

April 10, 2007

ERG

Log in

Please enter your pre-assigned survey password below.

If you have any questions about your participation, please contact the survey helpline at surveyhelp@erg.com.

Password: _____

[[Log in box with "Submit" button that goes to the Introduction page](#)]

INTRODUCTION

The U.S. Food and Drug Administration (FDA) needs your help to gain a better understanding of current manufacturing practices. FDA will use the information from this survey as it considers how to modernize the Food GMPs (21 CFR 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food). Thus, your participation is vitally important.

You have been selected to receive this survey because you registered your facility with the FDA and provided an email address that permits contact electronically.

This survey collects information on the following five (5) key areas in addition to some facility-specific information to characterize your responses:

- Training
- Sanitation and personal hygiene
- Allergen controls
- Process controls
- Recordkeeping

This survey will take around ?? minutes to complete. You will have the ability to leave the survey at any time and come back to finish it at a later time.

Your participation in this survey is voluntary, and we greatly appreciate your help. Your responses will be compiled by Eastern Research Group, Inc. (ERG), an FDA contractor, and will be kept CONFIDENTIAL. ERG will only provide aggregated data to FDA, without any facility or respondent identifiers. You can view more detail on how we are ensuring the confidentiality of your responses by clicking on "[Privacy and Security Statement](#)."

[["Next page" button that goes to the Instructions page](#)]

INSTRUCTIONS

1. If you are not the appropriate person to complete this survey, we ask that you forward the survey invitation we emailed you to the appropriate person in your organization.
2. Please answer each question as it pertains to your facility.
3. If you do not know the answer to a particular question, please consult with other members of your organization.
4. Throughout the survey, we use various words and phrases to have particular meanings. These are underlined. Please click on these to see a definition.
5. You need to provide a response to those questions marked with an asterisk (*) to be able proceed to the next applicable question.
6. If you would like to leave the survey at any time, just click on “Log out” at the top of the page. Your answers will be saved and you will be able to come back to finish the survey at a later time by logging in with your existing password.
7. If you have any questions throughout the survey, please refer to the frequently asked questions (FAQs) by clicking on “[FAQs](#)” at the top of the page. You can also contact the survey helpline at surveyhelp@erg.com.

Thank you very much for your participation! Please click on the “Next Page” button to start.

[“[Previous Page](#)” button that goes to the Introduction page and “[Next Page](#)” button that goes to the “Facility Profile” module]

FACILITY PROFILE

Q1.(*) For verification purposes (i.e., if you misplace your password and need to request it), please provide your email address below.

Email address _____

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Our records indicate that the name and location of your facility are as follows:

Facility Name _____
Street _____
City _____
State _____
Zip code _____

Q2. Please update and/or correct the information below as appropriate. This information will be used to confirm that you should be a respondent to this questionnaire because you manufacture or process food. The information you provide on this and the following questions will be kept strictly confidential. If the information does not need to be updated or corrected, please go to the next page of questions.

Facility Name _____
Street _____
City _____
State _____
Zip code _____

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Q3.(*) What is your *primary* operation at this facility? Please check only one.

- _____ Manufacturer/processor of food for human consumption [\[Go to Q4\]](#)
- _____ Manufacturer/processor of food additives/food ingredients [\[Go to Q5\]](#)
- _____ Manufacturer/processor of food for animal consumption [\[Go to END1\]](#)
- _____ Manufacturer/processor of dietary supplements [\[Go to END1\]](#)
- _____ Distributor [\[Go to END1\]](#)
- _____ Repacker/packer

_____ Warehouse/holding facility	[Go to END1]
_____ Labeler/relabeler	[Go to END1]
_____ Salvage operator (reconditioner)	[Go to END1]
_____ Contract sterilizer	[Go to END1]
_____ Interstate conveyance caterer/catering point	[Go to END1]
_____ Commissary	[Go to END1]
_____ Other _____ [verbatim]	[Go to END1]

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Q6.(*) Please choose from the list below the *primary* industry that corresponds to the types of products you process or pack at this facility. Please select only one.

_____ Drop-down 1

[Programmer Note 1:

- If Q7 = “Animal Slaughtering & Processing” or “Beverage Manufacturing-Breweries” or “Beverage Manufacturing-Wineries” or “Beverage Manufacturing-Distilleries”, go to END1
- If Q8 = “Postharvest Crop Activities,” go to Q9

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Q10.(*) Please choose from the list below the *secondary* industry or industries, if any, that corresponds to any additional types of food products you process or pack at this facility. Please select all that apply.

_____ Drop-down 2

[Programmer Note 2:

- If Q11 = “Seafood Product Preparation & Packaging-Seafood Canning” or “Seafood Product Preparation & Packaging-Fresh & Frozen Seafood Processing, go to Q12
- If Q13 = “Dairy Product Manufacturing-Fluid Milk Manufacturing” or “Dairy Product Manufacturing-Creamery Butter Manufacturing” or “Dairy Product Manufacturing-Cheese Manufacturing” or “Dairy Product Manufacturing-Dry, Condensed, & Evaporated Dairy Product Manufacturing” or “Dairy Product Manufacturing-Ice Cream & Frozen Desert Manufacturing”, go to Q14
- All others, go to Q15]

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Q16.(*) Please choose from the list below the one industry description that corresponds to your primary food-related business at this facility.

