entries, representing primary, subsequent, and amended reports, during Year 2.

The much higher number of Registry entries for Year 1 (2240) is largely attributable to three events:

- Contamination of a widely used flavor enhancer, Hydrolyzed Vegetable Protein (HVP), with *Salmonella* Tennessee, which resulted in 1071 Registry entries;
- Undeclared sulfites in prepared side dishes, which resulted in 109 Registry entries; and,
- Cheese spreads contaminated with *Listeria monocytogenes,* which resulted in 107 entries.

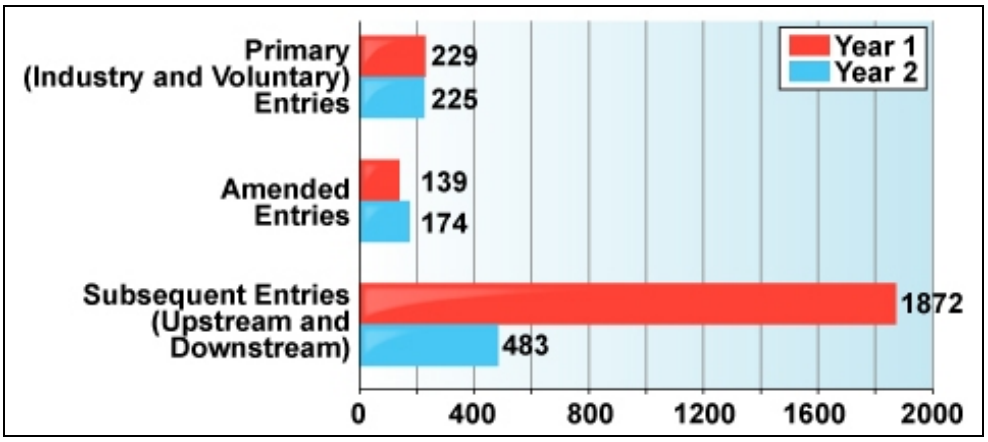
Table 2: Monthly Registry Entries Year 1 and 2

Period	Year 1	Year 2
September 8-30	37	45
October	92	48
November	236 (109 on undeclared sulfites in side dishes)	54
December	50	109 (38 on *Salmonella* in walnuts)
January	159 (107 on *Listeria monocytogenes* in cheese spreads)	75
February	144 (25 on *Salmonella* in soy grits; 70 on *Salmonella* in hydrolyzed vegetable protein (HVP))	76
March	1117 (1001 on *Salmonella* in HVP)	68
April	61	66
May	68	137 (65 on *Salmonella* in grape tomatoes)
June	71	42
July	71	31
August	117 (63 on *Salmonella* in shell eggs)	98
September 1-7	17	33
Total	**2240**	**882**

When there is a "spike" of 100 or more reports entered into the Registry in a single month, the cause is usually a large number of subsequent reports due to a primary report on a widely used food ingredient or a finished food distributed to many locations. The causal food or food ingredient may not itself generate 100 or more submissions in a given month, but may produce enough submissions to drive the number above the spike threshold as demonstrated by the submissions on shell eggs in August 2010. Table 2 above shows the spikes for Years 1 and 2. The number of entries related to each spike and the associated ingredient(s) or finished food product(s) are shown in parentheses. Of the 882 Year 2 RFR entries, 225 were primary reports (222 of these were mandatory industry reports and 3 were voluntary reports submitted by state regulatory officials); 483 were subsequent reports as a result of a primary report; and 174 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 Years 1 and 2 were similar, with four more in Year 1. Despite slightly fewer primary reports, there was an increase in the number of amended reports in Year 2; 174 compared with 139 in Year 1. This is an important development in the evolution of the RFR. 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.

Figure 1: RFR Entries by Report Type



As Table 3 shows, the 225 primary RFR entries in Year 2 included 206 for Human Food, and 19 concerning Animal Food/Feed (including pet food). The 19 primary reports in this commodity represent a decrease from the 28 primary reports in Year 1.

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

The 225 primary RFR entries in Year 2 involved 22 commodities as shown in Table 4 below. In addition to the decrease in Animal Food/Feed (including pet food) entries noted at Table 3 above, there were increases in entries for Produce – Raw Agricultural Commodities (Produce – RAC) and for Spices and Seasonings. Further information about these increases is presented in Section H.

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

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

For Year 1, the reporting period from September 8, 2009 to September 7, 2010, 229 primary (industry and voluntary) RFR entries encompassed nine food safety hazards: *E. coli* O157:H7, Excessive Urea, Foreign Object, *Listeria monocytogenes*, Other, *Salmonella*, Uneviscerated Fish, Undeclared Sulfites, and Undeclared Allergens. These were distributed across 25 commodities, as shown in Table 5.

