

THE 2014 ANNUAL CONFERENCE

DFA OF CALIFORNIA & SPECIALTY CROP TRADE COUNCIL PRESENTS

MISSION POSSIBLE

The Reportable Food Registry

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Before September, 2007...

- No legal obligation to report serious food defects/recalls to FDA.
- Serious recalls highlighted this fact:
 - Melamine/pet food
 - *Salmonella*/peanut butter
 - O157/spinach
- Congress took steps to change this.





What is the Reportable Food Registry (RFR)?

- Established by Sect. 1005, Food & Drug Amendments Act of 2007.
- Created an electronic portal to file reports of food adulteration to FDA.
- Improved tracking/quicker response = better protection of public health.

As the RFR Was Under Development...

- The Peanut Corporation of America *Salmonella* recall unfolded:
 - 714 illnesses/9 deaths.
 - 3,918 products recalled.
 - (+) lots shipped anyway!
- Congressional hearings led to additional legislation (FSMA).



Reportable Food Registry (RFR)

- Beginning September 8, 2009 the RFR required that any food facility that manufactures, processes, packs or holds food for human or animal consumption to file a report through the electronic portal when there is a reason to believe that a food will cause adverse health consequences or death to humans or animals.



Who Files the Report?

- The “Responsible Party”:
 - Person who submits the food facility registration.
 - Must report within 24 hours after determining that the article of food is reportable.
- Public health officials may voluntarily file.
 - Federal, state and local.
 - Information from their own investigations.
- General public does not file RFR reports.

Filing the Report

- Done electronically through the web link:
www.safetyreporting.hhs.gov
- Foods not covered by the RFR:
 - Dietary supplements.
 - Infant formula.
 - USDA regulated foods.
- Failure to report a reportable food is prohibited by the Federal Food, Drug and Cosmetic Act!



Types of Reports Generated

- Primary Report.
 - This is the initial report on the food/feed.
 - May be industry, public health official.
- Subsequent Report.
 - May be from a supplier (upstream).
 - May be from a recipient (downstream).
 - Food/feed or ingredients.
- Amended Reports.
 - Corrective actions, follow-ups.
 - Strongly encouraged.



Data Elements to Include in the Report.

- Food Facility Registration Number.
- Date the food was determined to be reportable.
- Description of reportable food, quantity/amount.
 - Includes commodity type.
- Extent/nature of adulteration.
 - Most common hazards are displayed on a checklist.
- Results of root cause investigation, when known.
 - Provide information on how this problem occurred.
 - Identify preventive controls, action plans.

Data Elements to Include in the Report.

- Brief description of corrective actions taken:
 - Manufacturing improvements, training, etc.
 - Goal is prevention.
- Disposition of reportable food, when known.
- Packaging information sufficient to identify the food.
- Contact information, when required:
 - Previous sources (suppliers).
 - Subsequent recipients (customers).



After the RFR Report is Submitted

- Receives an Individual Case Safety Report (ICSR) number.
- FDA Risk Control Review (RCR) team review:
 - Reportable foods referred to District for follow-up.
 - May require responsible party to:
 - ✓ Notify suppliers, customers.
 - ✓ Provide them with ICSR number.
- Reports are confidential.
 - May not be viewed by other submitters.
 - Freedom of Information Act applies.



What Hazards Create a Reportable Food?

- Class I Recalls
 - Reasonable probability of serious adverse health consequences or death:
 - Pathogens (*Salmonella*, *Listeria monocytogenes*, *E. coli* O157).
 - Undeclared Allergens (peanuts/tree nuts, milk, eggs, soy).
 - Undeclared Sulfites.
 - Excess levels of heavy metals.



What Hazards Create a Reportable Food?

- Foreign objects/physical hazards.
 - Glass, wood, metal, hard plastic.
 - 7 to 24 mm.
 - Class II recall issue.
- Undeclared wheat allergen.
 - Class II recall issue.
- Nutrient imbalances (animal feed).
- Drug contamination (animal feed).



To File or Not to File?!

- If I have a positive pathogen result for an environmental swab, do I file?
 - **NO!**
- If the reportable food has already shipped to a third-party warehouse, but I still own the product and have direct control over its distribution, do I file?

– **YES!**



No RFR Report Required When...

- The adulteration originated with the responsible party; **AND**
- The responsible party detected the adulteration prior to any transfer to another person of the article of food; **AND**
- The responsible party corrected the adulteration or destroyed or caused the destruction of the article of food.