Please select only one.

- Basic Chemical Manufacturing-Alkalies & Chlorine Manufacturing (e.g., sodium bicarbonate) [\[Go to Q17\]](#)
- Basic Chemical Manufacturing-All Other Basic Inorganic Chemical Manufacturing (e.g., zinc oxide) [\[Go to Q18\]](#)
- Basic Chemical Manufacturing-All Other Basic Organic Chemical Manufacturing (e.g., citric acid, lactic acid, tartrates, saccharin, alginates) [\[Go to Q19\]](#)
- Other Food Manufacturing-Spice & Extract Manufacturing (e.g., natural food colors, pectin) [\[Go to Q20\]](#)
- Other Food Manufacturing-All Other Miscellaneous Food Manufacturing (e.g., yeast) [\[Go to Q21\]](#)
- Pesticide, Fertilizer, & Other Agricultural Chemical Manufacturing-Phosphatic Fertilizer Manufacturing (e.g., phosphoric acid) [\[Go to Q22\]](#)
- Pharmaceutical & Medicine Manufacturing-Medicinal & Botanical Manufacturing (e.g., vitamins, ascorbic acid) [\[Go to Q23\]](#)
- Pharmaceutical & Medicine Manufacturing-Pharmaceutical Preparation Manufacturing (e.g., vitamins, zinc oxide) [\[Go to Q24\]](#)
- Resin, Synthetic Rubber, & Artificial Synthetic Fibers & Filaments Manufacturing-Plastics Material & Resin Manufacturing (e.g., methyl cellulose) [\[Go to Q25\]](#)
- Starch & Vegetable Fats & Oils Manufacturing-Soybean Processing (e.g., lecithin) [\[Go to Q26\]](#)
- Starch & Vegetable Fats & Oils Manufacturing-Other Oilseed Processing (e.g., coconut oil) [\[Go to Q27\]](#)
- Starch & Vegetable Fats & Oils Manufacturing-Fats & Oils Refining & Blending (e.g., linseed oil) [\[Go to Q28\]](#)

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Q29.(*) Does your post harvest operation involve packing of fresh produce?

- Yes
- No [\[Go to END1\]](#)

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Q30. Which of the following describes your structure, if any, where you pack fresh produce? Please check all that apply.

- Field with no special equipment or physical structure
- Field with specialized equipment, such as a mule train or rolling conveyor, but no physical structure
- Floor (e.g., concrete slab) and roof
- Floor, roof, and some walls or screening but not completely enclosed
- Enclosed structure with openings, such as unscreened doors and windows
- Completely enclosed structure
- Other _____ [verbatim]

Q31.(*) Which of the following describes your use of water when you pack fresh produce? Please check only one.

- Field with minimal processing and no water contact (e.g., minimal trimming and sorting) [\[Go to Q32\]](#)
- Field with some processing and water contact (e.g., significant trimming, coring, washing, and cooling) [\[Go to Q33\]](#)
- Physical structure with minimal processing and no water contact (e.g., minimal trimming and sorting)
- Physical structure with some processing and water contact (e.g., trimming, coring, washing, waxing, and cooling)

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Q34. Please indicate the type of cooling method that you use at your packing facility? Please check only one.

- Cold room (room cooling) [\[Go to Q35\]](#)
- Forced-air (pressure) cooling [\[Go to Q36\]](#)
- Hydrocooling [\[Go to Q37\]](#)
- Contact icing (top icing or package icing) [\[Go to Q38\]](#)
- Vacuum cooling [\[Go to Q39\]](#)
- Cooling is done off site [\[Go to Q40\]](#)

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Q41. Do you process any of the following refrigerated ready-to-eat products? Please check all that apply.

- Smoked seafood [\[Go to Q42\]](#)
- Raw seafood [\[Go to Q43\]](#)
- Preserved fish [\[Go to Q44\]](#)
- Cooked ready-to-eat crustaceans [\[Go to Q45\]](#)
- None of the above [\[Go to Q46\]](#)

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Q47. Do you process any of the following refrigerated ready-to-eat products? Please check all that apply.

- Fresh soft cheeses
- Soft unripened cheeses
- Soft ripened cheeses
- Semi-soft cheeses
- Hard cheeses
- Processed cheeses
- Pasteurized fluid milk
- Unpasteurized fluid milk
- Ice cream

- Frozen dairy products other than ice cream
- Cultured milk products other than yogurt
- Yogurt
- None of the above

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Q48.(*) Does this facility operate year round or on a seasonal basis?

- Year round
- Seasonal [\[Go to Q49\]](#)

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Q50. How many employees in *total* typically work at your facility?

- 20 or fewer
- Between 21 and 100
- Between 101 and 500
- Between 501 and 750
- Between 751 and 1,000
- 1,001 or more

Q51. What percent of your total employees are part-time or temporary?

- 0%
- 5% or less
- >5% to 10%
- >10% to 25%
- >25% to 50%
- >50% to 75%
- >75%

Q52. Approximately, how many production line managers/supervisors do you employ?

