REPORT VIEW: 1005 (Mandatory)
REPORTER TYPE:
Responsible Party
REPORT TYPE: Initial

- ☑ **INTRODUCTION**
- ☑ **RESPONSIBLE PARTY INFO**
- ☑ **FOOD/FEED FACILITY INFO**
- ☐ **PRODUCT PROBLEM SUMMARY**
  - ☐ **Problem Description**
  - ☐ **Additional Info**
- ☐ **ADULTERATION ORIGINATION SITE INFO**
- ☐ **SUPPLEMENTAL DOCUMENTS**
- ☐ **SUBMIT REPORT**

Report Created:	03-24-2009
Today's Date:	03-25-2009
Report Status:	In progress
Reporter:	Sandy Daston

SUMMARY OF PRODUCT PROBLEM

This section asks for a summary of the product problem including how and when you learned about the problem, information about suspect products (received or produced), and a description of the problem.

If you have additional details about any of the suspect products, you will be asked to 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 submit them on follow up report.

IMPORTANT: *To take the next step, notifying sites that you received suspect products from or distributed products to, you must have an FDA-supplied report ID. At the end of this section, instructions will be provided about how to submit this initial report and about the next steps for required reporting.*

Description of the Product Problem

1. **Date/time your site learned about the product problem:*** **[960/9255]**

   Date: [MM] [DD] [YYYY]

Suggest drop down for MM and DD and open text field for YYYY when date is requested.

2. **How your site first learn about the product problem:*** **[14.4/9272]**
   - ❍ Notified by another firm in the supply chain (show 2a)
   - ❍ Self discovery or Other (show 2b)

This is how we will handle the "other" option for R1. We can analyze and see if it is worth the effort for R2 or later

The FDA is providing better wording/definitions for self-discovery so that the meaning is clear.
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SUMMARY OF PRODUCT PROBLEM (continued)

Description of the Product Problem (cont')

If notified by another firm, show 2 a. There must be at least one firm in 2a.

2a. Who notified you? List all the sites that notified you about the product problem and indicate the involved product that they reported and their relationship to your Food/Feed Facility in the supply chain.

Other Firm/Site Info(*)	Suspect/Involved Products [2028/16090]???	Relationship in the Supply Chain (*) [see name field]
Site Name [7104/9288]-from [7004/9276]-to SITE 1 Other Site FDA-Issued Report ID [601.1/13059] ICSR NUMBER	Product Name 1 ADD ANOTHER PRODUCT If more than one suspect product, then the reporter can click to add more; the list would grow	❍ Received products from site ❍ Distributed products to site
Site Name [7104/9288]-from [7004/9276]-to SITE 2 Other Site FDA-Issued Report ID [601.1/13059] ICSR NUMBER	Product Name 2 ADD ANOTHER PRODUCT	❍ Received products from site ❍ Distributed products to site

DELETE SITE

CLICK TO ADD ANOTHER SITE

The ICSR Number is optional for this initial report but may be mandatory for follow up reports

If self discovery or other, show 2 b

2b. How your site learned bout the problem. (*) In the space below, describe how your site learned that there was a reportable food/feed problem. **[include with product problem narrative]**

Open Text

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FDA Action Items 1) to provide better wording and instructions with regard to what is wanted for package name and size 2) Also, the IDs for Product Name are unclear. Do they refer to Products Received or produced.

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SUMMARY OF PRODUCT PROBLEM (continued)

Description of the Product Problem (cont')

3. Reportable Food/Feed Product(s). List the reportable food or feed products that you are aware of; that is, the food(s) or feed(s) that are currently suspect even if you do not know the cause of the adulteration or what it is about the food or ingredient that may be causing the problem. These may be products that you have received or that you have produced or distributed. Include both the Product Name and Brand Name in the Product Name Field. For the container type and size of container, the product is defined as the smallest amount for retail sale or further distribution. Please provide as much information as is available.

If 2=self discovery or other OR if 2a does not include notification about received products, show 3a. Otherwise, automatically show the table, prefilling any previously provided information

3a. Did you receive any reportable food/feed products? ❍ Yes ❍ No ❍ Don't Know **[screener-no ID]**

If yes, show table below. Only Product Name & Received From is required.

