Description of 5 Scenarios

Filename	Conditionality Demonstrated
Scenario1 *Salmonella* as Agent.pub	*Salmonella* 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 *Salmonella* and Treatment.pub	*Salmonella* 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."

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 (I)
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?** Please select

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

***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)?** Please select

***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?** Please select

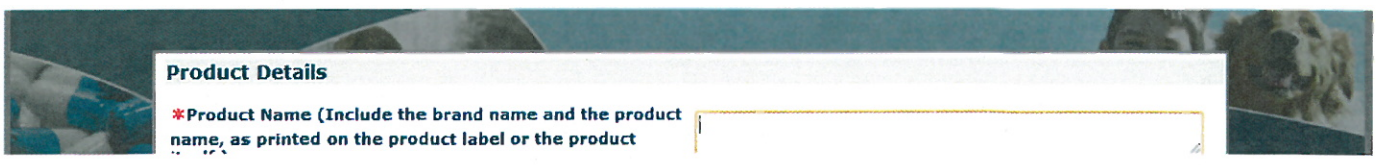
For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g, the patient's initials) to each adverse event. The assigned code will permit the responsible party to 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?** Please select

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

***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.**

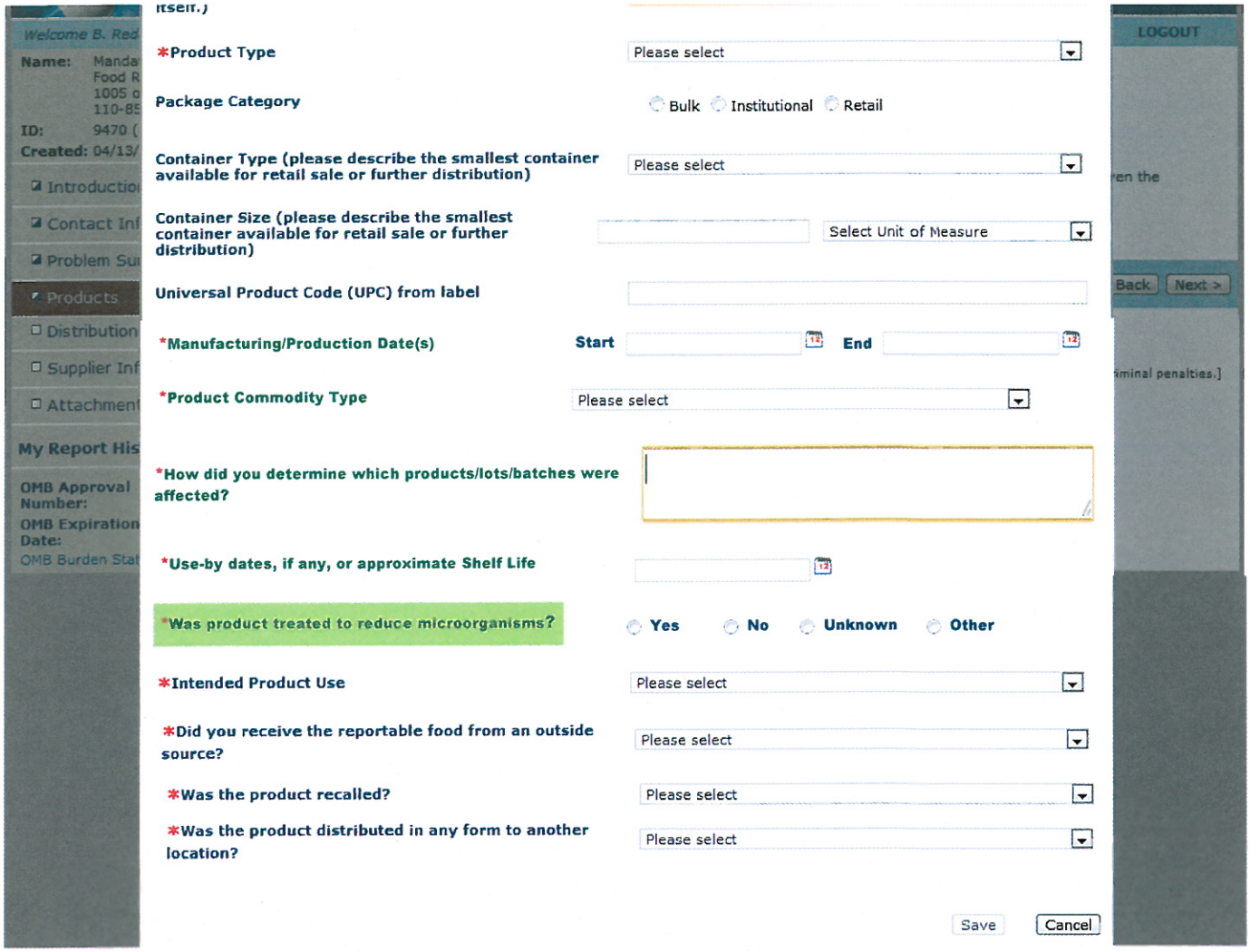
Save Draft | Exit | Submit Report | < Back | Next >