- 5 or fewer [\[Go to Q53\]](#)
- 6 to 10 [\[Go to Q54\]](#)
- 11 to 30 [\[Go to Q55\]](#)
- 31 to 50 [\[Go to Q56\]](#)
- 51 or more [\[Go to Q57\]](#)

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Q58. How many employees in *total* typically work at this facility during:

	<u>20 or fewer</u>	<u>21 to 100</u>	<u>101 to 500</u>	<u>501 to 750</u>	<u>751 to 1,000</u>	<u>1,001 or more</u>
a. Peak season?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Off season?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q59. What percent of your total employees are part-time or temporary during:

	<u>0%</u>	<u>5% or less</u>	<u>>5% to 10%</u>	<u>>10% to 25%</u>	<u>>25% to 50%</u>	<u>>50% to 75%</u>	<u>>75%</u>
a. Peak season?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Off season?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q60. Approximately, how many production line managers/supervisors do you employ during:

	<u>5 or fewer</u>	<u>6 to 10</u>	<u>11 to 30</u>	<u>31 to 50</u>	<u>51 or more</u>
a. Peak season?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Off season?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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Q61.(*) Is this facility independently owned and operated or does your company own and operate other food manufacturing or processing facilities?

- Independently owned [\[Go to Q62\]](#)
 Company operates other facilities

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Q63. How many food manufacturing or processing facilities *including this one* does your company own and operate?

- 2 to 5
 6 to 10
 10 to 20
 Greater than 20

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- Q64. For the most recent fiscal year, what was the gross sales revenue for the food manufactured or processed at this facility?
- \$500,000 or less
 - >\$500,000 to \$1 million
 - >\$1 million to \$6 million
 - >\$6 million to \$10 million
 - >\$10 million to \$50 million
 - >\$50 million to \$100 million
 - >\$100 million

[Programmer Note 3: If Q65 = “Yes,” go to Q66, otherwise go to Q67]

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TRAINING

Q68.(*) Which of the following *best* describes the type of food safety and sanitation training you provide for your newly hired hourly employees?

Please check only one.

- Classroom-type training
- Supervised on-the-job training conducted by facility personnel
- Informal (not supervised) on-the-job training
- Self-administered training (such as supplemental reading materials, videotapes, online courses, etc.)
- No training program

[\[Go to Q69\]](#)

[\[Go to Q70\]](#)

[\[Go to Q71\]](#)

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Q72. Does your food safety and training for newly hired hourly personnel cover the following areas?

	<u>Not applicable</u>	<u>Yes</u>	<u>No</u>
a. Principles of food safety hazards and prevention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Personal hygiene practices	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Basic cleaning and sanitizing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Allergen control	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Other GMP practices _____[verbatim]	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q73. On average, about how many hours of food safety and sanitation training does a newly hired hourly employee receive?

- 4 hours or less
- >4 to 8 hours
- >8 to 16 hours
- >16 to 48 hours
- >48 hours

Q74.(*) Do you provide refresher training in food safety and sanitation to your hourly personnel?

- Yes
- No [\[Go to Q75\]](#)

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Q76. How often do you provide refresher training?

- Monthly
- Quarterly

- Semiannually
- Annually
- Other _____ [verbatim]

Q77. What is the typical duration of your refresher-training sessions?

- 30 minutes or less
- >30 minutes to 1 hour
- >1 to 2 hours
- >2 to 4 hours
- >4 to 8 hours
- >8 hours

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Q78.(*) Approximately, what percentage of your hourly employees is able to read written procedures and training materials in English?

- 100 percent (All of our employees can read in English) [\[Go to Q79\]](#)
- 75 to 99 percent
- 50 to 74 percent
- 25 to 49 percent
- Less than 25 percent

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Q80. Please indicate the languages in which you provide food safety and sanitation training (including initial training provided upon hire and refresher training, if any) for your non-English speaking hourly personnel. Please check all that apply.

- Spanish
- Chinese
- Creole
- Korean
- Portuguese
- Vietnamese
- Thai
- Indigenous languages
- Other _____ [verbatim]
- None (We do not provide training in any language but English)

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Q81. Apart from your hourly employees, about how many hours of food safety and sanitation training do the following types of personnel receive within the first year of employment?

	<u>None</u>	<u>4 hours or less</u>	<u>>4 to 8 hours</u>	<u>>8 to 16 hours</u>	<u>>16 to 48 hours</u>	<u>>48 hours</u>
a. Food production operation managers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Production supervisors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Quality control managers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Sanitation and cleaning supervisors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q82.(*) Approximately, how many hours of continuing training in food safety and sanitation do the following types of personnel receive annually?

	<u>None</u>	<u>4 hours or less</u>	<u>>4 to 8 hours</u>	<u>>8 to 16 hours</u>	<u>>16 to 48 hours</u>	<u>>48 hours</u>
a. Food production operation managers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Production supervisors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Quality control managers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Sanitation and cleaning supervisors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[Programmer Note 4: If Q83a through Q84d = “None,” go to Q85, otherwise go to Q86]

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Q87. Which of the following types of ongoing training programs do you offer these personnel? Please check all that apply.

- Cross-training in various skills
- Tuition compensation for job-related outside courses
- Pay-for-skills program
- Industry short courses
- Other _____ [verbatim]

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Q88. Do you maintain the following types of records related to food safety and sanitation training received by your employees?