Table 5: Distribution of Primary RFR Entries by Commodity and Hazard - Year 1

Commodity	*E. coli* O157: H7	Excessive Urea	Foreign Object	*Listeria monocytogenes*	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Uneviscerated Fish	Total	%
Acidified/Low Acid Canned Foods (LACF)							2			2	0.9%
Animal Food/Feed		2	3		10	13				28	12.2%
Bakery	1					1	14			16	7.0%
Beverages					1	1	1			3	1.3%
Breakfast Cereals						1	1			2	0.9%
Chocolate/ Confections/ Candy						1	7			8	3.5%
Dairy	1			8		1	8			18	7.9%
Dressings/Sauces/ Gravies				1			5			6	2.6%
Egg					1	1				2	0.9%
Frozen Foods				3		3	3			9	3.9%
Fruit and Vegetable Products				2		1		9		12	5.2%
Game Meats	1									1	0.4%
Meal Replacement/ Nutritional Food and Beverages				1		5				6	2.6%
Multiple Products				1		1	2			4	1.7%
Nuts/Nut Products/Seed Products				1		12	3			16	7.0%
Oil/Margarine							1			1	0.4%
Pasta										0	0.0%
Prepared Foods				2			9			11	4.8%
Produce - Fresh Cut	2			5	1	5				13	5.7%
Produce – RAC						14				14	6.1%
Seafood				9	1		1	1	5	17	7.4%
Snack Foods						1	5	1		7	3.1%
Soup							4			4	1.7%
Spices and Seasonings						16	1			17	7.4%
Stabilizers/ Emulsifiers/ Flavors/Colors/ Texture Enhancers						6	2			8	3.5%
Sweeteners										0	0.0%
Whole & Milled Grains and Flours	1					3				4	1.7%
Total	6	2	3	33	14	86	69	11	5	229	
Percentage	2.6%	0.9%	1.3%	14.4%	6.1%	37.6%	30.1%	4.8%	2.2%		100%

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

For Year 2, the reporting period from September 8, 2010 to September 7, 2011, 225 primary (industry and voluntary) RFR entries tabulated by their food safety hazards were distributed across 22 commodities, as shown in Table 6.

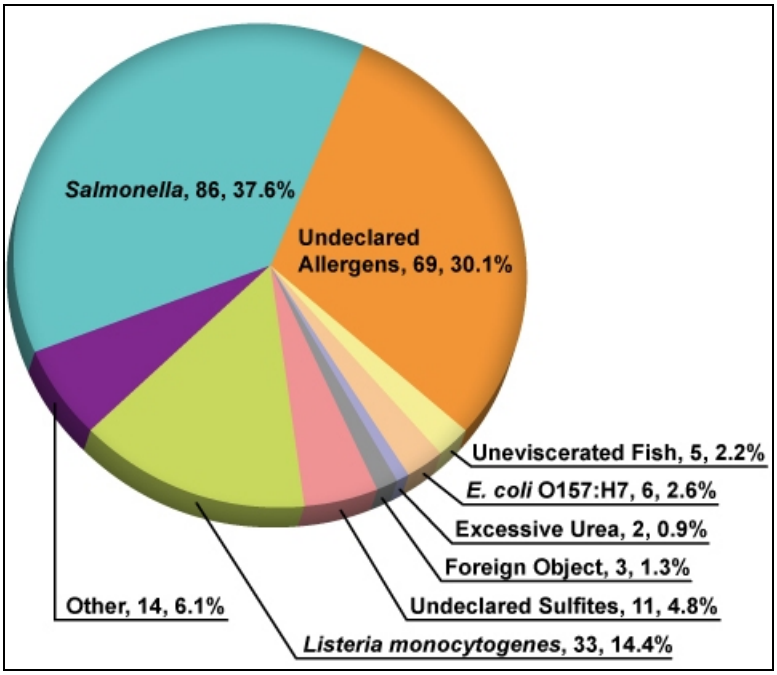
Table 6: Distribution of Primary RFR Entries by Commodity and Hazard - Year 2

