Reportable Food Registry: ASTA Regulatory Workshop

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Background

- In 2007, Congress required FDA to establish an electronic portal for reportable food submissions

- The electronic portal was opened on Sept 8, 2009 requiring responsible parties to report instances of reportable food within 24 hours

- In May 2010, an improved electronic portal was launched - the Safety Reporting Portal (SRP)

What is a reportable food?

"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

Report Types

- **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:**
  - Public Health Officials

Safety Reporting Portal

https://www.safetyreporting.hhs.gov

- If user creates a free account:
  - Reports are pre-populated with contact info
  - Reports can be saved as drafts
  - List of all reports submitted is available
- Guest User:
  - Reports or partial reports cannot be saved
  - Previous submissions cannot be viewed

Publications

- **First Annual RFR Report**

  Sept 8, 2009 – Sept 7, 2010

- **Second Annual RFR Report**

  Sept 8, 2010- Sept 7, 2011

www.fda.gov/ReportableFoodRegistry

Benefits of the RFR

- Increased speed with which FDA and its state and local partners can follow up on reports
- Enhanced FDA's understanding of how products are distributed through supply chain
- Helped FDA and industry identify key risk points

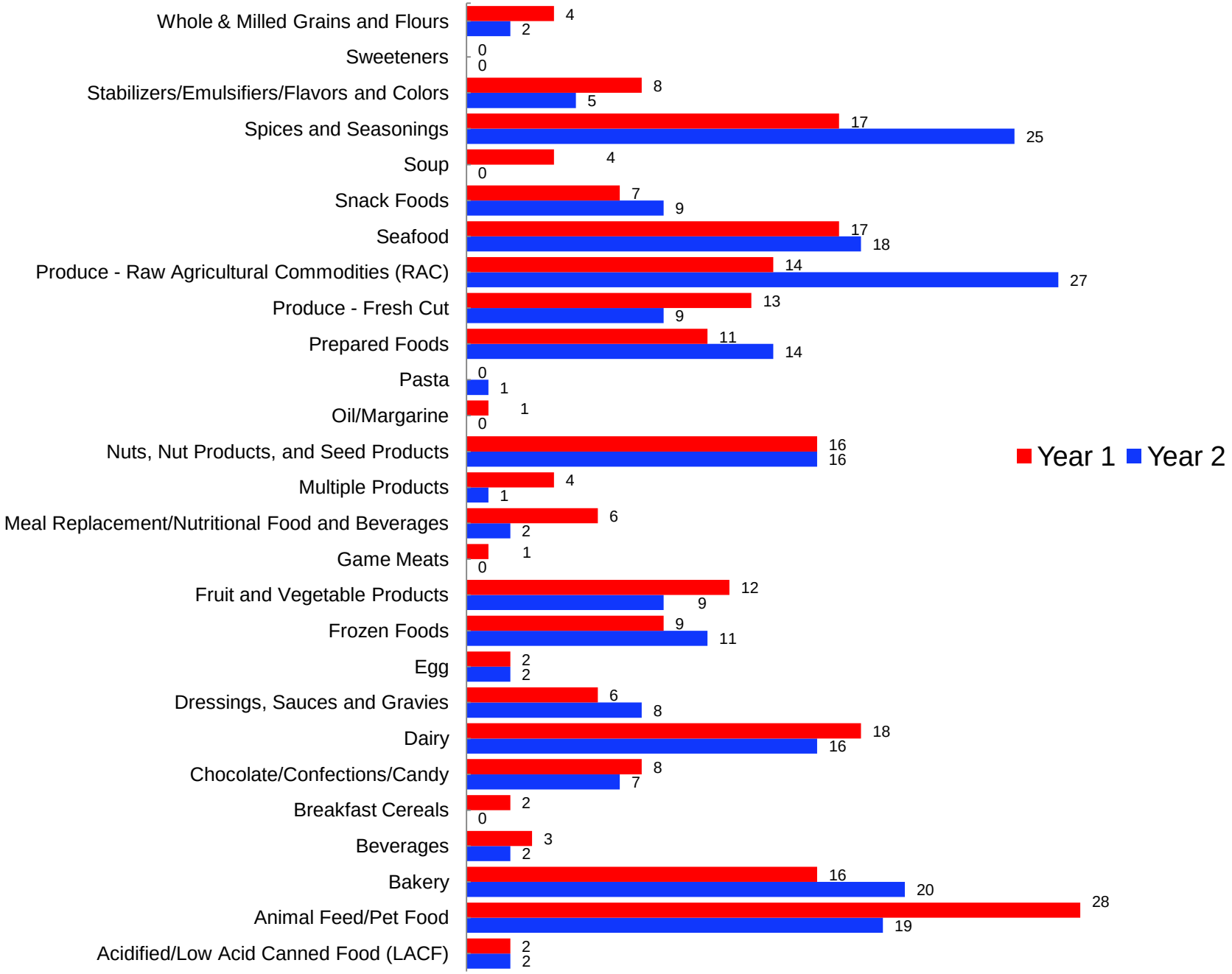
Benefits continued…

- Improved coordination among FDA headquarters, FDA field staff, and state and local regulators
- Provided data for FDA to issue import alerts and import bulletins
- Supplied key information to target inspections, plan work, and prioritize risks