	<u>Yes, for all employees</u>	<u>Yes, for all except hourly employees</u>	<u>Yes, for only hourly employees</u>	<u>No</u>
a. Documentation of administered training	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- b. Documentation of the training content
- c. Proof of management oversight
- d. Corrective actions
- e. Other _____[verbatim]

Q89. Which of the following methods do you use to assess the effectiveness of your food safety and sanitation training program? Please check all that apply.

- _____ Formal employee testing with records of such tests
- _____ Documented employee monitoring and performance evaluation
- _____ Other _____ [verbatim]
- _____ Do not formally evaluate training effectiveness

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SANITATION AND PERSONAL HYGIENE

Q90.(*) Do you have *written* cleaning procedures for your food contact equipment?

- Yes
- No [\[Go to Q91\]](#)

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Q92. Do your procedures for *cleaning* of food contact equipment cover any of the following elements?

	<u>Yes</u>	<u>No</u>
a. Descriptions of specific steps for cleaning	<input type="radio"/>	<input type="radio"/>
b. Frequency of cleaning	<input type="radio"/>	<input type="radio"/>
c. Chemicals and cleaners to be used	<input type="radio"/>	<input type="radio"/>
d. Descriptions for disassembling and reassembling equipment	<input type="radio"/>	<input type="radio"/>
e. Personnel responsibilities for cleaning equipment	<input type="radio"/>	<input type="radio"/>

Q93. Have you validated these procedures?

- Yes
- No
- Don’t know

Q94. On average, how frequently do you *clean* your food contact equipment?

- After each production run
- More than once per shift
- Every shift
- Daily
- Weekly
- Monthly
- Other _____ [verbatim]

Q95. Which of the following methods do you use to *clean* your food contact equipment? Please check all that apply.

- Clean-in-place (CIP)
- Clean-out-place (COP)
- Push-through with product flush
- Push-through with inert-material flush
- Dry cleaning: scraping or brushing

- Dry cleaning: compressed air
- Dry cleaning: vacuum
- Wet cleaning: water with aqueous detergent
- Wet cleaning: water without aqueous detergent
- Wet cleaning: high-pressure washing
- Other _____ [verbatim]

Q96. Which of the following methods do you use to assess the effectiveness of your food contact equipment *cleaning* ?

- Test for chemical residue
- Test for microbial contamination
- ATP bioluminescence testing
- Other _____ [verbatim]
- None of the above

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Q97.(*) Do you have *written* sanitizing procedures for your food contact equipment?

- Yes
- No [\[Go to Q98\]](#)

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Q99. Do your procedures for *sanitizing* of food contact equipment cover any of the following elements?

	<u>Yes</u>	<u>No</u>
a. Descriptions of specific steps for sanitizing	<input type="radio"/>	<input type="radio"/>
b. Frequency of sanitizing	<input type="radio"/>	<input type="radio"/>
c. Chemicals and sanitizers to be used	<input type="radio"/>	<input type="radio"/>
d. Descriptions for disassembling and reassembling equipment	<input type="radio"/>	<input type="radio"/>
e. Personnel responsibilities for sanitizing equipment	<input type="radio"/>	<input type="radio"/>

Q100. Have you validated these procedures?

- Yes
- No
- Don't know

Q101. On average, how frequently do you *sanitize* your food contact equipment?

- After each production run
- More than once per shift
- Every shift
- Daily
- Weekly
- Monthly
- Other _____ [verbatim]

Q102. Please indicate the types of *sanitizers* you use on your food contact equipment? Please check all that apply.

- Steam
- Hot water
- Ozone
- Chlorine-based sanitizers, such as chlorine gas, hypochlorites, or chloramines
- Chlorine dioxide (ClO₂)
- Iodophors (or iodine compounds)
- Quarternary ammonium compounds mixed with water
- Quarternary ammonium compounds mixed with alcohol
- Acid anionic surfactants (mainly phosphoric acid combined with surface-active agents)
- Carboxylic acid (or fatty acid) sanitizers
- Peroxy compounds, such as hydrogen peroxide (HP) or peroxyacetic acid (PAA)
- Other _____ [verbatim]

Q103. Which of the following methods do you use to assess the effectiveness of your food contact equipment *sanitizing*?

- Test for chemical residue
- Test for microbial contamination
- ATP bioluminescence testing
- Other _____ [verbatim]
- None of the above

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Q104.(*) Do you have *written* cleaning procedures for your non-food contact equipment?

- Yes
- No [\[Go to Q105\]](#)

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Q106. On average, how frequently do you *clean* your non-food contact equipment?

- After each production run
- More than once per shift
- Every shift
- Daily
- Weekly
- Monthly
- Other _____ [verbatim]

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Q107.(*) Do you have *written* cleaning procedures for your production areas?

- Yes
- No [\[Go to Q108\]](#)

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Q109. On average, how frequently do you *clean* your production areas?

- After each production run
- More than once per shift
- Every shift
- Daily
- Weekly
- Monthly
- Other _____ [verbatim]

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Q110.(*) Do you have *written* cleaning procedures for your finished goods storage areas?

- Yes
- No [\[Go to Q111\]](#)

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Q112. On average, how frequently do you *clean* the finished goods storage areas at your facility?

- After each production run
- More than once per shift
- Every shift
- Daily
- Weekly
- Monthly
- Other _____ [verbatim]

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Q113. Do you have *written* cleaning procedures for your raw material storage areas?

