U.S. Food and Drug Administration

A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: The Reportable Food Registry

First Reporting Period: September 2009 – March 2010

Introduction

The Reportable Food Registry (RFR or the Registry) was created by Public Law 110-85 which mandated that the Food and Drug Administration (FDA) establish an electronic portal to which industry must and public health officials may report when there is a reasonable probability that an article of human food or animal food/feed (including pet food) will cause serious adverse health consequences or death to humans or animals. The Congressional intent of the Registry is to help FDA better protect public health by tracking patterns of food and feed adulteration and targeting inspection resources. This report presents FDA's experience with the RFR from the opening of the Reportable Food electronic portal on Sept. 8, 2009 until March 31, 2010. Because the Registry has been operational for only a short period, FDA cautions that it is too early to draw inferences concerning patterns of food and feed adulteration.

Background

The Reportable Food Registry was established by section 1005 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by creating a new section 417, Reportable Food Registry [21 U.S.C. 350f], and required FDA to establish an electronic portal by which reports about instances of reportable food must be submitted to FDA within 24 hours by responsible parties and may be submitted by public health officials. These reports may be *primary*, the initial submission about a reportable food, or *subsequent*, a report by either a supplier (upstream) or a recipient (downstream) of a food or food ingredient for which a primary report has been submitted.

The RFR covers all human and animal food/feed (including pet food) regulated by FDA except infant formula and dietary supplements. Other mandatory reporting systems exist for problems with infant formula and dietary supplements. Submissions to the Reportable Food electronic portal provide early warning to FDA about potential public health risks from reportable foods and increase the speed with which the agency and its partners at the state and local levels can investigate the reports and take appropriate follow-up action, including ensuring that the reportable foods are removed from commerce when necessary.

The RFR does not receive reports about drugs or other medical products, reports about products under the exclusive jurisdiction of the U.S. Department of Agriculture, or reports from consumers.

Notable RFR Outcomes

1. Hydrolyzed Vegetable Protein (HVP) – A food manufacturing facility received a shipment of a flavor enhancer, HVP, which tests showed to be positive for *Salmonella* Tennessee. The facility submitted a reportable food report to FDA identifying the problem and its supplier. FDA conducted a Risk Control Review Analysis and consulted with both the primary report submitter and the supplier. The supplier voluntarily recalled the product and submitted a reportable food report to the FDA. FDA requested that the supplier notify the immediate subsequent recipients of the reported HVP which helped FDA identify the many other recipients of the ingredient. FDA worked with the recipients to address their specific situations. This resulted in: 177 products containing the recalled HVP being removed from commerce as of the date of this report. No illnesses associated with the recalled ingredient have been reported.

The HVP recall described here was responsible for 1001 RFR entries, most of them in March 2010 involving at least 11 different commodity categories.

Total RFR Entries Related to HVP Recall by Commodity	
Commodity	**Total RFR Entries**
Acidified/LACF	9
Dairy	178
Dressings, Sauces and Gravies	183
Frozen Foods	15
Meal Replacement/Nutritional Food and Beverages	1
Multiple Products	42
Prepared Foods	13
Snack Foods	154
Soup	57
Spices and Seasonings	113
Stabilizers/Emulsifiers/Flavors and Colors	209
Unknown	27
Total	**1001**

The supplier of the HVP conducted an analysis of the root cause and implemented additional preventive controls in consultation with FDA.

2. Prepared Side Dishes – A food manufacturing facility submitted a reportable food report notifying FDA that two nationally distributed prepared side dishes had been inadvertently produced with an ingredient containing sulfites, which were not mentioned on the labels. Individuals with a severe sensitivity to sulfites run the risk of a serious, potentially life-threatening reaction if they consume sulfites. Within three days the Reportable Food electronic portal received 108 subsequent reports from facilities that had received the implicated products and the manufacturer initiated a voluntary recall. No adverse events associated with these products have been reported as of the date of this report.