RECEIVED PRODUCTS—If you provided information previously about received products, the information appears below for your convenience.

Received Product Information

Product Name: (*) [2028/16090]??? — Open Text or Product Name Text Piped from 2a

Received from:(*) [7104/9288] — Open Text or Site Name (ICSR#) Piped from 2a

UPC: [####/9301] — Open Text

Pkg Category: ❍ Bulk ❍ Retail ❍ Institutional [1017.1/13046]

Container type: Drop down list of values [1018/9297] **Container Size** numeric [1016/13040] **UOM Drop down** [1016.1/13041]

Total Containers Received: numeric [7121/13043] **Total Amt Received:** numeric [7119/16012] **UOM Drop down**

DELETE PRODUCT

CLICK TO ADD ANOTHER PRODUCT

Info provided in 2a about site name and product would be piped in, if available, but would be editable (validations would occur to ensure edits make for consistent info). Reporter can add additional suspect products received that they had not been notified about. If the user says "yes" to 3a OR has been notified about a received product as indicated in 2a, at least one product must appear in the table. The products they have been notified about cannot be deleted. Products that they add (no notification) can be deleted. The delete button is shown here as a function, but a single product would not be deletable. Any empty rows would be deleted upon save.

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FDA Action Items 1) to provide better wording and instructions with regard to what is wanted for package name and size 2) Also, the IDs for Product Name are unclear. Do they refer to Products Received or produced.

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SUMMARY OF PRODUCT PROBLEM (continued)

Description of the Product Problem (cont')

The functionality for produced products will work much the same way as for 3a related to piping and editing of product name (reporter can edit and delete the product names any time prior to submitting the initial report).

If the reporter indicates in 2a that they were notified by a site to which they had distributed, automatically show the 3b table. Otherwise, ask the 3 b screener (this applies to those who answer "Self discovery or Other in question 2).

3b. Did your site produce/repackage for distribution a reportable food product?

❍ Yes ❍ No ❍ Don't Know [screener-no ID]

If yes, show table below. Only Product Name is required.

Manufactured or RePackaged/Distributed Product Information

Product Name: (*) [2028/16090]???
Open Text or Product Name Text Piped from 2a

UPC: [####/9301]
Open Text

Pkg Category: ❍ Bulk ❍ Retail ❍ Institutional
1017.1/13046]

Container type: Drop down list of values **Container Size** numeric **UOM Drop down**
[1018/9297] [1016/13040] [1016.1/13041]

Total Containers Produced: numeric **Total Amt Produced:** numeric **UOM Drop down**
[1061.2/9267] [[1061.3/9267] [1061.4/13058]

Product Name: (*) [2028/16090]???
Open Text or Product Name Text Piped from 2a

UPC: [####]
Open Text

Pkg Category: ❍ Bulk ❍ Retail ❍ Institutional
1017.1/13046]

Container type: Drop down list of values **Container Size** numeric **UOM Drop down**
[1018/9297] [1016/13040] [1016.1/13041]

Total Containers Produced: numeric **Total Amt Produced:** numeric **UOM Drop down**
[1061.2/9267] [[1061.3/9267] [1061.4/13058]

DELETE PRODUCT

CLICK TO ADD ANOTHER PRODUCT

REPORT VIEW: 1005 (Mandatory)
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FDA Action Items : Please review the breakdown in #4 Problem Narrative and provide any edits to categories. These will be all be concatenated in the final message. They are to assist the user in providing the relevant information.

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SUMMARY OF PRODUCT PROBLEM (continued)

Description of the Product Problem (cont')

4. Product Problem Narrative:* **[14/9271]** **Text boxes would be concatenated; something must appear in at least one text box.**

a. Describe the problem-including what the adulteration is, how it happened/any contributing factors, and how long this problem has been occurring. If known, specify if biological, physical, radiological or chemical adulteration.

Open Text

b. Describe any investigations in progress and any available investigation results.

Open Text

c. Describe the current status—including what is being done to contain or dispose of any affected products.