Commodity	*E. coli* O157: H7	Excessive Urea	Foreign Object	*Listeria monocytogenes*	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Uneviscerated Fish	Total	%
Acidified and Low Acid Canned Foods (LACF)							2			2	0.9%
Animal Food/Feed		3	1		7	8				19	8.4%
Bakery							20			20	8.9%
Beverages						1	1			2	0.9%
Chocolate/ Confections/ Candy							7			7	3.1%
Dairy				7		3	6			16	7.1%
Dressing/ Sauces/ Gravies					1		7			8	3.6%
Egg				2						2	0.9%
Frozen Foods				1		1	9			11	4.9%
Fruit and Vegetable Products				2		6		1		9	4.0%
Meal Replacement/ Nutritional Food and Beverages						1	1			2	0.9%
Multiple Food Products							1			1	0.4%
Nuts/Nut Products/Seed Products	1					11	4			16	7.1%
Oil/Margarine										0	0.0%
Pasta							1			1	0.4%
Prepared Foods				10		1	3			14	6.2%
Produce-Fresh Cut				7		2				9	4.0%
Produce- RAC				2		25				27	12.0%
Seafood				8			4	1	5	18	8.0%
Snack Foods							8	1		9	4.0%
Soup										0	0.0%
Spices and Seasonings			1		1	23				25	11.1%
Stabilizers/ Emulsifiers/ Flavors/Colors/ Texture Enhancers			1	1		3				5	2.2%
Sweeteners										0	0.0%
Whole & Milled Grains and Flours						1	1			2	0.9%
Total	1	3	3	40	9	86	75	3	5	225	
Percentage	0.4%	1.3%	1.3%	17.8%	4.0%	38.2%	33.3%	1.3%	2.2%		100%
Due to rounding, the combined sum may not total 100%.											

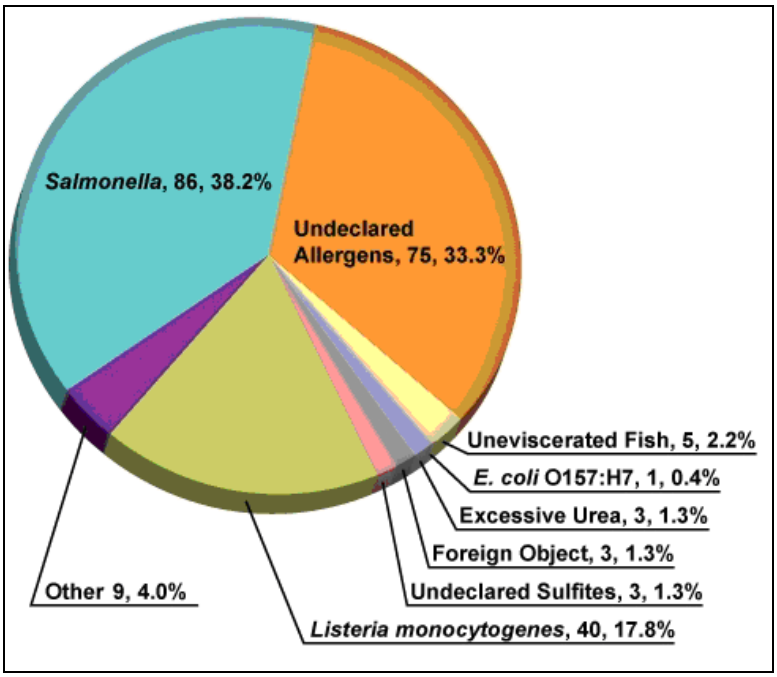
The 225 primary (industry and voluntary) RFR entries for Year 2 include nine food safety hazards: *E. coli* O157:H7 0.4%; Excessive Urea 1.3%; Foreign Object 1.3%; *Listeria monocytogenes* 17.8%; *Salmonella* 38.2%; Other 4%; Undeclared Allergens 33.3%; Undeclared Sulfites 1.3%; Uneviscerated Fish 2.2%. As Figure 2 shows, the distribution of food safety hazards for Year 2 was quite similar to Year 1.

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

Year 1



Year 2



F. RFR-RELATED FOOD 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 1 RFR report listed changes relating to third party food safety audit firms, plans for trade association guidance, and outreach by retailers to suppliers emphasizing their RFR responsibilities. In Year 2, the following industry-related initiatives were launched:

- **Spices and Seasonings Guidance:** The American Spice Trade Association published new guidance in March 2011 to reduce the risk of contamination with *Salmonella* and other pathogens and help the industry provide clean, safe products to its customers.

- Bakery Products Guidance: the nation's largest baking industry trade associations will be enhancing its industry guidance on avoiding undeclared allergens in bakery products.

- **Industry Webinars:**
  - Spicetec Flavors & Seasonings webinar entitled "Understanding Risk and Implementing Assurances in Snacks/Topical Seasoning Applications" to raise awareness of hazards and controls.
  - Grocery Manufacturers Association (GMA) Supplier Benchmarking Webinar that included discussion of RFR requirements.
  - United Fresh Produce Association webinar on Submitting an RFR Report
  - International Association for Food Protection's (IAFP) Fruit and Vegetable Safety and Quality Professional Development Group webinar on FDA's Reportable Food Registry, "What it Means to the Produce Industry."

