In this document:

FDA Foods Program

THE REPORTABLE FOOD REGISTRY: A NEW APPROACH TO TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION

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

FDA Foods Program

THE REPORTABLE FOOD REGISTRY: A NEW APPROACH TO TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION

First Annual Report: September 8, 2009 – September 7, 2010

January 2011

This report is a measure of our success in receiving early warning on problems with food and feed. The data in this report represent an important tool for targeting our inspection resources, bringing high risk commodities into focus, and driving positive change in industry practices – all of which will better protect the public health.

Several key U.S. industries are already re-evaluating their hazards and preventive controls, core principles of the Food Safety Modernization Act recently passed by Congress. We anticipate improved reporting as we continue our vigorous outreach to food facilities through federal, state, local and foreign agencies, to help us expand the positive effect of the RFR on the safety of the U.S. food supply.

-Michael R. Taylor
Deputy Commissioner for Foods

CONTENTS

A. 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 September 8, 2009 until September 7, 2010.

B. HIGHLIGHTS

- **2240 Reportable Food Submissions Were Entered into the Registry**
  A total of 2600 submissions were received of which 360 were determined to be non-reportable after review by the FDA Risk Control Review Team (see "Risk Control Review (RCR) Process for Assessing Reportable Food Reports").

- **RFR Migration**
  On May 24, 2010, FDA and the National Institutes of Health (NIH) launched the HHS Safety Reporting Portal (SRP), a new web site for reporting several types of problems, including reportable foods. 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 was available on the original RFR portal.

- **RFR-Driven Food Industry Changes**

  – Several large third party food safety audit firms have incorporated the requirements of the RFR into their audit standards or the guidance documents they provide their clients.

  – One of the nation's largest baking industry trade associations is reviewing and enhancing its industry guidance on preventing unintended allergens from being introduced into bakery products.

  – Following publication of reportable food data relating to *Salmonella* in spices and seasonings, a national spice trade association is developing guidance to reduce the risk of pathogen contamination in spices.

  – One of the nation's largest food retailers now instructs its suppliers around the world about their RFR responsibilities at its periodic summits for suppliers.

- **FDA Initiatives Associated with RFR Data**

  – In three notable situations, reportable food submissions alerted FDA to significant food safety issues and helped the agency to quickly respond to help ensure that potentially harmful products were not available in the marketplace.

— Because of reportable food submissions involving *Salmonella* in nuts and nut products, FDA intends to include an annex on nuts in guidance for industry currently under development on *Salmonella* in low-moisture foods.

— FDA is preparing a publication explaining FDA's sulfite regulation and labeling requirements as a result of reportable food data concerning imported dried fruits and vegetables containing undisclosed sulfites.

— In two cases reportable food submissions triggered follow-up investigations by FDA resulting in two firms being placed on Import Alert.

— FDA issued six Import Bulletins to increase surveillance by FDA investigators at ports of entry as a result of reportable food submissions.

— FDA issued four field assignments as a result of RFR data for increased inspection and sampling of certain imported and domestic products based on reportable food submissions

— FDA has revised its internal RFR system to distribute information on reportable food submissions automatically to commissioned officials at appropriate state agencies in addition to FDA District Offices.

C. 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 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.

D. IMPLEMENTATION AND OUTREACH

FDA published draft RFR guidance for industry 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.

FDA supplied RFR exhibits and information materials to agency field staff for use at local and regional food industry meetings and shows, as well as for distribution during inspections of food facilities. FDA sent 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, to all registered domestic food facilities and the U.S. agents for all registered foreign food facilities. In early June 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 September 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, FDA had these documents 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.

Safety Reporting Portal

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. The SRP replaces the electronic portal FDA launched in September 2009 for the RFR. The SRP features new, more user-friendly software than previously available on the Reportable Food electronic portal. Responsible parties and public health officials can open accounts that provide greater convenience than the former Reportable Food 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.

FDA issued a media release and constituent update announcing the opening of the SRP, and held teleconferences on the new portal for the media and for industry, regulatory and consumer stakeholders. The agency updated the RFR homepage on FDA.gov to explain the move to the SRP, and linked updated versions of The Reportable Food Registry at a Glance in English, Spanish, French, and Chinese to it. 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 public health officials when submitting RFR reports via the SRP. The agency posted the draft guidance for industry on FDA.gov for public comment and linked it to the RFR home page.

RFR presentations and briefings to food industry groups, state and local regulators, FDA and USDA headquarters and field staff, officials of other federal agencies, and international trade organizations and competent authorities, have continued with updated information about the portal, the new software, and the draft second edition of the guidance for industry.

RFR Assistance

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

- The RFR Center at RFRSupport@fda.hhs.gov which answers questions about Reportable Food Registry policies, procedures and interpretations.

- The SRP Service Desk at Support.srp@jbsinternational.com, for technical and computer-related questions about the SRP, which includes the Reportable Food Registry.

During the September 8, 2009 – September 7, 2010 period, the RFR Center received 357 questions. Of these 49 were not RFR-related; 56 asked for clarification of the definition of reportable food; 17 wanted further explanation of information required in reports to the portal; 19 concerned uncertainty about whether the sender was a responsible party; and 83 involved questions about when and how to submit a reportable food report.

E. **COLLABORATIVE REVIEW OF RFR SUBMISSIONS AND NOTIFICATIONS**

When a reportable food report is submitted to the SRP, 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. Appropriate regulatory commissioned officials in the state or states involved are automatically notified of any reportable food reports that pertain to their jurisdictions. 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 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 contacts the competent authority in the exporting country.

F. 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, 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 District Offices – FDA's Office of Regulatory Affairs maintains 19 district offices at locations throughout the Unites 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 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 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."

Import Alerts – guidance documents for FDA field staff concerning significant re-occurring, 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 U.S.

Other – food safety hazards other than *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, Uneviscerated Fish, Foreign Objects 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.

G. KEY FINDINGS

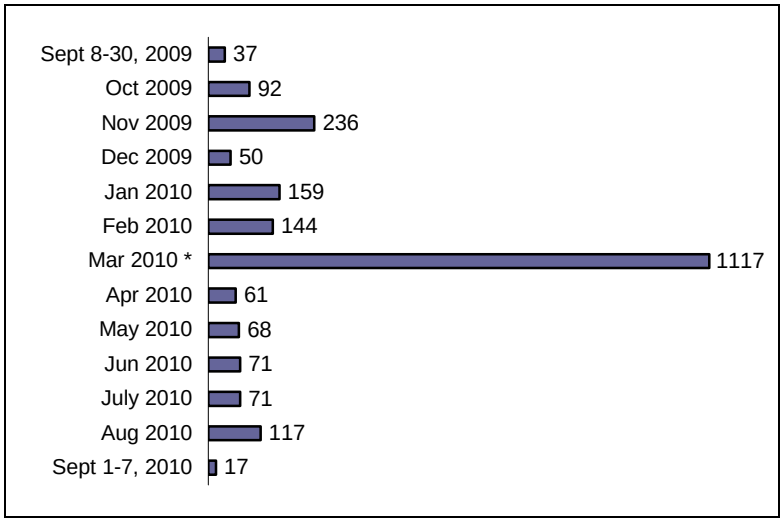
As shown in Figure 1, the Reportable Food electronic portal received a total of 2,600 submissions between September 8, 2009, and September 7, 2010. Of these, 360 were not submitted by FDA to the RFR, because FDA determined that they did not meet the reportable food definition after review by the FDA Risk Control Review (RCR) team. (See the "Risk Control Review (RCR) Process for Assessing Reportable Food Reports") These non-reportable submissions concerned drugs or medical devices which are regulated by FDA's other product Centers. Other non-reportable submissions were for foods under the exclusive jurisdiction of the U.S. Department of Agriculture. Others submissions were questions from consumers, or 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. Therefore, the number of Reportable Food Registry entries for the period was 2240 as shown in Figures 1 and 2.