The Reportable Food Registry Annual Report

- Summarizes findings.
- Role in FSMA:
 - Identify hazards.
 - Develop preventive controls.
 - Prioritize inspections.
 - Develop industry guidance.
- Available online:

<http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm>

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

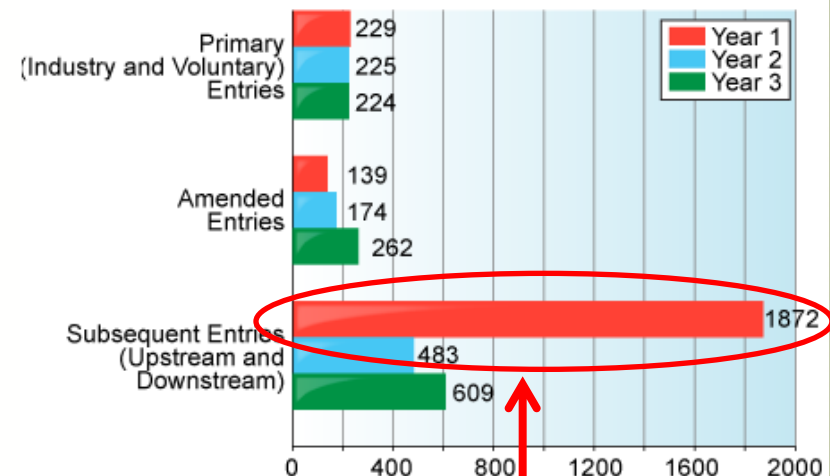
FDA Foods and Veterinary Medicine Program

