

INSTRUCTIONS FOR COMPLETING REPORT

Reporting Information

Employee Reporting the Incident

Incident Date: Enter the date the observation was made.

Name: Enter the Name of the agency employee reporting the incident.

Title: Enter title of employee reporting the incident

Agency: Select the Agency employee works for from the options in the dropdown box (FDA, OSHA, USDA FSIS, USDA AMS). Select N/A if not applicable.

Name of Agency's Contact: Enter the Name of the Person the agency receiving the report should contact for further information (may be the same as 'Name', if so, enter "N/A")

Contact's Title: Enter the title if different from title of employee reporting the incident, otherwise enter "N/A"

Email Address: Enter Email address for identified contact (either Employee reporting incident or the Agency Contact)

Telephone Number: Enter telephone information for the identified contact (either Employee reporting incident or the Agency Contact)

Mailing Address: Enter the full mailing address (including City, State and Zip) of the identified contact (either Employee reporting incident or the Agency Contact)

Employee Completing the Report

Name: Enter the Name of the employee completing the report (could be different of Name of employee reporting the incident). Enter N/A if not applicable.

Title: Enter title of employee completing the report (could be different of Name of employee reporting the incident). Enter N/A if not applicable.

Agency: Select the Agency of the employee completing the report from the options in the dropdown box (FDA, OSHA, USDA FSIS, USDA AMS). Select N/A if not applicable.

Agency the Incident is to be Reported to: Select the Agency receiving the report from the options in the dropdown box (FDA, OSHA, USDA FSIS, USDA AMS). Select N/A if not applicable.

Date Incident Phoned to Other Agency: Enter the date the report was submitted by phone (could be different date than Incident Date).

Additional Emails for the Report to be Sent: If copies of the report should be distributed to more than one person or organization, enter the name(s) and the email address(es) in this field. The email addresses should be separated by using a comma.

Comments: Provide any additional information regarding reporting process in this field.

Incident Information

Establishment Information

Name: Enter the Name of the firm.

Agency: Select the name of the Agency with jurisdiction over the product affected by the observation and associated with the identification number from the options in the dropdown box (FDA, OSHA, USDA FSIS, USDA AMS). Select N/A if not applicable.

Identification Number: Enter the establishment identification number. If you know the number as identified by the receiving Agency, enter it in this field. However, if you do not know this number, then enter your Agency's identification number for that establishment. For FDA, this is the Firm Establishment Identifier (FEI), NOT the Bioterrorism Act Registration number, which cannot be provided to you due to confidentiality issues; For FSIS, establishment numbers have a designated letter with the number that determines what type of establishment it is. For instance "G" represents an "Egg Products" plant (example G1632 or 01632 G); "I" represents an "import" establishment (example I271 or 00271 I); "M" represents a "Meat" establishment, and for these particular plants there does not necessarily need to be an "M" to accompany the number (example 19924 or 19924 M); and "P" represents a "Poultry" plant (example P9002 or 09002 P). For AMS, use the FDA or FSIS identification number.

Address Information: Enter requested firm address information (Address, City, State and Zip code) in these fields.

Facility Description: Describe the type of facility by primary function, i.e. manufacturer, warehouse, re-packer, distributor, farm, packing house, greenhouse, etc.

Violation Observation: Describe the observation reported, i.e. "Employee working on sandwich line #2 in the processing room observed dropping tomato slices on the floor and putting them back onto closed face tuna fish salad sandwiches; floor was filthy, rodent pellets observed under the line on the floor."

Description of Specific Location within a Facility Where Violation Occurred: Describe the location where observation was made, preferably with the name used by the firm, i.e. "Line 2, Fish Room". Describe the location also using operational terms, i.e. "Processing line #2 for sandwiches, main sandwich production room, building #3, near hallway to loading dock".

List of Products Potentially Affected: Enter the products being produced that could be potentially contaminated or otherwise made unfit for distribution/ consumption. For the example in Violation Observation field, product would be tuna fish salad sandwiches. If other sandwiches or products requiring manual assembly are produced on that line these could be listed here as well, i.e. other types of sandwiches, salads, etc. with the notation that production of these was not observed if that is the case.

Action Taken by Reporting Agency, if applicable/authorized: This applies mainly to Dual Jurisdiction Agencies such as FSIS/FDA, AMS/FDA, FSIS/AMS. Report any corrective action requested by the inspecting Agency and what, if anything, the firm did to correct the problem. NOTE: if your Agency doesn't have jurisdiction over the observed activity, requesting corrective action or giving notification to the firm should not be done. The Receiving Agency should conduct this type of follow up action. For example, the observation described in Violation Observation field instruction above, if made by FSIS regarding a FDA product being produced on the same line as FSIS sandwiches (i.e. open face sandwiches), FSIS may have brought this to the firm's attention and a correction made, and this would be noted here.

Additional Comments: Provide any additional observations, anecdotal information, descriptions of the firm in general, etc. that would enhance the information in the report.