G. RFR-RELATED REGULATORY 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 regulatory initiatives relating to the RFR's second year of operation are summarized below.

NOTABLE OUTCOMES

- **Frozen Breaded Seafood Products**: A food manufacturing facility submitted a reportable food report notifying FDA that it was recalling several frozen breaded seafood products due to an ingredient in the soy flour breading, provided by a foreign breading supplier that contained an undeclared peanut protein. People who are allergic to peanuts run a risk of having serious, even life threatening, reactions if they consume such products. Subsequent investigation indicated that six allergic reactions linked to products from the same foreign supplier had occurred in another country. Using FDA's confidential communication sharing agreement with officials in the other nation, FDA was able to gain valuable information on the depth and scope of this contamination problem. Twenty subsequent reports from facilities that had received the implicated seafood products and were initiating voluntary recalls were entered into the Registry. The affected products were quickly recalled and no adverse events in the United States associated with these products have been reported.
- ***Salmonella* in Smoked Pig Ear Dog Treats:** A pet treat distribution company was notified by the Missouri Department of Agriculture that their pig ear dog treats were contaminated with *Salmonella*. After an internal investigation, the company submitted a reportable food report notifying FDA that they had received the frozen raw pig ears from a Canadian meat packing firm. FDA's investigation confirmed that the lot of pig ear dog treats identified in the report was contaminated with *Salmonella*. After further review of the company's records, an additional lot was identified to be *Salmonella*-positive. The two lots had been distributed to 18 states. Both lots were recalled.
- ***Salmonella* in Grape Tomatoes:** FDA was notified that grape tomatoes from a Florida farm had been tested by USDA's Microbiological Data Program and found positive for *Salmonella*. The company that had packed and shipped the tomatoes submitted a reportable food report and issued a recall after investigators from FDA's Florida District Office notified them of the test finding. The tomatoes had been distributed to ten states and Canada. In addition, the tomatoes were used as ingredients in various downstream products that were also recalled. Ultimately, there were 65 RFR entries resulting from the incident. No illnesses associated with these products have been reported.

RFR entries in Year 2 triggered follow-up investigations by FDA that resulted in Import Alerts and Import Bulletins.

IMPORT ALERTS

- *Listeria monocytogenes* in avocado pulp from a facility in Peru
- Uneviscerated herring from a facility in Canada
- *Salmonella* in spices and seeds from a facility in Egypt

IMPORT BULLETINS

- *Listeria monocytogenes* in cheese from a facility in the United Kingdom
- *Salmonella* in macadamia nuts from facilities in Kenya and Malawi

GUIDANCE

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

- **Draft Compliance Policy Guide: *Salmonella* in Animal Feed:** Published for comment in August 2010, this draft guidance is intended to provide direction for FDA staff on regulatory policy relating to animal food/feed or animal food/feed ingredients that are contaminated with *Salmonella.*

- **Guidance for Industry: Testing for Salmonella Species in Human Foods and Direct-Human-Contact Animal Foods:** Published in March 2012, this guidance is intended for firms that manufacture, process, pack or hold human foods or direct-human-contact animal foods intended for distribution to consumers, institutions, or food processors. It does not apply to egg producers and other persons who are covered by FDA's final rule "Prevention of *Salmonella* Enteritidis in Shell Eggs during Production, Storage, and Transportation."

- **Guidance to Seafood Industry on Food Safety Hazards**: The 4th edition of the guidance, announced in April 2011, contains FDA's latest recommendations to the seafood industry for reducing or eliminating food safety hazards in the fish and fishery products they process. FDA requires processors of seafood intended for the U.S. market to identify potential hazards associated with the types of seafood they process and to develop and implement a Hazard Analysis Critical Control Point (HACCP) program to control those hazards that are reasonably likely to occur. Processors can use the guidance to help identify the likelihood that a food safety hazard may occur in their product and to guide them in the preparation of appropriate HACCP plans.

FDA PRESENTATIONS

- Selected Data Gaps Identified in the FDA Risk Profile: Pathogens and Filth in Spices — American Spice Trade Association (ASTA) Stakeholder Meeting, June 2011
- RFR Key Findings — Association of Food and Drug Officials, June 2011
- Value of Testing Based on Findings from Consumers, Industry and Regulatory Surveillance Testing via the RFR —International Association for Food Protection (IAFP) Symposium, August 2011
- Clean Safe Spices Guidance Document: FDA Perspective — American Spice Trade Association (ASTA) Regulatory/Legislative Workshop, October 2011

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.