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

Third Annual Report:
September 8, 2011 – September 7, 2012

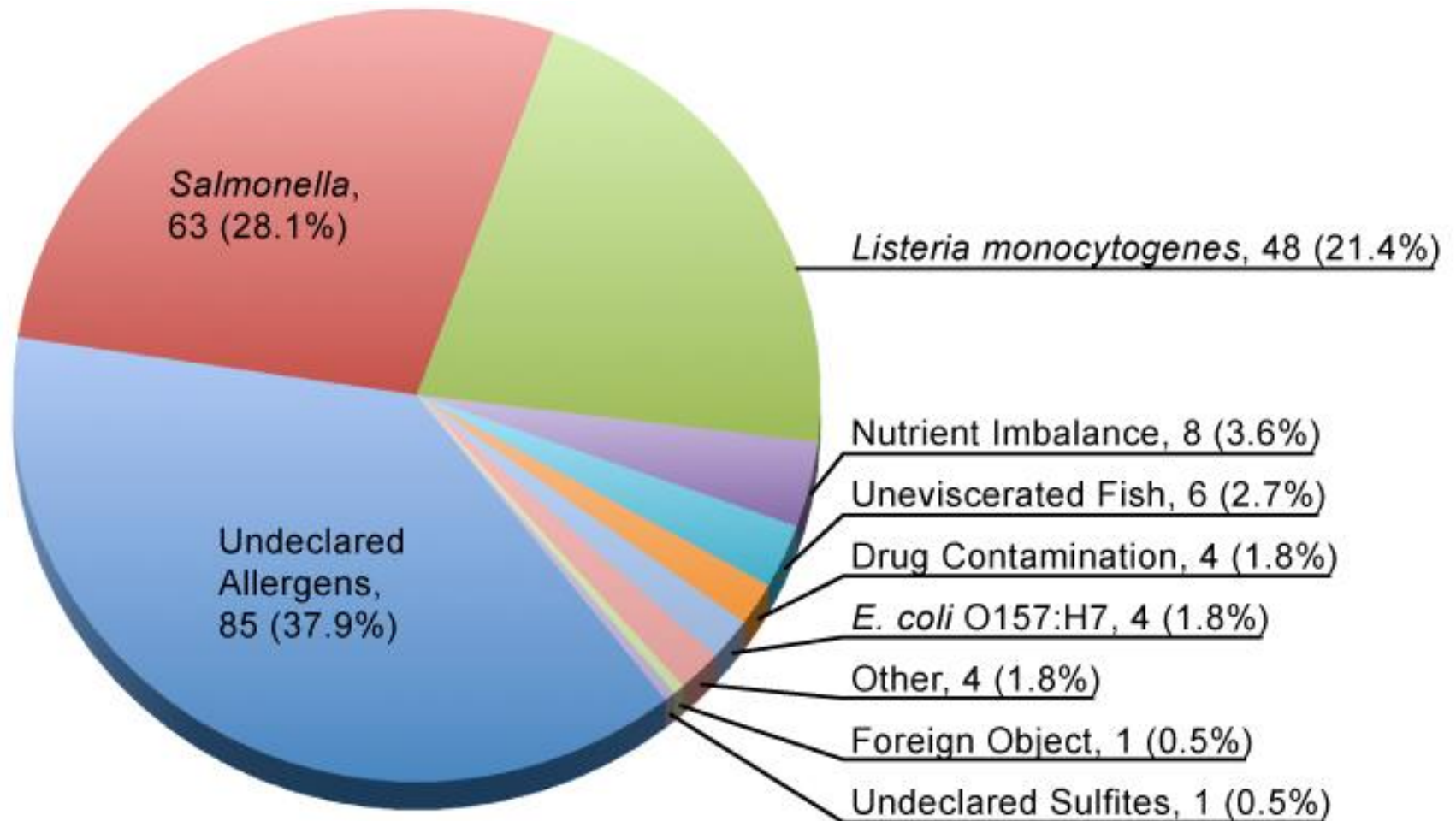
Highlights of the RFR Annual Report

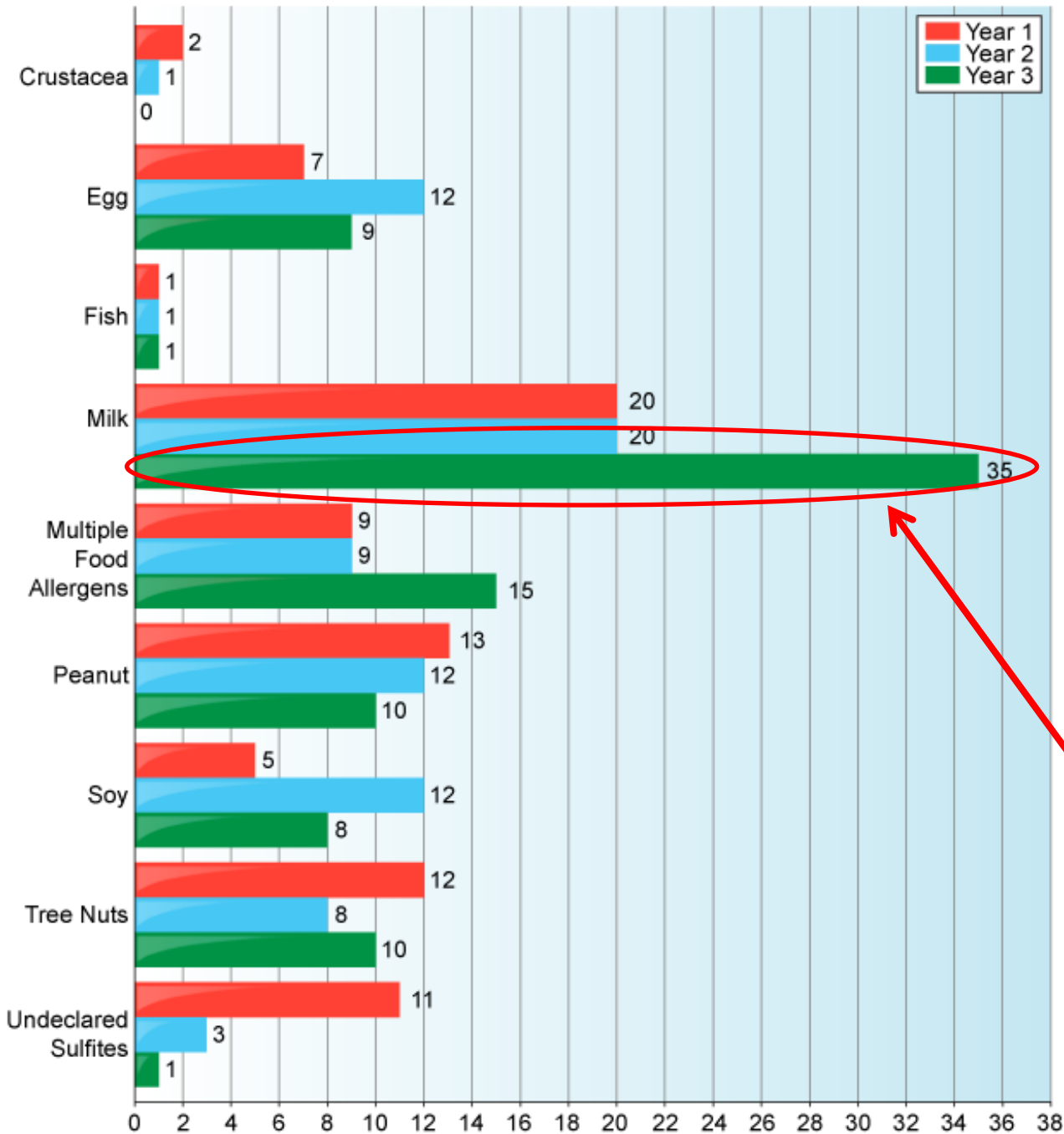
- There were 1,095 reports filed:
 - 224 Primary.
 - 221 Mandatory (industry)
 - 3 Voluntary (public health)
 - 609 Subsequent.
 - 262 Amended.
 - 88 % increase since the program began.