- Yes
- No [\[Go to Q114\]](#)

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Q115. On average, how frequently do you *clean* your raw material storage areas?

- More than once per shift
- Every shift
- Daily
- Weekly
- Monthly
- Other _____ [verbatim]

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Q116.(*) Do you monitor microbial contamination through environmental sampling and testing?

- Yes, testing done in-house
- Yes, testing done by an outside laboratory
- Yes, testing done both in house and by an outside laboratory
- No [\[Go to Q117\]](#)
- Don't know [\[Go to Q118\]](#)

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Q119.(*) Which of the following methods do you use to monitor microbial contamination? Please check all that apply.

- Conventional culture methods
- Rapid microbial detection systems
- ATP bioluminescence testing
- Other _____ [verbatim]

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Q120. How frequently do you monitor for microbial contamination?

- After each production run
- More than once per shift
- Every shift
- Daily
- Weekly
- Monthly
- Other _____ [verbatim]

Q121. Please indicate from the following, the personal hygiene practices for your production personnel. Please check all that apply.

- Employer-provided outer clothing
- Employer-provided uniform
- Employer-provided footwear
- Hair nets or restraints for head and facial hair
- Sanitary gloves
- Hand dips
- Footbaths
- Other _____ [verbatim]

Q122. Which of the following are your employee hand-washing requirements? Please check all that apply.

- Hand washing at the start of work
- Hand washing after breaks (e.g., eating, drinking, or smoking)
- Hand washing after using the restroom
- Hand washing after touching something unclean
- Hand washing after touching body parts
- Do not have an employee hand washing policy

Q123.(*) Do you have a pest control program?

- Yes, we have a written pest control program

- Yes, we have an unwritten pest control program
- No [\[Go to Q124\]](#)

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Q125. For which of the following types of pests do you control?

- Flying insects
- Food storage insects
- Birds
- Rodents

Q126. Which of the following *best* characterizes the inspections for assessing your applicable pest control program’s effectiveness?

	<u>Not applicable</u>	<u>Regular inspections required</u>	<u>Inspections conducted on an as needed basis</u>	<u>Inspections not required</u>
a. Flying insects		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Food storage insects		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Birds		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Rodents		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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Q127. Does your water supply meet the U.S. Environmental Protection Agency’s (EPA’s) drinking water standards?

- Yes
- No
- Don’t know

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ALLERGEN CONTROLS

Q128.(*) Do you manufacture or process ingredients that are, or are derived from any of the following main (8) allergenic foods or food groups? Please check all that apply.

- Soybean or soybean-based ingredients, including miso, tofu, and soy flour
- Peanuts or peanut-based ingredients, including peanut butter and peanut flour
- Fish, including fresh and saltwater finfish
- Crustacea, including shrimp, lobster, crab, and crayfish
- Tree nuts, including almonds, chestnuts, macadamia, pecans, walnuts, and hazelnuts
- Milk, including butter, buttermilk, casein, cheese, cottage cheese, curds, whey, and caseinate
- Eggs, including egg yolks, egg whites or albumin, mayonnaise, or meringue
- Wheat, including bran, bread crumbs, farina, malt, wheat germ, wheat gluten, semolina, and spelt
- None of the above [\[Go to Q129\]](#)
- Don't know [\[Go to Q130\]](#)

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Q131.(*) Do you also manufacture or process food ingredients or products that:

	<u>Yes</u>	<u>No</u>	<u>Don't know</u>
a. Do not contain any of the main eight (8) allergens identified in Question 132 above, i.e., products that are <u>allergen free</u> ?	○	○	○
b. Foods that contain various mixes of different allergens listed in Question 133, such as a candy bar with peanuts and a candy bar with almonds?	○	○	○

[\[Programmer Note 5: If Q134a or Q135b=“Yes,” continue; otherwise go to Q136\]](#)

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Q137.(*) Do you have a written plan for the control of allergens?

- Yes
- No [\[Go to Q138\]](#)

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Q139. Of the following manufacturing or process issues, please identify those that are addressed by your written plan. Please check all that apply.

- New product development
- Product reformulation
- Receipt of raw materials
- Storage of raw materials
- Handling of raw materials
- Cleaning of food contact equipment
- Sharing of food contact equipment between allergen and non allergen containing products
- Cleaning of environmental surfaces
- Production sequencing/scheduling
- Workflow
- Labeling finished products
- Testing for allergen residues on food contact equipment surfaces
- Testing for allergen residues elsewhere
- Storage and handling of packaging materials
- Rework storage
- Rework handling
- Other _____ [verbatim]

Q140. Which, if any, of the following procedures do you use to reduce the cross contact of allergen-free with allergen-containing products or between products with different allergens? Please check all that apply.

- Clean between production runs of allergen-containing products and allergen-free products or between production runs of products with different mixes of allergens
- Utilize dedicated, separate equipment and production lines for allergen-containing and allergen-free products or for products with different mixes of allergen containing products
- Schedule production runs for allergen-containing products at the end of the day or production period
- Separate maintenance tools and utensils for allergen-free and allergen-containing products
- Change the protective clothing for employees, including gloves, aprons, and uniforms between production runs
- Other _____ [verbatim]
- None of the above

[\[“Previous Page” and “Next Page” buttons\]](#)

Q141. Do you have an air filtration system for your production areas that is capable of removing airborne allergen particles?