Product Details

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

pg 1


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
*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
Back
Next >
Welcome B. Red
Name:
ID:
Created: 04/13/
Introductio
Contact Inf
Problem Su
Products
Distribution
Supplier Inf
Attachment
My Report His
OMB Approval Number:
OMB Expiration Date:
OMB Burden Stat

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 (I)
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?** Please select

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

***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)?** Please select

***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?** Please select

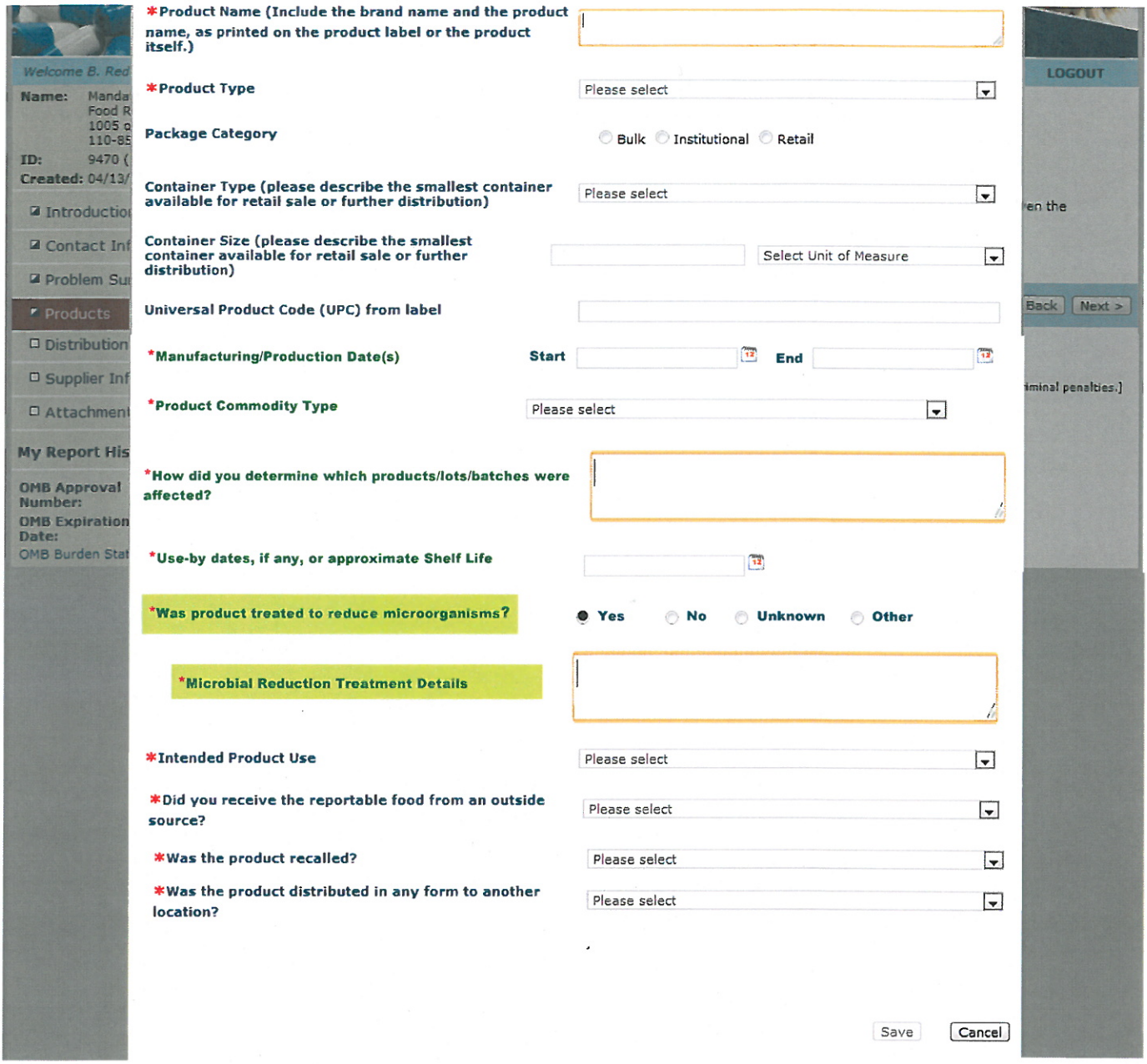
For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g, the patient's initials) to each adverse event. The assigned code will permit the responsible party to 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?** Please select

