

NATIONAL ENVIRONMENTAL ASSESSMENT REPORTING SYSTEM (NEARS)

FOOD PROCESSOR/MANUFACTURING MODULE

This tool collects data and is reported to NEARS on facility policies, practices, and characteristics. Data is collected in response to a foodborne outbreak, a positive microbiological food sample, or other situation that necessitates an environmental assessment and is attributable to the facility. This information should be gathered as part of the environmental assessment – it does not replace the environmental assessment/investigation.

NOTE: Throughout the data collection instrument, boxes (☐) indicate that there could be multiple answers to the question (check all that apply), while circles (○) indicate that there should be only one answer to the question. If you run out of space providing an explanation, please use an additional sheet and it can be combined when entered online. Fill out Part I and then parts II-VI as appropriate (e.g., if no microbiological samples were collected then you would not complete Part V).

Part I – General Characterization of the Incident: Complete this form for each incident, in consultation with the investigation team.

Incident Description		
1.	What was the reason that an environmental assessment was conducted?	<input type="radio"/> Foodborne outbreak <input type="radio"/> Positive food sample <input type="radio"/> Other: _____
2.	Was the suspected/implicated incident associated with a single or multiple facilities (e.g., a single processing plant or multiple plants)?	<input type="radio"/> Single (go to 3) <input type="radio"/> Multiple (go to 2a)
	a. <i>If multiple facilities</i> , did the exposure(s) occur in one or multiple states?	<input type="radio"/> Single State <input type="radio"/> Multiple States
3.	Was a primary agent identified for this incident?	<input type="radio"/> Yes (go to 3a) <input type="radio"/> No (go to 4)
	a. <i>If a primary agent was identified</i> : What was the identified agent?	<input type="radio"/> Hepatitis A <input type="radio"/> <i>Bacillus cereus</i> <input type="radio"/> <i>Campylobacter</i> spp. <input type="radio"/> <i>Clostridium perfringens</i> <input type="radio"/> <i>Cryptosporidium</i> <input type="radio"/> <i>Cyclospora</i> spp. <input type="radio"/> <i>E. coli</i> O157:H7 <input type="radio"/> Other <i>E. coli</i> STEC/VTEC <input type="radio"/> <i>Listeria</i> spp. <input type="radio"/> Norovirus <input type="radio"/> <i>Salmonella</i> spp. <input type="radio"/> <i>Shigella</i> spp. <input type="radio"/> <i>Staphylococcus aureus</i> <input type="radio"/> <i>Vibrio parahaemolyticus</i> <input type="radio"/> Other <i>Vibrio</i> spp. <input type="radio"/> <i>Yersinia</i> spp. <input type="radio"/> Toxic agent: <input type="radio"/> Other: <input type="radio"/> Chemical hazard: <input type="radio"/> Physical hazard
	b. <i>If a primary agent was identified</i> : Was the agent that was identified either suspected or confirmed?	<input type="radio"/> Suspected (go to 4) <input type="radio"/> Confirmed (go to 3c)
	c. <i>If a primary agent was identified</i> : Was a serotype or allele code identified for this incident?	<input type="radio"/> Yes (go to 3.c.i/3.c.ii) <input type="radio"/> No (go to 4)
	i. <i>If a serotype was identified</i> : What was the identified serotype?	
	ii. <i>If an allele code was identified</i> : What was the identified code?	
Suspected/Confirmed Food		
4.	Was a specific ingredient or multi-ingredient food suspected or confirmed in this incident (e.g., were they able to identify the specific food or only the processor)? (specific information on the food will be captured in Part IV)	<input type="radio"/> Yes (Food suspected) <input type="radio"/> Yes (Food confirmed) <input type="radio"/> No (Processor only) <input type="radio"/> Not applicable
Contributing Factors/Environmental Antecedent(s)		
5.	Were any contributing factors identified in this incident? (Identify specific contributing factors in Part VI)	<input type="radio"/> Yes <input type="radio"/> No
6.	Were any environmental antecedents identified in this incident? (Identify specific environmental antecedents in Part VI)	<input type="radio"/> Yes <input type="radio"/> No

Part II – Incident Response Characteristics: Complete this form once for each state responding to an incident.

Incident Response Characteristics		
1.	Within your State, how many agencies were involved with conducting environmental assessments to investigate the incident (enter the number of programs that were involved by agency [e.g., if two program areas from the Dept. of Agriculture were involved enter 2 next to State Dept. of Ag.]). For “other,” include name of agency and number of organizational components.	State Dept. of Ag.: ____ State Dept. of Health: ____ County EH: ____ FDA: ____ USDA FSIS: ____ Other: _____/_____
2.	How many food-processing facilities within your jurisdiction were associated with this incident?	#:
3.	How many environmental assessments were conducted at food processing facilities in your jurisdiction as a part of this incident?	#: (if >0 then go to 3a, if 0 go to 3b)
	a. <i>If <u>any</u> environmental assessments were conducted:</i> Briefly describe the reason(s) why environmental assessments were conducted in your jurisdiction as a part of this incident. (go to 4)	
	b. <i>If <u>no</u> environmental assessments were conducted:</i> Why were no environmental assessments conducted in your jurisdiction as a part of this incident? (go to 4)	
4.	How many retail food service establishments (e.g., restaurants, schools, grocery stores, etc.) in your jurisdiction were associated with this incident?	#: (if 0 go to 5 else go to 4a) <input type="radio"/> Unknown (go to 5) <input type="radio"/> Not applicable (go to 5)
	a. <i>If retail establishments were associated,</i> how many environmental assessments were conducted at these facilities in response to this incident?	#: <input type="radio"/> Unknown
5.	How many non-food processing/retail food service establishments within your jurisdiction were associated with this incident?	#: <input type="radio"/> Unknown <input type="radio"/> Not applicable
6.	Was this incident reported to/from a state or local Communicable Disease Program?	<input type="checkbox"/> State – Incident reporting number assigned by state: _____ <input type="checkbox"/> Local – Incident reporting number assigned by jurisdiction: _____ <input type="checkbox"/> Other: _____ <input type="radio"/> Not reported