- Yes
- No

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Raw Materials, In-process Materials, and Rework

Q142. Which of the following describes how your allergen-containing raw materials are stored and handled? Please check all that apply.

- Marked or color-coded storage bins for allergen-containing raw materials
- Dedicated storage bins for allergen-containing raw material use only
- Separate storage room for allergen-containing raw materials
- Separate area, such as a dedicated rack, for allergen-containing raw materials in the same storage room with other raw materials
- Storage of like above like on storage racks
- Storage of allergen-containing materials on the bottom rack
- Dedicated scoops and utensils for handling allergen-containing raw materials
- Other _____ [verbatim]
- None of the above

Q143. Do you require any of the following from your raw material suppliers? Please check all that apply.

- Written plan for the control of allergens
- Certificates of analysis (COA) or letters of guarantee
- Detailed ingredient lists (e.g., artificial colors, flavors, or incidental additives)
- Prior notification of product formulation changes in writing
- Other _____ [verbatim]
- None of the above

Q144. Do you test your raw materials for allergens? Please check only one.

- Yes, each incoming lot
- Yes, periodically using a statistical sampling plan
- Yes, sporadically when the need arises
- No

Q145. Which of the following describes how your allergen-containing in-process materials are stored and handled? Please check all that apply.

- Marked or color-coded storage bins for allergen-containing in-process materials
- Dedicated storage bins for allergen-containing in-process materials use only
- Separate storage room for allergen-containing in-process materials
- Separate area, such as a dedicated rack, for allergen-containing in-process materials in the same storage room with other in-process materials
- Storage of like above like on storage racks

- Storage of allergen-containing materials on the bottom rack
- Dedicated scoops and utensils for handling allergen-containing in-process materials
- Other _____ [verbatim]
- None of the above

Q146. Which of the following describes how your allergen-containing rework are stored and handled? Please check all that apply.

- Marked or color-coded storage bins for allergen-containing rework
- Dedicated storage bins for allergen-containing rework use only
- Separate storage room for allergen-containing rework
- Separate area for allergen-containing rework in the same storage room with other raw materials and/or rework
- Use rework with the same run only
- Rework like into like only
- Track rework to document how it is eventually used
- Other _____ [verbatim]
- None of the above

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Testing

Q147. Which of the following methods do you use to monitor the effectiveness of your cleaning to remove allergenic residue from food contact surfaces? Please check all that apply.

- Visual inspection
- Commercially available enzyme linked immunosorbent assay (ELISA) allergen test kit
- Other _____ [verbatim]
- We do not monitor the effectiveness of our cleaning for allergenic residues

Q148. Please indicate the frequency with which you conduct the following testing to ensure the absence of specific allergens?

	<u>Not applicable</u>	<u>Each batch is tested</u>	<u>Statistical batch sampling</u>	<u>Other</u>	<u>Don’t know</u>
a. <u>Finished-product testing</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. <u>In-process testing</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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Labeling

Q149. Do you have *written* procedures for label review to ensure that all of the allergenic ingredients are accurately identified in your ingredient statements?

Yes

No

Q150.(*) Do you have *written* procedures for the reconciliation of the number of labels issued and the number of labels used?

Yes

No [\[Go to Q151\]](#)

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Q152. Do your written procedures include any of the following? Please check all that apply.

Verification that labels are correctly printed

Verification that labels match their intended products at the beginning of every production run

Verification that labels match their intended products at the end of every production run

Other _____ [verbatim]

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Q153. Do any of your finished product labels contain any of the following or similar versions of advisory labeling for allergenic ingredients? Please check all that apply.

May contain “_____.”

May contain traces of “_____.”

Has been processed on equipment that is also used to process “_____.”

Processed in a plant that also processes “_____.”

Other _____ [verbatim]

We do not use any advisory labeling.

Q154. Within the last 12 months, approximately how many of your product batches were rejected due to incorrect labeling of allergenic ingredients or presence of allergenic ingredients in products that were not intended to contain them?

batches were rejected because of incorrect labeling

batches were rejected because of the presence of allergenic ingredients in products

[\[Programmer Note 6: Restrict Q155 to be between 0 and 10,000. If entry is out of range, prompt user.\]](#)

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PROCESS CONTROLS

Raw Materials and Ingredients

Q156. Do you have *written* procedures for receiving and handling incoming raw materials, ingredients, and other components?
 Yes
 No

Q157.(*) Do you have *written* procedures for approving vendors of raw materials, ingredients, and other components?
 Yes
 No [\[Go to Q158\]](#)

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Q159.(*) Do you ever use raw materials, ingredients and/or other components supplied by other than approved vendors?
 Yes
 No [\[Go to Q160\]](#)

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Q161. Within the last 12-month period, approximately what percentage of your *vendors* were not approved?
 5 percent or less
 >5 to 10 percent
 >10 to 25 percent
 >25 percent

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Q162. Which of the following methods do you use to approve your raw materials, ingredients, and other components? Please check all that apply.
 Conduct vendor audits at the vendor’s location
 Request independent auditor’s evaluation
 Require Certificates of Analyses (COAs)
 Require Letters of Guarantee
 Rely on vendor reputation
 Other _____ [\[verbatim\]](#)

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Q163.(*) Do you have *written* procedures to ensure the condition of incoming raw materials, ingredients and other components?