The manufacturer of the prepared side dishes implemented additional preventive controls in consultation with FDA, and enhanced their employee training.

3. Glass in animal feed – A dairy farmer received a trailer load of pelleted feed that contained glass of various colors dispersed among the pellets. The dairy farmer reported the incident to the feed company. Upon notification of the incident, the feed company submitted a reportable food report. An investigation by the feed company determined that the glass was a result of an incomplete cleaning of the delivery trailer. The feed company surmised that the glass contamination was due to the nature of the floor in the trailer causing glass, which fell between cracks in the trailer floor boards, to work its way up into the load of feed. The carrier that the feed company hired reported shipping a prior load of recycled glass in the trailer. However, between the shipping of the recycled glass and the feed to the dairy farmer, a load of a raw feed ingredient was delivered to a feed processing facility. An inspection of the processing facility by the state regulatory agency determined that this processing facility had adequate preventive measures in place to remove the glass. No glass was found in the processing facility's finished product. The feed delivered to the dairy farmer was destroyed. No animals were injured. As a result, the feed company re-evaluated the method by which they transport their products.

Implementation and Outreach

FDA published draft RFR Guidance for comment on June 11, 2009. The availability of the guidance was announced in a Federal Register (FR) Notice, constituent updates which are posted on FDA.gov and emailed to a listserv of nearly 54,000 addresses, and a media release. On June 26, 2009 the agency announced three RFR Public Workshops in the FR, constituent updates and a media release, as well as through emails to foreign industry associations and trade bureaus, U.S. Department of Agriculture–Foreign Agricultural Service (USDA-FAS) *attachés*, Washington DC embassies, and FDA/USDA foreign office directors. The workshops were held in College Park MD, Chicago IL and Oakland CA during July and August, 2009.

RFR exhibits and information materials were supplied to FDA field staff for use at local and regional food industry meetings and shows, as well as for distribution during inspections of food facilities. A postcard briefly explaining the RFR and the concomitant importance of maintaining an up-to-date food facility registration, as well as sources of additional information, was sent to all registered domestic food facilities and the U.S. agents for all registered foreign food facilities. In early June of 2009, FDA began and continues to present RFR briefings to food industry groups, state and local regulators, FDA and USDA headquarters and field staff, officials of the Departments of State and Homeland Security and other federal agencies, as well as international trade organizations and competent authorities.

On Sept. 8, 2009, Commissioner of Food and Drugs Margaret A. Hamburg, MD, announced the opening of the Reportable Food electronic portal at the 2009 National Food Policy Conference. FDA issued a media release and held teleconferences for the media and for industry, regulatory and consumer stakeholders. The agency also opened an RFR home page on FDA.gov and linked the updated, final RFR Guidance and a summary, "The Reportable Food Registry At A Glance," to it. Subsequently these documents were translated into Spanish, French and Chinese and posted on FDA.gov. FDA also held an outreach session on the RFR at a meeting of the World Trade Organization Committee on Sanitary-Phytosanitary Measures in Geneva, Switzerland in October, 2009. The meeting was attended by 120 delegates representing 74 countries.

To respond to industry concerns and questions regarding the RFR, FDA established two email contact points, one for technical and computer-related questions about the Reportable Food electronic portal, and another, the RFR Center, to answer questions about Reportable Food Registry policies, procedures and interpretations. During the September 8, 2009 – March 31, 2010 period, the RFR Center received 280 questions. Of these 37 were not RFR-related; 48 asked for clarification of the definition of Reportable Food; 16 wanted further explanation of information required in reports to the portal; 19 concerned uncertainty about whether the sender was a *Responsible Party*; and 81 involved questions about when and how to submit a *Reportable Food report*.