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

***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 | < Back | Next >


Welcome B. Red
Name: Manda
Food R
1005 g
110-85
ID: 9470 (
Created: 04/13/
Introductio
Contact Inf
Problem Su
Products
Distribution
Supplier Inf
Attachment
My Report His
OMB Approval Number:
OMB Expiration Date:
OMB Burden Stat
LOGOUT
en the
Back
Next >
iminal penalties.]
*Product Name (Include the brand name and the product 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
*Was product treated to reduce microorganisms?
Yes
No
Unknown
Other
*Microbial Reduction Treatment Details
*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

4

Scenario 3 → Foreign object in 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 (I)
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?** Please select

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

***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)?** Please select

***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?** Please select

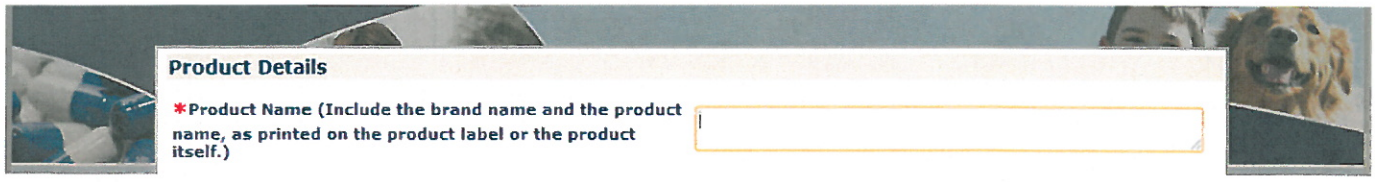
For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g, the patient's initials) to each adverse event. The assigned code will permit the responsible party to 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?** Please select