Hydrolyzed vegetable protein recall (major ingredient).

Primary RFR Entries by Hazard (Year 3)





**Primary RFR
Entries by
Specific
Undeclared
Major
Allergen and
Undeclared
Sulfites**

Snack Bar Recall

25 Commodity Categories Exist

**Acidified/Low acid
canned foods (LACF)**

Egg

Pasta

Spices/Seasoning

Animal Food/Feed

Frozen Foods

Prepared Foods

**Stabilizers,
Emulsifiers/Flavors
and Colors/Texture
Enhancers**

Bakery

**Fruit and Vegetable
Products**

Produce-Fresh Cut

Sweeteners

Beverages

**Meal Replacement/
Nutritional Food and
Beverage**

Produce-RAC

**Whole & Milled
Grains and Flour**

**Chocolate/
Confections/Candy**

**Multiple Food
Products**

Seafood

Dairy

**Nuts/Nut
Products/Seed
Products**

Snack Foods

**Dressing/Sauces/
Gravies**

Oil/Margarine

Soup

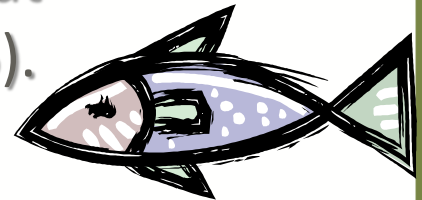


Primary RFR Entries by Commodity (Year 3)

- Produce (Raw Agricultural Commodities) was #1.
 - 33 entries (22 *Salmonella*, 10 *L. mono* and one *E. coli* O157).
- Nuts/Nut Products/Seed Products was #7.
 - 13 entries (8 *Salmonella*, 4 undeclared allergens and one *E. coli* O157).
- Fruit/Vegetable Products was #13.
 - 5 entries (4 *Salmonella*, one undeclared sulfite).
 - Includes dried & processed fruits/vegetables, juice concentrates, jams, jellies, tofu, dried celery/onion/spinach.

Primary RFR Entries for Imported Foods

- Accounted for 20 % of Total (46 entries)
 - Top 3 countries were Canada (8), China (6) & Mexico (6).
 - Top 3 hazards were *Salmonella* (23), allergens (9) & *Listeria monocytogenes* (6).
 - Top 3 commodities were Seafood (11), Nuts/Nut Products/Seed Products (6) & Produce-RACs (5).
- Nuts/Nut Products/Seed Products:
 - 6 entries (5 *Salmonella*, 1 undeclared allergen).
- Fruit/Vegetable Products:
 - 3 entries (2 *Salmonella*, 1 undeclared sulfite).



Trends for Primary RFR Entries (Years 1-3)

- *Salmonella* entries declined 26.7%:
 - From 86 (years 1,2) to 63 (year 3).
 - Biggest decline in spices/seasonings:
 - From 16 & 23 (years 1,2) to 5 (year 3).
 - Animal food/feed declines:
 - From 13 & 8 (years 1,2) to 5 (year 3).
 - Nuts/Nut Products/Seed products:
 - From 12 & 11 (years 1,2) to 8 (year 3).



Trends for Primary RFR Entries (Years 1-3)

- *Listeria monocytogenes* entries up 45 %.
 - From 33 & 40 (years 1,2) to 48 (year 3).
 - Produce-fresh cut is 1/3 of the total (15).
 - Salad products, bagged leafy greens.
 - Dairy had 11 entries.
 - Cheese products.
 - Produce-RAC had 10 entries.
 - Sprouts, cantaloupes.