Figure 1 - Reportable Food Submissions and Registry Entries by Month

Month/Year	Sept 8-30 2009	Oct 2009	Nov 2009	Dec 2009	Jan 2010	Feb 2010	Mar 2010	Apr 2010	May 2010	June 2010	July 2010	Aug 2010	Sept 1-7 2010	Total
Total Submissions Received	50	118	260**	93	224	162	1148 ***	92	94	128	80	134	17	2600
Non-Reportable Submission *	(13)	(26)	(24)	(43)	(65)	(18)	(31)	(31)	(26)	(57)	(9)	(17)	0	(360)
Total RFR Entries	37	92	236	50	159	144	1117	61	68	71	71	117	17	2240

*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

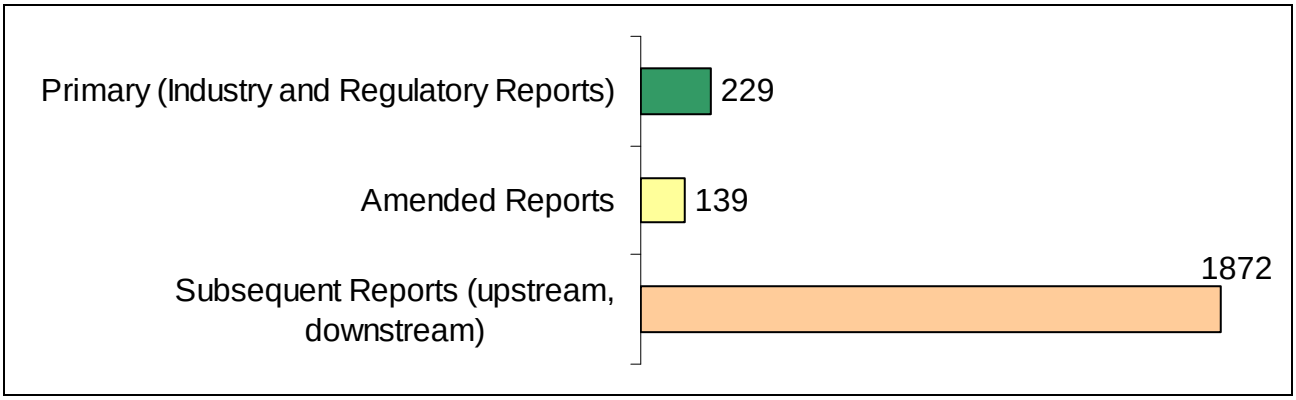
Figure 2 - Reportable Food Registry Entries by Month



*1001 of the 1117 Reportable Food Registry Entries in March 2010 were due to *Salmonella* in Hydrolyzed Vegetable Protein

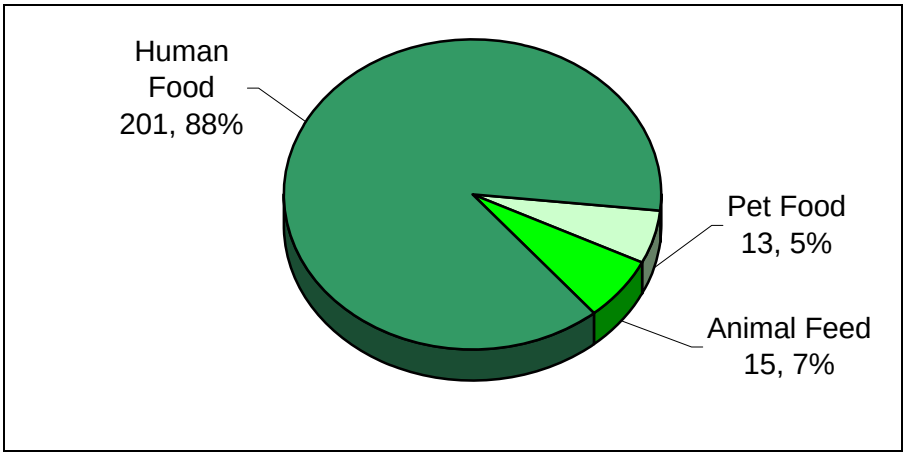
Of the 2240 RFR entries, 229 were primary reports (226 were industry primary reports and 3 were regulatory primary reports submitted voluntarily by federal and state regulatory officials);1872 were subsequent reports as a result of a primary report; and 139 were amendments to previously submitted primary or subsequent reports as shown in Figure 3.

Figure 3 - Distribution of Reportable Food Registry Entries by Report Type



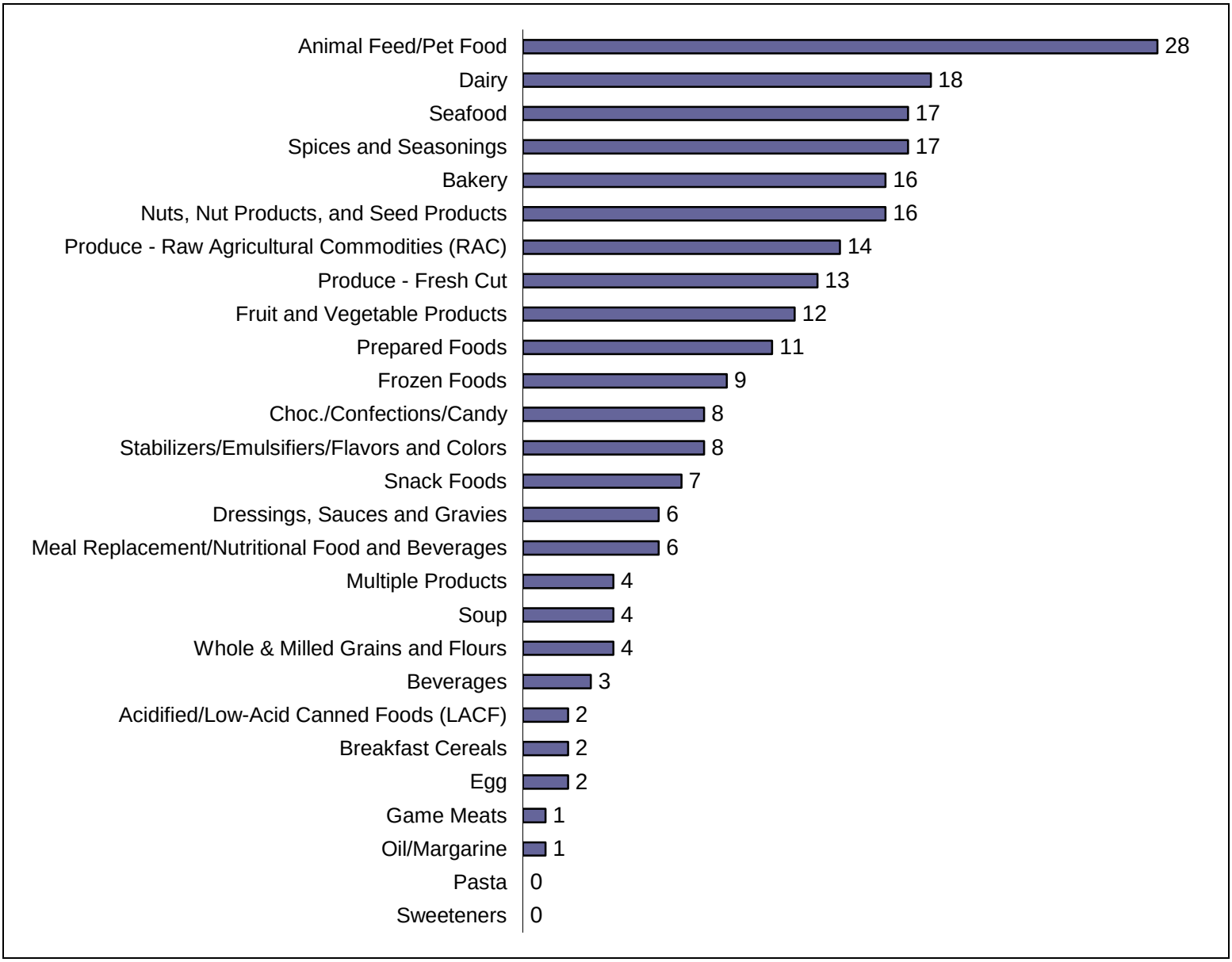
The 229 primary RFR entries included 201 concerning Human Food, and 28 concerning Pet Food and Animal Feed as shown in Figure 4.

