

The background of the slide is a close-up, slightly blurred image of the American flag, showing the stars and stripes. The flag is oriented vertically, with the stars in the upper left and the stripes extending downwards.

ASTA Legislative/Regulatory Meeting

September 29, 2010

Kathy Gombas

**Acting Deputy Director
Office of Food Defense, Communications, &
Emergency Response
Center for Food Safety and Applied Nutrition**

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Reportable Food Registry (RFR)

- **Background**
- **Recent Activities**
- **Key Findings**
- **Things to Come**



FDAAA of 2007 – Section 1005

- Amends FD&C Act by creating new section 417, Reportable Food Registry
- Requires the Secretary of HHS to establish a Reportable Food Registry within FDA
- Requires FDA to establish an electronic portable by which instances of reportable food may be submitted



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Reportable Food Registry (RFR)

- “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 -
SAHCODHA



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Reportable Food Registry (RFR)

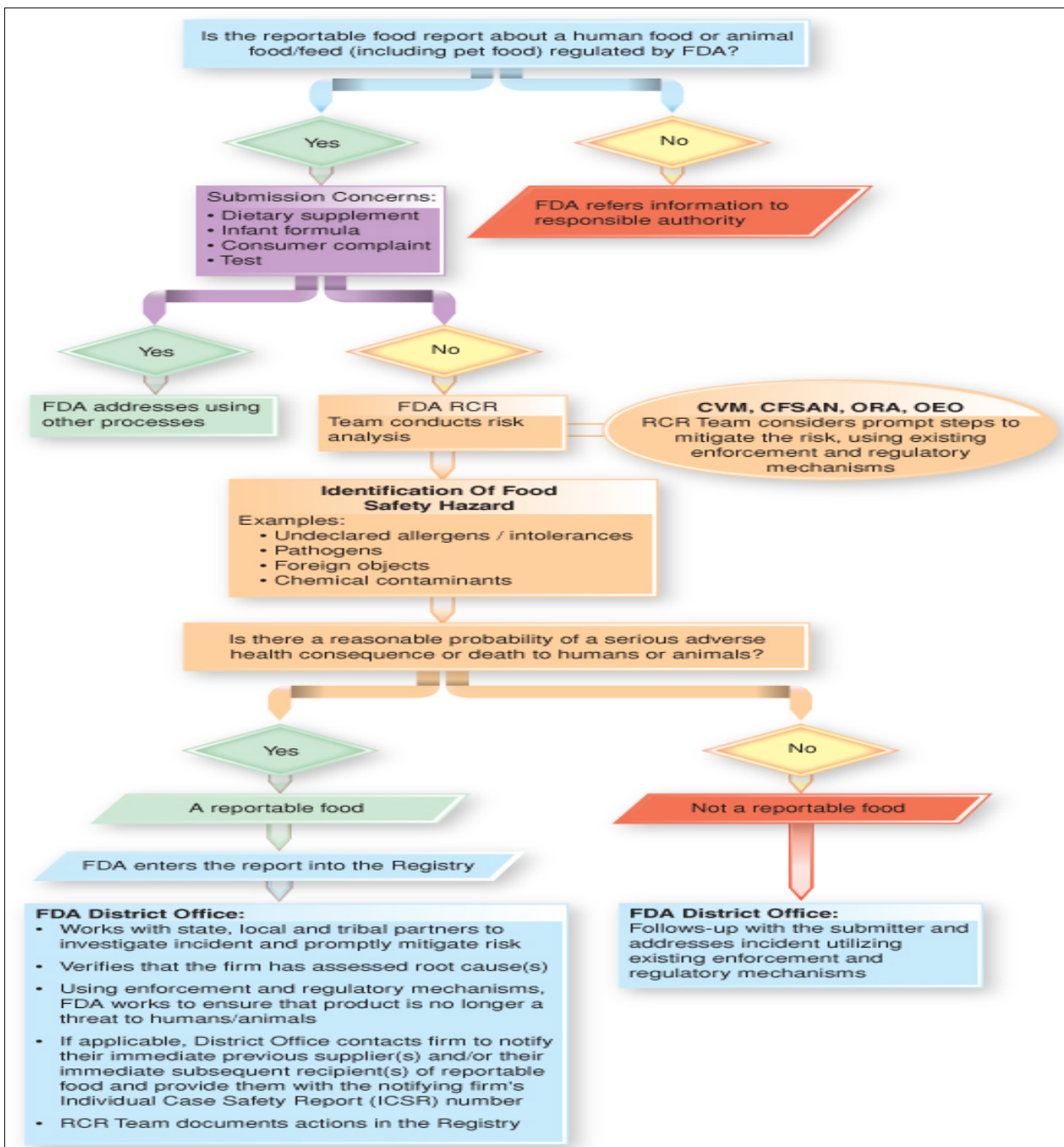
- **Mandatory - Instances of reportable food must be submitted by:**
 - A “responsible party,” i.e., the individual who submits the food facility registration under section 415(a)
- **Voluntary - Instances of reportable food may be submitted by:**
 - Federal, State, and Local Public Health Officials

