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# **FDA Reportable Food Registry**

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# Reportable Food Registry

- Congressional intent: provide a reliable mechanism to track patterns of adulteration in food in order to support efforts by FDA to target limited inspection resources to protect the public health
- Industry compliance became **mandatory** as of **September 8, 2009**, when the electronic portal opened
- Failure to comply is a prohibited act under the FFD&CA

# What is a “reportable food”?

- “Reportable food” – an article of food ... which has a *reasonable probability of causing serious adverse health consequences or death to humans or animals*
  - All FDA-regulated foods, except dietary supplements and infant formula.
  - Domestic and imported foods
  - Includes animal feed

# Who has to report?

- Instances of reportable food shall be submitted by:
  - A “responsible party,” i.e., the individual who submits the food facility registration under section 415(a), and
  - Voluntarily by federal, state, and local public health officials

# Who is a “responsible party”?

- FFDC 415(a): “any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States [shall] be registered”
- “does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels”

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# 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
- Must investigate the cause of the reportable food if the reportable food may have originated with the responsible party

# Responsible Party:

- Must submit initial information; followed by supplemental reports
- Must work with the FDA authorities to follow up as needed
- 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

# A responsible party is not required to report:

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

## Food

### Food Safety

#### Food Safety Programs

#### ▶ Reportable Food Registry

[Reportable Food Registry Annual Report](#)

### 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](#)

## 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 \(French\)](#)
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- [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 electronic portal for Industry to report when there is reasonable

### Spotlight

- [Reportable Food Registry Annual Report](#)
- [Draft Guidance for Industry: Questions and Answers Regarding the RFR as Established by the FDA Amendments Act of 2007 \(Edition 2\)](#)

### Contact Us

#### Reportable Food Registry

**RFR Center** for questions about policies, procedures and interpretations

[RFRSupport@fda.hhs.gov](mailto: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](mailto:support.srp@jbsinternational.com)



# 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

Or

[Forgot your password?](#)

Remember me

[Log In](#)

### 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.](#)





# Safety Reporting Portal

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## Account Registration

\*=Required

\*Which of the following best describes you?

- A **food facility** or **responsible party** that manufactures, processes, packs, or holds foods who is submitting a **reportable food** report.
- A federal, state, or local **public health official** who is submitting a **reportable food** report involving human and/or animal food.
- A **veterinarian or veterinary staff member** who is submitting a product problem and/or adverse event report involving **pet food**.
- A **consumer or concerned citizen** who is submitting a product problem and/or adverse event report involving **pet food**.
- A **marketing authorization holder (manufacturer)** for an **animal drug** who is submitting a report on a product problem and/or an adverse event.
- A clinical trial **primary investigator or researcher** who needs to report an adverse event involving a **gene research study**.
- None of these describe me.

Submit

Exit



[PRIVACY POLICY](#) | [FREEDOM OF INFORMATION ACT](#) | [ACCESSIBILITY](#) | [DISCLAIMER](#)

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

### Your Site Information

\*Food Facility Registration Number (FFRN)

Federal Establishment Inventory (FEI) Number

Data Universal Numbering (DUNS) Number

Food Canning Establishment (FCE) Number

\*Organization Type (check all that apply)

Acidified Food Processor

Caterer/Catering Point

Certified Shellfish Establishment

Commissary

Contract Sterilizer

Grower

Labeler/Relabeler

Low Acid Canned Processor

Manufacturer

Own Label Distributor

Repacker/Packer

Salvage Operation

Shipper

Warehouse-Ambient Storage

Warehouse-Frozen Storage

Warehouse-Refrigerated Storage

### Your Contact Information

\*First Name

\*Last Name

Job Title

\*Organization Name

\*Primary Phone

Other Phone

Fax

\*Country

\*Street Address Line 1

# Safety Reporting Portal

Welcome Guest

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## New Guest Report

You have chosen to use this portal as a Guest reporter.

Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

\*Select the option that best describes why you are reporting:

- Start a new report
- Follow-up on a report previously submitted
- Follow-up on a report previously submitted by another person
- None of the above

Message from webpage

Due to lack of activity your session will timeout in 1 minute, click OK to continue.

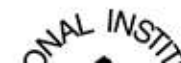
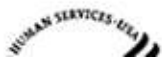
OK Cancel

\*Which of the following best describes you?