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

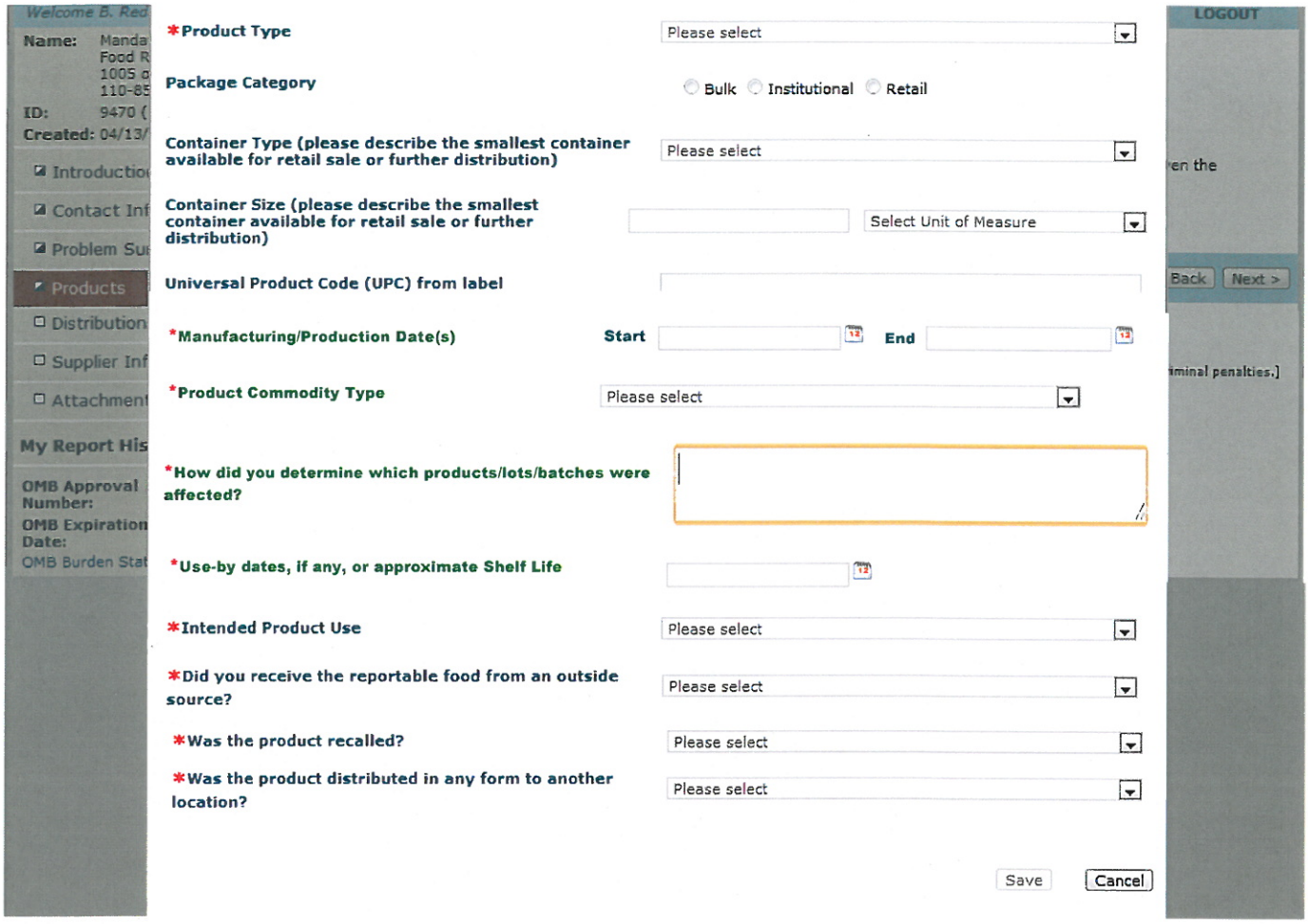
***You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem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