Open Text

d. Other relevant details — use the space below to tell us about any other pertinent details

Open Text

5. Do you believe the suspect product was intentionally adulterated?* **[2028.2/9254]**

❍ Yes ❍ No ❍ Unknown

6. Related adverse events reported to your site?* **[screener-no id]**

❍ Yes ❍ No ❍ Unknown

If yes, show 6a

6a. Types of adverse events reported: (*) (check all that apply) **[14.5 &14.61/9272]**

❑ Human Adverse Events (show 6a.1)
❑ Animal Adverse Events (show 6a.2)

6a.1 (*) Describe the human adverse events—including affected individuals, symptoms, lab results, date/time of onset relative to product consumption. **[N65/15997]**

Open Text

6a.2 (*) Describe the animal adverse events—including affected animals, symptoms, lab results, date/time of onset relative to product consumption. **[N64/15993]**

Open Text

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SUMMARY OF PRODUCT PROBLEM (continued)

Additional Information About Suspect Products Received or Produced

Types of information that will be helpful in the investigation appear in the box below. Any additional information that you can provide at this time will be helpful. You need not provide all listed info.

Products Received Information
- Lot Numbers/Manufacturer IDs
- Expiration or Use-by Dates
- Product imported?
- Receipt Dates
- Method/details of product disposal
- Contact information for Source Sites

Products Produced/Repackaged Info
- Lot Numbers/Manufacturer IDs
- Expiration or Use-by Dates
- Method/details of product disposal
- Amounts distributed
- Distribution sites & dates distributed

1. **You indicated you received or distributed the following products. Can you provide any of the above information for these products at this time?*** **[screener-no ID]**

PRODUCTS RECEIVED

Information Already Provided	Able to provide more info? (as listed above)
Piped in info for product received #1 from table on pg 3	❍ Yes ❍ No
Piped in info for product received #2 from table on pg 3	❍ Yes ❍ No
Piped in info for product received #n from table on pg 3	❍ Yes ❍ No

PRODUCTS PRODUCED/REPACKAGED

Information Already Provided	Able to provide more info? (as listed above)
Piped in info for "new" product #1 from table on pg 4	❍ Yes ❍ No
Piped in info for "new" product #2 from table on pg 4	❍ Yes ❍ No
Piped in info for "new" product #n from table on pg 4	❍ Yes ❍ No

For all yes, answers, the reporter would be given additional forms to complete as on the next two pages.

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SUMMARY OF PRODUCT PROBLEM (continued)

Additional Information About Suspect Products Received

Thank you for providing additional information about one or more suspect products received. A summary of information you have already given for each product appears below. We appreciate your filling in as much of the other information as you can.

Product name and site name would be piped in for each product. The chart would repeat for all products received for which the reporter indicates he/she can provide more info.

Product Name Received from Site Name

Summary of information already provided: (Information filled in as an example)

- **UPC:** 1234
- **Site notified you?** Yes
- **Pkg category:** Not provided
- **Container type**: Can
- **Container Size**: 12 ounces
- **# Containers Rec'd**: 144
- **Total Amt Received:** 1728 ounces

Click to edit this info

Information About the Site From Which the Product Was Received

1.Type of Site: (Check all that apply)

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

Source Site Location & Contact Information

2.Country Drop Down Select—assume U.S.

3.Street Address Open Text

Open Text

4. City Open Text

5. State Drop Down Select

6. Zip Code Numeric

7. Contact Person Title Open Text

8. Contact First Name Open Text

9. Contact Last Name Open Text

10. Email Address Open Text

11. Primary Phone numeric numeric numeric

12. Other Phone numeric numeric numeric

13. Fax numeric numeric numeric

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SUMMARY OF PRODUCT PROBLEM (continued)

Additional Information About Suspect Products Received (continued)

On the web page, this would be contiguous (one page) with the form on page 7.

Product Name Received from Site Name (continued)

Information About the Product

14. Was product imported? ❍ Yes ❍ No ❍ Unknown
If yes, show 14a
14a. Port of entry: Drop down select

15. Product recalled? ❍ Yes ❍ No ❍ Unknown
If yes, show 15a
15a. Recall #: Open Text

16. Number of Lots or Batches of Product Received: Integer
Lots or batches are defined as ……

FDA to provide a definition of lot or batch that reporter will be able to complete & still provide meaning for the report itself.