7.	Which national surveillance systems was this incident reported to?	<input type="checkbox"/> NORS – CDCID: _____ <input type="checkbox"/> NORS – StateID: _____ <input type="checkbox"/> NEARS-Retail – Report ID: _____ <input type="checkbox"/> Pulsenet – outbreak code: _____ <input type="checkbox"/> CaliciNet – reporting number: _____ <input type="checkbox"/> NNDSS – reporting number: _____ <input type="checkbox"/> FDA RRT – Incident Identifier: _____ <input type="checkbox"/> FSIS – Foodborne illness Number: _____ <input type="checkbox"/> Other: _____ <input type="radio"/> Not reported to another national surveillance system
8.	Please rate the quality of communication between regulatory partners and communicable disease programs during this investigation,	<input type="radio"/> Very good <input type="radio"/> Good <input type="radio"/> Fair <input type="radio"/> Poor <input type="radio"/> Very Poor <input type="radio"/> No communication
9.	Were any immediate control or preventive measures implemented for this incident? (Check all that apply)	<input type="checkbox"/> Trained food workers <input type="checkbox"/> Embargoed food <input type="checkbox"/> Discarded food <input type="checkbox"/> Initiated a food recall <input type="checkbox"/> Agency consumer alert initiated <input type="checkbox"/> Cleaned and sanitized/disinfected affected area/equipment <input type="checkbox"/> Temporary closure of facility <input type="checkbox"/> Permanent closure of facility <input type="checkbox"/> Excluded infectious workers <input type="checkbox"/> Changed operational process(es) <input type="checkbox"/> Repaired/Replaced/Removed equipment <input type="checkbox"/> Developed food safety/HACCP plan <input type="checkbox"/> Revised food safety/HACCP plan <input type="checkbox"/> Developed/implemented in house sampling plan <input type="checkbox"/> Hired external consultants/auditors <input type="checkbox"/> Other: _____ <input type="radio"/> No control measures implemented

Part III – Environmental Assessment/Facility Characteristics: Complete this form once for each environmental assessment.

Environmental Assessment Characteristics		
1.	Date the facility was identified for an environmental assessment (MM/DD/YYYY)	___/___/___
2.	Date of first contact with facility management about this potential incident by responding agency (MM/DD/YYYY)	___/___/___
3.	Date of initial environmental assessment (MM/DD/YYYY)	___/___/___
4.	Number of visits to the facility to complete this environmental assessment	#:
5.	Approximate number of contacts with the facility other than visits (e.g., phone calls, emails, phone interviews with staff, faxes, etc.) to complete this environmental assessment?	#:
6.	Were any samples taken during the environmental assessment (e.g. product, environmental, etc.)?	<input type="radio"/> Yes <input type="radio"/> No
7.	Was a translator needed to conduct the environmental assessment?	<input type="radio"/> Yes (go to 7a) <input type="radio"/> No (go to 8)
	a. <i>If yes</i> , was a translator used to conduct the environmental assessment?	<input type="radio"/> Yes <input type="radio"/> No
Facility Characteristics		
8.	Facility type (select the appropriate categories for this facility)	
	Warehouse/ Product Storage	Packer/ Re-packer (minimal processing)
	Processor (convert raw agricultural product into a commodity)	Manufacturer (converts commodities into food product)
	<input type="checkbox"/> Refrigerated warehouse	<input type="checkbox"/> Produce
	<input type="checkbox"/> Non-refrigerated warehouse	<input type="checkbox"/> Seafood
	<input type="checkbox"/> Other Warehouse:	<input type="checkbox"/> Other Packer:
	<input type="checkbox"/> Poultry	<input type="checkbox"/> Beef
	<input type="checkbox"/> Pork	<input type="checkbox"/> Low acid canned food
	<input type="checkbox"/> Egg	<input type="checkbox"/> Candy
	<input type="checkbox"/> Produce	<input type="checkbox"/> Cereal
	<input type="checkbox"/> Grain (Milling/Malting)	<input type="checkbox"/> Beverage (other than dairy)
	<input type="checkbox"/> Seafood	<input type="checkbox"/> Ice Cream
	<input type="checkbox"/> Bottled Water	<input type="checkbox"/> Ready to eat meals
	<input type="checkbox"/> Dairy	<input type="checkbox"/> Frozen Foods
	<input type="checkbox"/> Juice	<input type="checkbox"/> Infant formula
	<input type="checkbox"/> Honey	<input type="checkbox"/> Acidified foods
	<input type="checkbox"/> Other Processor:	<input type="checkbox"/> Other Manufacturer:
9.	What types of food products does the facility handle? (Include if the food is raw, pasteurized, ready to eat, etc. if needed [e.g., raw milk cheese])	
10.	How many Critical/Major items were noted during the last routine inspection?	#:

11.	Is the facility properly licensed/permitted?	<input type="radio"/> Yes <input type="radio"/> No
12.	What is the facility's source of potable water? (Question 53 asks about water treatment)	<input type="radio"/> PWS – Municipally operated <input type="radio"/> PWS – Operated by facility <input type="radio"/> Non-PWS – operated by facility <input type="radio"/> Other:
13.	Does the facility reuse water?	<input type="radio"/> Yes (go to 13a) <input type="radio"/> No (go to 14)
	a. <i>If yes</i> , is the water treated properly?	<input type="radio"/> Yes <input type="radio"/> No
14.	What is the facility's method of sewage disposal?	<input type="radio"/> Public sewage <input type="radio"/> On-site sewage disposal <input type="radio"/> Other:
15.	Have there been any issues with water treatment/sewage disposal in the past year?	<input type="radio"/> Yes <input type="radio"/> No
16.	The INCOMING products are RECEIVED at this facility: (check all that apply) NOTE: If products only require refrigeration for quality then mark no refrigeration required TCS=Time/Temperature Control for Safety	<input type="checkbox"/> Raw – TCS – requires refrigeration <input type="checkbox"/> Raw – non-TCS – no refrigeration required <input type="checkbox"/> Cooked/processed – TCS – requires refrigeration <input type="checkbox"/> Cooked/processed – non-TCS <input type="checkbox"/> Other:
17.	The FINISHED products that LEAVE this facility are: (check all that apply)	<input type="checkbox"/> Raw – TCS – requires refrigeration <input type="checkbox"/> Raw – non-TCS – no refrigeration required <input type="checkbox"/> Cooked/processed – TCS – requires refrigeration <input type="checkbox"/> Cooked/processed – non-TCS <input type="checkbox"/> Other:
18.	The FINISHED products are intended to be consumed: (check all that apply)	<input type="checkbox"/> In final state – TCS - no further processing needed <input type="checkbox"/> Cooked by end-user- TCS <input type="checkbox"/> Reheated by end-user – TCS <input type="checkbox"/> NOT TCS – product is shelf-stable <input type="checkbox"/> Other:
Policies and Practices		
19.	Has the facility done a risk assessment of the hazards in the process?	<input type="radio"/> Yes <input type="radio"/> No
Employee Training		
20.	Does the facility provide position specific training on their food safety policies?	<input type="checkbox"/> Yes – Employees (go to 20a) <input type="checkbox"/> Yes – Managers (go to 20a) <input type="radio"/> No (go to 21)
	a. <i>If yes</i> , do they provide ongoing training or is it only at initial hire or change of job duties? (Check all that apply)	<input type="checkbox"/> Ongoing <input type="checkbox"/> Initial hire <input type="checkbox"/> Annually <input type="checkbox"/> Change of job duties <input type="checkbox"/> Other: _____
	b. <i>If yes</i> , are materials provided in other languages as needed?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to determine