Save Draft | Exit | Submit Report | < Back | Next >



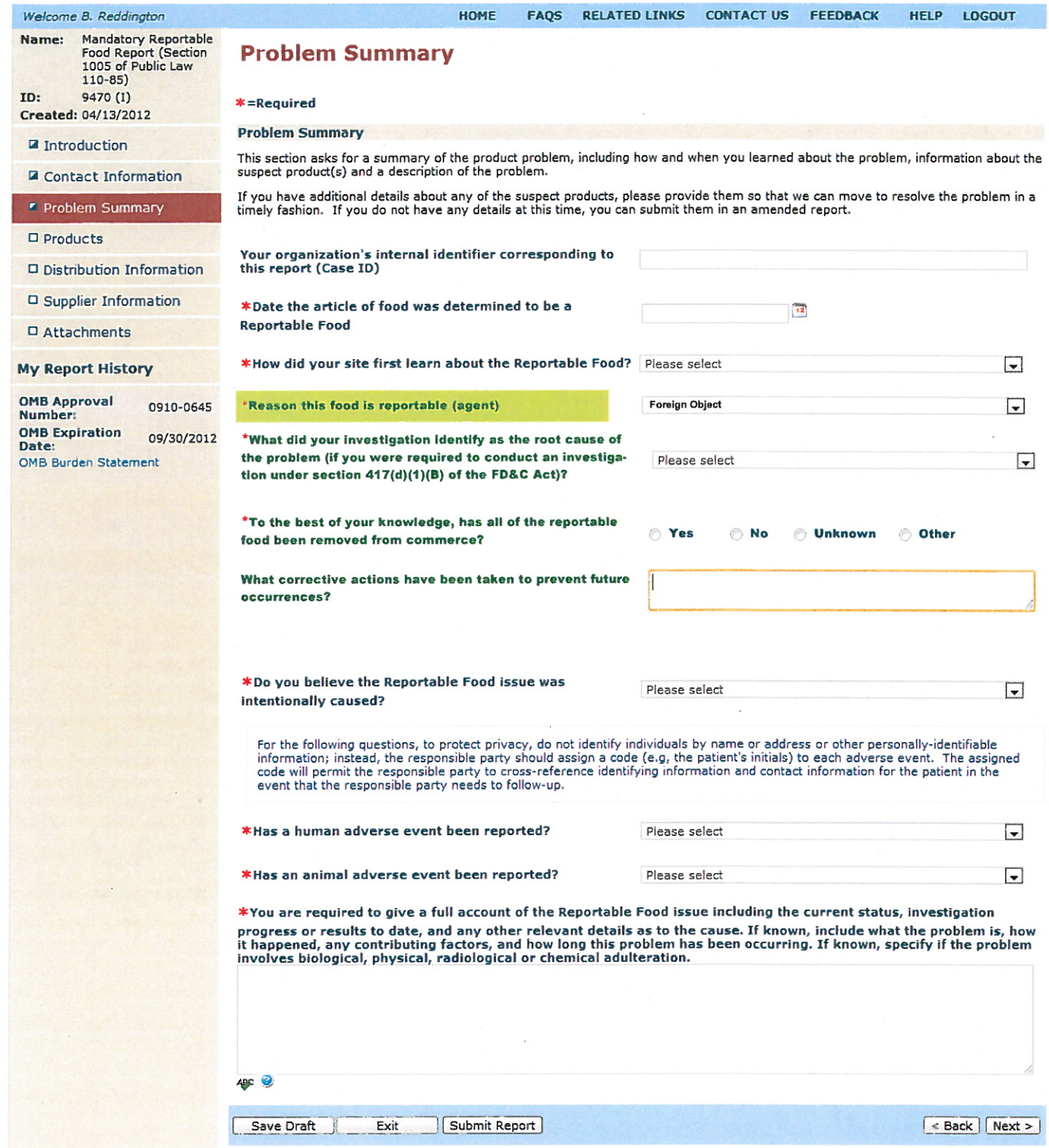
Product Details

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


Welcome B. Red
Name: Manda
Food R
1005 c
110-85
ID: 9470 (
Created: 04/13/
Introductio
Contact Inf
Problem Su
Products
Distribution
Supplier Inf
Attachment
My Report His
OMB Approval Number:
OMB Expiration Date:
OMB Burden Stat
LOGOUT
en the
Back
Next >
iminal penalties.]
*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
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

6

Scenario 4 – Foreign object hazard and For Animal consumption 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 (I)
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?** Please select