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Reportable Food Registry (RFR)

FDA:

- Will establish an electronic portal to receive submissions
- Shall promptly review and assess information submitted and submit entries of reportable foods to the RFR
- FDA has established process to triage reportable food report submissions



Past Activities

- 9/8/09-Electronic portal opens and FDA published final 1st Ed. industry guidance
- 3/16/10-published guidance for industry on submitting a report for multiple facilities
- 5/24/10-New Safety Reporting Portal (SRP) opens and draft guidance 2nd Ed. posted for comment

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Reportable Food Registry (RFR)

New SRP is gateway to:

- FDA Reportable Food Electronic Portal
- FDA Pet Food Safety Reports
- FDA Animal Drugs Safety Reports
- NIH Gene Replacement Therapy Clinical Trials



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Reportable Food Registry (RFR)

The SRP provides greater functionality

- User creates a free account:
 - Reports pre-populated with contact info
 - Reports can be saved as drafts
 - See list of all reports submitted
- Guest User:
 - Reports or partial reports can not be saved
 - Previous submissions can not be viewed

Past Activities

- 7/28/10 – Published first RFR report on-line
www.fda.gov/ReportableFoodRegistry

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

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Food Safety

- Food Safety Programs
- ▶ Reportable Food Registry**
A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: The Reportable Food Registry

Reportable Food Registry for Industry

The Reportable Food Registry (RFR) is now part of the **FDA-NIH Safety Reporting Portal**. New, user-friendly software offers conveniences to reporters to the RFR. Reports can be pre-populated with contact information and saved as drafts or partially completed reports. Users can now view any previous submissions they have made to the Safety Reporting Portal.

For Industry/Regulators:
Submit a Report

For Consumers:
Contact FDA

Spotlight

- The Reportable Food Registry Report: First Reporting Period Sept 2009 - Mar 2010
- The RFR Report: First Reporting Period Questions and Answers
- Draft Guidance for Industry: Questions and Answers Regarding the RFR as Established by the FDA Amendments Act of 2007 (Edition 2)

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Reportable Food Registry (RFR)

**WHAT HAVE THE RESULTS
BEEN SO FAR?**



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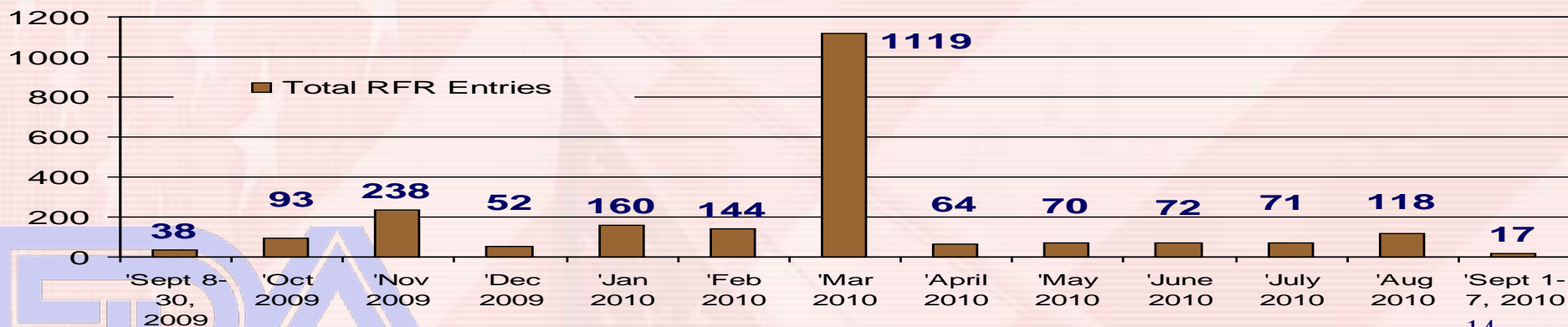
Reportable Food Registry (RFR)

- Have received both domestic and international reports
- Have received voluntary reports from public health officials
- Have received reports on biological, chemical, and physical contaminants