Collaborative Review of RFR Submissions and Notifications

When a report is submitted to the Reportable Food electronic portal, it is sent to the 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. Each report is reviewed 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 District Office 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 also notifies the appropriate state regulatory agency of the report. 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 them 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 U.S. Department of Agriculture, a copy of the report is sent to USDA. If a submission involves a food or feed or an ingredient imported into the U.S., FDA makes contact with the competent authority in the exporting country.

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.

Commodities – in summarizing the statistics generated by reports to the RFR during its first seven months, FDA has sorted the data by type of report (primary, subsequent, amended), by food safety hazard, and by commodity. For explanations of the commodity categories used in this report, please go to "RFR Commodities Definitions."

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 – foreign objects that pose physical hazards typically are hard or sharp objects 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".

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 U.S.

Other – food safety hazards other than *E. coli* O157:H7, *Salmonella*, foreign objects, *Listeria monocytogenes*, or undeclared allergens/intolerances, for which there were two reports or less during the period of this report.

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.

Regulatory 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 under FDA's jurisdiction, including animal feed/food (including pet food) may be reportable foods, except for dietary supplements and infant formula.

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.

Subsequent Report – a report submitted by either a supplier (upstream) or a recipient (downstream) of a food/feed (including ingredients) for which a primary report has been submitted.

Undeclared Food Allergens/Intolerances – 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 soy beans) or proteins derived from them. This category also includes undeclared sulfites. Sulfite intolerances mimic the symptoms caused by a food allergy.

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

Key Findings

Submissions:

As the table below shows, the Reportable Food electronic portal received a total of 2055 submissions between September 8, 2009 – March 31, 2010. A number of these were not submitted by FDA to the RFR, because they concerned drugs or foods within the exclusive jurisdiction of the U.S. Department of Agriculture, they were questions from consumers, or they were test submissions by individuals testing (familiarizing themselves with) the electronic portal. A few reports were not submitted to the RFR because they were subsequently nullified by responsible parties indicating that the reports were submitted in error. Other reports were not submitted to the RFR because FDA determined that they did not meet the reportable food definition after review by the FDA Risk Control Review (RCR) team. (See the "Risk Control Review (RCR) Process For Assessing Reportable Food Reports"). Therefore, the number of Reportable Food Registry entries for the period was 1844.

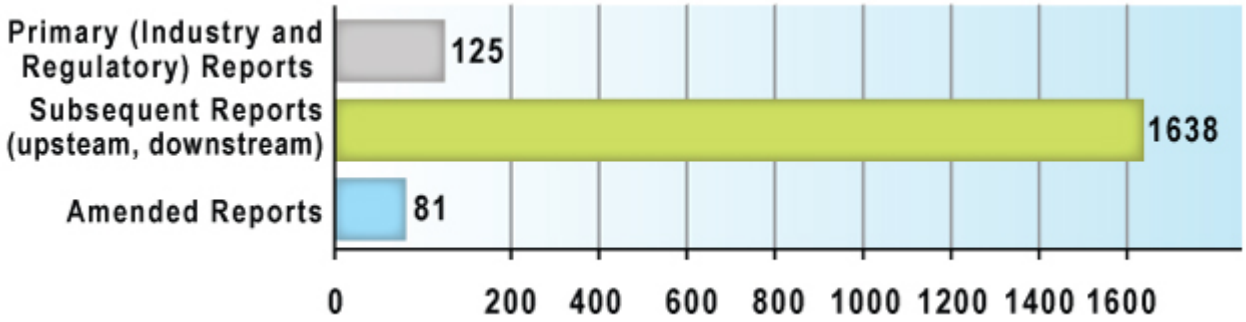
FDA notes that the data presented here represent only a very short period of time at the beginning of the Reportable Food Registry's operation. Future data sets generated from the RFR may or may not be comparable to this data set as a result of the ongoing nature of the implementation of the RFR.

