# Recalls and Root Causes

AMANDEEP DHILLON

# *Definition:* **RECALL**

Firm's removal of marketed product that the Food & Drug Administration considers to be in violation of the law it administers and against which the agency would initiate legal action; e.g., seizure.

Does not include a **market withdrawal** or a **stock recovery**.

21 CFR Part 7.3(g)


CAUTION
POTENTIAL
RECALL AHEAD

# What is a Reportable Food Registry?

The federal Food and Drug Administration (FDA) requires that food companies inform the agency about any food (for both humans and animals) they have manufactured and released for sale that has a reasonable probability of **causing a serious adverse health consequence or death**. In FDA jargon, these are referred to as ‘reportable foods’.

# Reportable Food Registry!

- ✓Must report as soon as practicable, but within 24 hours after it is determined that an article of food is a reportable food
- ✓Must submit certain data elements report
- ✓Must investigate the cause of the adulteration
- ✓May be required to provide notification to immediate previous sources and immediate subsequent recipients of the reportable food after consultation with FDA
- ✓Must provide amended reports
- ✓Must consult with FDA to follow up
- ✓Must maintain records related to each report for 2 years


ABOUT THE PORTAL | SAFETY REPORT DIRECTORY | FAQS | RELATED LINKS | CONTACT US

## The Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all.

## Begin Reporting Here

### 1. Login

**EMAIL**

**PASSWORD**

Forgot your password?

Remember me

Log In

Or

### 2. Report As Guest

Not ready to create an account but would like to submit a report?

You can do that here.

Report as Guest

### Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

Create Account

# What is causing these RFRs?

**Table 6: Distribution of Primary RFR Entries by the Three Most Frequently Reported Food Safety Hazards and Year**

| Hazard | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total |
|---|---|---|---|---|---|---|
| *Salmonella* | 86 (37.6%) | 86 (38.2%) | 63 (28.1%) | 58 (28.7%) | 50 (24.9%) | 343 (36.1%) |
| *Listeria monocytogenes* | 33 (14.4%) | 40 (17.8%) | 48 (21.4%) | 35 (17.3%) | 38 (19.0%) | 194 (20.4%) |
| Undeclared Allergens | 69 (30.1%) | 75 (38.3%) | 85 (37.9%) | 88 (43.6%) | 95 (47.0%) | 412 (43.4%) |
| **No. of entries (percentage)** | **188 (82.1%)** | **201 (94.3%)** | **196 (87.4%)** | **181 (89.6%)** | **183 (90.6%)** | **949 (100%)** |

Sept 2009-Sept 2014

# What to do after RFR?

- Communicate with the regulatory agency as soon as a potential or actual recallable issue is known.
- Prepare a press release to the public to make them aware of the recall.
- Define the scope of the recall
- Prompt communication to the public aids in mitigating potential serious consequences to the consumers and also for the business.
- Notification to all other stakeholders will be distributed simultaneously to ensure that unsafe product is removed from commerce.

# Communication-External

| Type of Communication | External |
|---|---|
| Agency Notification Letter | Regulatory Agency |
| Reportable Food Registry | FDA |
| Press Release Specific to the Issue: Allergen, Pathogen, Foreign Material | Regulatory Agency/ General Public |
| Recall Notification | Consignee/Customer |
| Recall Notification | Company Website and Social Media |
| Recall Notification | Insurance Company |
| Recall Notification | Special Networks: hospitals, physicians, schools etc. |
| Prepared Key Statements | Media (if necessary) |

# Communication-External

| Type of Communication | External |
|---|---|
| Recall Signage/Placards/Posters | Stores/ Consumers |
| Register Lock Out | Stores/ Consumers |
| Recall Return Survey Email/Postcard | Consignee/Customer |
| Recall Effectiveness Letter | Consignee/Customer |
| Recall Effectiveness Questionnaire | Consignee/Customer |
| Recall Status Reports | Regulatory Agency |
| Certificate of Destruction | Consignee/Customer |
| Request for Recall Termination | Regulatory Agency |

# Communication-Internal

| What to Communicate | Internal |
|---|---|
| Media / External Communications Policy | Employees |
| Complaint Info for Investigation/ CAPA | Quality |
| Stop/ Hold/ Destroy Product | Production/ Operations |
| Stop Delivery/ Return or Destroy Product | Logistics |
| Credit/ Replacement/ Stop Promotions | Marketing/Sales |
| Track All Expenses | Finance/ Accounting |
| Prepared Key Statements | Consumer Affairs |
| Product Return and Replacement | Customer Service |

# Getting ahead of a regulatory action

- Voluntary Actions Memo to Regulatory agency
- Share the start up plan
- Notify your local, state and FDA at the same time
- Keep record of the communications


Thank You!