		<input type="radio"/> Not applicable
21.	Are there job aids/instructions/signs posted in the facility related to food safety?	<input type="radio"/> Yes (go to 21a) <input type="radio"/> No (go to 22)
	a. <i>If yes</i> , which language(s) or methods are present on the signs? (check all that apply)?	<input type="checkbox"/> Uses pictures/symbols <input type="checkbox"/> English <input type="checkbox"/> Spanish <input type="checkbox"/> French <input type="checkbox"/> Chinese (traditional or simplified) <input type="checkbox"/> Japanese <input type="checkbox"/> Other:
Employee Health & Hygiene		
22.	Does the facility require employees to report to management when they are sick?	<input type="radio"/> Yes <input type="radio"/> No
23.	Does this facility have a written sick worker/employee health policy?	<input type="radio"/> Yes (go to 23a) <input type="radio"/> No (go to 24)
	a. <i>If there is a policy</i> , does it specify the specific symptoms that would prompt restricting or excluding ill employees from working?	<input type="radio"/> Yes (go to 23.a.i) <input type="radio"/> No (go to 24)
	i. What are those symptoms (check all that apply)	<input type="checkbox"/> Vomiting <input type="checkbox"/> Diarrhea <input type="checkbox"/> Jaundice (yellow eyes or skin) <input type="checkbox"/> Sore throat with fever <input type="checkbox"/> A lesion containing pus (for example, boil or infected wound that is open or draining) <input type="checkbox"/> Other:
	ii. <i>If it does exclude employees</i> , when would employees be able to return to work (check all that apply)	<input type="checkbox"/> With a doctor's note <input type="checkbox"/> 24 hours symptom-free <input type="checkbox"/> 48 hours symptom free <input type="checkbox"/> >48 hours symptom free <input type="checkbox"/> Other: <input type="radio"/> Not applicable
24.	Do they provide paid sick leave? (check all that apply)	<input type="checkbox"/> Yes – for management <input type="checkbox"/> Yes – for employees <input type="checkbox"/> No <input type="checkbox"/> Other:
25.	Do they allow employees to make up missed shifts?	<input type="radio"/> Yes <input type="radio"/> No
26.	Were any employee(s) diagnosed or report illness in the two weeks prior to the onset of the incident?	<input type="radio"/> Yes (go to 26a) <input type="radio"/> No (go to 27)
	a. <i>If yes</i> , did any of these employee(s) have symptoms or a diagnosis consistent with the suspected agent?	<input type="radio"/> Yes (go to 26.a.i) <input type="radio"/> No (go to 27)
	i. <i>If consistent symptoms/diagnosis</i> , what were the employee(s) job duties during the two weeks prior to the onset of the incident:	
27.	Does the facility have a policy indicating when employees should wash their hands?	<input type="radio"/> Yes – Written (go to 27a) <input type="radio"/> Yes – Verbal (go to 27a) <input type="radio"/> Yes – Combination of verbal and written (go to 27a)

		<input type="radio"/> No (go to 28)
	a. <i>if yes</i> , does it cover required/recommended situations?	<input type="radio"/> Yes <input type="radio"/> No
28.	Are handsinks available in or directly outside of the employee <u>restrooms</u> ?	<input type="radio"/> Yes (go to 28a) <input type="radio"/> No (go to 29) <input type="radio"/> Could not observe (go to 29)
	a. <i>if yes</i> , is warm water available at all employee restroom handsinks?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>if yes</i> , is soap available at (or near) all employee restroom handsinks?	<input type="radio"/> Yes <input type="radio"/> No
	c. <i>if yes</i> , are hand drying devices available at (or near) all employee restroom handsinks?	<input type="checkbox"/> Yes – disposable paper towels <input type="checkbox"/> Yes – continuous roll cloth towel <input type="checkbox"/> Yes – electric air hand dryer <input type="checkbox"/> Yes – Other _____ <input type="checkbox"/> No
	d. <i>if yes</i> , is the handsink easily accessible (e.g., not blocked or containing other items)?	<input type="radio"/> Yes <input type="radio"/> No
	e. <i>if yes</i> , is there evidence that the employee restroom handsinks have been used recently (e.g., discarded towels in trash, wet sink, hot water on opening valve)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to tell
29.	Are handsinks available in the <u>food handling/work areas</u> ?	<input type="radio"/> Yes (go to 29a) <input type="radio"/> No (go to 30) <input type="radio"/> Could not observe (go to 30)
	a. <i>if yes</i> , is warm water available at all employee work area handsinks?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>if yes</i> , is soap available at (or near) all employee work area handsinks?	<input type="radio"/> Yes <input type="radio"/> No
	c. <i>if yes</i> , are hand drying devices available at (or near) all employee work area handsinks?	<input type="checkbox"/> Yes – disposable paper towels <input type="checkbox"/> Yes – continuous roll cloth towel <input type="checkbox"/> Yes – electric air hand dryer <input type="checkbox"/> Yes – Other _____ <input type="checkbox"/> No
	d. <i>if yes</i> , is the handsink easily accessible (e.g., not blocked or containing other items)?	<input type="radio"/> Yes <input type="radio"/> No
	e. <i>if yes</i> , is there evidence that the employee work area handsinks have been used recently (e.g., discarded towels in trash, wet sink, hot water on opening valve)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to tell
30.	Were any employees observed washing their hands at appropriate times during the environmental assessment?	<input type="radio"/> Yes (go to 30a) <input type="radio"/> No (go to 31)
	a. <i>if yes</i> , did they wash their hands properly? (check all that apply)	<input type="checkbox"/> Yes <input type="checkbox"/> No
31.	Was bare hand contact observed with any ready to eat food items?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable

Cleaning/Sanitation		
32.	Does the facility have policies/procedures for cleaning of <u>raw product storage areas</u> ?	<input type="radio"/> Yes – Written (go to 32a) <input type="radio"/> Yes – Verbal (go to 32a) <input type="radio"/> Yes – Combination of verbal and written (go to 32a) <input type="radio"/> No (go to 33) <input type="radio"/> Not Applicable (go to 33)
	a. <i>If yes</i> , is it being implemented properly and at the appropriate frequency?	<input type="radio"/> Yes <input type="radio"/> No
33.	Does the facility have policies/procedures for cleaning of <u>food processing equipment</u> ?	<input type="radio"/> Yes – Written (go to 33a) <input type="radio"/> Yes – Verbal (go to 33a) <input type="radio"/> Yes – Combination of verbal and written (go to 33a) <input type="radio"/> No (go to 34) <input type="radio"/> Not Applicable (go to 34)
	a. <i>If yes</i> , is it being implemented properly?	<input type="radio"/> Yes <input type="radio"/> No
34.	Does the facility have policies/procedures for cleaning of <u>surfaces that may come into contact with food containers (with or without the food in the container) (e.g., conveyors, bottle washers, overhead drips, etc.)?</u>	<input type="radio"/> Yes – Written (go to 34a) <input type="radio"/> Yes – Verbal (go to 34a) <input type="radio"/> Yes – Combination of verbal and written (go to 34a) <input type="radio"/> No (go to 35) <input type="radio"/> Not Applicable (go to 35)
	a. <i>If yes</i> , is it being implemented properly?	<input type="radio"/> Yes <input type="radio"/> No
35.	Does the facility have policies/procedures for cleaning of <u>food processing areas (e.g., rooms)?</u>	<input type="radio"/> Yes – Written (go to 35a) <input type="radio"/> Yes – Verbal (go to 35a) <input type="radio"/> Yes – Combination of verbal and written (go to 35a) <input type="radio"/> No (go to 36) <input type="radio"/> Not Applicable (go to 36)
	a. <i>If yes</i> , is it being implemented properly?	<input type="radio"/> Yes <input type="radio"/> No
36.	Does the facility have policies/procedures for cleaning of <u>finished product storage areas</u> ?	<input type="radio"/> Yes – Written (go to 36a) <input type="radio"/> Yes – Verbal (go to 36a) <input type="radio"/> Yes – Combination of verbal and written (go to 36a) <input type="radio"/> No (go to 37) <input type="radio"/> Not Applicable (go to 37)
	a. <i>If yes</i> , is it being implemented properly?	<input type="radio"/> Yes <input type="radio"/> No
37.	Does the facility have policies for cleaning of <u>restrooms/locker-rooms</u> ?	<input type="radio"/> Yes – Written (go to 37a) <input type="radio"/> Yes – Verbal (go to 37a) <input type="radio"/> Yes – Combination of verbal and written (go to 37a) <input type="radio"/> No (go to 38) <input type="radio"/> Not Applicable (go to 38)
	a. <i>If yes</i> , is it being implemented properly?	<input type="radio"/> Yes <input type="radio"/> No

38.	Is there a dedicated employee for cleaning of <u>restrooms/locker-rooms (e.g., separate janitorial company)</u> ?	<input type="radio"/> Yes (go to 39) <input type="radio"/> No (go to 38a)
	a. <i>If no</i> , does the employee rotate cleaning (e.g., clean the restrooms and then clean the food processing equipment)?	<input type="radio"/> Yes <input type="radio"/> No
39.	Does the facility have policies for cleaning of <u>areas NOT noted in 32-37 (please specify)</u> ? (Indicate areas and if policies and procedures are present or if no additional locations choose Not Applicable)	<input type="radio"/> Yes – Written (go to 39a) <input type="radio"/> Yes – Verbal (go to 39a) <input type="radio"/> Yes – Combination of verbal and written (go to 39a) <input type="radio"/> No (go to 40) <input type="checkbox"/> AREA(s) _____ <input type="radio"/> Not Applicable (go to 40)
	a. <i>If yes</i> , is it being implemented properly?	<input type="radio"/> Yes <input type="radio"/> No
Environmental/Product Sampling		
40.	Does the facility perform microbiological testing of <u>incoming ingredients</u> or require a Certificate of Analysis?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Handled at corporate/purchasing level
41.	Does the facility perform testing of <u>incoming packaging materials</u> or require a Certificate of Analysis?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Handled at corporate/purchasing level
42.	Does the facility perform environmental microbiological testing? (check all that apply) Zone 1 - product contact surfaces (e.g., slicers, peelers, utensils, dicers, etc.) Zone 2 - non-product contact surfaces in close proximity to product (e.g., exterior of equipment, etc.) Zone 3 - non-product contact sites adjacent to zone 2 (e.g., hand trucks, floors, walls, drains, etc.) Zone 4 - areas remote from zone 1 (e.g., locker rooms, restrooms, warehouse, loading dock, etc.)	<input type="checkbox"/> Zone 1 <input type="checkbox"/> Zone 2 <input type="checkbox"/> Zone 3 <input type="checkbox"/> Zone 4 <input type="radio"/> No environmental microbiological sampling is performed
43.	Does the facility perform microbiological testing of <u>finished product</u> ?	<input type="radio"/> Yes <input type="radio"/> No
44.	Number of positive environmental or product monitoring results in the past year? (Enter number of positive results)	#: _____ (if >0 go 44a, else go to 45)
	a. <i>If >0</i> , were actions taken to investigate or address the root cause of the contamination?	<input type="radio"/> Yes – investigate only (go to 45) <input type="radio"/> Yes – investigate and address (go to 44b) <input type="radio"/> No actions were taken (go to 45)
	b. <i>If >0</i> , what actions were taken (mitigation strategy) List continues on the following page	<input type="checkbox"/> Trained food workers <input type="checkbox"/> Reconditioned food <input type="checkbox"/> Discarded food <input type="checkbox"/> Initiated a food recall <input type="checkbox"/> Cleaned and sanitized/disinfected affected area/equipment <input type="checkbox"/> Temporary closure of facility <input type="checkbox"/> Excluded infectious workers <input type="checkbox"/> Changed operational process(es)

