

Description of 5 Scenarios

Filename	Conditionality Demonstrated
Scenario1 <i>Salmonella</i> as Agent.pub	<i>Salmonella</i> is an example of a microbiological hazard. Shows the questions “*Is a Bacterial Isolate Available for collection?” and “*Was product treated to reduce microorganisms?” displayed when a microbiological agent is chosen in response to “*Reason this food is reportable (agent).”
Scenario2 <i>Salmonella</i> and Treatment.pub	<i>Salmonella</i> is an example of a microbiological hazard. In addition to Scenario1’s questions, this shows “Microbial Reduction Treatment Details” question when Yes is chosen in response to “*Was product treated to reduce microorganisms?”
Scenario3 Foreign Object.pub	Shows what questions are displayed when a non-microbiological agent is chosen in response to “*Reason this food is reportable (agent).”
Scenario4 Foreign Object for Animal.pub	In addition to Scenario3’s questions, this shows the two questions displayed when “*Intended Product Use” is answered with the selection of “Animal:” “*Animal Species Intended For,” and “*Lifestage of Animal Intended For.”
Scenario5 Foreign Object Received and Distributed for Animal.pub	Building on Scenario4, shows the followup questions presented when “*Did you receive the reportable food from an outside source?” and “*Was the product distributed in any other form to another location?” are answered “Yes.”

Safety Reporting Portal - Windows Internet Explorer

https://www.safetyreporting.nhs.gov/for/Work/Report.aspx?mainInstance=1&MP=5594240A42395A2E68E0F6CA5493DCD08E7

File Edit View Favorites Tools Help

Safety Reporting Portal

Safety Reporting Portal

Welcome Guest

HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP

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.

Done

Start Microsoft Office Inboxes - Microsoft Out Proposed RFR IT Mod Safety Reporting Por Local intranet

1st high level condition - must be a mandatory reportable food submission in RFR RQ

Scenario 1 → microbiological hazard condition (Salmonella)

Welcome B. Reddington HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85)
ID: 9470 (1)
Created: 04/13/2012

Problem Summary

- Introduction
- Contact Information
- Problem Summary**
- Products
- Distribution Information
- Supplier Information
- Attachments

My Report History

OMB Approval Number:	0910-0645
OMB Expiration Date:	09/30/2012
OMB Burden Statement	

***=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?

*Reason this food is reportable (agent)

*What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?

*To the best of your knowledge, has all of the reportable food been removed from commerce?
 Yes No Unknown Other

What corrective actions have been taken to prevent future occurrences?

*Is a Bacterial Isolate Available for collection? Yes No Unknown Other

*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?

*Has an animal adverse event been reported?

*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.

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Product Details

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

Pg 1

Welcome B. Red

Name: Manda
Food R
1005 d
110-85
ID: 9470 (
Created: 04/13/

Introduction

Contact Inf

Problem Su

Products

Distribution

Supplier Inf

Attachment

My Report His

OMB Approval
Number:

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Date:

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Insert.)

*Product Type

Please select

Package Category

Bulk Institutional Retail

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

Please select

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

Select Unit of Measure

Universal Product Code (UPC) from label

*Manufacturing/Production Date(s)

Start End

*Product Commodity Type

Please select

*How did you determine which products/lots/batches were affected?

*Use-by dates, if any, or approximate Shelf Life

*Was product treated to reduce microorganisms?

Yes No Unknown Other

*Intended Product Use

Please select

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

Please select

*Was the product recalled?

Please select

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

Please select

Save

Cancel

LOGOUT

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Scenario 2 → microbiological hazard (Salmonella) and
 Product was treated to reduce microorganisms
 (2 conditions)

Welcome B. Reddington HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

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

ID: 9470 (1)

Created: 04/13/2012

- Introduction
- Contact Information
- Problem Summary
- Products
- Distribution Information
- Supplier Information
- Attachments

My Report History

OMB Approval Number: 0910-0645

OMB Expiration Date: 09/30/2012

[OMB Burden Statement](#)

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?**

***Reason this food is reportable (agent)**

***What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?**

***To the best of your knowledge, has all of the reportable food been removed from commerce?** Yes No Unknown Other

What corrective actions have been taken to prevent future occurrences?

***Is a Bacterial Isolate Available for collection?** Yes No Unknown Other

***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?**

***Has an animal adverse event been reported?**

***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.**

Save Draft
Exit
Submit Report
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Welcome B. Red

Name: Manda
Food R
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110-85

ID: 9470 (

Created: 04/13/

- Introduction
- Contact Inf
- Problem Sur
- Products**
- Distribution
- Supplier Inf
- Attachmen

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Number:

OMB Expiration
Date:

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

***Product Type**

Package Category

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

***Manufacturing/Production Date(s)**

***Product Commodity Type**

***How did you determine which products/lots/batches were affected?**

***Use-by dates, if any, or approximate Shelf Life**

***Was product treated to reduce microorganisms?**

***Microbial Reduction Treatment Details**

***Intended Product Use**

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

***Was the product recalled?**

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

Please select

Bulk Institutional Retail

Please select

Select Unit of Measure

Start End

Please select

Yes No Unknown Other

Please select

Please select

Please select

Please select

Save Cancel

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Scenario 3 → Foreign object is hazard

Welcome B. Reddington

HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85)
ID: 9470 (1)
Created: 04/13/2012

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?**

Reason this food is reportable (agent)

***What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?**

***To the best of your knowledge, has all of the reportable food been removed from commerce?** Yes No Unknown Other

What corrective actions have been taken to prevent future occurrences?