H. ISSUES IDENTIFIED BY RFR ENTRIES

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

SALMONELLA

Data from the second year of operation of the RFR indicates that Animal Food/Feed (including pet food); Nuts, Nut Products, and Seed Products; Produce - RAC; and Spices and Seasonings commodities continue to account for the majority of Salmonella related reports. The number of primary reports for *Salmonella* was the same for Year 1 and Year 2. As indicated in the descriptions of regulatory initiatives in Sections F and G above, FDA is working with industry to reduce *Salmonella* contamination.

There was an increase in the number of Produce - RAC primary reports for *Salmonella* because of the Microbiological Data Program (MDP). The MDP was initiated by USDA's Agricultural Marketing Service to establish microbial baseline data for the prevalence of foodborne pathogens in select fresh fruits and vegetables through nation-wide sampling and testing. While this information is intended to determine the effectiveness of procedures to reduce or eliminate harmful microorganisms, the results of MDP tests are shared with RFR responsible parties who may be required to submit the information to the SRP.

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

Commodity	Year 1		Year 2	
	Number	Percentage	Number	Percentage
Animal Food/Feed	13	15.1%	8	9.3%
Bakery	1	1.1% 0 0.0%		
Beverages	1	1.1% 1 1.1%		
Breakfast Cereals	1	1.1% 0 0.0%		
Chocolate/Confections/Candy	1	1.1% 0 0.0%		
Dairy	1	1.1% 3 3.4%		
Egg	1	1.1% 0 0.0%		
Frozen Foods	3	3.4% 1 1.1%		
Fruit and Vegetable Products	1	1.1%	6	6.9%
Meal Replacement/Nutritional Food and Beverages	5	5.8% 1 1.1%		
Multiple Products	1	1.1% 0 0.0%		
Nuts/Nut Products/Seed Products	12	13.9%	11	12.7%
Prepared Foods	0	0.0% 1 1.1%		
Produce - Fresh Cut	5	5.8%	2	2.3%
Produce - RAC	14	16.2% 25		29.0%
Snack Foods	1	1.1% 0 0.0%		
Spices and Seasonings	16	18.6%	23	26.7%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	6	6.9% 3 3.4%		
Whole & Milled Grains and Flours	3	3.4%	1	1.1%
Total	**86**	**100%**	**86**	**100%**
Due to rounding, the combined sum may not total 100%.				

Note: The following nine commodities had zero entries related to *Salmonella* hazards for both Year 1 and Year 2: Acidified/Low Acid Canned Food (LACF), Dressing/Sauces/Gravies, Oil/Margarine, Pasta, Soup, Other, Sweeteners, Game Meats, and Seafood.

LISTERIA MONOCYTOGENES

The 40 primary reports in Year 2 for *Listeria monocytogenes* (*Lm*) show a 21% increase over the 33 primary reports in Year 1. The Prepared Foods commodity accounts for a quarter of the *Lm* reports with 10 primary reports, with prepared sandwiches responsible for 5 entries, and ready-to-eat salads, such as potato salad and seafood salads, the cause of the other 5. Seafood accounted for 8 entries, with smoked fish products accounting for 6 entries. The 7 entries for the Dairy commodity included 5 entries for various cheese products. Produce - Fresh Cut was also responsible for 7 entries, 5 of which involved bagged leafy greens.

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

Commodity	Year 1		Year 2	
	Number	Percentage	Number	Percentage
Dairy	8	24.2% 7		17.5%
Dressing/Sauces/Gravies	1	3.0%	0 0.0%	
Egg	0	0.0%	2 5.0%	
Frozen Foods	3	9.0%	1 2.5%	
Fruit and Vegetable Products	2	6.0%	2	5.0%
Meal Replacement/Nutritional Food and Beverages	1	3.0%	0 0.0%	
Multiple Products	1	3.0%	0 0.0%	
Nuts/Nut Products/Seed Products	1	3.0%	0	0.0%
Prepared Foods	2	6.0%	10	25.0%
Produce - Fresh Cut	5	15.1%	7	17.5%
Produce - RAC	0	0.0%	2 5.0%	
Seafood	9	27.2% 8		20.0%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	0	0.0%	1	2.5%
Total	**33**	**100%**	**40**	**100%**
Due to rounding, the combined sum may not total 100%.				

Note: The following 15 commodities had zero entries related to *Listeria monocytogenes* hazards for both Year 1 and Year 2: 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.” Similarly, because 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).

Year 2 witnessed a small increase (9%), from 69 to 75, in the number of primary reports for Undeclared Major Food Allergens, with Bakery goods accounting for 20 of the total of 75 entries relating to this hazard category. Within Bakery, cookies (7), breads/croissants (5), and batters/mixes (4) were the reported food types. The nine entries for Frozen Foods were caused predominantly by breading ingredients for frozen foods. The eight entries for Snack Foods were accounted for by potato and tortilla chips (4), popcorn/puffcorn (2), and trail mixes (2).