- A **food facility or responsible party** that manufactures, processes, packs, or holds foods who is submitting a **reportable food** report.
- A federal, state, or local **public health official** who is submitting a **reportable food** report involving human and/or animal food.
- A **veterinarian or veterinary staff member** who is submitting a product problem and/or adverse event report involving **pet food**.
- A **consumer or concerned citizen** who is submitting a product problem and/or adverse event report involving **pet food**.
- A **marketing authorization holder (manufacturer)** for an **animal drug** who is submitting a report on a product problem and/or an adverse event.
- A clinical trial **primary investigator or researcher** who needs to report an adverse event involving a **gene research study**.
- None of these describe me.

Begin Report

Exit





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## New Guest Report

You have chosen to use this portal as a Guest reporter.

Reports submitted as a Guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

### \*Select the option that best describes what you want to do:

- Start a new report
- Follow-up on a report previously submitted as a guest portal user.
- Follow-up on a report previously submitted as a logged in user.
- None of the above

### \*Which of the following best describes you?

- A **food facility** or **responsible party** that manufactures, processes, packs, or holds foods who is submitting a **reportable food** report.
- A federal, state, or local **public health official** who is submitting a **reportable food** report involving human and/or animal food.
- A **veterinarian or veterinary staff member** who is submitting a product problem and/or adverse event report involving **pet food**.
- A **consumer or concerned citizen** who is submitting a product problem and/or adverse event report involving **pet food**.
- A **marketing authorization holder (manufacturer)** for an **animal drug** who is submitting a report on a product problem and/or an adverse event.
- A clinical trial **primary investigator or researcher** who needs to report an adverse event involving a **gene research study**.
- None of these describe me.

[Begin Report](#)

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**Name:** Mandatory Reportable Food Report (Section 1005 of Public Law 110-85)

**ID:** 5240 (I)

**Created:** 08/15/2011

## Introduction

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**OMB Approval Number:** 0910-0645

**OMB Expiration Date:** 09/30/2012

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## Introduction

**\* =Required**

Reportable Food reports are for facilities that manufacture, process, pack, or hold FDA-regulated food or animal feed for consumption in the U.S., or Federal, state, or local public health officials.

Consumers, food retailers and food service operations who wish to report a food risk or an illness associated with food to FDA, please see [Your Guide to Reporting Problems at FDA](#).

You have chosen to submit a Mandatory Reportable Food Report to the FDA. Please be advised that under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. Persons who are required to submit a facility registration under section 415 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 350d] are responsible parties required by law to submit reports regarding instances of reportable foods to FDA through the Safety Reporting Portal.

This report has up to seven sections. After you answer the questions on this page, you may complete the other pages in any order. The amount of time required to complete this report will vary depending upon the information you have to provide. As you complete each field, your responses are automatically saved. To submit this report, you must complete all required fields that are marked with a red asterisk.

After consultation with the responsible party, FDA may require the responsible party to amend its report and/or provide notification to the immediate previous source(s) and/or immediate subsequent recipient(s) of the article of food. When you submit this initial report, you will receive an FDA-assigned report ID, also known as Individual Case Safety Report (ICSR) number, on the confirmation page. It is important that you use this report ID/ICSR number if you submit amended reports and/or consult with FDA regarding this instance of reportable food. Depending on the circumstances, you may also need to use this number if you notify immediate previous sources or immediate subsequent recipients of the reportable food.

**Please note:** This report is not considered an admission that an article of food (or feed) is adulterated or caused or contributed to serious injury, illness or death. This report shall be considered to be a safety report under section 756 of the Food, Drug, and Cosmetic Act [21 U.S.C. 379v] and may be accompanied by a statement, which shall be part of any report released for public disclosure, that denies that the report constitutes an admission that the product involved caused or contributed to a death, serious injury, or serious illness. You may upload such a statement as an attachment to this report, if desired.

**\*Enter a title to help you identify this report (max length: 50 characters)**

Exit

Submit Report

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## Contact Information

**\*=Required**


The responsible party that must submit a report regarding instances of reportable food to FDA through the Reportable Food electronic portal is a person (including individuals, partnerships, corporations, and associations) who submits the registration under section 415(a) of the FD&C Act [21 U.S.C. 350d] for a food/feed facility required to register under section 415(a), at which the reportable food is manufactured, processed, packed, or held.

**\*Are you located in the food or feed facility for which you are reporting?**

### Your Site Information

**\*Organization Name**

**Organization Type (check all that apply)** 

Please select   
Please select  
Yes  
No, I am the responsible party, but not located at the Food Facility  
No, I am the US Agent

- Acidified Food Processor
- Caterer/Catering Point
- Certified Shellfish Establishment
- Commissary
- Contract Sterilizer
- Grower
- Labeler/Relabeler
- Low Acid Canned Processor
- Manufacturer
- Own Label Distributor
- Repacker/Packer
- Salvage Operation
- Shipper
- Warehouse-Ambient Storage
- Warehouse-Frozen Storage
- Warehouse-Refrigerated Storage

**\*Food Facility Registration Number (FFRN)** 

## Your Contact Information

First Name

Last Name

Job Title

Email

Confirm Email

Primary Phone

Other Phone

Fax


## Location of the Reportable Food

The Location of the Reportable Food is where the food is located within the responsible party's organization or company.