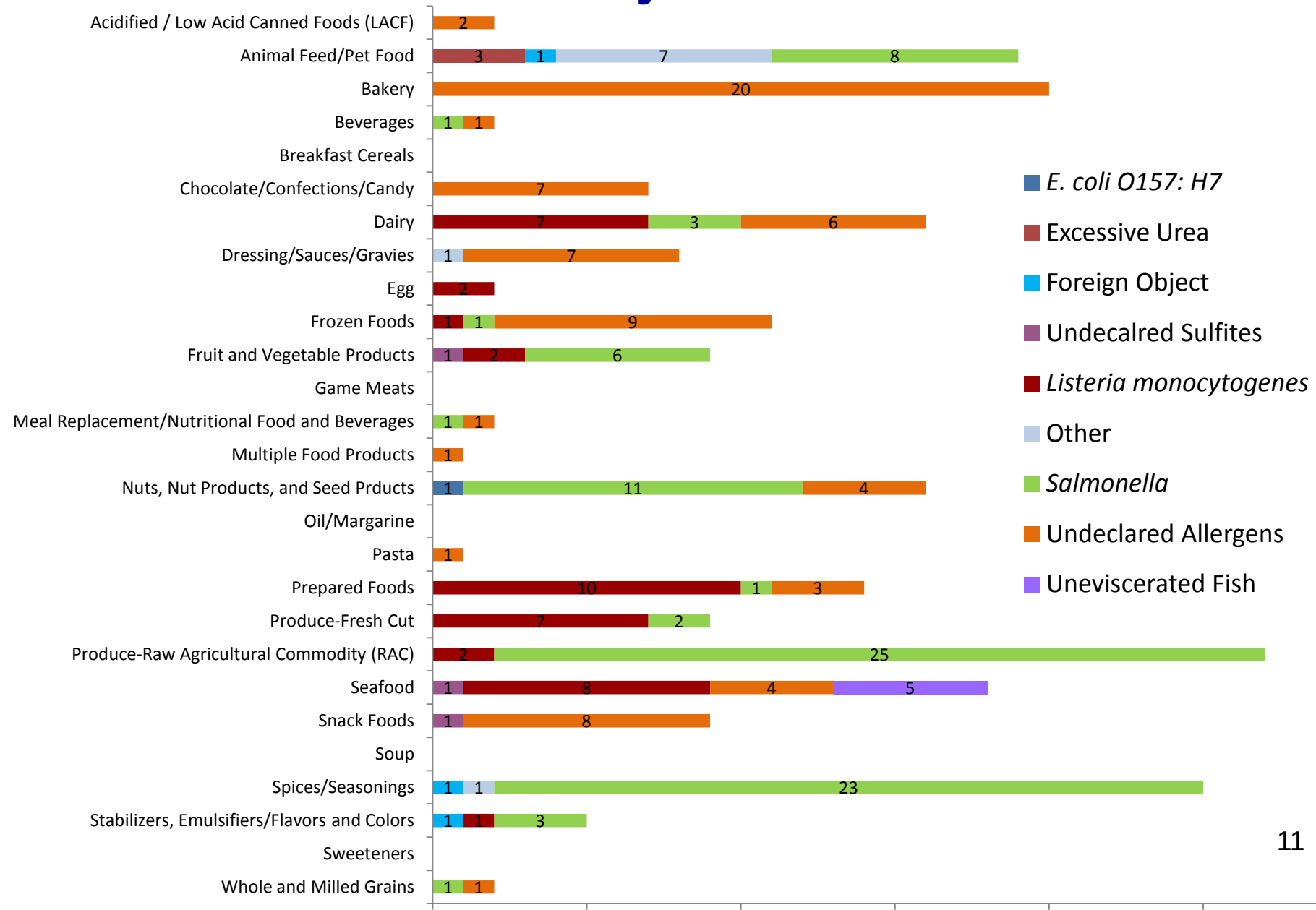
Distribution of Report Types

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

Primary RFR Entries by Commodity



Year 2 Distribution of 225 Primary Entries by Commodity and Hazard



Amending Reports

- Root Cause
- Corrective Actions
- Disposition
- Distribution

New Data Elements

- On June 4, 2012, additional data elements were added to the electronic questionnaire
- The new data elements will improve the quality of information received
- Mandatory input

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Problem Summary

* =Required

Problem Summary

This section asks for a summary of the product problem, including how and when you learned about the problem, information about the suspect product(s) and a description of the problem.

If you have additional details about any of the suspect products, please provide them so that we can move to resolve the problem in a timely fashion. If you do not have any details at this time, you can submit them in an amended report.

Your organization's internal identifier corresponding to this report (Case ID): Example Report Submission

*Date the article of food was determined to be a Reportable Food: 6/18/2012

*How did your site first learn about the Reportable Food?: Self discovery

Reason this food is reportable (agent)

- [x] *Salmonella*
- [ ] *Listeria monocytogenes*
- [ ] *E. coli* O157:H7
- [ ] Foreign Object
- [ ] Undeclared Allergens
- [ ] Undeclared Sulfites
- [ ] Uneviscerated Fish
- [ ] Other
- [ ] Unknown

New data elements