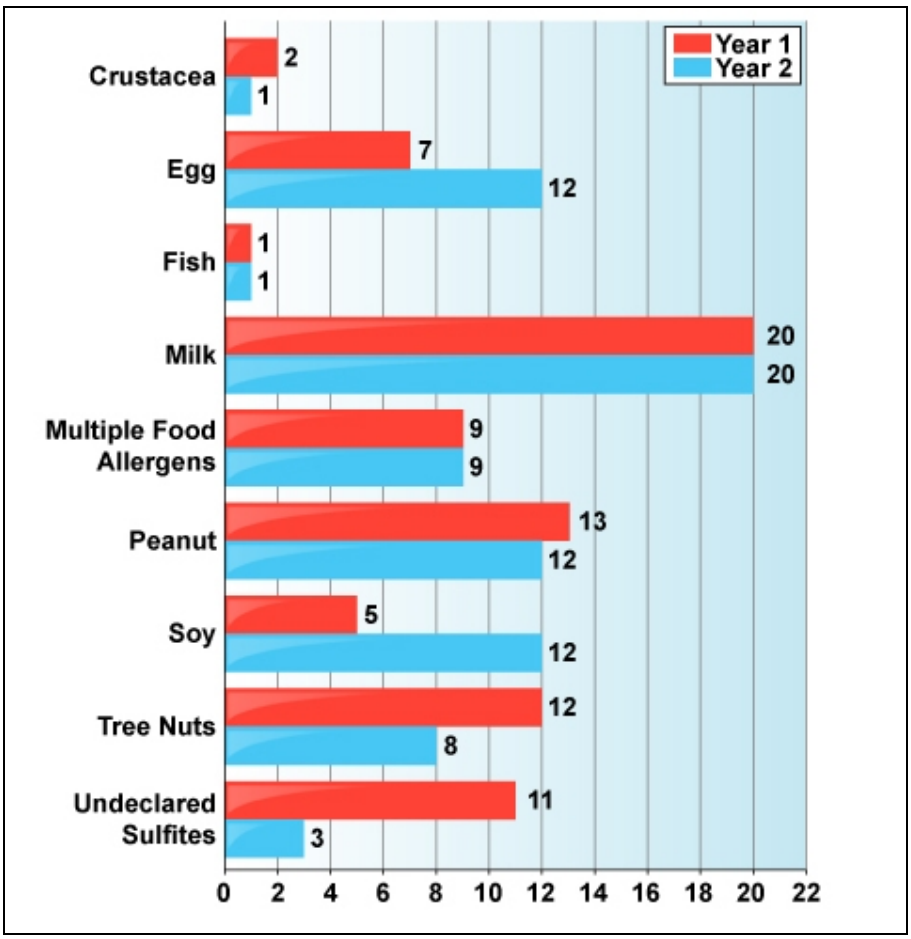
Table 9: Distribution of Undeclared Major Food Allergens Primary RFR Entries by Commodity

Commodity	Year 1		Year 2	
	Number	Percentage	Number	Percentage
Acidified and Low Acid Canned Foods (LACF)	2	2.9%	2	2.6%
Animal Food/Feed	N/A	0.0%	N/A	0.0%
Bakery	14	20.2%	20	26.6%
Beverages	1	1.4%	1	1.3%
Breakfast Cereals	1	1.4%	0	0.0%
Chocolate/Confections/Candy	7	10.1%	7	9.3%
Dairy	8	11.5%	6	8.0%
Dressing/Sauces/Gravies	5	7.2%	7	9.3%
Eggs	0	0.0%	0	0.0%
Frozen Foods	3	4.3%	9	12.0%
Fruit and Vegetable Products	0	0.0%	0	0.0%
Game Meat	0	0.0%	0	0.0%
Meal Replacement/Nutritional Food and Beverages	0	0.0%	1	1.3%
Multiple Food Products	2	2.9%	1	1.3%
Nuts/Nut Products/Seed Products	3	4.3%	4	5.3%
Oil/Margarine	1	1.4%	0	0.0%
Other	0	0.0%	0	0.0%
Pasta	0	0.0%	1	1.3%
Prepared Foods	8	11.5%	3	4.0%
Produce - Fresh Cut	0	0.0%	0	0.0%
Produce - RAC	0	0.0%	0	0.0%
Seafood	1	1.4%	4	5.3%
Snack Foods	6	8.7%	8	10.6%
Soup	4	5.8%	0	0.0%
Spices and Seasonings	1	1.4%	0	0.0%
Stabilizers/Emulsifiers/Flavors/Colors/ Texture Enhancers	2	2.9%	0	0.0%
Sweetener	0	0.0%	0	0.0%
Whole and Milled Grains and Flours	0	0.0%	1	1.3%
Total	**69**	**100%**	**75**	**100%**
Due to rounding, the combined sum may not total 100%.; “N/A” means Not Applicable				