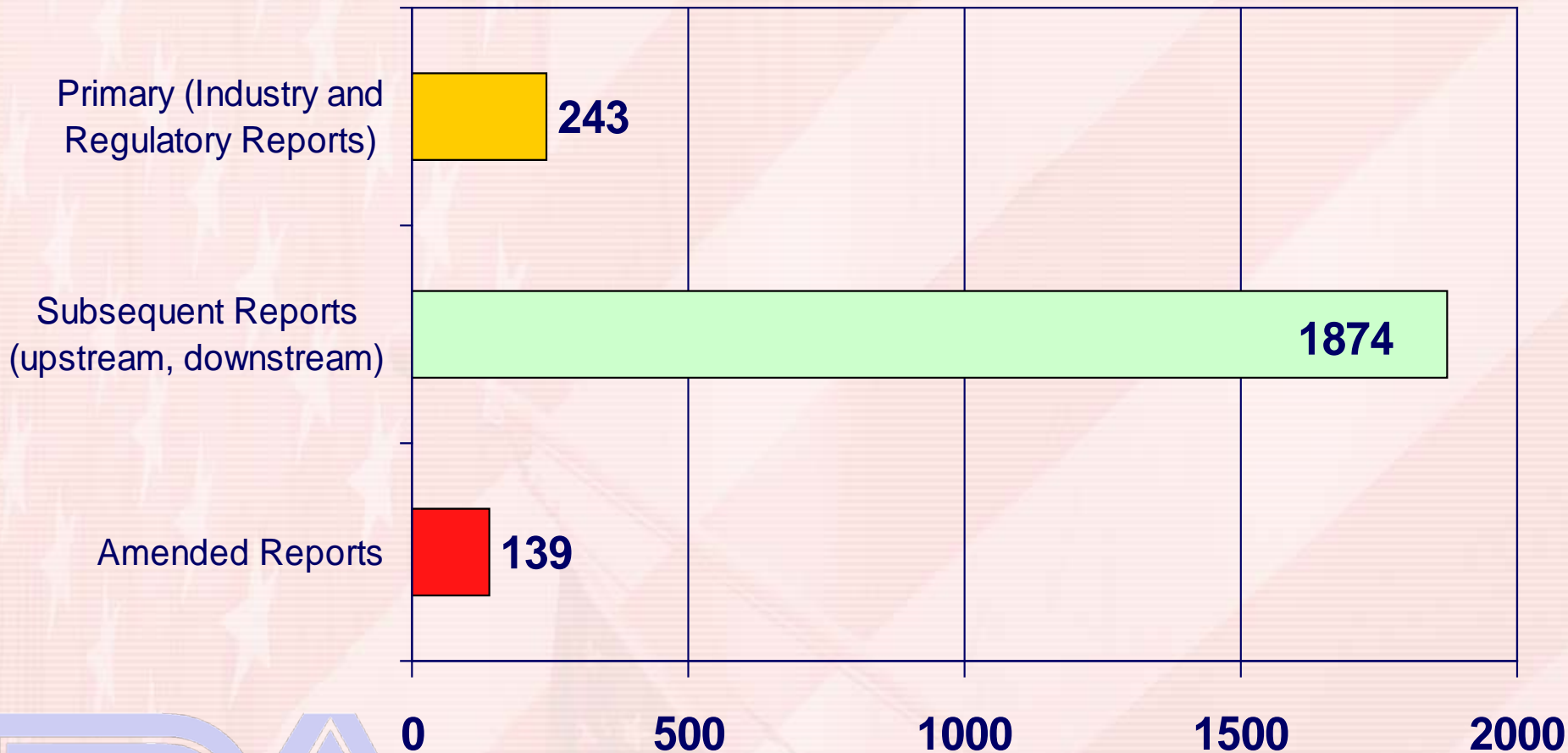


Reportable Food Submissions & Entries (Sept 8, 2009 – Sept 7, 2010)