		<input type="checkbox"/> Repaired/Replaced/Removed equipment <input type="checkbox"/> Developed food safety/HACCP plan <input type="checkbox"/> Revised food safety/HACCP plan <input type="checkbox"/> Revised in house sampling plan <input type="checkbox"/> Hired external consultants/auditors <input type="checkbox"/> Conducted a root cause analysis <input type="checkbox"/> Other: _____ <input type="radio"/> No mitigation/control measures were implemented
Product Traceability		
45.	Does the facility use production codes and if so, can they identify the date and time the food is processed, the plant where it is processed (check if only one plant), the line it was processed on (check if only one line), and/or the production lot code? (Check all that apply)	<input type="checkbox"/> Date food is processed <input type="checkbox"/> Time food is processed <input type="checkbox"/> Plant where food is processed <input type="checkbox"/> Line where food is processed <input type="checkbox"/> Lot number <input type="checkbox"/> Other: _____ <input type="radio"/> No production codes are used
46.	Does the facility have procedures for product tracing (traceback/traceforward)?	<input type="radio"/> Yes - Written (go to 46a) <input type="radio"/> Yes - Verbal (go to 46a) <input type="radio"/> Yes – Combination of written and verbal (go to 46a) <input type="radio"/> No (go to 47)
	a. <i>If yes</i> , has this procedure ever been tested or incorporated into any recalls?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>If yes</i> , how are records maintained/organized?	<input type="radio"/> Electronic system <input type="radio"/> Hardcopy/paper-based system <input type="radio"/> Combination of electronic and written
	c. <i>If yes</i> , can they trace where their incoming ingredients came from (traceback)?	<input type="radio"/> Yes – by supplier only <input type="radio"/> Yes – by supplier and lot number/product identifier <input type="radio"/> Unable to do so
	d. <i>If yes</i> , how can they trace where their processed or manufactured products have been distributed to (trace forward)? (Check all that apply)	<input type="checkbox"/> Businesses/customers picking product up <input type="checkbox"/> Businesses/customers receiving deliveries or shipments <input type="checkbox"/> Specific lot/product numbers of items distributed by date, shipment or customer <input type="checkbox"/> Records of which raw ingredient lots were used in which finished product lots <input type="checkbox"/> Other _____ <input type="radio"/> Unable to do so

Establishment Food Processing Practices		
47.	Does the facility inspect incoming TCS ingredients/products to ensure that they are under 41F/45F?	<input type="radio"/> Yes (go to 47a) <input type="radio"/> No (go to 48) <input type="radio"/> Not applicable (go to 48)
	a. <i>If yes</i> , are temperature records maintained to show ingredients/products were $\leq 41F/45F$?	<input type="radio"/> Yes <input type="radio"/> No
48.	Does the facility maintain TCS foods at or below 41F/45F as appropriate?	<input type="radio"/> Yes (go to 48a) <input type="radio"/> No (go to 49) <input type="radio"/> Not applicable (go to 49)
	a. <i>If yes</i> , are all refrigeration units $\leq 41F/45F$?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>If yes</i> , are temperature records maintained to show units remained $\leq 41F/45F$?	<input type="radio"/> Yes <input type="radio"/> No
49.	<p>Do food items go through a critical control step in the facility? (Check all that apply)</p> <p>A Critical Control step is a step in which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level</p>	<input type="checkbox"/> Heat treatment <input type="checkbox"/> Dried or processed to reduce the $a_w < 0.85$ <input type="checkbox"/> Processed to reduce the pH ≤ 4.6 <input type="checkbox"/> Pasteurized <input type="checkbox"/> Smoked (cold/hot) as a means of preservation <input type="checkbox"/> Aged as a means of preservation <input type="checkbox"/> Metal detection <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ (if any of the above boxes are checked go to 49a) <input type="radio"/> No critical control step (go to 50)
	a. <i>If yes</i> , are items processed properly?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>If yes</i> , are records maintained for this process?	<input type="radio"/> Yes <input type="radio"/> No
	c. <i>If yes</i> , enter any additional comments about your observation of the process (e.g., if it was being monitored, system failures, etc.)	
50.	Are items cooled/chilled?	<input type="radio"/> Yes (go to 50a) <input type="radio"/> No (go to 51)
	a. <i>If yes</i> , are items chilled/cooled within allowable parameters?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>If yes</i> , are records maintained for this process?	<input type="radio"/> Yes <input type="radio"/> No
51.	Is there any post-critical control step processing (e.g., addition of spices)?	<input type="radio"/> Yes (go to 51a) <input type="radio"/> No (go to 52)
	a. <i>If yes</i> , are items processed properly?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>If yes</i> , are records maintained for this process?	<input type="radio"/> Yes <input type="radio"/> No
52.	Does the facility treat their own water (for use as an ingredient or for sanitation)?	<input type="radio"/> Yes (go to 52a) <input type="radio"/> No (go to 53)
	a. <i>If yes</i> , is water treated/protected properly (e.g., no introduction of contaminants)?	<input type="radio"/> Yes <input type="radio"/> No