Table 10: Top 3 Commodities with Undeclared Major Food Allergens by Specific Food Allergen in Year 2

Commodity	Egg	Fish	Milk	Multiple Food Allergens	Peanut	Soy	Tree Nuts	Total
Bakery	7	0	5	2	2	0	4	20
Frozen Foods	1	1	4	1	0	2	0	9
Snack Foods	0	0	4	1	0	3	0	8

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



UNDECLARED SULFITES

Table 11: Primary RFR Entries of Undeclared Sulfites by Commodity

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

I. REPORTS ASSOCIATED WITH IMPORTED FOODS

After the Year 1 review of primary RFR entries concerning foods and ingredients from international sources, FDA made a concerted effort to make international trade organizations, foreign government authorities, and foreign food facilities aware of the RFR's requirements. The training video (closed captioning in Arabic, Chinese, French, Japanese, Korean, Portuguese, and Spanish) described in Section C of this report and distribution of the *RFR At A Glance* publication (translated into Spanish, French, and Chinese) were part of the international outreach effort. In addition, the RFR was discussed with 18 delegations of foreign government and industry representatives that visited FDA in FY 2011. The RFR was also the subject of a presentation in Bogotá, Colombia to food safety leaders from 19 countries in the Americas.

Table 12: Distribution of Primary RFR Entries Involving Imported Foods by Commodity and Food Safety Hazard, Year 1

Commodity	*E. coli* O157: H7	Excessive Urea	Foreign Object	*Listeria monocytogenes*	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Uneviscerated Fish	Total	%
Acidified / Low Acid Canned Foods (LACF)										0	0.0%
Animal Food/Feed										0	0.0%
Bakery	1					1	1			3	5.7%
Beverages										0	0.0%
Chocolate/ Confections/Candy							1			1	1.9%
Dairy							2			2	3.8%
Dressing/Sauces/ Gravies										0	0.0%
Egg										0	0.0%
Frozen Foods				2		2				4	7.5%
Fruit and Vegetable Products				1		1		9		11	20.8%
Meal Replacement/ Nutritional Food and Beverages				1			1			2	3.8%
Multiple Food Products										0	0.0%
Nuts/ Nut Products/Seed Products						5	1			6	11.3%
Oil/Margarine										0	0.0%
Pasta										0	0.0%
Prepared Foods										0	0.0%
Produce - Fresh Cut										0	0.0%
Produce - RAC						2				2	3.8%
Seafood				6			1		4	11	20.8%
Snack Foods										0	0.0%
Soup										0	0.0%
Spices/Seasonings						10				10	18.9%
Stabilizers, Emulsifiers/Flavors and Colors/ Texture Enhancers						1				1	1.9%
Sweeteners										0	0.0%
Whole & Milled Grains and Flour										0	0.0%
Total	1	0	0	10	0	22	7	9	4	53	
Percentage	1.8%	0.0%	0.0%	20.7%	0.0%	39.6%	13.2%	17%	7.5%		100%
Due to rounding, the combined sum may not total 100%.											

Primary RFR entries for foods from international sources increased slightly, from 53 in Year 1 to 56 in Year 2. The 56 entries encompassed the following 5 food safety hazards: *Listeria monocytogenes*, *Salmonella*, Other, Uneviscerated Fish, and Undeclared Allergens, distributed across 15 commodities, as shown in Table 13.

Table 13: Distribution of Primary RFR Entries Involving Imported Foods by Commodity and Food Safety Hazard, Year 2