Figure 4 – Distribution of 229 Primary Reports by Human Food, Pet Food and Animal Feed



The 229 Primary RFR entries involved 25 commodities as shown in Figure 5.

Figure 5 – Distribution of 229 Primary RFR Entries by Commodity
RFR Commodity Definitions



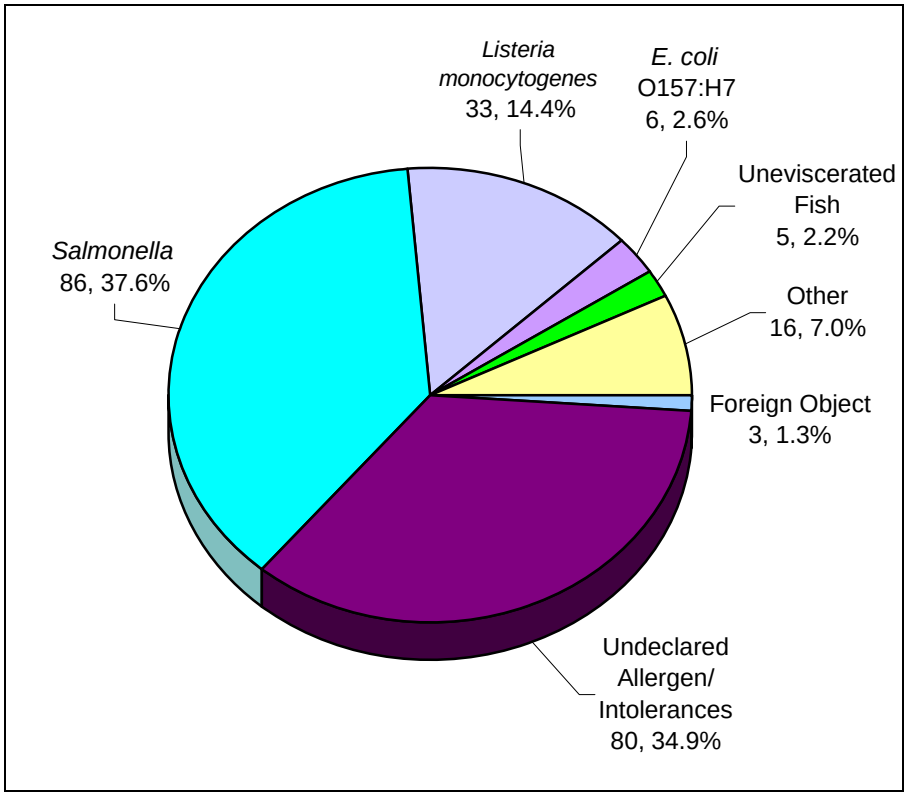
The 229 primary (industry and regulatory) RFR entries encompassed seven categories of food safety hazards (*E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, uneviscerated fish, foreign object, undeclared allergens/intolerances, and other) distributed across 25 commodities for the reporting period from September 8, 2009 to September 7, 2010 as shown in Figure 6.

Figure 6 – Distribution of 229 Primary RFR Entries by Commodity and Food Safety Hazard
RFR Commodity Definitions

Commodity/ Food Safety Hazard	*E. coli* O157:H7	*Listeria monocytogenes*	*Salmonella*	Uneviscerated Fish	Foreign Object	Undeclared Allergens/ Intolerances	Other	Total
Animal Feed/Pet Food	0	0	13	0	3	0	12	28
Dairy	1	8	1	0	0	8	0	18
Seafood	0	9	0	5	0	2	1	17
Spices and Seasonings	0	0	16	0	0	1	0	17
Bakery	1	0	1	0	0	14	0	16
Nuts, Nut Products, and Seed Products	0	1	12	0	0	3	0	16
Produce - RAC	0	0	14	0	0	0	0	14
Produce - Fresh Cut	2	5	5	0	0	0	1	13
Fruit and Vegetable Products	0	2	1	0	0	9	0	12
Prepared Foods	0	2	0	0	0	9	0	11
Frozen Foods	0	3	3	0	0	3	0	9
Choc./Confections/ Candy	0	0	1	0	0	7	0	8
Stabilizers/ Emulsifiers/Flavors and Colors	0	0	6	0	0	2	0	8
Snack Foods	0	0	1	0	0	6	0	7
Dressings, Sauces and Gravies	0	1	0	0	0	5	0	6
Meal Replacement/ Nutritional Food and Beverages	0	1	5	0	0	0	0	6
Multiple Products	0	1	1	0	0	2	0	4
Soup	0	0	0	0	0	4	0	4
Whole & Milled Grains and Flours	1	0	3	0	0	0	0	4
Beverages	0	0	1	0	0	1	1	3
Acidified/LACF	0	0	0	0	0	2	0	2
Breakfast Cereals	0	0	1	0	0	1	0	2
Egg	0	0	1	0	0	0	1	2
Game Meats	1	0	0	0	0	0	0	1
Oil/Margarine	0	0	0	0	0	1	0	1
Pasta	0	0	0	0	0	0	0	0
Sweeteners	0	0	0	0	0	0	0	0
Grand Total	**6**	**33**	**86**	**5**	**3**	**80**	**16**	**229**
Percentage	**2.6%**	**14.4%**	**37.6%**	**2.2%**	**1.3%**	**34.9%**	**7.0%**	**100.0%**

The 229 primary (industry and regulatory) RFR entries encompassed seven categories of food safety hazards: *Listeria monocytogenes* – 14.4%; *E. coli* O157:H7 – 2.6%; uneviscerated fish – 2.2%; other – 7%; foreign objects – 1.3%; undeclared allergens/intolerances – 34.9%; and *Salmonella* – 37.6% as shown in Figure 7.

Figure 7 - Distribution of 229 Primary RFR Entries by Food Safety Hazard



H. RFR-DRIVEN FOOD INDUSTRY CHANGES

Changes have occurred in areas of the food industry regulated by FDA because of the RFR's reporting requirements or the information resulting from reports to the Reportable Food electronic portal.

Audit Firms

Third Party Food Safety Audit Firms: Several large providers of food safety audits have incorporated the requirements of the RFR into their audit standards or their guidance documents they provide their clients, both domestic and foreign. Additional initiatives by some of these firms include webinars and articles in their newsletters for clients and other industry publications explaining the principles of the RFR and the information necessary to submit a report. At least one audit company has included an RFR question on its audit form for food plants to determine the plant's awareness of its RFR obligations and another company's audit

form asks if the facility to be audited has a written standard for complying with the RFR's requirements.

Guidance

New Industry Guidance for Spices: Following a high number of primary reports involving *Salmonella* in spices and seasonings (see Figure 9 which shows the distribution of RFR entries involving *Salmonella* by commodity group), a national trade association is developing guidance to reduce risk of pathogen contamination in spices.

Enhanced Industry Guidance for Baked Goods: A national baking trade association is reviewing and enhancing its guidance on preventing unintended allergens from being introduced into bakery products. Reportable food reports concerning undeclared allergens in the baking industry are shown in Figure 10 which shows the distribution of RFR entries involving undeclared allergens/intolerance by commodity group.

Outreach

Large Food Retailer Stresses Suppliers' RFR Responsibilities: One of the nation's largest food retailers has instructed its suppliers around the world about their RFR responsibilities and requires suppliers to provide the retailer with the Individual Case Safety Report number issued when a submission is made to the RFR.

I. REGULATORY INITIATIVES RESULTING FROM RFR DATA

FDA studies Reportable Food Registry 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 resulting from the RFR's first year of operation include the following.

Notable Outcomes

- **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. 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 was responsible for 1001 RFR entries, most of them in March 2010 involving at least 11 different commodity categories.

Figure 8 - Total RFR Entries Related to HVP Recall by Commodity

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

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

- **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 since the report was submitted.

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

- **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.

RFR entries triggered follow-up investigations by FDA that resulted in Import Alerts, Import Bulletins, field assignments, and new or revised guidance documents and procedures.