***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?**


***Has an animal adverse event been reported?**

***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.**

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Product Details

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



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Name: Manda
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ID: 9470 (
Created: 04/13/

- Introduction
- Contact Inf
- Problem Su
- Products**
- Distribution
- Supplier Inf
- Attachment

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Number:
OMB Expiration
Date:
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***Product Type**

Please select [dropdown]

Package Category

Bulk Institutional Retail

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

Please select [dropdown]

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

[text input] Select Unit of Measure [dropdown]

Universal Product Code (UPC) from label

[text input]

***Manufacturing/Production Date(s)**

Start [calendar] End [calendar]

***Product Commodity Type**

Please select [dropdown]

***How did you determine which products/lots/batches were affected?**

[text area]

***Use-by dates, if any, or approximate Shelf Life**

[calendar]

***Intended Product Use**

Please select [dropdown]

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

Please select [dropdown]

***Was the product recalled?**

Please select [dropdown]

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

Please select [dropdown]

Save Cancel

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Scenario 4 - Foreign object hazard and For Animal consumption conditions

Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85)
ID: 9470 (1)
Created: 04/13/2012

Problem Summary

- Introduction
- Contact Information
- Problem Summary
- Products
- Distribution Information
- Supplier Information
- Attachments

My Report History

OMB Approval Number: 0910-0645
OMB Expiration Date: 09/30/2012
[OMB Burden Statement](#)

***=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?**

***Reason this food is reportable (agent)**

***What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?**

***To the best of your knowledge, has all of the reportable food been removed from commerce?**
 Yes No Unknown Other

What corrective actions have been taken to prevent future occurrences?

***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?**

***Has an animal adverse event been reported?**

***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.**

Welcome B. Red
Name: Manda
Food R
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ID: 9470 (
Created: 04/13/
Introduction
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Problem Su
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Distribution
Supplier Inf
Attachment

My Report His
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Number:
OMB Expiration
Date:
OMB Burden Stat

name, as printed on the product label or the product itself.)

*Product Type

Please select

Package Category

Bulk Institutional Retail

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

Please select

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

Select Unit of Measure

Universal Product Code (UPC) from label

*Manufacturing/Production Date(s)

Start End

*Product Commodity Type

Please select

*How did you determine which products/lots/batches were affected?

*Use-by dates, if any, or approximate Shelf Life

*Intended Product Use

Animal

*Animal Species Intended For

<Checkboxes for various species>

*Lifestage of Animal Intended For

<Checkboxes for various lifestages>

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

Yes

*Was the product recalled?

Please select

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

Yes

Save Cancel

LOGOUT

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Scenario 5 → foreign object
 For Animal Consumption
 Lots of product distributed
 Lots of product reviewed
 (4 conditions)

Welcome B. Reddington HOME FAQs RELATED LINKS CONTACT US FEEDBACK HELP LOGOUT

Name: Mandatory Reportable Food Report (Section 1005 of Public Law 110-85)
ID: 9470 (1)
Created: 04/13/2012

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?**

***Reason this food is reportable (agent)**

***What did your investigation identify as the root cause of the problem (if you were required to conduct an investigation under section 417(d)(1)(B) of the FD&C Act)?**

***To the best of your knowledge, has all of the reportable food been removed from commerce?**
 Yes No Unknown Other

What corrective actions have been taken to prevent future occurrences?

***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?**

***Has an animal adverse event been reported?**

***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.**

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Product Details

***Product Name (Include the brand name and the product**

Welcome B. Red
Name: Manda
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ID: 9470
Created: 04/13/12
Introduction
Contact Inf
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Products
Distribution
Supplier Inf
Attachment

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Number:
OMB Expiration
Date:
OMB Burden Stat

name, as printed on the product label or the product itself.)

*Product Type

Please select

Package Category

Bulk Institutional Retail

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

Please select

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

Select Unit of Measure

Universal Product Code (UPC) from label

*Manufacturing/Production Date(s)

Start End

*Product Commodity Type

Please select

*How did you determine which products/lots/batches were affected?

*Use-by dates, if any, or approximate Shelf Life

*Intended Product Use

Animal

*Animal Species Intended For

<Checkboxes for various species>

*Lifestage of Animal Intended For

<Checkboxes for various lifestages>

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

Yes

Have you notified all immediate previous sources of this reportable food?

Yes No Unknown Other

*Was the product recalled?

Please select

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

Yes

*Have you notified all immediate subsequent recipients of this reportable food?

Yes No Unknown Other

Save Cancel

LOGOUT

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