- A description of the root cause of the reportable food (if applicable);
- A brief justification of the process used to determine which product(s), lot(s), or batch(es) were affected;
- Whether or not the submitter believes all of the reportable food has been removed from commerce;

New data elements

- A brief description of the corrective actions taken to avoid repeating the reportable event;
- Whether or not a bacterial isolate is available for FDA collection;
- The commodity type of the reportable food;

New data elements

- The dates that the product was manufactured;
- Whether or not the reportable food underwent treatment to reduce microorganisms;
- A brief description of the microbial reduction treatment;

New data elements

- For reportable foods intended for animal consumption, the animal species that the reportable food was intended to be consumed by;

- For reportable foods intended for animal consumption, the life stage of the animal that the reportable food was intended to be consumed by;

New data elements

- Whether the responsible party has notified all of its immediate previous sources (suppliers) of the reportable food (if applicable)*; and

- Whether the responsible party has notified all of its immediate subsequent recipients (customers) for the reportable food (if applicable).

Resources

- RFR main page and training video: www.fda.gov/ReportableFoodRegistry
- Safety Reporting Portal site: http://www.safetyreporting.hhs.gov
- RFR Assistance
  - Policy/Interpretation Questions: RFRSupport@fda.hhs.gov
  - IT & Technical Questions: support.srp@jbsinternational.com

Questions?