Import Alerts

- *Listeria monocytogenes* in cold smoked salmon from Poland
- *Listeria monocytogenes* in cooked shrimp from Indonesia

Import Bulletins

- *Salmonella* in imported macadamia nuts from several African countries
- *Salmonella* in blueberries from a facility in Canada
- Undeclared peanuts in sesame candy products from Vietnam
- *Clostridium botulinum* potential in uneviscerated whole fish
- *Salmonella* in macadamia nuts from a firm in South Africa
- *Listeria monocytogenes* in sushi rolls from a firm in the United Kingdom

Field Assignments

- *Salmonella* in imported produce
- *Salmonella* in hydrolyzed vegetable protein
- Undeclared allergens in baked goods
- *Salmonella* in nutrition bars

Guidance, Publications, and Procedures

- **FDA Draft Guidance for Industry on *Salmonella* in Low-Moisture Foods:** FDA is developing industry guidance on the control of *Salmonella* in low-moisture foods and intends to include an annex on nuts because of a high incidence of primary RFR entries involving *Salmonella* in nuts and nut products.
- **Publication on Sulfite Labeling Requirements:** FDA is preparing a publication explaining FDA's sulfite regulation and labeling requirements because of RFR entries concerning imported dried fruits and vegetables with undisclosed sulfites. The publication will be targeted to FDA's regulatory counterparts and the food industry in countries exporting dried fruits and vegetables to the United States.
- **Automatic Notification to State Agencies:** FDA has revised its internal RFR communications system so that information on all submissions to the RFR is automatically emailed to appropriate commissioned officials in the state or states involved.

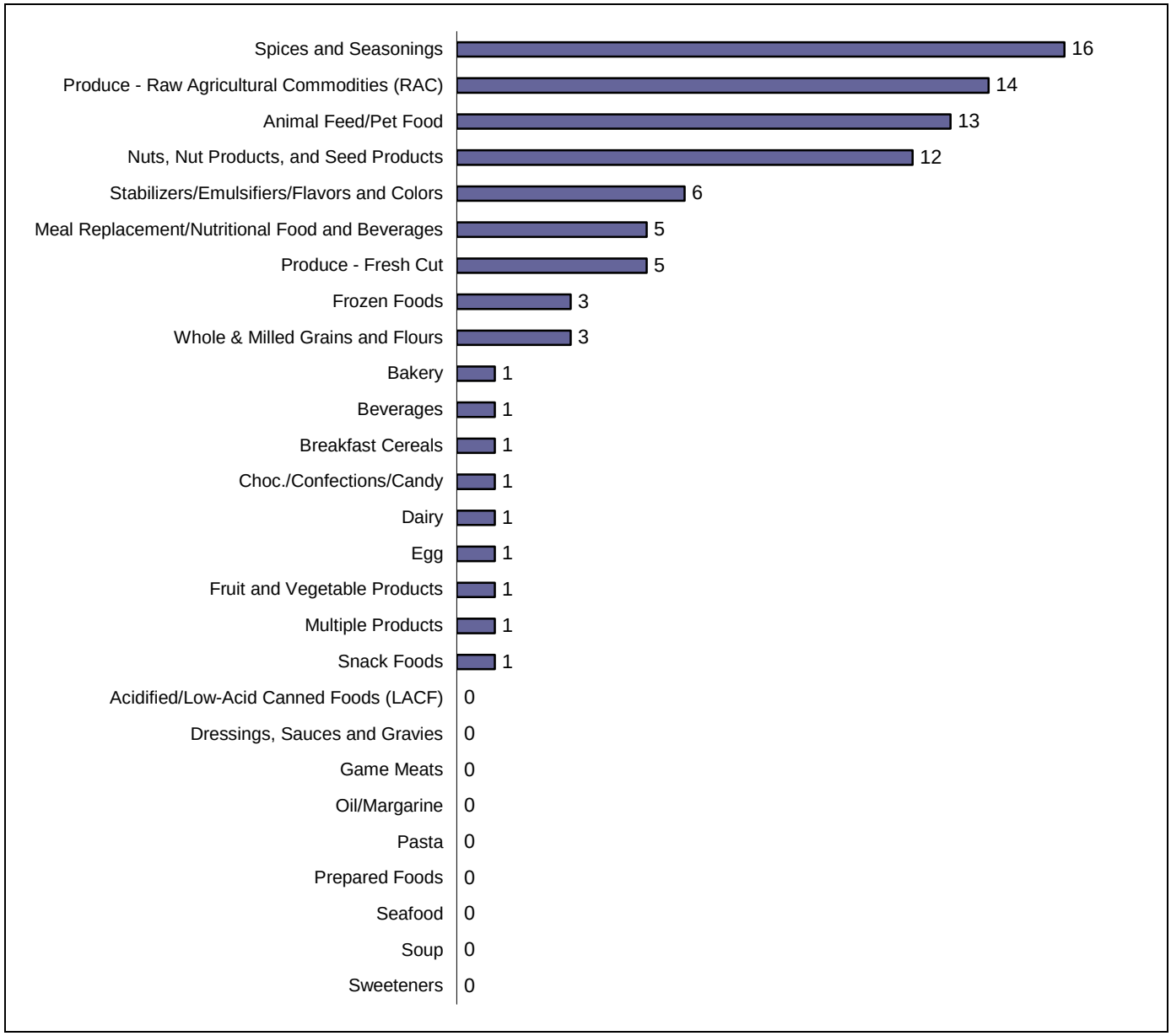
J. FOOD INDUSTRY ISSUES IDENTIFIED BY RFR ENTRIES

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. Data from the first year of operation of the RFR suggest two particularly significant issues in multiple commodity groups that require attention: *Salmonella* and undeclared allergens/intolerance as shown in Figures 9 and 10.

Salmonella

Because of the relatively large number of primary RFR entries caused by *Salmonella* contamination (37.6 %), FDA is including specific information in this report about the commodities involved (see Figure 9) to increase food industry awareness of *Salmonella* contamination issues. There were 86 RFR entries because of *Salmonella* contamination, involving 18 commodity categories.

Figure 9 – Distribution of *Salmonella* Primary RFR Entries by Commodity



Undeclared Allergens/Intolerances

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 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 sulfites be declared on food labels. Because of the relatively large number of RFR entries caused by undeclared allergens/intolerances (34.9%), FDA is including more specific allergens/intolerances and commodity information about these entries in this document to increase food industry awareness of undeclared allergens/intolerances problems.

Figure 10 identifies the commodities involved in reports of undeclared allergens/intolerances and the number of entries for each commodity.

Figure 10 – Distribution of Primary RFR Entries of Undeclared Allergen/Intolerance by Commodity

