

# Reportable Food Registry - Industry Perspectives -

Annual Meeting  
International Life Sciences Institute  
January 24, 2011  
Lake Buena Vista, FL

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Illinois Institute of Technology



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Advancing Innovations in Food Safety and Nutrition Science [www.iit.edu/ncfst](http://www.iit.edu/ncfst)



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# Background



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# Food and Drug Administration Amendments Act of 2007

- Signed into law on September 27, 2007
- Amends FFD&CA
  - Revise and extend the user fee programs for prescription drugs and medical devices
  - Enhance the postmarket authorities

# Food and Drug Administration Amendments Act of 2007

- TITLE X – Food Safety
  - Section 1002 – Ensuring the Safety of Pet Food
  - Section 1003 – Ensuring Efficient and Effective Communications During a Recall
  - Section 1004 – State and Federal Cooperation
  - **Section 1005 – Reportable Food Registry**
  - Section 1006 – Enhanced Aquaculture and Seafood Inspection
  - Section 1007 – Consultation Regarding Genetically Engineered Seafood Products
  - Section 1009 – Annual Report To Congress
  - Section 1010 – Publication of Annual Reports



# FDAAA §1005

## Reportable Food Registry

### Reportable Food Registry

- Establish a Reportable Food Registry, to which instances of reportable food may be submitted via an electronic portal and a unique number issued to the person submitting the report upon receipt



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# FDAAA §1005

## Reportable Food Registry

FDA:

- Will establish an electronic portal to receive submissions
- Shall promptly review and assess information submitted to the Reportable Food Registry



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The logo for the Illinois Institute of Technology (IIT) is a red, stylized graphic resembling a triangle or a fan shape, composed of many small dots or segments.

# FDAAA §1005

## Reportable Food Registry

### Responsible Party:

- Must report as soon as practical, but no later than **24 hours** after a responsible party determines that an article of food is a reportable food
- Must submit a report through the electronic portal



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# FDAAA §1005

## Reportable Food Registry

### Responsible Party:

- Must **investigate** the cause of the reportable food if the reportable food may have originated with the responsible party
- Must **work with the FDA** authorities to follow up as needed

# FDAAA §1005

## Reportable Food Registry

### Responsible Party:

- May need to provide **notification to immediate prior sources and immediate subsequent recipients** of the article(s) of food
- Must **maintain records** of report submitted & any notifications made to FDA for **2 years**



# Past Issues



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# Past Issues

- Portal functionality (v 1.0)

# Reportable Food Registry

The screenshot shows a Microsoft Internet Explorer browser window displaying the MedWatch website. The browser's address bar shows the URL: <http://www.fda.gov/Safety/MedWatch/default.htm>. The website header includes the U.S. Department of Health & Human Services logo and the text "www.hhs.gov". Below this is the FDA logo and "U.S. Food and Drug Administration". A search bar is present with the text "A-Z Index" and "Search". The main content area features a "Safety" section with a breadcrumb trail: "Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program". The central heading is "MedWatch: The FDA Safety Information and Adverse Event Reporting Program". To the left, there is a "Resources for You" section with a list of links. To the right, there are "Spotlight" and "Recalls & Alerts" sections. The "Spotlight" section lists: "2010 Safety Alerts for Human Medical Products", "Medical Product Safety Educational Resources", "MedWatch Widget", and "MedWatch Partners". The "Recalls & Alerts" section lists: "MedWatch Safety Alerts for Human Medical Products", "FDA Patient Safety News Video Broadcasts", and "FDA Drug Safety Newsletter". The "Stay Informed" section lists: "Join the MedWatch E-list". The browser's taskbar at the bottom shows the start button, several open applications, and the system tray with the time 1:38 PM.



# Reportable Food Registry

MedWatch Online Reporting Form 3500 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm> Go Links

LEXMARK Print Now: Normal Black and White Text Only Picnik Preview Schedule

**FDA** U.S. Food and Drug Administration Department of Health and Human Services

[FDA Home Page](#) | [MedWatch Home](#) | [Contact FDA](#)

**MEDWATCH** The FDA Safety Information and Adverse Event Reporting Program

Search MedWatch  Go

## MedWatch Online Voluntary Reporting Form (3500)

Click the BEGIN button to report serious adverse events for human medical products, including potential and actual product use errors and product quality problems associated with the use of:

- FDA-regulated drugs,
- biologics (including human cells, tissues, and cellular and tissue-based products)
- medical devices (including in vitro diagnostics)
- special nutritional products and cosmetics

### A Message about Privacy

You can continue to make adverse event reports under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The HIPAA Privacy Rule is not intended to disrupt or discourage adverse event reporting in any way. In fact, the Privacy Rule specifically permits covered entities (such as pharmacists, physicians or hospitals) to report adverse events and other information related to the quality, effectiveness and safety of FDA-regulated products both to the manufacturers and directly to FDA.