Organization Name

Organization Type (check all that apply) 

- Acidified Food Processor
- Caterer/Catering Point
- Certified Shellfish Establishment
- Commissary
- Contract Sterilizer
- Grower
- Labeler/Relabeler
- Low Acid Canned Processor
- Manufacturer
- Own Label Distributor
- Repacker/Packer
- Salvage Operation
- Shipper
- Warehouse-Ambient Storage
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\*Food Facility Registration Number (FFRN) 

Federal Establishment Inventory (FEI) Number

Data Universal Numbering System (DUNS) Number

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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)**

**\*Date the article of food was determined to be a Reportable Food**



**\*How did your site first learn about the Reportable Food?**

**\*You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem has been occurring. If known, specify if the problem involves biological, physical, radiological or chemical adulteration.**



**\*Do you believe the Reportable Food issue was intentionally caused?**

For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g, the patient's initials) to each adverse event. The assigned code will permit the responsible party to cross-reference identifying information and contact information for the patient in the event that the responsible party needs to follow-up.

**\*Has a human adverse event been reported?**

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**ID:** 5240 (I)  
**Created:** 08/15/2011

## Products

**\*=Required**

Please add all products related to the Reportable Food issue you are reporting. On subsequent screens you will be given the opportunity to provide supplier and distribution information.

**\*Product Details**

Product Brand Name	Distributed?	Received?
Click on the <b>Add</b> button to add an item		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>

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[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

## Product Details

**\* Product Name (Include the brand name and the product name, as printed on the product label or the product itself.)**

**\* Product Type**

**Package Category**

 Bulk Institutional Retail

**Container Type (please describe the smallest container available for retail sale or further distribution)**

**Container Size (please describe the smallest container available for retail sale or further distribution)**

**Universal Product Code (UPC) from label**

**\* Intended Product Use**

**\* Did you receive the reportable food from an outside source?**

**Was the product imported into USA?**

**\* Was the product recalled?**

**\* Was the product distributed in any form to another location?**

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## Distribution Information

**\*=Required**

For each product distributed, please provide information on where the product was distributed, and which lots went to each distribution location.

### Step 1: Select a distributed product

Product Name	
<input checked="" type="radio"/>	aasdf

|< < Page 1 of 1 > >|

Please enter information for at least one distribution site. After you enter at least one record, you may upload a file with any remaining sites in the Attachment section.

### \*Step 2: Add distribution sites for aasdf

Site Name	City/Town	State/Province	Site Contact
<input checked="" type="radio"/>			

|< < Page 1 of 1 > >|

### Step 3: Add information about the lots or batches of aasdf sent to

Lot/Batch ID	Expiration/Use By Date
<input type="button" value="Add"/>	

Click on the **Add** button to add an item


## Step 2: Add distribution sites for aasdf

Site Name	<input type="text"/>
Country	<input type="text" value="Please select"/>
Street Address Line 1	<input type="text"/>
Street Address Line 2	<input type="text"/>
City/Town	<input type="text"/>
State	<input type="text" value="Please select"/>
ZIP/Postal Code	<input type="text"/>
<b>* Was this site notified about the Reportable Food?</b>	<input type="text" value="Please select"/>
Site Contact First Name	<input type="text"/>
Site Contact Last Name	<input type="text"/>
Job Title	<input type="text"/>
Email	<input type="text"/>
Confirm Email	<input type="text"/>
Primary Phone	<input type="text"/>
Other Phone	<input type="text"/>
Fax	<input type="text"/>

Save

Cancel


**Step 3: Add information about the lots or batches of aasdf sent to**

Lot/Batch ID	<input type="text" value="123"/>
Expiration/Use By Date	<input type="text"/> 
First Date Sent	<input type="text"/> 
Last Date Sent	<input type="text"/> 
Total Number of Containers of this Lot Sent	<input type="text"/>
Total Amount of this Lot Sent	<input type="text"/> <input type="text" value="Select Unit of Measure"/>

Save

Cancel

**PRODUCT NAME**

 aasdf
---

Page 1 of 1

Please enter information for at least one distribution site. After you enter at least one record, you may upload a file with any remaining sites in the Attachment section.