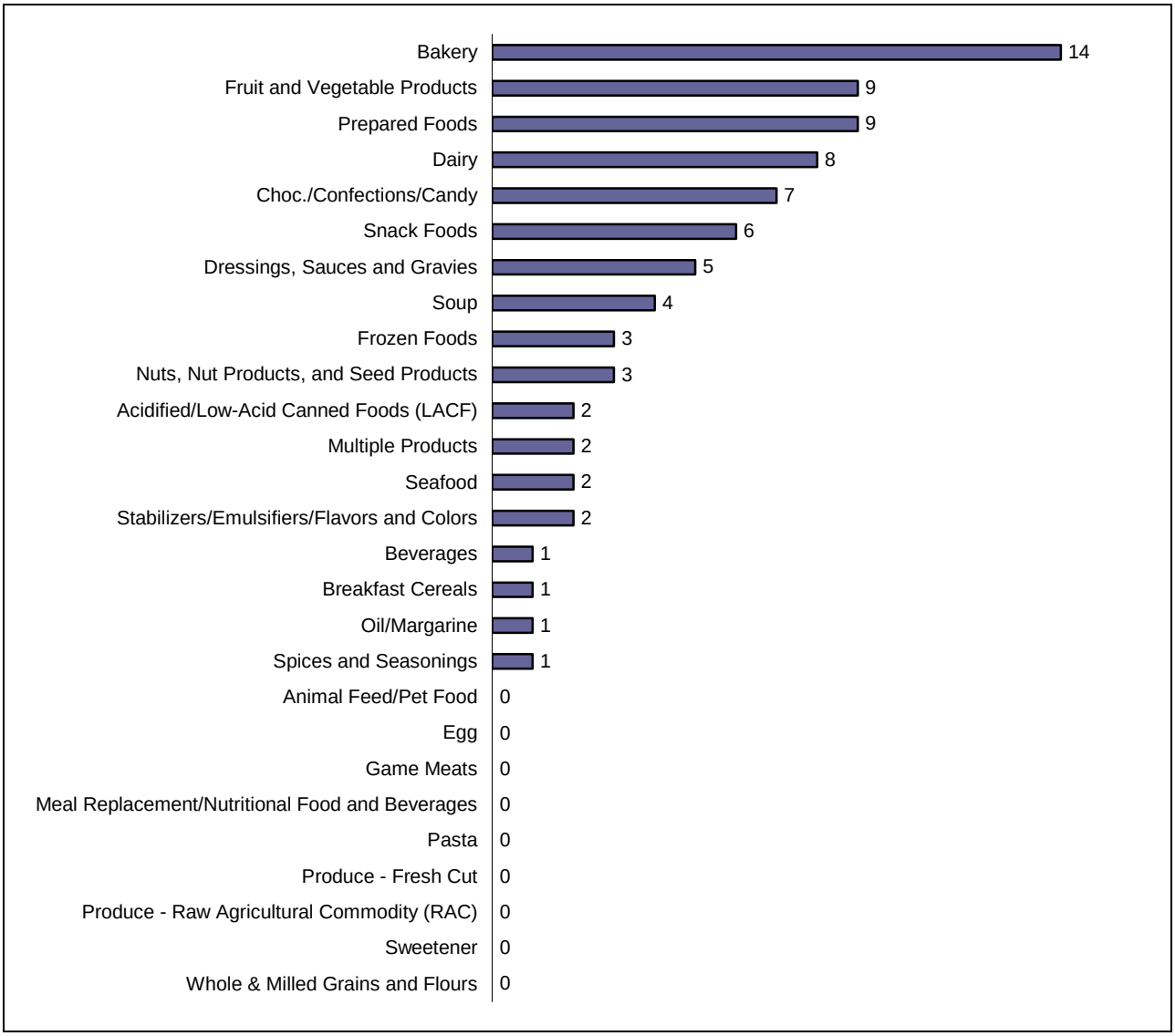
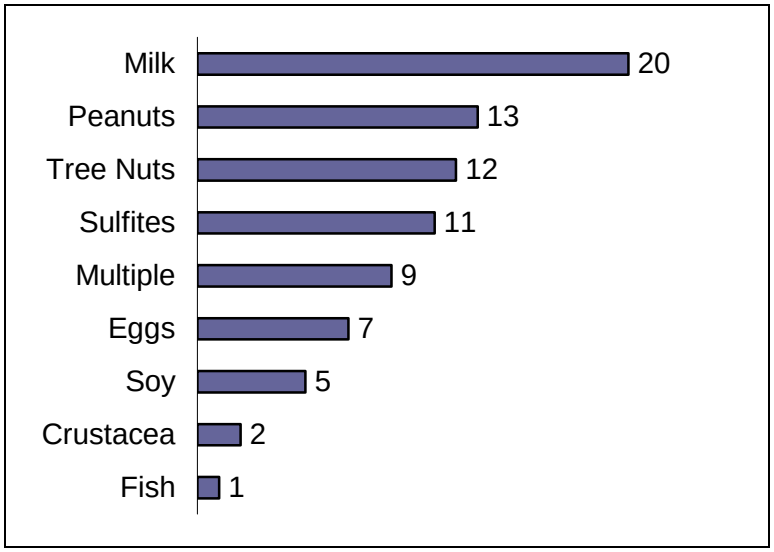


Figure 11 identifies the number of reports by specific allergen/intolerance. There were 80 primary RFR entries because of undeclared allergens/intolerances of which 69 were due to undeclared allergens and 11 were due to undeclared sulfites.

Figure 11 – Distribution of Primary RFR Entries of Undeclared Allergen/Intolerance by Specific Major Allergen and Intolerance (sulfites)



K. REPORTS ASSOCIATED WITH INTERNATIONAL SOURCES

Primary RFR Entries for the reporting period were reviewed to determine how many of them concerned foods and ingredients from international sources. The 53 primary RFR entries encompassed five categories of food safety hazards (*E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, uneviscerated fish, and undeclared allergens/intolerances) distributed across 12 commodities for the reporting period from September 8, 2009 to September 7, 2010 as shown in Figure 12.

Figure 12 – Distribution of International-Sourced Primary RFR Entries by Commodity and Food Safety Hazard

Commodity/Food Safety Hazard	*E. coli* O157:H7	*Listeria monocytogenes*	*Salmonella*	Uneviscerated Fish	Foreign Object	Undeclared Allergens/ Intolerances	Other	Total
Fruit and Vegetable Products	0	1	1	0	0	9	0	11
Seafood	0	6	0	4	0	1	0	11
Spices and Seasonings	0	0	10	0	0	0	0	10
Nuts, Nut Products, and Seed Products	0	0	5	0	0	1	0	6
Frozen Foods	0	2	2	0	0	0	0	4
Bakery	1	1	0	0	0	1	0	3
Dairy	0	0	0	0	0	2	0	2
Produce - RAC	0	0	2	0	0	0	0	2
Choc./ Confections/ Candy	0	0	0	0	0	1	0	1
Meal Replacement/ Nutritional Food and Beverages	0	1	0	0	0	0	0	1
Soup	0	0	0	0	0	1	0	1
Stabilizer/ Emulsifiers/ Flavors and Colors	0	0	1	0	0	0	0	1
Acidified/LACF	0	0	0	0	0	0	0	0
Animal Feed/Pet Food	0	0	0	0	0	0	0	0
Beverages	0	0	0	0	0	0	0	0
Breakfast Cereals	0	0	0	0	0	0	0	0
Dressings, Sauces and Gravies	0	0	0	0	0	0	0	0
Egg	0	0	0	0	0	0	0	0
Game Meats	0	0	0	0	0	0	0	0
Multiple Products	0	0	0	0	0	0	0	0
Oil/Margarine	0	0	0	0	0	0	0	0
Pasta	0	0	0	0	0	0	0	0
Prepared Foods	0	0	0	0	0	0	0	0
Produce - Fresh Cut	0	0	0	0	0	0	0	0
Snack Foods	0	0	0	0	0	0	0	0
Whole & Milled Grains and Flours	0	0	0	0	0	0	0	0
Grand Total	**1**	**11**	**21**	**4**	**0**	**16**	**0**	**53**
Percentage	**1.9%**	**20.8%**	**39.6%**	**7.5%**	**0.0%**	**30.2%**	**0.0%**	**100.0%**

The review showed that 53 of the 229 primary reports were caused by foods or ingredients from foreign sources, coming from at least 21 different countries as shown in Figure 13.

Figure 13 – Distribution of Internationally-Sourced Primary RFR Entries by Country of Origin

Country	Entries
China	13
Mexico	5
Canada	4
India	4
Turkey	4
Guatemala	2
Poland	2
Russia	2
South Africa	2
United Kingdom	2
Vietnam	2
Afghanistan	1
Greece	1
Indonesia	1
Italy	1
Malawi	1
Nicaragua	1
Nigeria	1
Norway	1
Pakistan	1
Venezuela	1
Multiple (China, India, and Vietnam)	1
Total	**53**

L. NEXT STEPS

All facilities engaged in manufacturing, processing, packing, or holding FDA-regulated food for consumption by humans or animals in the United States are required by Section 415 of the FD&C Act to register with FDA. As of February 2010, there were 156,008 registered domestic food facilities and 230,730 registered foreign food facilities.[1] During the first year of the Reportable Food Registry, the number of primary RFR entries involving foods and ingredients from international sources was relatively small. FDA believes this may be, in part, the result of a lack of awareness of the RFR and its requirements by many foreign food facilities. Therefore, in addition to the vigorous RFR outreach program begun in June, 2009, FDA intends to pursue the following initiatives in 2011 to target the international arena:

[1] See FY 2011 Food and Drug Administration Congressional Justification of Estimates for Appropriations Committee.