For more information, please go to the [Medwatch HIPAA Compliance page](#).

Click the BEGIN button below to begin the MedWatch Online reporting process

**BEGIN**

**Please note:** Javascript must be enabled for this application to work properly. Please click [here](#) if you are unsure if your javascript is enabled.

start In... 4 W... Gui... Reg... Bra... 4 I... Search Desktop 1:41 PM



# Reportable Food Registry

The screenshot shows a Microsoft Internet Explorer browser window displaying the 'Reportable Food Registry for Industry' page. The browser's address bar shows the URL: <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>. The page header includes the U.S. Department of Health & Human Services logo and the FDA U.S. Food and Drug Administration logo. A search bar and navigation links are visible. The main content area is titled 'Reportable Food Registry for Industry' and features a 'Food' sidebar with a 'Reportable Food Registry' link. The central text explains the registry's purpose and provides links for industry and consumers. A 'Spotlight' section highlights guidance for industry and a PDF report. A 'Contact Us' section provides an email address for the RFR Center and a help desk for technical issues. The Windows taskbar at the bottom shows the start button, several open applications, and the system clock at 1:45 PM.

Reportable Food Registry for Industry - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm> Go Links

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

FDA U.S. Food and Drug Administration A-Z Index Search

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

**Food** Share Email this Page Print this page Change Font Size

Home > Food > Food Safety > Food Safety Programs

**Food Safety**

- Food Safety Programs
- Reportable Food Registry**
- Reportable Food Registry
- Technical FAQs

**Resources for You**

- Food and Drug Administration Amendments Act (FDAAA) of 2007
- Sec. 417. [21 USC 350f] Reportable food registry.

**Reportable Food Registry for Industry**

**For Industry:** Submit a Report

**For Consumers:** Contact FDA

**Spotlight**

- Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007
- Reportable Food Registry (RFR) At a Glance (PDF - 89KB)

**Contact Us**

**RFR Center** for questions about policies, procedures and interpretations  
[RFRSupport@fda.hhs.gov](mailto:RFRSupport@fda.hhs.gov)

**RFR Help Desk** for technical and computer-related

start Inb... W. Gui... Reg... Bra... 2 I... Search Desktop 1:45 PM



# Past Issues

- Portal functionality (v 1.0)
  - Based on Medwatch
  - FDA website
  - Clunky
  - Couldn't save
  - Couldn't edit



# Past Issues

- Portal functionality
- Vague definitions
  - “Ownership”
    - Does one “own” the product based on purchase order?
    - Does one “own” the product when possession is taken?



# Past Issues

- Portal functionality
- Vague definitions
  - “Ownership”
  - “Transfer”
    - Movement to different locations within the same company?
    - Movement to third-party locations (eg. warehouses)
    - Acceptance of product?



# Past Issues

- Portal functionality
- Vague definitions
- Determination criteria
  - Testing results
    - Conflicting results
    - Indicator results
      - Eg. *Listeria* spp vs *L. monocytogenes*



# What Has Changed



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# What Has Changed

- Portal
  - Moved to NIH
  - MUCH better Functionality

# Reportable Food Registry 2011

Safety Reporting Portal - Windows Internet Explorer  
https://www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=D34686A332E8801F942A5DFAE48C21BF0613EB71

Safety Reporting Portal

## Safety Reporting Portal

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  
[Forgot Password](#)

**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](#)

### Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances.

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- Drug Manufacturers

Others, including concerned citizens, health professionals, and public health officials, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

[Learn more about mandatory and voluntary reporting](#)

### Reports You Can Submit Through this Portal

FDA safety issues involving:

- Human or animal reportable foods
- Animal drugs
- Pet foods

NIH safety issues involving:

- NIH gene-transfer research

For other issues, [find out where to submit your report](#).

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

Internet | Protected Mode: On 65%

9:50 PM  
1/23/2011



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# What Has Changed

- Portal
  - Moved to NIH
  - MUCH better Functionality
  - Allows for “accounts”
    - System pre-populates fields with information (e.g., names, addresses, phone numbers, etc.) provided when establishing the account.
    - Reports can be saved and finished at a later time.
    - One can see a list of all of your submitted reports.



# Reportable Food Registry 2011

**Safety Reporting Portal**

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

## The Safety Reporting Portal

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Forgot your password?

Remember me

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### Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may

### Reports You Can Submit Through this Portal

FDA safety issues involving:

# What Has Changed

- Portal
  - Moved to NIH
  - MUCH better Functionality
  - Allows for “accounts”
  - Allows attachments in multiple formats
    - pdf, jpg, bmp, jif, tif, rtf, txt, etc.