	b. <i>If yes</i> , are records maintained for this process?	<input type="radio"/> Yes <input type="radio"/> No
53.	Are incoming ingredients checked upon receipt for conformance with purchase specifications?	<input type="radio"/> Yes (go to 53a) <input type="radio"/> No (go to 54)
	a. <i>If yes</i> , are records maintained for this assessment?	<input type="radio"/> Yes <input type="radio"/> No
54.	Does the facility use in-line monitoring sensors (e.g., pH probes, temperature measurements, metal detectors, etc.)?	<input type="radio"/> Yes (go to 54a) <input type="radio"/> No (go to 55)
	a. <i>If yes</i> , are the sensors routinely validated against bench standards?	<input type="radio"/> Yes <input type="radio"/> No
	b. <i>If yes</i> , are the sensors routinely calibrated?	<input type="radio"/> Yes <input type="radio"/> No
Pest Management		
55.	Does the facility have contracted pest control services provided?	<input type="radio"/> Yes <input type="radio"/> No
56.	Does the facility have an Integrated Pest Management (IPM) plan (includes exclusion, attractant removal, etc. in addition to pesticide application)?	<input type="radio"/> Yes <input type="radio"/> No
57.	Are any pests or evidence of pest activity observed that could contaminate food or food processing equipment or food packaging materials?	<input type="radio"/> Yes <input type="radio"/> No
Other Issues		
58.	Is there a language barrier between the management and the employees?	<input type="radio"/> Yes <input type="radio"/> No
59.	Is there a dedicated food safety assurance person(s)?	<input type="radio"/> Yes (go to 59a) <input type="radio"/> No (go to 60)
	a. <i>If yes</i> , what is the title of the person(s)?	
60.	Does the facility have a preventative maintenance plan for food processing equipment?	<input type="radio"/> Yes – Written (go to 60a) <input type="radio"/> Yes – Verbal (go to 60a) <input type="radio"/> Yes – Combination of verbal and written (go to 60a) <input type="radio"/> No (go to 61) <input type="radio"/> Not Applicable (go to 61)
	a. <i>If yes</i> , is it followed?	<input type="radio"/> Yes <input type="radio"/> No
61.	<p>During the likely time that the ingredient/food was prepared, were any events, change in processes, or ingredient suppliers noted that appeared to be different from the ordinary operating circumstances or procedures?</p> <p>List continued on next page</p>	<input type="checkbox"/> Differences with ingredients (e.g., different source, different form (fresh vs canned), or a substitution) <input type="checkbox"/> Differences with food processing process <input type="checkbox"/> Differences with cleaning/sanitizing <input type="checkbox"/> Different employees <input type="checkbox"/> Ill employees <input type="checkbox"/> Ill family members of employees <input type="checkbox"/> Ill animals <input type="checkbox"/> Differences with equipment

		<input type="checkbox"/> Increased production (e.g., large order) <input type="checkbox"/> Changed hours of operation <input type="checkbox"/> Facility closure/reopening <input type="checkbox"/> Recent construction/ remodeling <input type="checkbox"/> Other _____ <small>(if any of the above boxes are checked go to 62a)</small> <input type="radio"/> No differences (go to 62)
	a. <i>If yes</i> , Briefly explain the differences.	
62.	Any additional comments?	

Part IVa – Suspected/Confirmed Food: Complete this form once for the suspected/confirmed food associated with this incident.

1.	Was a specific food suspected or confirmed in this incident?	<input type="radio"/> Yes (go to 1b also fill out Part IVb) <input type="radio"/> No (go to 1a)
	<i>a. If the facility was suspected, but an ingredient/food was <u>not</u> suspected or confirmed: Explain why the facility was suspected in this incident. (end part IV)</i>	
	<i>b. If an ingredient/food was suspected or confirmed: Is this food a single specific ingredient (for example, lettuce or tomato) or multi-ingredient (Ex: pasta sauce)?</i>	<input type="radio"/> Single ingredient <input type="radio"/> Multiple ingredient
	<i>c. If an ingredient/food was suspected or confirmed: What is the name of the suspected or confirmed ingredient/food vehicle? (Ex: lettuce or pasta sauce)</i>	
	<i>d. If an ingredient/food was suspected or confirmed: Select the reasons that this food item is suspected/confirmed (Check all that apply)</i>	<input type="checkbox"/> Product tracing <input type="checkbox"/> Epidemiological study <input type="checkbox"/> Positive clinical sample <input type="checkbox"/> Positive food sample <input type="checkbox"/> Positive environmental sample (e.g. on common equipment) <input type="checkbox"/> Other: _____
	<i>e. If an ingredient/food was suspected or confirmed: Select the method(s) of processing that occurred for the implicated product in this facility (Check all that apply)</i>	<input type="radio"/> No processing CCP's <input type="checkbox"/> Heat treatment <input type="checkbox"/> Dried or processed to reduce the $a_w < 0.85$ <input type="checkbox"/> Processed to reduce the pH ≤ 4.6 <input type="checkbox"/> Pasteurized <input type="checkbox"/> Smoked (cold/hot) as a means of preservation <input type="checkbox"/> Aged as a means of preservation <input type="checkbox"/> Metal detection <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ Other Processing <input type="checkbox"/> Washing <input type="checkbox"/> Cutting/Dicing <input type="checkbox"/> Milling <input type="checkbox"/> Chilling <input type="checkbox"/> Freezing <input type="checkbox"/> Pressure treatment <input type="checkbox"/> Spraying/Chemical treatment <input type="checkbox"/> Other: _____