Video

FDA is preparing an RFR training video that will explain the RFR and its requirements. FDA intends to post the video on FDA.gov and provide close-captioning in Arabic, Chinese, French, Japanese, Korean, Portuguese and Spanish.

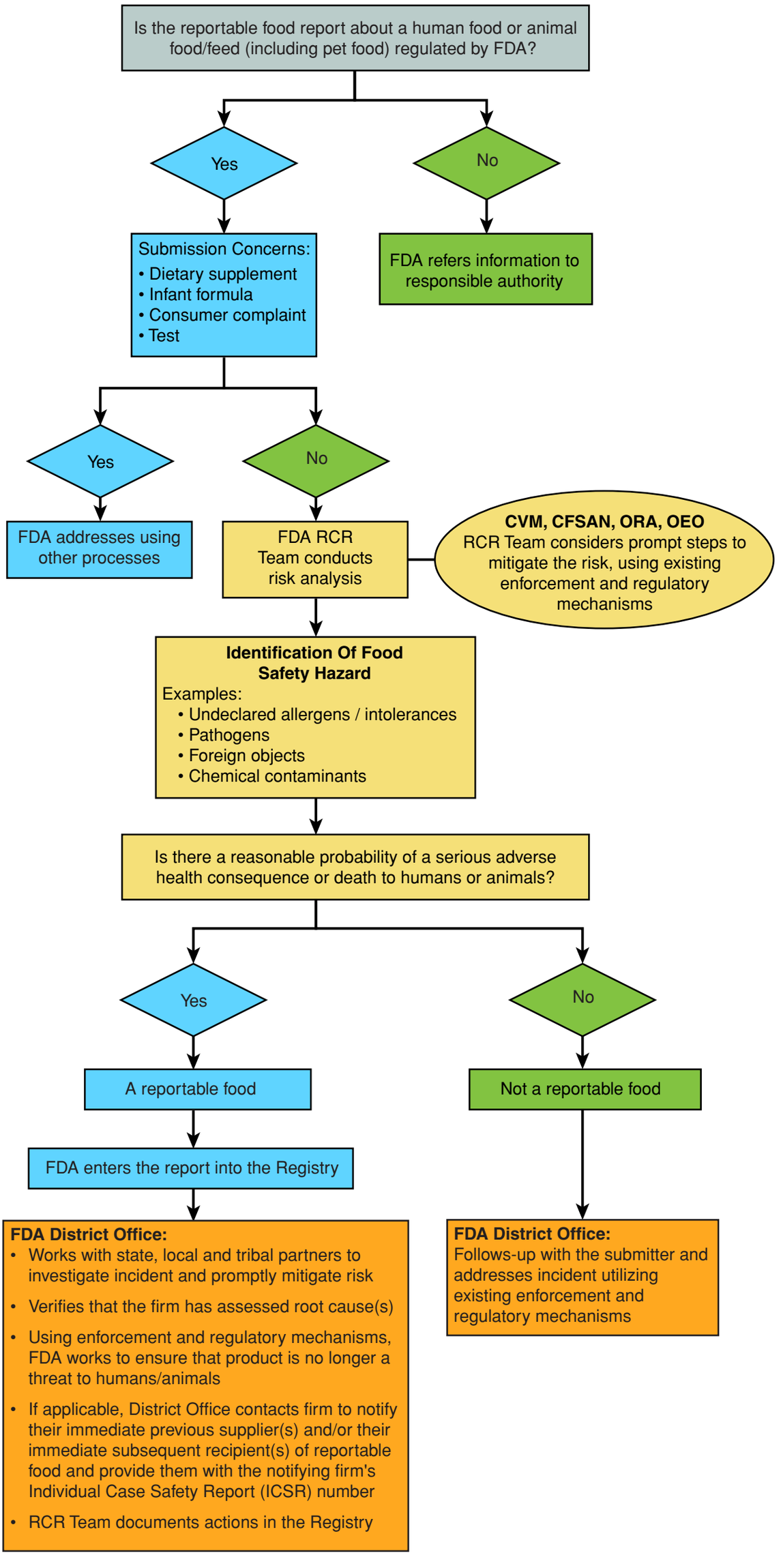
The Reportable Food Registry at a Glance Available in Other Languages

The Reportable Food Registry at a Glance, a summary that has been widely distributed to U.S. food facilities by FDA field staff as well as state and local regulatory staff, has been available in Chinese, French and Spanish only on FDA.gov. Print copies are now available in these languages for distribution by FDA foreign posts to food facilities and competent authorities around the world.

RFR Presentations to International Delegations

Some 70 delegations of foreign government and industry representatives from over 50 countries visit FDA's Center for Food Safety and Applied Nutrition annually. These delegations represent both developed and developing countries. The subjects of presentations made to them are in part determined by requests from the delegations but, beginning in 2011, FDA intends to make an RFR presentation to each visiting delegation.

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.



U.S. Food and Drug Administration

Reportable Food Summary Report
Definitions

May 10, 2010

Listed below are the commodity categories FDA will use to trend the reportable food data. Within each category, examples have been provided for the purpose of illustration only and are not meant to be an exhaustive list.

RFR COMMODITIES

Acidified / LACF:

Acidified foods mean low-acid foods to which acid(s) or acid food(s) are added. They have a water activity (aw) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods would have a scheduled process with FDA per 21 CFR Part 113.

Low acid [canned] foods means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85. These foods would have a scheduled process with FDA per 21 CFR Part 114. Products included are canned (retorted) foods and aseptically processed and packaged foods.

Including but not limited to:

- Soups
- Chicken / Beef Broth
- Diet and Nutritional Drinks
- Pickles
- Beans
- Aseptic products – including dairy
- Baby Food

Animal Feed/Pet Food:

Includes Animal Feed and Pet Food

Bakery:

Baked goods including fresh, refrigerated, and frozen products that are ready-to-eat or ready-to-bake products and mixes that require preparation before serving.

Including but not limited to:

- Dough
- Fresh and Frozen bread
- Pastries
- Cookies
- Tortilla
- Pies
- Cakes
- Scones

- Wafers
- Biscuits
- Croutons
- Bread crumbs
- Croissants
- Cookie Dough
- Mixes - Cake, Muffin, Biscuit, Pancake

Beverages:

Beverages and beverages bases, alcoholic and non-alcoholic.

Including but not limited to:

- Water
- Soft Drinks
- Juices
- Coffee/Tea
- Hot Chocolate
- Chocolate Powders / Mixes
- Flavored Drink Syrups
- Beverage Mixes
- Alcoholic Beverages, e.g. malt beverages, wine, distilled liquors
- Cocktail Mixes
- Non-dairy Milks

Breakfast Cereals:

Ready-to-eat and instant and regular hot cereals.