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

***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)?** Please select

***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?** Please select

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?** Please select

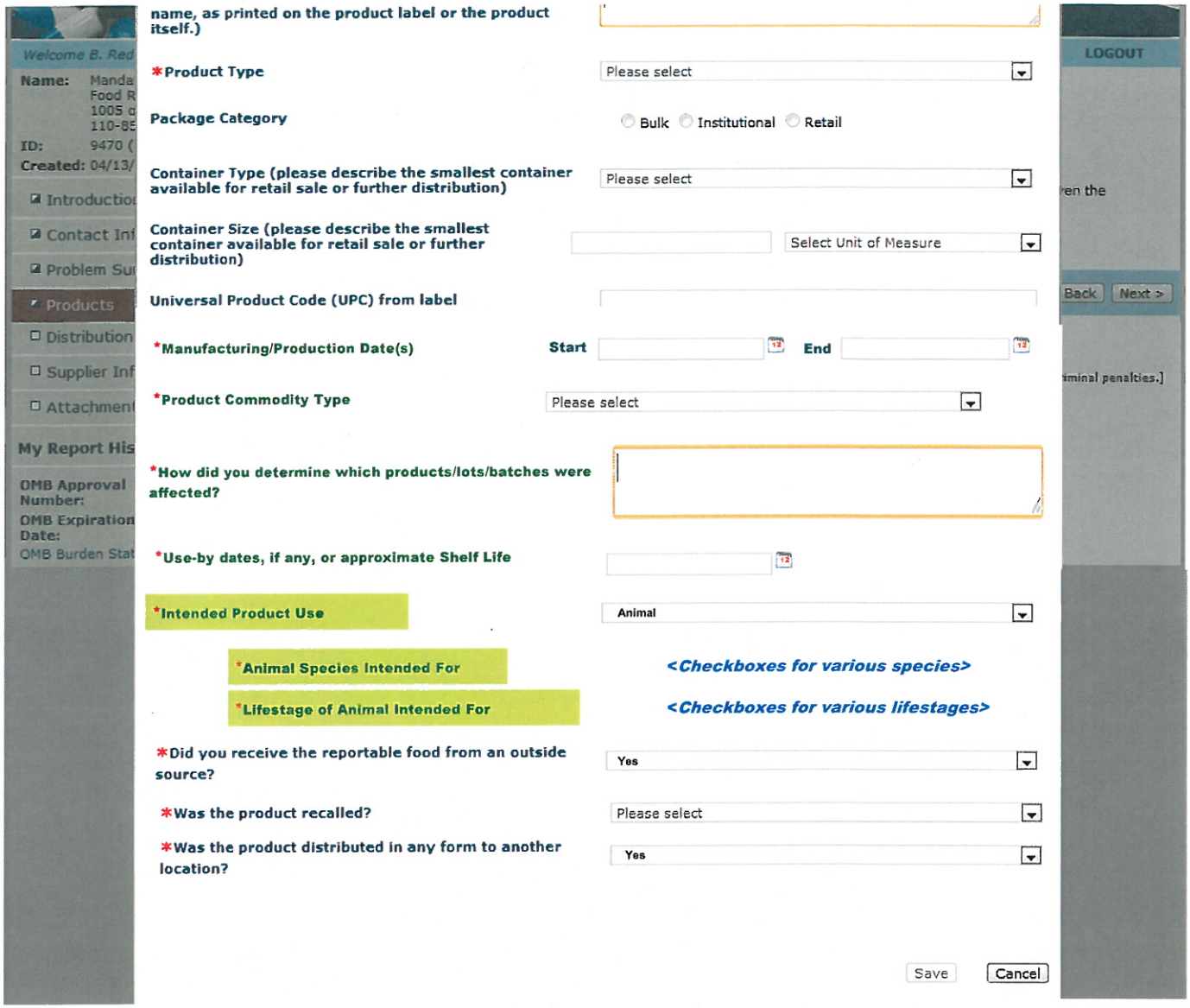
***Has an animal adverse event been reported?** Please select

***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 | < Back | Next >

Product Details

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


Welcome B. Red
Name: Manda Food R 1005 a 110-85
ID: 9470 (
Created: 04/13/
Introductio
Contact Inf
Problem Su
Products
Distribution
Supplier Inf
Attachmen
My Report His
OMB Approval Number:
OMB Expiration Date:
OMB Burden Stat
LOGOUT
en the
Back
Next >
iminal penalties.]
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

8

Scenario 5 → foreign object
For Animal Consumption
Lots of product distributed
Lots of product recieved
(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 (I)
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?** Please select

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

***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)?** Please select

***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?** Please select

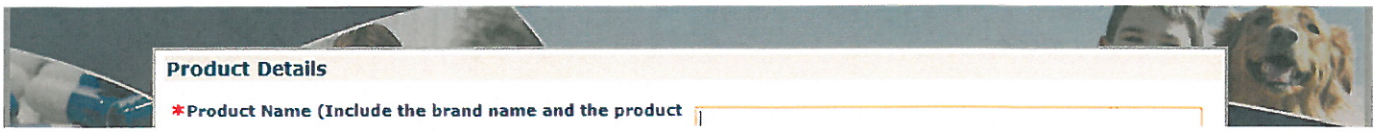
For the following questions, to protect privacy, do not identify individuals by name or address or other personally-identifiable information; instead, the responsible party should assign a code (e.g, the patient's initials) to each adverse event. The assigned code will permit the responsible party to 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?** Please select