- Yes
- No [\[Go to Q164\]](#)

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Q165. Do your written procedures require any of the following inspections or analyses? Please check all that apply.

- Visual inspection
- Chemical analysis
- Foreign material contamination checks
- Microbiological evaluation
- Review of Certificates of Analyses and/or Letters of Guarantee
- Other _____ [verbatim]
- Our written procedures do not require inspections or analyses

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Process and Product Evaluation

Q166. Approximately, how many finished product batches did you produce in the last 12 months?

_____ batches

Q167. Approximately, how many of these finished product batches were rejected due to safety and quality problems, such as microbiological contamination and mislabeling, in the last 12 months?

_____ batches

Q168.(*) Do you have a Hazard Assessment and Critical Control Point (HACCP) system ?

- Yes
- No [\[Go to Q169\]](#)

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Q170. Is your HACCP system currently certified by any of the following third parties? Please check all that apply.

_____ Do not use a third party for HACCP system certification

- NSF International
- Silliker Laboratories
- International Dairy Foods Association (IDFA)
- American Society for Quality (ASQ)
- American Institute of Baking (AIB)
- Other _____ [verbatim]

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Q171. Do you have ISO 9000 certification?

- Yes
- No

Q172. Do you have *written* procedures that specify your operational control practices for ensuring product safety and quality?

- Yes
- No

Q173. Which, if any, of the following types of operational control systems do you use?

- Programmable logic controller (PLCs)
- Statistical process controller (SPC)
- Material-requirements planning system (MRP)
- Manufacturing-resource planning system (MRPII)
- Supervisory Control and Data Acquisition (SCADA)
- Manufacturing execution system (MES)
- Predictive control system
- Other _____ [verbatim]
- We do not use operational control systems

Q174. Do you use statistical methods to evaluate data collected from operational control points?

- Yes
- No

Q175. Do you have *written* procedures for the routine calibration of operating equipment and measuring devices?

- Yes, for all devices
- Yes, for some devices
- No

Q176. Do you conduct in-process testing to ensure product *safety*?

Yes

No

Q177.(*) Do you conduct finished-product testing to ensure *safety*?

Yes

No [\[Go to Q178\]](#)

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Q179. Which of the following best describes your finished-product testing program?

Each finished-product lot is tested

Statistical lot sampling

Other _____ [verbatim]

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Validation

Q180. Do you use any of the following techniques to validate the effectiveness of your pathogen control measures? Please check all that apply.

Rely on previous validation studies or historical knowledge of the effectiveness of essential control measures

Receive documentation from equipment manufacturer

Conduct a challenge study

Conduct culture-ID studies to identify pathogen strains present in the processing environment

Use independently recognized process authority

Other _____ [verbatim]

We do not validate the effectiveness of our pathogen control measures.

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Audits

Q181.(*) Apart from routine sanitation inspections, do you or others also conduct [audits of your food safety control systems](#)?

Yes

No [\[Go to Q182\]](#)

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- Q183. Who *typically* requires these audits? Please check all that apply.
- Your plant management
 - Your insurance company
 - Your retail customers
 - International government agencies
 - State/local governments
 - Other _____ [verbatim]

[\[Programmer Note 7: If Q184 = “Your retail customers,” go to Q185, otherwise go to Q186\]](#)

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- Q187. Which of the following retail customers *typically* require these audits? Please check all that apply.
- Supermarkets
 - Restaurants
 - Military
 - Schools
 - Other _____ [verbatim]

- Q188. Who *typically* performs your audits? Please check all that apply.
- Your QC or other specialized personnel
 - Your customers or another independent 2nd party
 - Specialized GMP auditors or another 3rd party contractor
 - Your insurance company’s auditors
 - Other _____ [verbatim]

- Q189. What is the frequency of these audits?
- Quarterly
 - Semi-annually
 - Annually
 - Randomly
 - Other _____ [verbatim]

Q190. Which of the following areas do these audits typically cover? Please check all that apply.

- Administrative procedures
- Operational procedures
- Allergen control program
- Personnel
- Equipment
- Calibration
- Label design
- Label production procedures
- Material resources
- Environmental conditions of processing areas
- Manufacturing processes
- Product conformance
- Documentation and recordkeeping
- Consumer complaints
- Other _____ [verbatim]

Q191. In addition to the above, are you also audited against any of the following standards? Please check all that apply.

- USDA National Organic Program (NOP) Standard
- European Union (EU) Organic Standard
- European Union (EU) Directive on Genetically Modified Food and Feed
- Food Standards Australia New Zealand (FSANZ) Genetically Modified Food Standard
- Other _____ [verbatim]

Q192. In which of the following ways do you use the results from your audits? Please check all that apply.