Including but not limited to:

- Boxed cereals
- Granola
- Instant cereals (add hot water), e.g. oatmeal

Chocolate/Confections/Candy:

Including but not limited to:

- Chocolate
- Confections / Coatings
- Candy Bars
- Chewing Gum
- Fudge
- Caramel Apples
- Frosting
- Marshmallows

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Reportable Food Summary Report
Definitions

Dairy:

Milk and milk product
Including but not limited to:

- Fluid white milk
- Flavored milks
- Buttermilk
- Condensed Milk
- Creams, e.g. heavy, light, whipping
- Eggnog
- Cheeses, e.g. natural, process, cream cheese
- Cultured Products, e.g. sour cream, cottage cheese
- Dairy based dips
- Dairy based spreads
- Dried milk
- Ice cream,
- Whey
- Butter

Not included

- Pudding
- Non-dairy products
- Cheese Analogs (these would be categorized as “other”)

Dressing/Sauces/Gravies:

Including but not limited to:

- Condiments, e.g. ketchup, mustard, mayonnaise
- Salad Dressings
- Salsa
- Marinades
- Soy Sauce
- Barbeque Sauce
- Specialty Sauces
- Dry Powder Dips
- Gravies (dry and liquid)
- Vinegar
- White and red pasta sauces

Not included:

- Acidified / LACF Products

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Reportable Food Summary Report
Definitions

Egg:

Including but not limited to:

- Shell Eggs
- Hardboiled Eggs

Not included

- Dried Egg Powders (USDA regulated)
- Pasteurized Liquid Eggs (USDA regulated)

Frozen Foods:

Including but not limited to:

- Fruits and Vegetables
- Frozen Meals
- TV Dinners
- Pizza

Not included:

- Bakery
- Seafood
- Pasta
- Dairy

Fruit and Vegetable Products:

Including but not limited to:

- Process Fruits and Vegetables
- Dried Fruits and Vegetables
- Jams and Jellies
- Apple butter
- Apple Sauce
- Fruit Concentrates, e.g. apple juice concentrate, orange juice concentrate
- Raisins
- Tofu

Not included:

- Fresh Produce
- Frozen
- Acidified / LACF Products

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Reportable Food Summary Report
Definitions

Game Meats:

Including but not limited to:

- **E**xotic meats such as snake, bush meats, rabbit, guinea pigs, bison, venison
- All birds and animals not regulated under the Meat and Poultry Act

Not included:

- USDA Regulated Meat under the Meat and Poultry Act (horse, cattle, sheep, goats, swine, ratites, poultry)

Meal Replacement/ Nutritional Food and Beverages:

Including but not limited to:

- Powdered Drinks
- Granola Bars
- Medical Foods
- Energy Shakes and Drinks
- Dry Instant Breakfast

Excludes:

- Acidified / LACF Products

Multiple Food Products:

Use this classification when an RFR has multiple products listed that are not from the same category.

Nuts, Nut Products, and Seed Products

Including but not limited to:

- Whole or Shelled Tree Nuts
- Peanuts
- Coconut
- Nut Butters, e.g. Marzipan,
- Tahini
- Hummus

Not included:

- Sesame Seeds, Poppy Seeds (these are spices)

Oil/Margarine:

Including but not limited to:

- Fats and Oils
- Vegetable Oils
- Cooking Oils
- Margarine
- Shortenings

U.S. Food and Drug Administration

Reportable Food Summary Report
Definitions

Pasta:

Including but not limited to:

- Fresh, Refrigerated, or Frozen Pasta
- Dried Pasta
- Filled Pasta
- Macaroni
- Noodles

Prepared Foods:

Including but not limited to:

- Refrigerated and Ready-to-Eat Salads
- Sandwiches (closed faced)
- Appetizers
- Pasta Side Dishes (multiple components)
- Rice Side Dishes (multiple components)

Not included:

- Open faced Sandwiches (USDA Regulated)
- Frozen Foods
- Produce – Fresh-cut Salads
- Acidified / LACF Products

Produce- Fresh Cut:

Including but not limited to:

- Bagged leafy greens
- Fresh cut fruits and vegetables
- Apple slices

Not included:

- Frozen
- Acidified / LACF Products
- Raw Agricultural Commodities (RAC)

Produce- Raw Agricultural Commodities (RAC):

Including but not limited to:

- Fresh produce (vegetables and fruits)
- Cored head lettuce
- Fresh herbs

Not included:

- Processed
- Frozen
- Dried
- Acidified / LACF Products
- Fresh Cut

U.S. Food and Drug Administration

Reportable Food Summary Report Definitions

Seafood:

Including but not limited to:

- All Fishery and Seafood Products
- Refrigerated, Frozen and Fresh Products
- Fin Fish
- Shell Fish (Mollusks and Crustacea)
- Turtles, frogs, alligator

Not included:

- Acidified / LACF Products

Snack Foods:

Including but not limited to:

- Chips
- Pretzels
- Pudding
- Gelatin Desserts
- Popcorn
- Novelty snacks
- Sorbet
- Trail Mix

Soup:

Including but not limited to:

- Refrigerated soups
- Dry Mixes
- Ramen
- Bouillon Cubes

Not included:

- Acidified / LACF Products

Spices/Seasonings:

Including but not limited to:

- Spices identified in 21 CFR 182.10
- Whole and ground
- Sesame Seeds, Poppy Seeds, Caraway Seeds
- Meat Coatings and Rub
- Seafood Seasonings
- Dried Herbs

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Reportable Food Summary Report
Definitions

Stabilizers, Emulsifiers, Flavors, Colors, and Texture Enhancers:

Including but not limited to:

- **S**oy and Egg Lecithin
- Gums and Thickeners
- Hydrolyzed Vegetable Proteins
- Flavor Enhancers
- Monosodium Glutamate
- Flavorings
- Pectin
- Starches
- Yeast / Yeast Extracts
- Leavening agents
- Food Colorings

Sweeteners:

Including but not limited to:

- Natural and Artificial Sweeteners
- Corn Syrups
- Sugar
- Sugar Substitutes
- Honey

Whole & Milled Grains and Flours:

Including but not limited to:

- Whole Grains
- Milled Grains
- Flours, e.g. wheat, rice, soy
- Corn meal
- Oatmeal
- Grits
- Rice

Other: includes products that can not be categorized within one of the 27 categories above. Examples may be non-dairy products, analog cheese.

FDA Foods Program

THE REPORTABLE FOOD REGISTRY: A NEW APPROACH TO TARGETING INSPECTION RESOURCES AND IDENTIFYING PATTERNS OF ADULTERATION

First Annual Report: September 8, 2009 – September 7, 2010

Questions and Answers

1. **What is the first Reportable Food Registry Annual Report?**
   A synopsis of FDA's experience with the Reportable Food Registry during its first year of operation. The report covers the period from September 8, 2009, when the Reportable Food electronic portal opened, through September 7, 2010.

2. **What is the Reportable Food Registry (RFR)?**
   An electronic portal to which industry *must*, and public health officials *may*, report when they have information about a Reportable Food. Congress mandated that FDA establish the Reportable Food Registry (RFR or the Registry) in Section 1005 of the FDA Amendments Act of 2007. 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.

3. **What is a Reportable Food?**
   An article of food 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.

4. **What is the significance of this first RFR Annual Report?**
   The report indicates that, in its first year, the RFR has demonstrated that it can help FDA track patterns of food and feed adulteration and target inspection resources to identify adulterated food/feed and prevent foodborne illnesses.

5. **What does the first RFR Annual Report show?**
   During its first year of operation the RFR received 2600 submissions, of which 360 were determined to be non-reportable after review by the FDA Risk Control Review Team. The remaining 2240 submissions were logged into the Reportable Food Registry. Of these, 229 were primary reports, the initial submission about a safety concern with a food or animal feed (including food ingredients). The remaining 1872 were subsequent reports on the same food or feed from suppliers (upstream) or recipients (downstream) in the food supply chain.

6. **What are the implications of the RFR Annual Report concerning food and feed adulteration?**
   Among the 229 primary reports, *Salmonella* accounted for 38 percent of hazards and Undeclared Allergens/Intolerances accounted for 35 percent. The primary reports involved products in 25 commodity categories. The report draws the attention of the food industry to the RFR data on two particular hazards:
   - *Salmonella* in spices and seasonings; raw agricultural produce; animal feed/pet food; and nut and seed products, and
   - Allergens/Intolerances in bakery goods; fruit and vegetable products; prepared foods; dairy and candy

   The report notes that these RFR findings have spurred efforts to improve preventive measures in affected commodity areas , both by industry and FDA, and have helped the agency better target its inspection and sampling activities.

7. **How does the RFR Annual Report differ from the RFR Report issued July 2010?**
   The report issued July 2010 covered a seven-month period. The annual report covers the full 12-month period since the Reportable Food electronic portal opened on September 8, 2009.