Commodity	*E. coli* O157: H7	Excessive Urea	Foreign Object	*Listeria monocytogenes*	Other	*Salmonella*	Undeclared Allergens	Undeclared Sulfites	Uneviscerated Fish	Total	%
Acidified, Low Acid Canned Foods (LACF)							1			1	1.8%
Animal Food/Feed						3				3	5.4%
Bakery						1				1	1.8%
Beverages										0	0.0%
Chocolate/ Confections/ Candy							2			2	3.6%
Dairy				1						1	1.8%
Dressing/Sauces/ Gravies							1			1	1.8%
Egg										0	0.0%
Frozen Foods						1				1	1.8%
Fruit and Vegetable Products				1		6				7	12.5%
Meal Replacement/ Nutritional Food and Beverages										0	0.0%
Multiple Food Products										0	0.0%
Nuts/ Nut Products/Seed Products						6	1			7	12.5%
Oil/Margarine										0	0.0%
Pasta							1			1	1.8%
Prepared Foods						1				1	1.8%
Produce - Fresh Cut										0	0.0%
Produce - RAC				1		3				4	7.1%
Seafood				1			2		5	8	14.3%
Snack Foods							1			1	1.8%
Soup										0	0.0%
Spices and Seasonings					1	16				17	30.4%
Stabilizers/ Emulsifiers/Flavors/ Colors/ Texture Enhancers										16	28.6%
Sweeteners										0	0.0%
Whole & Milled Grains and Flour										0	0.0%
Total	0	0	0	4	1	37	9	0	5	56	
Percentage	0.0%	0.0%	0.0%	7.1%	1.8%	66.1%	16.1%	0.0%	8.9%		100%
Due to rounding, the combined sum may not total 100%.											

Fifty-six of the 225 primary reports for Year 2 (25%) concerned imported foods or ingredients, coming from at least 19 different countries. When entries for both years are combined, there are more than 30 different countries represented, as shown in Table 14 below.

Table 14: Distribution of Primary RFR Entries for Imported Foods by Country of Origin

Country	Year 1		Year 2	
	Number	Percentage	Number	Percentage
Afghanistan	1	1.9%	0	0.0%
Canada	4	7.6%	6	10.7%
China	13	24.5%	16	28.6%
Colombia	0	0.0%	1	1.8%
Egypt	0	0.0%	4	7.1%
Greece	1	1.9%	0	0.0%
Guatemala	2	3.8%	0	0.0%
India	4	7.5%	7	12.5%
Indonesia	1	1.9%	2	3.6%
Israel	0	0.0%	1	1.8%
Italy	1	1.9%	0	0.0%
Japan	0	0.0%	1	1.8%
Kenya	0	0.0%	1	1.8%
Malawi	1	1.9%	2	3.6%
Mexico	5	9.4%	6	10.7%
Multiple	1	1.9%	0	0.0%
Netherlands	0	0.0%	1	1.8%
Nicaragua	1	1.9%	0	0.0%
Nigeria	1	1.9%	0	0.0%
Norway	1	1.9%	0	0.0%
Pakistan	1	1.9%	0	0.0%
Peru	0	0.0%	1	1.8%
Philippines	0	0.0%	1	1.8%
Poland	2	3.8%	0	0.0%
Russia	2	3.8%	0	0.0%
South Africa	2	3.8%	1	1.8%
Thailand	0	0.0%	1	1.8%
Turkey	4	7.5%	0	0.0%
United Kingdom	2	3.8%	1	1.8%
Venezuela	1	1.9%	1	1.8%
Vietnam	2	3.8%	2	3.6%
Total	**53**	**100%**	**56**	**100%**
Due to rounding, the combined sum may not total 100%.				

J. NEXT STEPS

NEW RULES

FDA's proposed rules on Preventive Controls and Produce Safety which are expected to publish in the near future will 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 will co-convene an International Association for Food Protection (IAFP) Short Symposium with industry entitled "Food Allergen Labeling: Challenges and Best Practices" in July 2012.

IMPORTANCE OF AMENDING REPORTS

FDA will prepare a handout for distribution by FDA field investigators to remind responsible parties to submit amended reports as they gather information to identify the root cause(s) that rendered a food reportable. The handout will explain the importance of the information, both to the individual facility and in helping to protect public health.

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. FDA will increase its efforts to encourage Federal and, particularly, state and local health officials to submit voluntary RFR reports. In addition to reminding State and local officials of the availability of the electronic portal, FDA will produce a 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 FDA's web site and as a DVD.

RFR IMPROVEMENTS

The Food Safety Modernization Act (FSMA) included Section 211, which amends Section 417 of the FD&C Act to provide that:

- FDA may require a responsible party to submit to FDA consumer-oriented information regarding a reportable food. The 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.

- FDA is required to develop and publish a list of acceptable conspicuous locations and manners from which grocery stores must select at least one method for displaying a consumer notification about the reportable food. The list must include:
    - Posting the notification at or near the register;
    - Providing the location of the reportable food;
    - Providing targeted recall information to customers upon purchase of a food; and,
    - Posting in other such prominent and conspicuous locations and manners utilized by grocery stores as of the date of enactment of FSMA to provide notice of such recalls to consumers as considered appropriate by the FDA.

FDA is gathering information and evaluating methods of meeting these requirements efficiently and with minimum disruption of the operations of grocery stores.

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.

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."

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.

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.