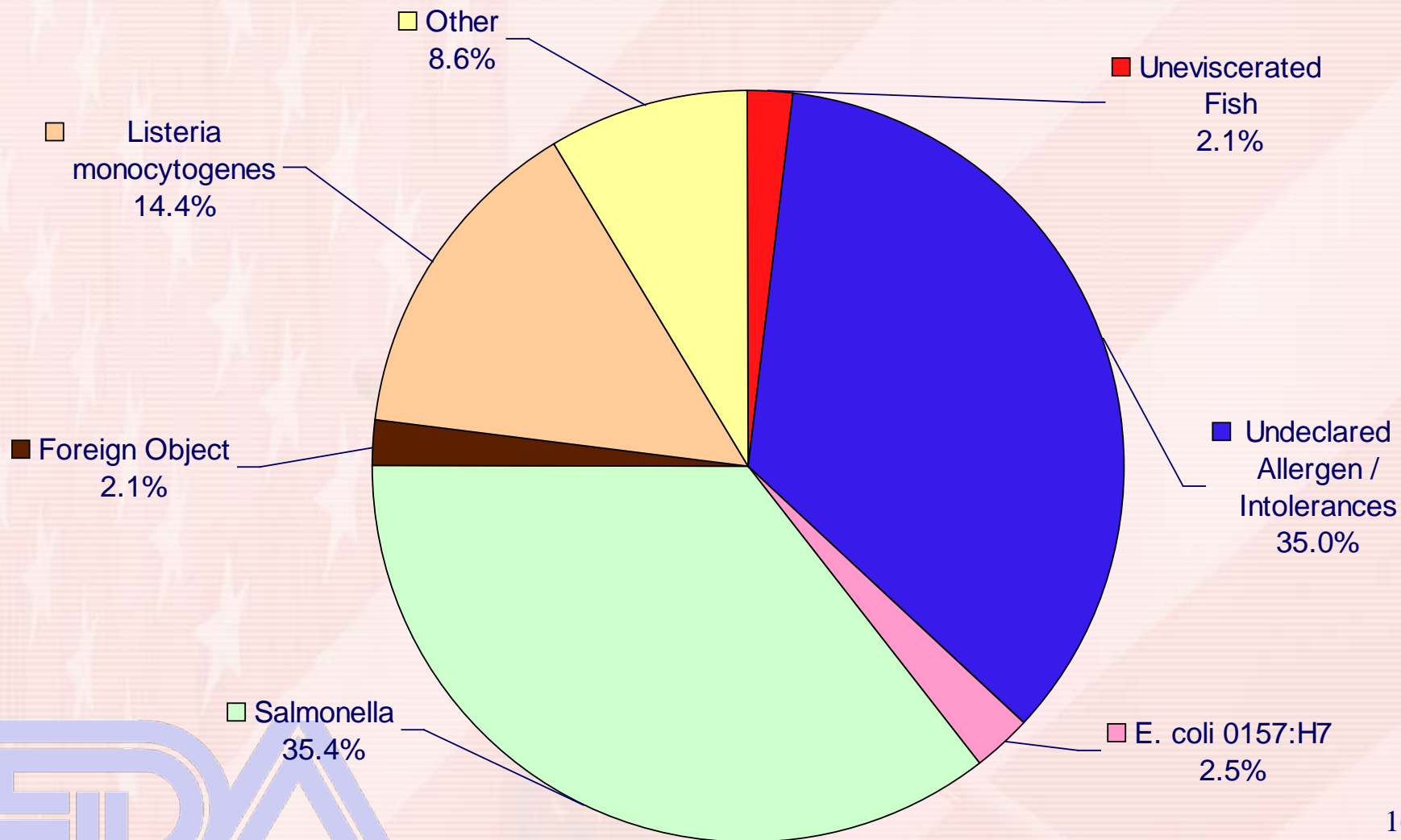
Submission by Month/Year	Sept 8-30 2009	Oct 2009	Nov 2009	Dec 2009	Jan 2010	Feb 2010	Mar 2010	Apr 2010	May 2010	June 2010	July 2010	Aug 2010	Sept 1-7, 2010	Total
Total Submissions Received	50	118	260	93	224	162	1148	92	94	128	80	134	17	2600
Non-Reportable Submission	(12)	(25)	(22)	(41)	(64)	(18)	(29)	(28)	(24)	(56)	(9)	(16)	0	(344)
Total RFR Entries	38	93	238	52	260	144	1119	64	70	72	71	118	17	2256