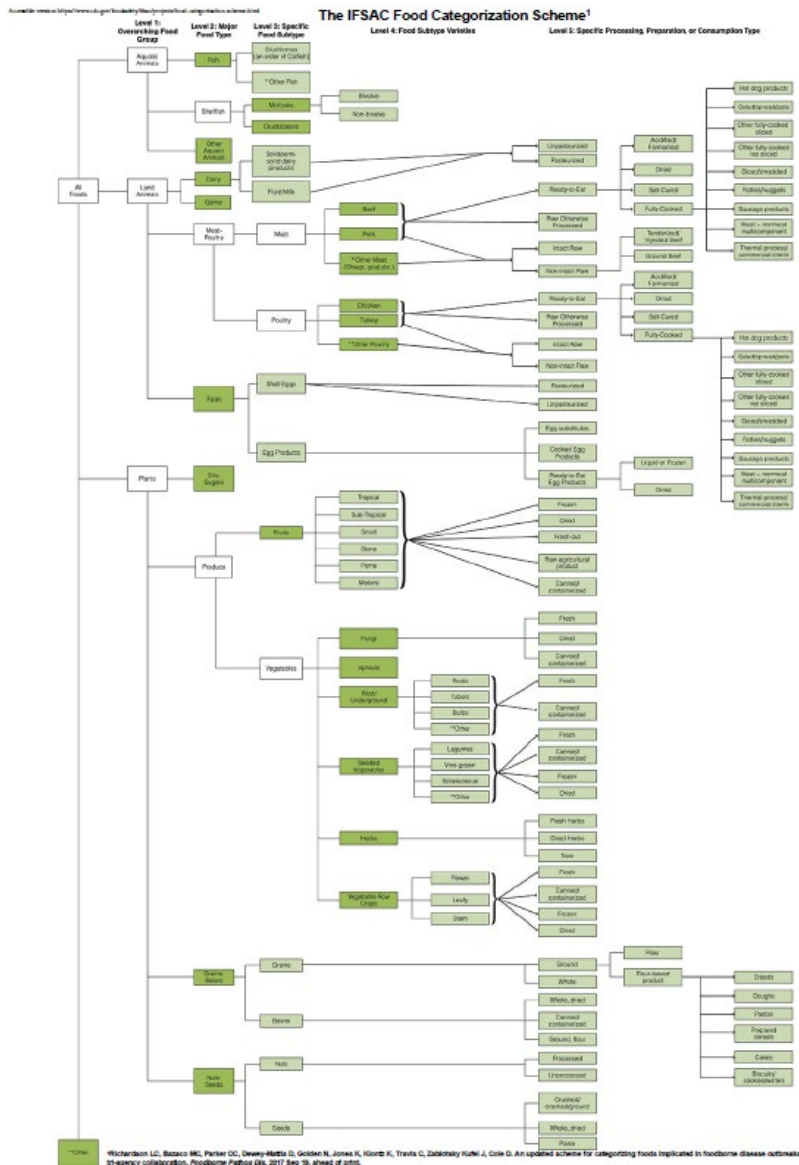
	<p>f. <i>If an ingredient/food was suspected or confirmed:</i> During the likely time that the ingredient/food was prepared, were any differences noted that varied from the ordinary operating conditions or procedures? (Check all that apply)</p>	<p> <input type="radio"/> No differences <input type="checkbox"/> Ingredient(s) used (ex. Supplier) <input type="checkbox"/> Process <input type="checkbox"/> Equipment <input type="checkbox"/> Employee(s) <input type="checkbox"/> Other: _____ <input type="checkbox"/> Describe: _____ </p>
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Fill out Part IVb for each suspected/confirmed ingredient food. (e.g., if a hamburger is the suspected food item you would fill out Part IVb for the ground beef, the bun, each of the condiments [e.g., ketchup, mustard, pickles, etc.], and any other toppings. However, if the ground beef has been identified as the suspected ingredient then you would only fill out Part IVb for the ground beef).

Part IVb- Suspected/confirmed Food, ingredients: Complete this section for EACH ingredient in the suspected/confirmed food(s). If a specific item has been identified this only needs to be filled out for that specific ingredient.

2. Name of ingredient							
3. If any information is present (product manifests, records, tags) that shows this ingredient is an imported food item or from an unapproved source or recall, describe							
4. Food Group	Major Food Type	Specific Food Type	Food Subtype Varieties	Food Subtype	Specific Processing	Specific Preparation	Consumption Type
5. Other Food (Please describe)							

For an accessible version of the food categorization scheme (question 4) see: <https://www.cdc.gov/foodsafety/ifsac/projects/food-categorization-scheme.html>



Part Va – Sample Results: Complete this section for all microbiological samples taken as part of the environmental assessment. Complete Part Vb for any positive samples only.

	Item #	Area	# Samples	# Positive (if >0 fill out Part Vb for each positive sample)
Environmental	1.	Zone 1 surfaces (product contact surfaces [e.g., slicers, peelers, utensils, dicers, etc.])		
	2.	Zone 2 surfaces (non-product contact surfaces in close proximity to product [e.g., exterior of equipment, etc.])		
	3.	Zone 3 surfaces (non-product contact surfaces adjacent to zone 2 [e.g., hand trucks, floors, walls, drains, etc.])		
	4.	Zone 4 surfaces (areas remote from zone 1 [e.g., locker rooms, restrooms, warehouse, loading dock, etc.])		
	5.	Other areas		
Food	6.	Incoming ingredients		
	7.	In process food		
	8.	Finished product		
	9.	Other food/packaging samples		

Part Vb – Sample Results: Complete this section for each positive sample (if a sample was positive for more than one agent please select all agents present)

Item#	Question	Response
10.	Where was the sample collected?	
11.	Briefly describe the food, ingredient or location	
12.	What agent(s) was/were identified in the sample? (Check all that apply)	<input type="checkbox"/> <i>Salmonella</i> spp. <input type="checkbox"/> <i>Campylobacter</i> spp. <input type="checkbox"/> <i>Clostridium perfringens</i> <input type="checkbox"/> <i>Cryptosporidium</i> <input type="checkbox"/> STEC/VTEC <input type="checkbox"/> Other <i>E. coli</i> <input type="checkbox"/> <i>Listeria</i> <input type="checkbox"/> <i>Shigella</i> spp. <input type="checkbox"/> <i>Vibrio</i> spp. <input type="checkbox"/> <i>Cyclospora</i> spp. <input type="checkbox"/> Norovirus <input type="checkbox"/> Hepatitis A <input type="checkbox"/> Chemical hazard: _____ <input type="checkbox"/> Physical hazard: _____ <input type="checkbox"/> Toxic agent: _____ <input type="checkbox"/> Other: _____
	a. If a serotype was identified please enter it here	
	b. If an allele code was identified please enter it here	
	c. Additional comments about the sample?	