Total Submissions and RFR entries by Month (2009-2010)								
Submission by Month/Year	September 2009	October 2009	November 2009	December 2009	January 2010	February 2010	March 2010	**TOTAL**
Total Submissions Received	50	118	260**	93	224	162	1148***	**2055**
Non-Reportable Submissions*	(12)	(25)	(22)	(41)	(64)	(18)	(29)	**(211)**
Total RFR Entries	38	93	238	53	160	144	1119	**1844**

*See Collaborative Review of RFR Submission and Notifications
** 109 of the 260 were due to undeclared sulfites in Prepared Side Dishes
***1001 of the 1148 were due to Salmonella in Hydrolyzed Vegetable Protein

Of the 1844 RFR entries, 122 were primary reports from industry; 3 were regulatory primary reports submitted voluntarily by federal and state regulatory officials; 1638 were subsequent reports as a result of a primary report; and 81 were amendments to previously submitted Primary or Subsequent Reports.

1844 RFR Entries by Report Type



The 125 primary (industry and regulatory) report RFR entries encompassed seven categories of food safety hazards (*E. coli* O157:H7, Foreign Object, *Listeria monocytogenes*, *Salmonella*, Undeclared Allergens/Intolerances, Uneviscerated Fish, and Other) distributed across 25 commodities for the reporting period from September 8, 2009 to March 31, 2010.

Distribution of 125 Primary RFR Entries by

Commodity and Food Safety Hazard

September 2009 - March 2010

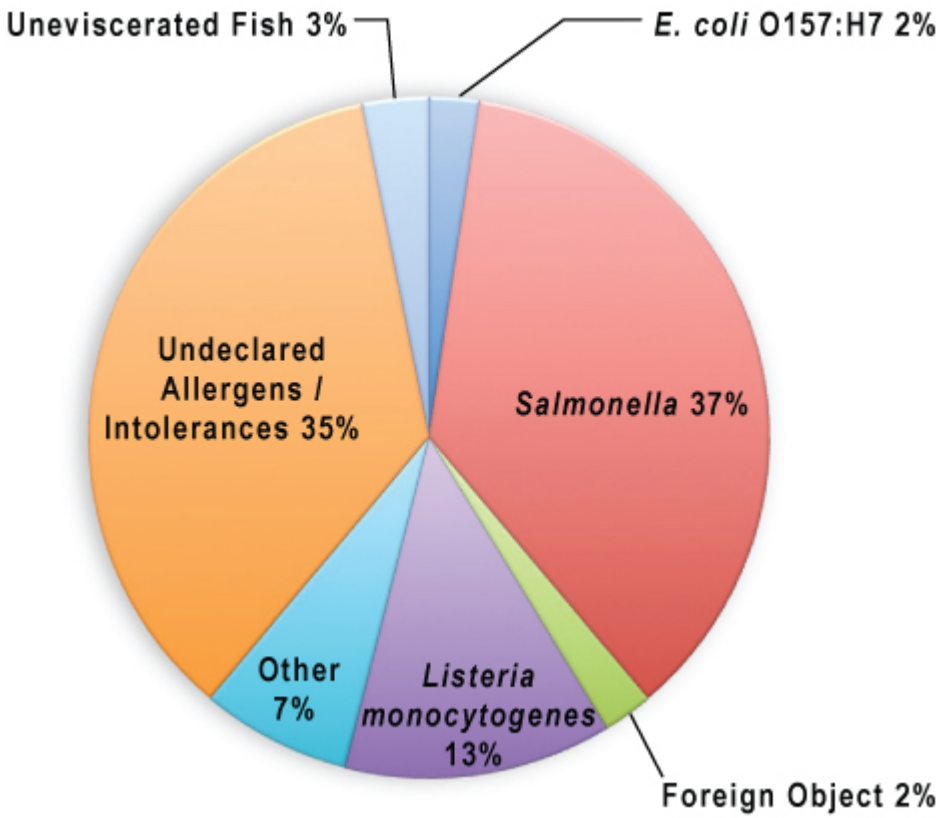
"RFR Commodities Definitions"