Trends for Primary RFR Entries (Years 1-3)

- Undeclared Major Allergen entries up 23 %.
 - From 69 & 75 (years 1,2) to 85 (year 3).
 - 18 entries for bakery.
 - Cookies, cakes.
 - Included undeclared tree nuts (3).
 - 11 entries for chocolate/confections/candy.
 - Chocolate/yogurt-coated dried fruit, icings/ganaches and chocolate candies.
 - Included undeclared peanuts (4).



Trends for Primary RFR Entries (Years 1-3)

- Undeclared Sulfites entries are down 91 %
 - From 11 & 3 (years 1,2) to 1 (year 3).
 - Biggest decline in Fruit/Vegetable Products:
 - 9 entries (year 1)-imported.
 - 1 entry (year 2)-domestic.
 - 1 entry (year 3)-imported.
 - Other entries for seafood, snack foods, prepared foods.





Putting the RFR to Use





Some Notable Outcomes of the RFR

- Hydrolyzed Vegetable Protein (HVP).
 - Food processor detected *Salmonella tennessee* during routine ingredient testing.
 - Risk control review (supplier & primary reporter).
 - Supplier recall and recipient notification.
 - 177 products recalled, 1001 RFR entries.
 - Root cause analysis/preventive controls changes.
 - No reported illnesses.

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

Some Notable Outcomes of the RFR

- *Salmonella infantis* in dog food.
 - State of Michigan detected contamination.
 - Filed a voluntary RFR.
 - State/Federal Investigation:
 - Product from a plant in South Carolina.
 - Linked to 53 human illnesses.
 - 17 national brands recalled
 - 13 subsequent RFR reports.



Some Notable Outcomes of the RFR

- Glass in Animal Feed.
 - Trailer of dairy feed contained glass.
 - Feed company filed RFR upon customer complaint.
 - State investigation.
 - Trailers hauled feed ingredients & recycled glass.
 - Contaminated feed destroyed.
 - Changes to transportation practices.
 - No animals harmed.



Some Notable Outcomes of the RFR

- Milk Protein in Snack Bars.
 - Consumer complaint of severe allergic reaction.
 - Manufacturer files RFR & investigates.
 - Chocolate ingredient had undeclared milk protein.
 - Product recall, 43 subsequent RFR entries.
 - Preventive controls change:
 - Ingredient supplier information review.
 - Product label review.
 - No additional illnesses.



Generate Import Bulletins

- Informs FDA field staff on suspected problems.
 - Usually call for increased surveillance:
 - Field examination.
 - Sample collection
 - May result in an import alert.
- Examples:
 - *Salmonella* in African macadamia nuts.
 - Undeclared milk in Belgian chocolate.
 - *Listeria monocytogenes* in Canadian cheese.





Generate Import Alerts

- Guidance to FDA field staff about “significant recurring, new or unusual problems”.
 - Include background data & enforcement action:
 - Usually detention w/o physical examination.
- Examples:
 - *Salmonella* in Egyptian spices/seeds.
 - Undeclared sulfites in Chinese dried potatoes.
 - Uneviscerated herring from Canada, Ukraine.

Generate Regulatory Initiatives

- FDA Draft Guidance for Industry on *Salmonella* in Low-Moisture Foods.
 - Under development.
 - Annex focusing on nuts/nut products.
- Sulfite-Labeling Publication.
 - Targeted at countries importing dried fruits/vegetables into the US.



Generate Regulatory Initiatives

- Automatic Notification to State Agencies
 - RFR Submissions are shared with appropriate commissioned state officials.
- Risk Profile on Spices.
 - Pathogens/filth in spices.
 - Nature/extent of public health risk.
- Cantaloupe Industry Letter.
 - Food safety/best practices.



Generate Industry Initiatives

- Third-Party Audit Firms Including RFR in:
 - Guidance documents
 - Audit standards.
- Enhanced Guidance on Bakery Products.
 - American Bakers Association.
 - Focusing on undeclared allergens.
 - Direct result of RFR submissions.



Generate Industry Initiatives

- Cantaloupes and Netted Melons Guidance.
 - Western Growers, Produce Marketing Association.
 - Emphasize GAPs/GMPs.
 - Recall/Traceability.
- Industry Guidance for Spices and Seasonings.
 - American Spice Trade Association.
 - Minimize the introduction of filth.
 - Emphasize reducing the risk of *Salmonella*.