8. **In the July 2010 RFR Report, the Total RFR Entries by Month for the first seven months of the RFR are different than the numbers for the same months in the RFR Annual Report. What is the reason for this?**
   When a Reportable Food report is submitted, it is sent to the Risk Control Review (RCR) team for review. Each report is reviewed to assess whether the subject food or feed meets the definition of a reportable food. The RFR draft guidance states that FDA interprets the definition of reportable food to include those foods that would meet the definition of a Class I recall situation. When a Reportable Food report is received, the RCR team decides, based on the information available at the time, whether the risk presented by a food or feed product in a given report meets the definition of a Class I recall situation. If the RCR team finds that it does, the Reportable Food report is entered into the Reportable Food Registry. In a few cases, however, when the risk later receives an official recall classification, it is determined that it is not a Class I recall. When that occurs, the RFR entry for that food is removed from the Registry and the numbers for the month in which the Reportable Food report was entered into the Registry change.

9. **What foods are covered by the RFR?**
   All foods regulated by FDA, including animal feed and pet food. Infant formula and dietary supplements are covered by other mandatory reporting systems and are *not* subject to the RFR. 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, for whom FDA has other reporting systems.

10. **Who is required to report to the RFR?**
    A *Responsible Party*, i.e., the person who submits the registration information to FDA under section 415(a) of the Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 350d(a)) for a food/feed facility that manufactures, processes, packs, or holds food for human or animal consumption in the U.S. The term *person,* as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)) includes individuals, partnerships, corporations and associations. Federal, state, and local public health officials who may have information about reportable foods may submit reports but are not required to do so.

11. **What does FDA do with the information in these reports?**
    FDA determines whether the food/feed reported meets the Reportable Food standard, i.e., presents 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. FDA then works with the food /feed facilities that submit the reports and the state and local public health officials with jurisdiction over the reporting facilities to locate the hazardous foods in the supply chain in order to prevent them from reaching consumers.

12. **Does the RFR Annual Report include examples of how the RFR has worked to protect consumers?**
    Yes. The report cites two major examples:
    - A February 2010 recall of hydrolyzed vegetable protein (HVP) was spurred by industry reports to the RFR. More than 1,000 reports specifically for products containing HVP resulted in the removal of 177 products from commerce without any report of illness.
    - A November 2009 recall of two nationally distributed prepared side dishes that were not labeled as containing sulfites, but which had been inadvertently prepared with an ingredient containing sulfites. The recall was prompted by 109 RFR reports and was accomplished within 72 hours.

13. **Is the RFR FDA's only source of information about hazardous food/feed?**
    No. Reportable Food reports are one of many signals FDA receives. Other signals include inspection findings, recall data, PetNet, adverse event reports, consumer complaints and pet food reports. FDA has begun major initiatives to address all the signals it receives, e.g., the proposed produce rule, modernization of current Good Manufacturing Practices regulations to include preventive controls, Spice Risk Profile, targeted inspection

assignments such as hydrolyzed vegetable protein, baked goods, nutrition bars and imported produce.

14. **What are the next steps for the RFR?**
    The annual report includes an analysis of primary reports involving foods and ingredients from international sources, finding that the number was relatively small. Because FDA believes this may be, in part, the result of a lack of awareness of the RFR and its requirements by many foreign food facilities, the agency plans to focus more of its RFR outreach efforts on the international arena during 2011.

15. **How has FDA improved the RFR since the portal opened in September 2009?**
    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 the Reportable Food Registry. The SRP replaces the electronic portal FDA launched in September 2009 for the Reportable Food Registry. The SRP features more user-friendly software than previously available on the former Reportable Food portal. Responsible parties and/or public health officials can open accounts which allow them 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 instructions to aid responsible parties and/or public health officials when submitting Reportable Food reports via the SRP.

16. **Is help available for food facilities that have questions about the RFR?**
    FDA has created an RFR home page at www.fda.gov/ReportableFoodRegistry, which provides detailed information about the RFR and includes a link to the RFR Draft Guidance for Industry, as well as links to the summary, *RFR At A Glance* in English, Spanish, French and Chinese). FDA also provides two RFR email help desks:
    - The RFR Center for questions about policies, procedures and interpretations at RFRSupport@fda.hhs.gov, and
    - The SRP Service Desk for technical and computer-related questions about the RFR report and Safety Reporting Portal at support.srp@jbsinternational.com.

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.

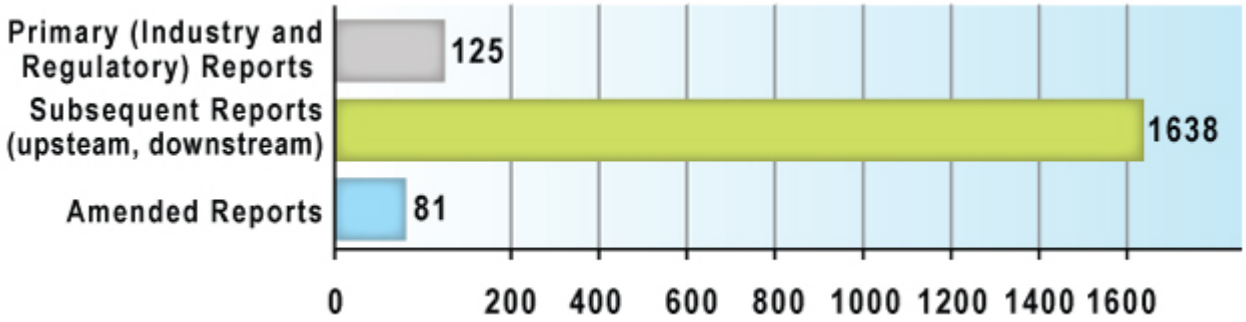
FDA notes that the data presented here represent only a very short period of time at the beginning of the Reportable Food Registry's operation. Future data sets generated from the RFR may or may not be comparable to this data set as a result of the ongoing nature of the implementation of the RFR.

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

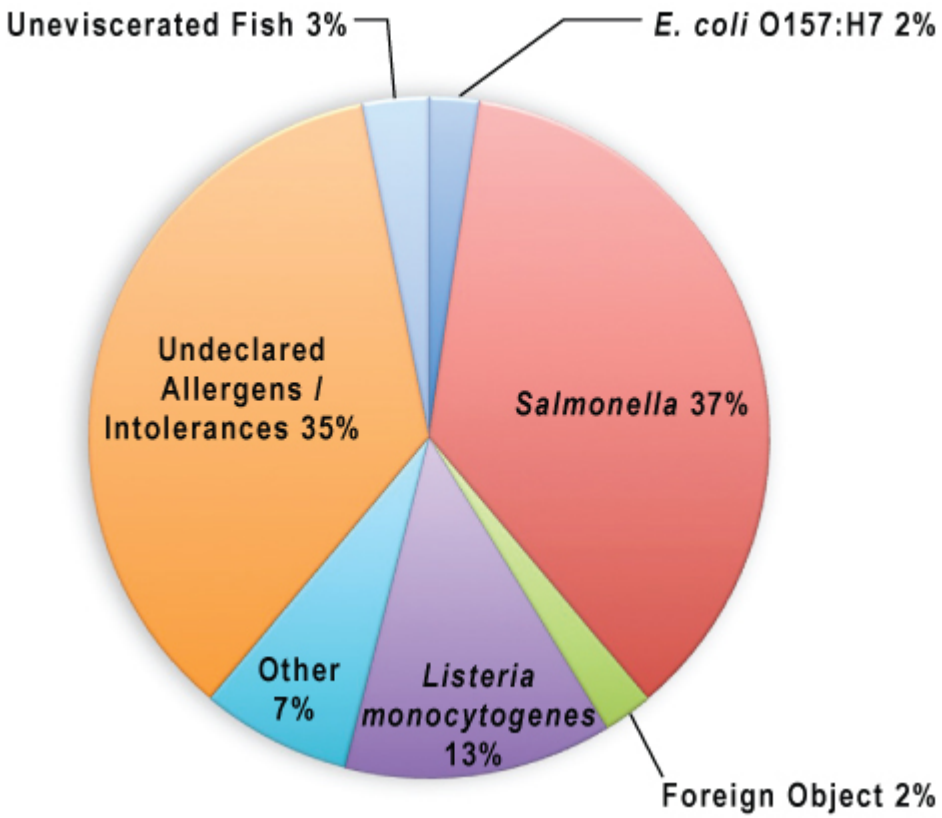
"RFR Commodities Definitions"

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.