Part VIa – Contributing Factor: The environmental antecedents and contributing factors should be determined by the investigative team based on all the information that has been obtained during the environmental assessment. This may be filled out for each environmental assessment. If no Contributing Factors were identified, do not fill this out.

1.	Is this the facility where the incident occurred?	<input type="radio"/> Yes <input type="radio"/> No		
2.	What were the top 3 possible environmental antecedent(s) of this incident? <i>(Check up to 3 that apply)</i> <div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <input type="checkbox"/> No environmental antecedents were identified <input type="checkbox"/> Lack of training of employees on specific processes <input type="checkbox"/> Lack of oversight of employees/ enforcement of policies <input type="checkbox"/> High turnover of employees or management <input type="checkbox"/> Low/insufficient staffing <input type="checkbox"/> Lack of a food safety culture/ attitude towards food safety <input type="checkbox"/> Language barrier between management and employees <input type="checkbox"/> Insufficient capacity of equipment (not enough equipment for the processes) <input type="checkbox"/> Equipment is improperly used <input type="checkbox"/> Lack of preventative maintenance on equipment </div> <div style="width: 48%;"> <input type="checkbox"/> Improperly sized or installed equipment for the facility <input type="checkbox"/> Poor facility design <input type="checkbox"/> Lack of sick leave or other financial incentives to adhere to good practices <input type="checkbox"/> Lack of needed supplies for the operation of the facility <input type="checkbox"/> Insufficient process to mitigate the hazard <input type="checkbox"/> Employees or managers are not following the facility's process <input type="checkbox"/> Food not treated as TCS (may include non-TCS foods that have been contaminated) <input type="checkbox"/> Other, <i>Describe:</i> </div> </div> <p style="text-align: right; font-size: small;">(if any boxes are checked go to 2a, else go to 3)</p>			
	a. <i>If an environmental antecedent was identified:</i> Briefly describe any other information about the underlying causes of the incident (e.g., order of antecedents).			
3.	During the investigation, what activities were used to try to identify the contributing factors? <i>(Check all that apply)</i> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> <input type="checkbox"/> Previous Routine Inspection(s) <input type="checkbox"/> Environmental Assessment(s) <input type="checkbox"/> Other Investigation, <i>Describe:</i> <input type="checkbox"/> Prior compliance/enforcement actions <input type="checkbox"/> Interview of Manager <input type="checkbox"/> Interview with Food Worker(s) <input type="checkbox"/> Observation of general food manufacturing activities </td> <td style="width: 50%; padding: 5px;"> <input type="checkbox"/> Determined based on etiologic agent <input type="checkbox"/> Environmental Sampling <input type="checkbox"/> Product Sampling <input type="checkbox"/> Clinical Samples/Syndrome <input type="checkbox"/> Epidemiologic Investigation (Case-Control or Cohort Study) <input type="checkbox"/> Other, <i>Describe:</i> </td> </tr> </table>		<input type="checkbox"/> Previous Routine Inspection(s) <input type="checkbox"/> Environmental Assessment(s) <input type="checkbox"/> Other Investigation, <i>Describe:</i> <input type="checkbox"/> Prior compliance/enforcement actions <input type="checkbox"/> Interview of Manager <input type="checkbox"/> Interview with Food Worker(s) <input type="checkbox"/> Observation of general food manufacturing activities	<input type="checkbox"/> Determined based on etiologic agent <input type="checkbox"/> Environmental Sampling <input type="checkbox"/> Product Sampling <input type="checkbox"/> Clinical Samples/Syndrome <input type="checkbox"/> Epidemiologic Investigation (Case-Control or Cohort Study) <input type="checkbox"/> Other, <i>Describe:</i>
<input type="checkbox"/> Previous Routine Inspection(s) <input type="checkbox"/> Environmental Assessment(s) <input type="checkbox"/> Other Investigation, <i>Describe:</i> <input type="checkbox"/> Prior compliance/enforcement actions <input type="checkbox"/> Interview of Manager <input type="checkbox"/> Interview with Food Worker(s) <input type="checkbox"/> Observation of general food manufacturing activities	<input type="checkbox"/> Determined based on etiologic agent <input type="checkbox"/> Environmental Sampling <input type="checkbox"/> Product Sampling <input type="checkbox"/> Clinical Samples/Syndrome <input type="checkbox"/> Epidemiologic Investigation (Case-Control or Cohort Study) <input type="checkbox"/> Other, <i>Describe:</i>			

Part VIb – Contributing Factor – for each identified contributing factor fill out the table below. A current list of contributing factors is available at: <https://www.cdc.gov/nceh/ehs/nears/cf-definitions.htm>

<p>4. Which contributing factor was identified?</p>	<p> <input type="radio"/> C1 <input type="radio"/> P1 <input type="radio"/> S1 <input type="radio"/> C2 <input type="radio"/> P2 <input type="radio"/> S2 <input type="radio"/> C3 <input type="radio"/> P3 <input type="radio"/> S3 <input type="radio"/> C4 <input type="radio"/> P4 <input type="radio"/> S4 <input type="radio"/> C5 <input type="radio"/> P5 <input type="radio"/> S5 <i>Other,</i> <input type="radio"/> C6 <input type="radio"/> P6 <i>Describe:</i> <input type="radio"/> C7 <input type="radio"/> P7 <input type="radio"/> C8 <input type="radio"/> P8 <input type="radio"/> C9 <input type="radio"/> P9 <input type="radio"/> C10 <input type="radio"/> P10 <input type="radio"/> C11 <input type="radio"/> P11 <input type="radio"/> C12 <input type="radio"/> P12 <i>Other, Describe:</i> <input type="radio"/> C13 <input type="radio"/> C14 <input type="radio"/> C15 <i>Other, Describe:</i> </p>
<p>5. In your judgment, was this the primary contributing factor for this incident?</p>	<p><input type="radio"/> Yes <input type="radio"/> No</p>
<p>6. Briefly explain why this is a contributing factor in this incident.</p>	
<p>7. When did this factor most likely occur?</p>	<p> <input type="radio"/> Before vehicle entry into the facility <input type="radio"/> While the vehicle was at the facility <input type="radio"/> After the vehicle left the facility </p>