2256 Reportable Food Entries in Registry by Report Type

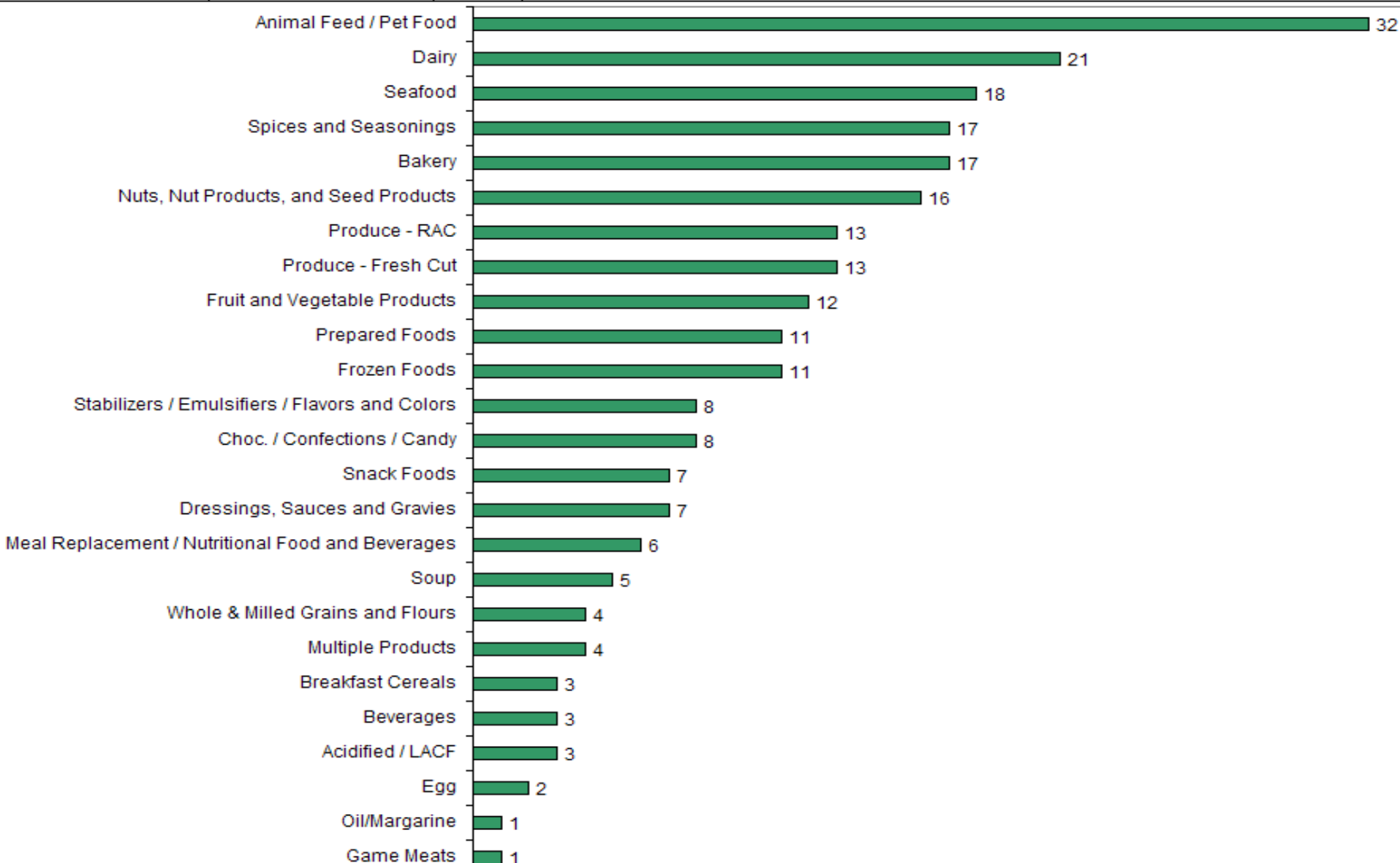


Percent Distribution of Primary Reports by Food Safety Hazard (243)



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

Distribution of Primary Reports by Commodity (243)