**\*Step 2: Add distribution sites for aasdf**

Site Name	City/Town	State/Province	Site Contact
			

Add Edit Delete

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Add Edit Delete

Exit

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## Supplier Information

**\*=Required**

For each product received, please provide information on the supplier and the lots or batches received.

### Step 1: Select a received product

Product Name	
<input checked="" type="radio"/>	aasdf

< < Page 1 of 1 > >

Please enter information for at least one supplier. After you enter at least one record, you may upload a file with any remaining suppliers in the Attachment section.

### \*Step 2: Add supplier sites for aasdf

Site Name	City/Town	State/Province	Site Contact
<input checked="" type="radio"/>			

< < Page 1 of 1 > >

### Step 3: Add information about the lots of aasdf received from

Lot/Batch ID	Expiration/Use By Date	Disposed?
Click on the <b>Add</b> button to add an item		

## Step 2: Add supplier sites for aasdf

Site Name

Type of Site (check all that apply)

- Acidified Food Processor
- Caterer/Catering Point
- Certified Shellfish Establishment
- Commissary
- Contract Sterilizer
- Grower
- Labeler/Relabeler
- Low Acid Canned Processor
- Manufacturer
- Own Label Distributor
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- Salvage Operation
- Shipper
- Warehouse-Ambient Storage
- Warehouse-Frozen Storage
- Warehouse-Refrigerated Storage

Country

Street Address Line 1

Street Address Line 2

City/Town

State

ZIP/Postal Code

\*Did this site notify you about the Reportable Food?

Site Contact First Name

Site Contact Last Name

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**Step 3: Add information about the lots of aasdf received from**

Lot/Batch ID

Expiration/Use By Date

 12

Date First Received

 12

Date Last Received

 12

Total Number of Containers of this Lot Received

Total Amount of this Lot Received

Select Unit of Measure

**\*Was any of this lot disposed of? (e.g. destroyed, reconditioned)**

Please select

Please select

Yes

No

Unknown At This Time

Save

Cancel

Please enter information for at least one supplier. After you enter at least one record, you may upload a file with any remaining suppliers in the Attachment section.

**\*Step 2: Add supplier sites for aasdf**

Site Name	City/Town	State/Province	Site Contact
+			
Add	Edit	Delete	< < Page 1 of 1 > >

Add Edit Delete

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## Attachments

**\*=Required**

You may upload up to 5 (10 MB each) attachments per submission. The following file extensions are permitted: .doc,.docx,.pdf,.bmp,.gif,.jpg,.jpeg,.png,.tif,.tiff,.txt,.rtf,.xls,.xlsx,.wpd.

File Name	Type	Description
Click on the <b>Add</b> button to add an item		
<input type="button" value="Add"/>	<input type="button" value="Edit"/>	<input type="button" value="Delete"/>

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[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

## Attach File

\*File to attach

Browse

\*Required

\*Description of Attachment

\*Type of Attachment

Please select

Save

Cancel

Welcome Guest

Name: Manda  
Food R  
1005 o  
-85)

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.doc,.docx,.pdf,.bmp,.gif,.jpg,.jpeg,.png,.tif,.tiff,.txt,.rtf,.xls,.xlsx,.wpd.

File Name	Type	Description
-----------	------	-------------

Click on the **Add** button to add an item.

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**I received a confirmed positive microbiological test result indicating the presence of a pathogen in a food. Based on this test result, I determined the food to be “reportable”. However, I retested the food for the pathogen and the second test result did not indicate the presence of the pathogen in the food. Should I still consider the food to be reportable?**

Yes. There are a number of explanations why a food may test positive for a pathogen in one test and negative in one or more additional tests although the food continues to be contaminated. For example, the distribution of a pathogen in the food may not be homogeneous. Therefore, absent other circumstances clearly demonstrating the inaccuracy of the first test result, the first test result upon which the reportable food determination was made should be considered valid.

**If a food facility enters into a contract with a farmer whereby the food facility agrees it will purchase the produce grown by that farmer when that produce is harvested, and the facility tests the produce in the field before it is harvested and determines that it meets the definition of a reportable food, must the food facility that contracted with the farmer submit a reportable food report?**

No, the food facility that contracted with the farmer and tested the produce in the field is not required to submit a reportable food report, provided that the facility did not manufacture, process, pack, or hold the produce and therefore never became a responsible party with respect to the produce. However, if the field had been harvested and the contaminated produce had been moved to the food facility, the facility would have become a responsible party because it “held” the food and would be required to submit a reportable food report.

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# **FDA Reportable Food Registry**

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**Questions?**