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

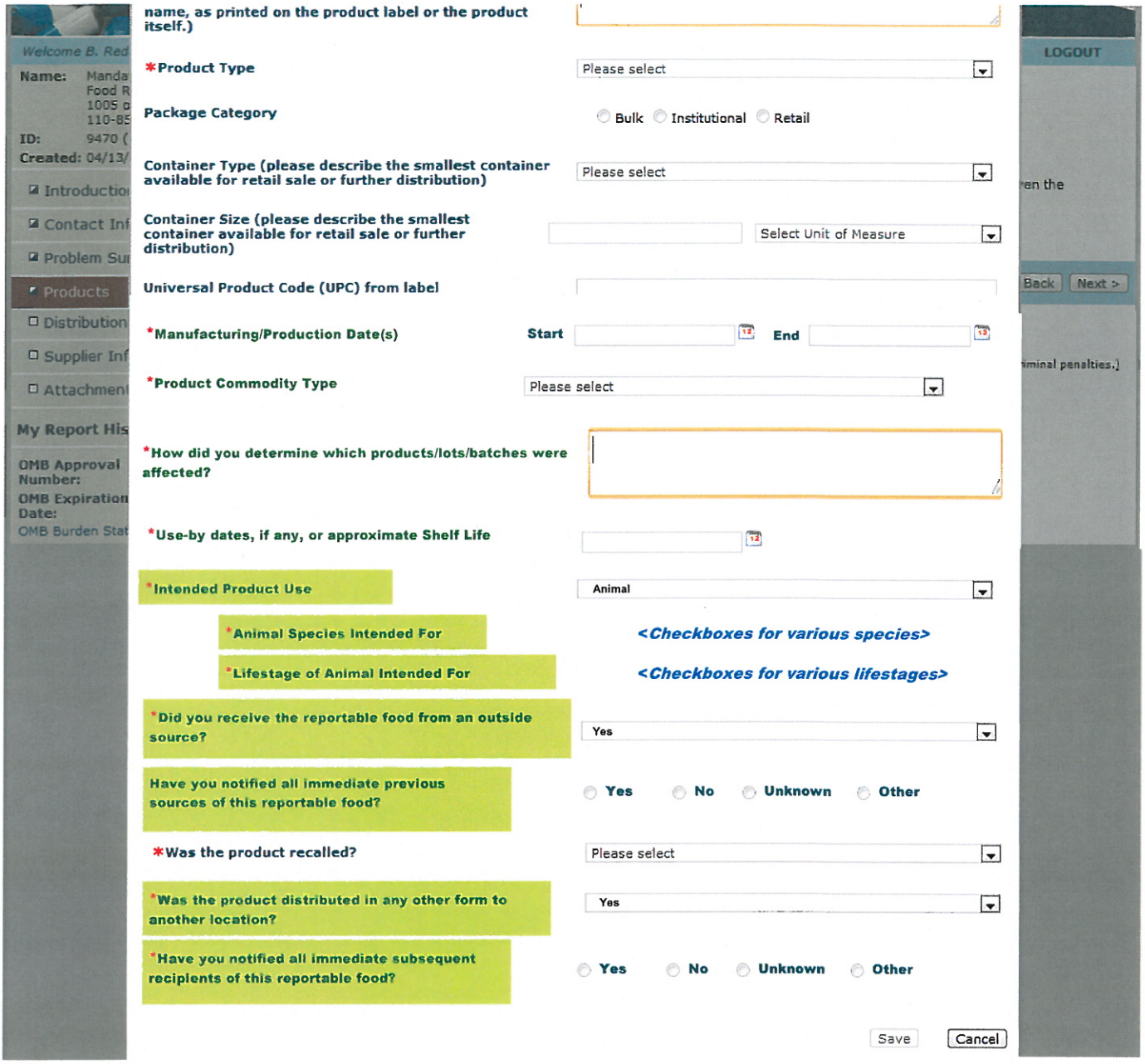
***You are required to give a full account of the Reportable Food issue including the current status, investigation progress or results to date, and any other relevant details as to the cause. If known, include what the problem is, how it happened, any contributing factors, and how long this problem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

Save Draft | Exit | Submit Report | < Back | Next >



Product Details

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


Welcome B. Red
Name: Manda Food R 1005 a 110-85
ID: 9470 (
Created: 04/13/
Introductio
Contact Inf
Problem Su
Products
Distribution
Supplier Inf
Attachmen
My Report His
OMB Approval Number:
OMB Expiration Date:
OMB Burden Stat
LOGOUT
ren the
Back
Next >
minal penalties.)
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