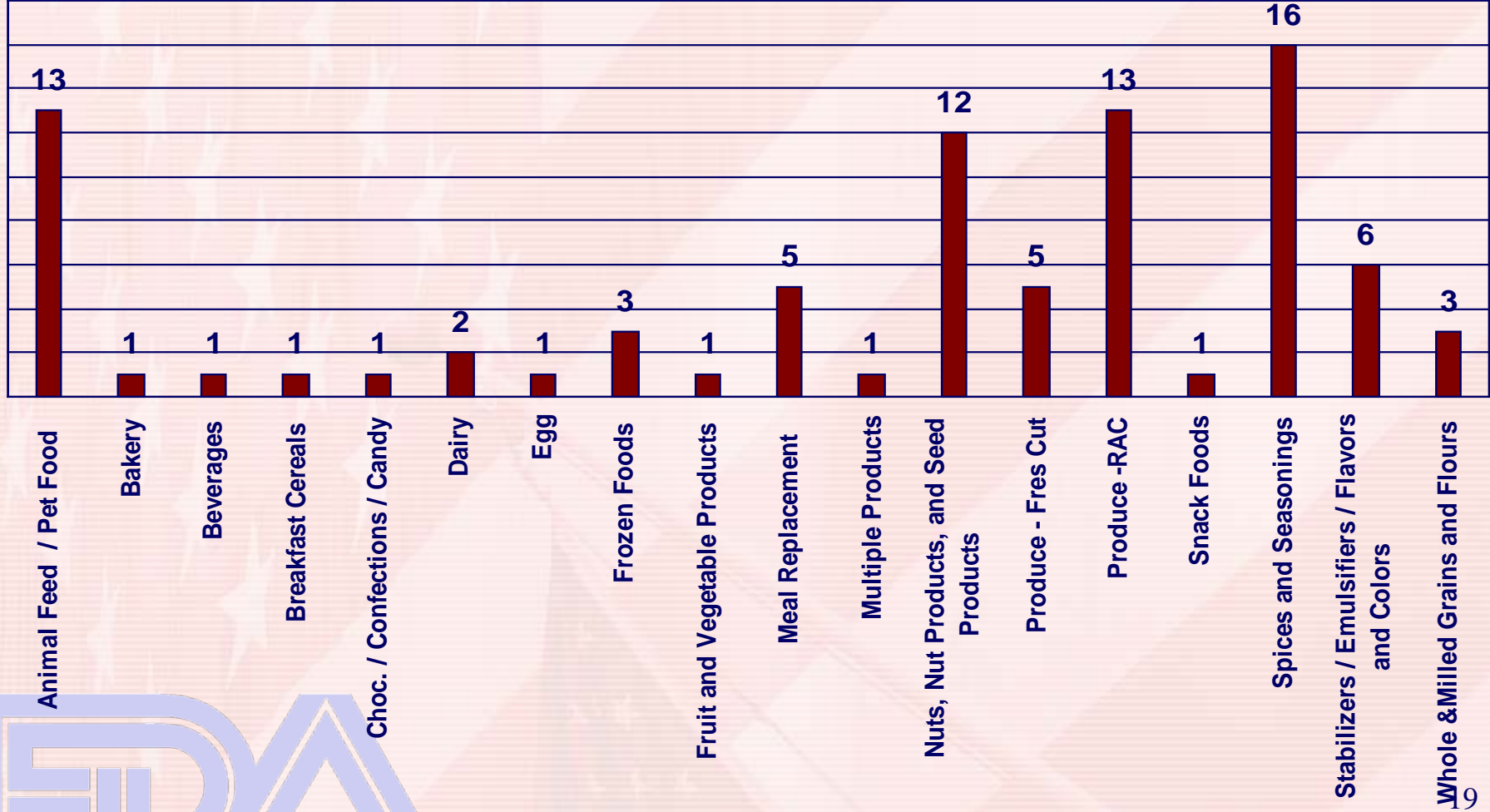


Distribution of 243 Primary RFR Entries by Commodity and Food Safety Hazard

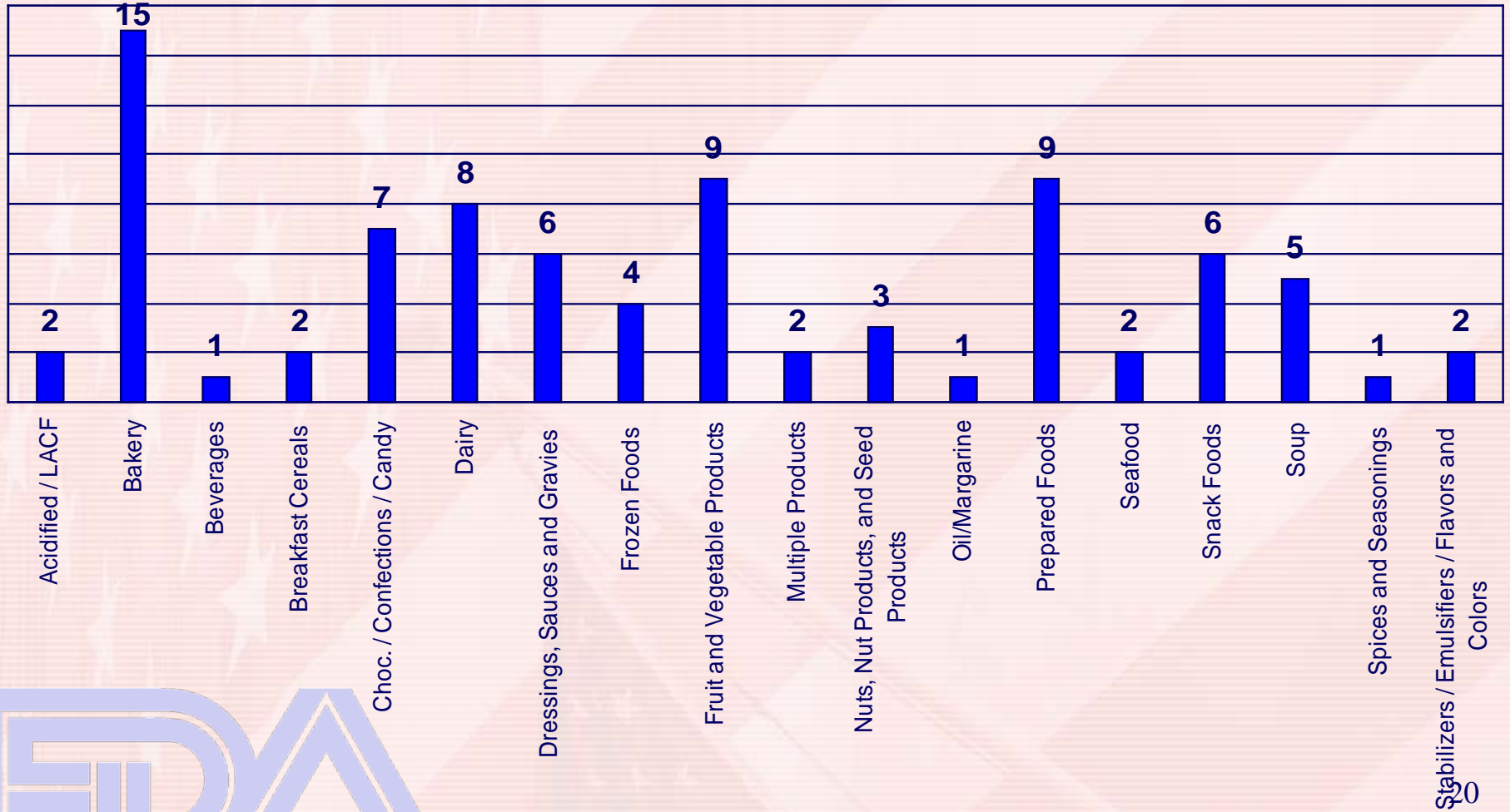
September 8, 2009 – September 7, 2010

	E. coli O157:H7	Foreign Object	<i>Listeria monocytogenes</i>	Other	<i>Salmonella</i>	Undeclared Allergens / Intolerances	Uneviscerated Fish	Grand Total
Acidified / LACF				1		2		3
Animal Feed / Pet Food		5		14	13			32
Bakery	1				1	15		17
Beverages				1	1	1		3
Breakfast Cereals					1	2		3
Choc. / Confections / Candy					1	7		8
Dairy	1		9	1	2	8		21
Dressings, Sauces and Gravies			1			6		7
Egg				1	1			2
Frozen Foods			4		3	4		11
Fruit and Vegetable Products			2		1	9		12
Game Meats	1							1
Meal Replacement / Nutritional Food and Beverages			1		5			6
Multiple Products			1		1	2		4
Nuts, Nut Products, and Seed Products			1		12	3		16
Oil/Margarine						1		1
Prepared Foods			2			9		11
Produce - Fresh Cut	2		5	1	5			13
Produce - RAC					13			13
Seafood			9	2		2	5	18
Snack Foods					1	6		7
Soup						5		5
Spices and Seasonings					16	1		17
Stabilizers / Emulsifiers / Flavors and Colors					6	2		8
Whole & Milled Grains and Flours	1				3			4
Grand Total	6	5	35	21	86	85	5	243

Distribution by Commodity of *Salmonella* Primary Reports (86/243)



Distribution of Primary Reports of Undeclared Allergen/Intolerance by Commodity Group (85/243)



Distribution of Primary Reports by Specific Allergen / Intolerance (85)



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Reportable Food Registry (RFR)

HELP DESK SUPPORT

- Policy/Interpretation Questions:

RFRSupport@fda.hhs.gov

- IT & Technical Questions

support.srp@jbsinternational.com



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Food Safety Programs

▶ Reportable Food Registry

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

Resources for You

- [Food and Drug Administration Amendments Act \(FDAAA\) of 2007](#)
- [Sec. 417. \[21 USC 350f\] Reportable Food Registry.](#)
- [Information on the FDA Reportable Food Registry \(RFR\) for Foreign Governments](#)
- [FDA and NIH Launch Electronic Safety Reporting Portal](#)
- [FR Notice of Availability: Draft Guidance for Industry: Questions and Answers Regarding the RFR as Established by the FDA Amendments Act of 2007](#)

Reportable Food Registry for Industry

The Reportable Food Registry (RFR) is now part of the **FDA-NIH Safety Reporting Portal**. New, user-friendly software offers conveniences to reporters to the RFR. Reports can be pre-populated with contact information and saved as drafts or partially completed reports. Users can now view any previous submissions they have made to the Safety Reporting Portal.