Commodity by Food Safety Hazard	*E. coli* O157:H7	Foreign Object	*Listeria monocytogenes*	Other	*Salmonella*	Undeclared Allergens / Intolerances	Uneviscerated Fish	Total
Acidified / LACF						1		**1**
Animal Feed / Pet Food		3		7	4			**14**
Bakery	1					8		**9**
Beverages				1	1	1		**3**
Breakfast Cereals						1		**1**
Choc. / Confections / Candy						4		**4**
Dairy	1		4			5		**10**

Dressings, Sauces and Gravies			1			4		**5**
Egg				1				**1**
Frozen Foods					1	4		**5**
Fruit and Vegetable Products					1	2		**3**
Meal Replacement / Nutritional Food and Beverages					4			**4**
Multiple Products					1			**1**
Nuts, Nut Products, and Seed Products			1		5	1		**7**
Oil/Margarine						1		**1**
Prepared Foods			1			5		**6**
Produce - Fresh Cut			2					**2**
Produce - RAC					9			**9**
Seafood			7			1	4	**12**
Snack Foods					1	2		**3**
Soup						4		**4**
Spices and Seasonings					11			**11**
Stabilizers / Emulsifiers / Flavors and Colors					5			**5**
Sweeteners								
Whole & Milled Grains and Flours	1				3			**4**
Total	3	3	16	9	46	44	4	**125**

The 125 primary (industry and voluntary) report RFR entries encompassed seven categories of food safety hazards: *E. coli* O157:H7 - 2%; *Salmonella* - 37%; Foreign Objects - 2%; *Listeria monocytogenes* - 13%, Other - 7%; Undeclared Allergens/Intolerances - 35%; and Uneviscerated Fish - 3%.

Percent Distribution of 125 Primary RFR Entries by Food Safety Hazard



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

Current Developments

On May 24, 2010, FDA and the National Institutes of Health (NIH) launched the Safety Reporting Portal (SRP), a new web site for reporting several types of problems, including reportable foods. Consumers can also use the site to report problems with pet foods and pet treats. The SRP replaces the electronic portal FDA launched in September 2009 for the Reportable Food Registry (RFR). The SRP features new, more user-friendly software than previously available on the Reportable Food electronic portal. Responsible parties and/or public health officials can open accounts that provide greater convenience than the old electronic portal: account holders are able to save partial or completed reports; have new or amended reports pre-populated with much of their information; view any previous submissions they have made via the SRP; and submit attachments as unified parts of their submissions. Concurrently with the launch of the SRP, FDA published "Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)" containing draft explanations to aid responsible parties and/or public health officials when submitting RFR reports via the SRP.

In order to protect public health by improved tracking of patterns of adulteration, all responsible parties need to be aware of their obligations under this law to report instances of reportable food. As of the date of this report, there are approximately 161,000 domestic and 244,000 foreign facilities that manufacture, process, pack, or hold food for human and animal consumption in the U.S. that have registered with the FDA under the requirements of Sec. 415(a) of the FD&C Act. The requirement to submit reportable food reports to the FDA applies to all of them. Extensive outreach, direct and indirect, domestic and international, has been conducted to raise awareness among the regulated firms. This significant outreach effort is continuing with presentations at annual meetings and conferences of various industry associations and other food/feed safety events; in concert with USDA's Foreign Agricultural Service and FDA foreign posts, through both in-person presentations and via webinars. In addition, FDA inspectors and public affairs personnel continue to distribute information about the RFR to the food/feed industry at the state and local level.

Also, FDA is working to enhance collaboration with other federal partners and state and local public health officials in conducting follow-up to reportable food reports and associated recalls in order to use resources and expertise more efficiently. A system is under development that will electronically notify the appropriate state agencies when a reportable food report is filed in their jurisdiction, even further improving the response time for the federal-state collaborations. For more information concerning the RFR or the key findings in this report, please contact the RFR Center at RFRSupport@fda.hhs.gov.