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# What Has Changed

- Portal
- Guidance has been updated
  - <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>

# Reportable Food Registry 2011

GuidanceComplianceRegulatoryInformation.pdf - Adobe Acrobat Pro

File Edit View Document Comments Forms Tools Advanced Window Help

Create Combine Collaborate Secure Sign Forms Multimedia Comment

1 / 13 139% Find

U.S. Department of Health & Human Services

**FDA U.S. Food and Drug Administration**

[Home](#) > [Food](#) > [Guidance, Compliance & Regulatory Information](#) > [Guidance Documents](#)

**Food**

**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)**  
Contains Nonbinding Recommendations

Available in [PDF](#).

*Additional copies are available from:*  
*Additional copies from:*  
*Office of Food Defense, Communication and Emergency Response, HFS-005*  
*Center for Food Safety and Applied Nutrition*  
*Food and Drug Administration*  
*5100 Paint Branch Parkway*  
*College Park, MD 20740*  
*(Tel) 301-436-1500*  
<http://www.fda.gov/FoodGuidances>

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

6:01 AM  
1/24/2011

# What Has Changed

- Portal
- Guidance has been updated
  - <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>
  - Vague definitions are better described



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# Example - “Transfer”

- Intra-company transfer to a warehouse in another state (country?) – NOT a transfer
- Company transfers product to a commercial warehouse next door to the companies facility – “Transferred!”

**Trigger is WHO controls or “holds” the product.**

# Unresolved Issues



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# Unresolved Issues

- Unresolved Issues
  - “Presumptive” positive test results (vague)
    - When does sample become “reportable”?
      - Depends....method, circumstances
      - Could affect downstream customers



# Unresolved Issues

- Unresolved Issues
  - “Presumptive” positive test results (vague)
  - “Transfer” vs “Ownership”
    - Although clearer, is not often rational
      - Warehouse (leased?)
      - Delivery truck



# Unresolved Issues

- Unresolved Issues
  - “Presumptive” positive (vague)
  - Transfer (although clearer, is not often rational)
  - Impact of Food Safety Modernization Act\*
    - Need for “accredited” laboratories?
    - Potential for additional recalls to avoid “mandatory”
    - Downstream impact of a suspended registration?
    - Increased importance of validated preventive controls
    - Traceability changes



# Unresolved Issues

- Unresolved Issues
  - “Presumptive” positive (vague)
  - Transfer (although clearer, is not often rational)
  - Impact of Food Safety Modernization Act\*
  - Role of Guidance?
    - RFR
    - Other?

# Unintended Consequences



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# Unintended Consequences

- More large, widespread recalls



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# Unintended Consequences

- More large, widespread recalls
- Increased “chasing zeros” mentality
  - Based on “adulteration” standard vs risk

# Unintended Consequences

- More large, widespread recalls
- Increased “chasing zeros” mentality
- Prompted need for better lot definition
  - Limit scope of recall



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# Unintended Consequences

- More large, widespread recalls
- Increased “chasing zeros” mentality
- Prompted need for better lot definition
- **Role of testing?**
  - To test or not to test?
  - WHEN to test?
  - Reporting of test results?
    - Some small companies still do not know RFR requirements



# Unintended Consequences

- More large, widespread recalls
- Increased “chasing zeros” mentality
- Prompted need for better lot definition
- Role of testing?
- Regulatory scrutiny on foreign vs. domestic establishments?

# Unintended Consequences

- More large, widespread recalls
- Increased “chasing zeros” mentality
- Prompted need for better lot definition
- Role of testing?
- Regulatory scrutiny on foreign vs. domestic establishments?
- **Potential for more litigation**



# Summary



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# Summary

- Benefits to industry
  - RFR makes easier to assess “blame” (liability)



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# Summary

- Benefits to industry
  - RFR makes easier to assess “blame” (liability)
  - Better understanding of contaminants (paper trail)
    - “reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health”



# Summary

- Benefits to industry
  - RFR makes easier to assess “blame” (liability)
  - Better understanding of contaminants (paper trail)
  - Enhanced consumer confidence



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# Summary

- Benefits to industry
  - RFR makes easier to assess “blame” (liability)
  - Better understanding of contaminants (paper trail)
  - Enhanced consumer confidence
  - Safer food, fewer outbreaks?



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# Summary

- Benefits to industry
- Negative impact on industry
  - More paperwork and bureaucracy



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# Summary

- Benefits to industry
- Negative impact on industry
  - More paperwork and bureaucracy
  - Increases costs of business



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# Summary

- Benefits to industry
- Negative impact on industry
  - More paperwork and bureaucracy
  - Increases costs of business
  - Complicates testing strategy



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# Summary

- Benefits to industry
- Negative impact on industry
  - More paperwork and bureaucracy
  - Increases costs of business
  - Complicates testing strategy
  - Impacts product holds and logistics



# Summary

- Benefits to industry
- Negative impact on industry
  - More paperwork and bureaucracy
  - Increases costs of business
  - Complicates testing strategy
  - Impacts product holds and logistics
  - Could damage reputation of company



# Questions?



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