For Industry/Regulators:

[Submit a Report](#)

For Consumers:

[Contact FDA](#)

- [About the Reportable Food Registry](#)
- [Reportable Food Registry \(RFR\) At A Glance](#)
 - [available en français \(French\)](#)
 - [available en español \(Spanish\)](#)
 - [available 在中国人中 \(Chinese\)](#)
- [Who Should Use the Reportable Food Registry?](#)
- [Where Should Consumers, Food Retailers and Food Service Operators Report a Problem with Food?](#)
- [What to Do if the Safety Reporting Portal is Not Operating](#)

About the Reportable Food Registry

The Reportable Food Registry (RFR or the Registry) is an

Spotlight

- [The Reportable Food Registry Report: First Reporting Period Sept 2009 - Mar 2010](#)
- [The RFR Report: First Reporting Period Questions and Answers](#)
- [Draft Guidance for Industry: Questions and Answers Regarding the RFR as Established by the FDA Amendments Act of 2007 \(Edition 2\)](#)

Contact Us



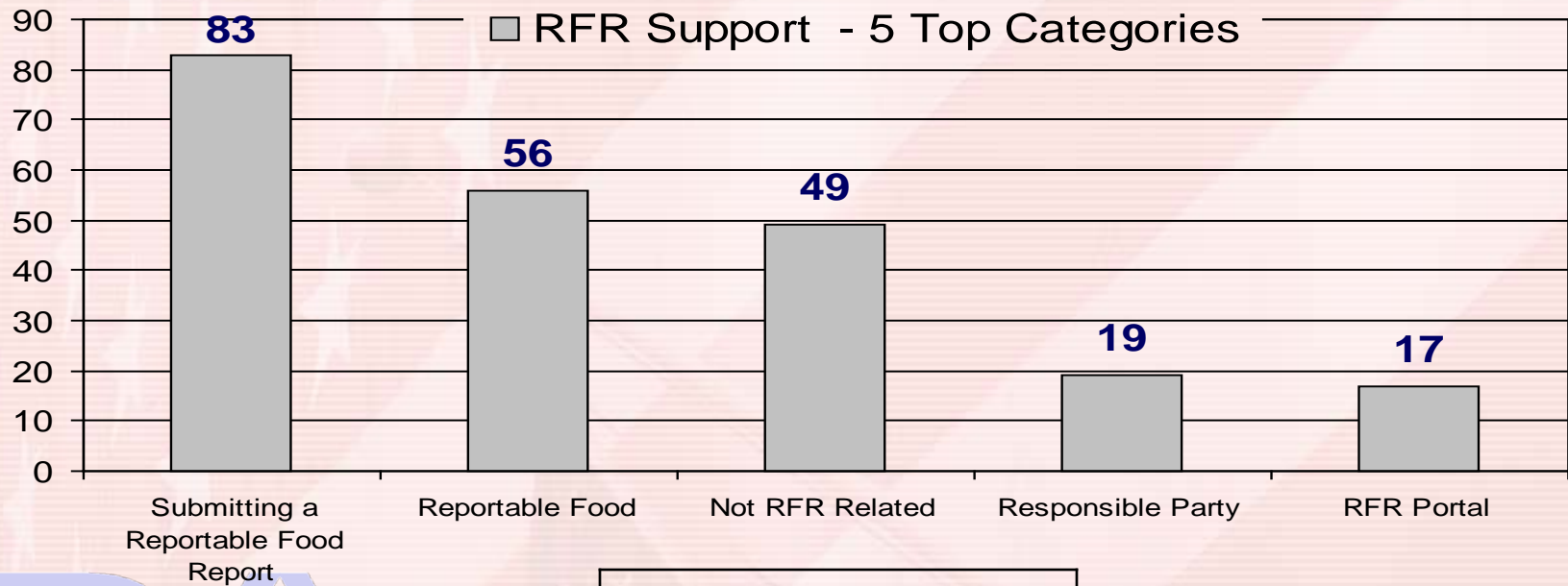
RFR Center for questions about policies, procedures and interpretations
RFRSupport@fda.hhs.gov

SRP Service Desk for technical and computer-related questions about the RFR report and Safety Reporting Portal
support.srp@jbsinternational.com

RFR Help Desk – Stat Sheet

9/8/09 - 9/7/10

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
RFR Support Total Questions	58	41	42	29	41	19	47	18	14	15	15	16	2	357



Outstanding Questions	
Open	0
Total	0%

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Reportable Food Registry (RFR)

What are the benefits of the RFR?

- Timely identification of upstream and downstream food distribution patterns
- More quickly narrow the scope and possible causes of reportable food
- Expeditious removal of reportable food from commerce



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Reportable Food Registry (RFR)

NEXT STEPS:

- Finalize 2nd Ed. Guidance Document
- Publish annual RFR Report
- Continue Outreach Efforts



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Reportable Food Registry (RFR)

RFR Home Page

www.fda.gov/ReportableFoodRegistry

- RFR Guidance
- Reportable Food Registry “At A Glance”
- Help Desk Contacts
- Seven Month Report
- RFR Electronic Portal via
<http://safetyreporting.hhs.gov>



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Reportable Food Registry (RFR)

QUESTIONS