Please provide as much information as you can for each suspect lot or batch received, by lot or batch. If you do not have the information, leave it blank. **A form would be provided for each lot indicated in #16 above**

INFORMATION FOR LOT 1

17. Lot # or ID: Open Text

18. Expiration/ Use-by Date: MM/YYYY

19. # Containers Rec'd: Integer

20. Total Amt Received: Numeric **UOM drop down**

21. First Receipt Date MM/DD/YYYY

22. Last Receipt Date: MM/DD/YYYY
May be the same as First Receipt date.

23. Disposed as Received? (All or Part)
❍ Yes ❍ No ❍ Unknown
If yes, show 23 a through d

23a. Disposal Date: MM/DD/YYYY

23b: # Containers Disposed: Integer

23c: Total Amt Disposed: Numeric **UOM drop down**

23d: Method of Disposal (check all that apply)
❑ Destroyed ❑ Reconditioned
❑ Diverted to Animal Food
❑ Other ❑ Unknown

NOTE: On the follow up form, after the ICSR # is obtained, the following questions will appear for sites that did not notify the reporting site. "Did you notify this site?" If yes, "Date of notification"

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SUMMARY OF PRODUCT PROBLEM (continued)

Additional Information About Suspect Products Produced/Repackaged

Thank you for providing additional information about one or more suspect products produced or repackaged for distribution by your site A summary of information you have already given for each product appears below. We appreciate your filling in as much of the other information as you can.

Product name would be piped in for each product. The chart would repeat for all products produced/ repackaged for which the reporter indicates he/she can provide more info.

Product Name Information

Summary of information already provided: (Information filled in as an example)

- **UPC:** 1234
- **Pkg category:** Retail
- **Container type**: Can
- **Container Size**: 12 ounces
- **# Containers Produced**: 144
- **Total Amt Produced:** 1728 ounces

Click to edit this info

1. Number of Lots or Batches of Suspect Product Produced: Integer

Lots or batches are defined as ……

FDA to provide a definition of lot or batch that reporter will be able to complete & still provide meaning for the report itself.

Please provide as much information as you can for each suspect lot or batch received, by lot or batch. If you do not have the information, leave it blank. **A form would be provided for each lot indicated in #1 above**

INFORMATION FOR LOT 1

2. Lot # or ID: Open Text

3. Expiration/Use -by Date: MM/YYYY

4. # Containers Produced: Integer

5. Total Amt Produced: Numeric **UOM drop down**

6. Distributed to other sites?
❍ Yes ❍ No ❍ Unknown
If yes, show 6a and 8 through 22
6a. # of sites distributed to: Integer

7. Disposed as Produced? (All or Part)
❍ Yes ❍ No ❍ Unknown
If yes, show 7 a through d

7a. Disposal Date: MM/DD/YYYY

7b: # Containers Disposed: Integer

7c: Total Amt Disposed: Numeric **UOM drop down**

7d: Method of Disposal (check all that apply)
❑ Destroyed ❑ Reconditioned
❑ Diverted to Animal Food
❑ Other ❑ Unknown

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SUMMARY OF PRODUCT PROBLEM (continued)

Additional Information About Suspect Products Produced/Repackaged (cont')

On the web page, this would be contiguous (one page) with the form on page 9.

Product Name Information (continued)

LOT 1 INFORMATION (continued)

The reporter would be provided with a separate form for each distribution site indicated.

Please provide as much information as you have for the sites you distributed this product to.

DISTRIBUTION SITE 1

8. Name of Site: Open Text

9. Container Qty Distributed: Integer

10. Total Amt Distributed: Numeric UOM drop down

Distribution Contact & Location Information

11.Country Drop Down Select—assume U.S.

12.Street Address Open Text

Open Text

13. City Open Text

14. State
Drop Down Select

15. Zip Code Numeric

16. Contact Person Title Open Text

17. Contact First Name Open Text

18. Contact Last Name Open Text

19. Email Address Open Text

20. Primary Phone numeric numeric numeric

21. Other Phone numeric numeric numeric

22. Fax numeric numeric numeric

NOTE: On the follow up form, after the ICSR # is obtained, the following questions will appear for sites that did not notify the reporting site. "Did you notify this site?" If yes, "Date of notification" Response options should be: Yes; No, but they notified our site; No and they did not notify our site.