Concluding Remarks

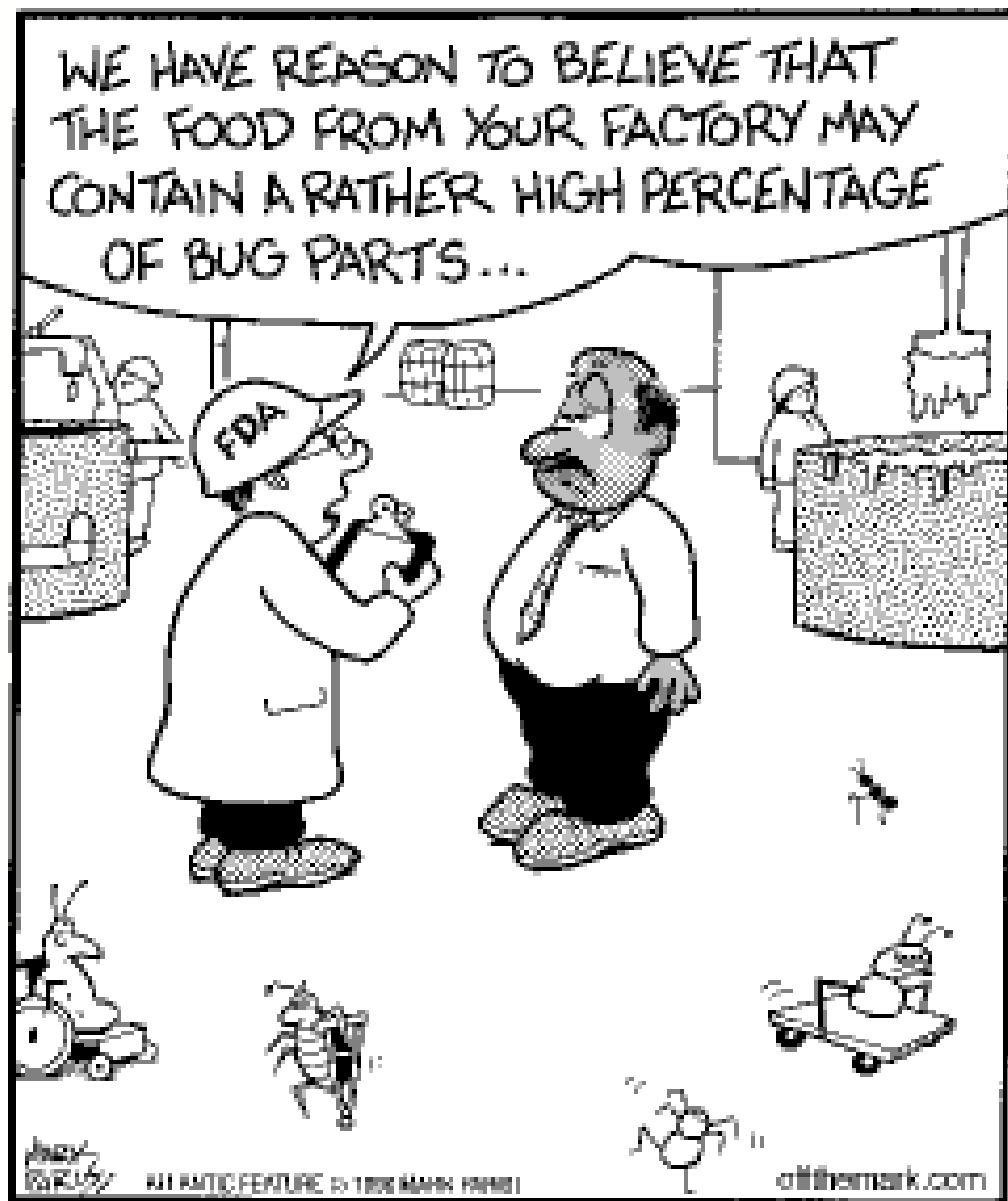
- The Reportable Food Registry has had a positive impact on food safety.
 - Illnesses/injuries have been avoided.
 - Progress on some major problem-areas:
 - *Salmonella*/spices.
 - Undeclared sulfites/imports.
- There is room for improvement.
 - *Listeria monocytogenes*.
 - Undeclared allergens.



Concluding Remarks

- The Reportable Food Registry Annual Reports are a valuable resource for industry.
 - Indicates which hazards are the most significant for your commodity.
 - Provides links to regulatory & industry guidance for controlling these hazards.
 - Indicates hazards of greatest concern for regulators in your commodity.





Thank you!

Questions?