- To conduct a trend analysis of changes in food safety measures
- To identify areas for corrective actions
- Other _____ [verbatim]

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RECORDKEEPING

- Q193. Do you regularly maintain the following types of *buildings and facilities* records?
- | | <u>Yes, some</u> | <u>Yes, all</u> | <u>No</u> |
|---|-----------------------|-----------------------|-----------------------|
| a. Plant design review records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. Environmental monitoring records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
-
- Q194. Do you regularly maintain the following types of *equipment and utensils* records?
- | | <u>Yes, some</u> | <u>Yes, all</u> | <u>No</u> |
|--|-----------------------|-----------------------|-----------------------|
| a. Equipment maintenance records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. Equipment cleaning and sanitation records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
-
- Q195. Do you regularly maintain the following types of *materials* records?
- | | <u>Yes, some</u> | <u>Yes, all</u> | <u>No</u> |
|---|-----------------------|-----------------------|-----------------------|
| a. Supplier qualification records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. Incoming raw material inspection records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
-
- Q196. Do you regularly maintain the following types of *personnel* records?
- | | <u>Yes, some</u> | <u>Yes, all</u> | <u>No</u> |
|--|-----------------------|-----------------------|-----------------------|
| a. Plant personnel records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. Consultant/contractor records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
-
- Q197. Do you regularly maintain the following types of *production and process controls* records?
- | | <u>Yes, some</u> | <u>Yes, all</u> | <u>No</u> |
|--|-----------------------|-----------------------|-----------------------|
| a. Production process records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. Sampling and testing records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c. Planned and unplanned process deviation records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
-
- Q198. Do you regularly maintain the following types of *QA/QC and laboratory operations* records?
- | | <u>Yes, some</u> | <u>Yes, all</u> | <u>No</u> |
|---|-----------------------|-----------------------|-----------------------|
| a. Analytical testing records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| b. Verification records | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c. Consumer complaints | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Q199. Do you regularly maintain the following types of *validation* records?

	<u>Yes, some</u>	<u>Yes, all</u>	<u>No</u>
a. Equipment validation records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Process validation records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Cleaning validation records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q200. Do you regularly maintain the following *warehousing and distribution* records?

	<u>Yes, some</u>	<u>Yes, all</u>	<u>No</u>
a. Warehousing and storage records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Shipment and distribution records	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q201. On average, how long do you retain your records?

- _____ Less than a year
- _____ One year
- _____ One to two years
- _____ Two to three years
- _____ Three to five years
- _____ More than five years
- _____ Indefinitely
- _____ Other _____ [verbatim]

Q202. If FDA were to modernize the GMPs, on average, how much total management time would be necessary to review the new FDA requirements for training, SSOPs, process controls, recordkeeping and allergen controls to determine whether your existing procedures are adequate or whether modifications/additions might be necessary?

- _____ Less than 1 day
- _____ 1 day to 1 week
- _____ 1 week to 2 weeks
- _____ 2 weeks to 4 weeks
- _____ 4 weeks or more

[\["Previous Page" button and "Next Page" button that goes to END2\]](#)

TRAINING (Fresh Produce)

Q203.(*) Which of the following *best* describes the type of food safety and sanitation training you provide for your newly hired personnel? Please check only one per row.

	<u>Classroom- type</u>	<u>Supervised on- the-job</u>	<u>Informal (not supervised) on-the-job</u>	<u>Self- administered</u>	<u>No training program</u>	<u>Not applicable</u>
a. Permanent supervisors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Permanent packing line employees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Seasonal employees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

[Programmer Note 8: If Q204a or Q205b or Q206c =“Classroom-type training” or “Supervised on-the-job training conducted by facility personnel,” continue, otherwise go to Q207]

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Q208. Does your food safety and sanitation training for newly hired employees cover the following areas?

	<u>Yes</u>	<u>No</u>
a. Microbial contamination prevention	<input type="radio"/>	<input type="radio"/>
b. Reporting illnesses and injuries to supervisors	<input type="radio"/>	<input type="radio"/>
c. Use of toilet facilities	<input type="radio"/>	<input type="radio"/>
d. Proper hand washing	<input type="radio"/>	<input type="radio"/>
e. Personal cleanliness and hygiene	<input type="radio"/>	<input type="radio"/>
f. Facility cleaning	<input type="radio"/>	<input type="radio"/>
g. Equipment cleaning	<input type="radio"/>	<input type="radio"/>
h. Equipment sanitizing	<input type="radio"/>	<input type="radio"/>
i. Product handling	<input type="radio"/>	<input type="radio"/>
j. Other practices _____[verbatim]	<input type="radio"/>	<input type="radio"/>

Q209. On average, about how many hours of food safety and sanitation training does a newly hired employee receive? Please check only one per column.

	<u>None</u>	<u>Not applicable</u>	<u><5 hours</u>	<u>5-8 hours</u>	<u>>8-16 hours</u>	<u>>16-48 hours</u>	<u>>48 hours</u>
a. Permanent supervisors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Permanent packing line employees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Seasonal employees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q210. Do you utilize signage in your packing facility to reinforce training concepts, such as hand washing, personal cleanliness, and product handling?
 Yes
 No

Q211.(*) Approximately, what percentage of your packing facility employees is able to read written procedures and training materials in English?
 100 percent (All of our employees can read in English) [\[Go to Q212\]](#)
 75 to 99 percent
 50 to 74 percent
 25 to 49 percent
 Less than 25 percent

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Q213. Please indicate the languages in which you provide food safety and sanitation training (including initial training provided upon hire and refresher training, if any) for your non-English speaking packing facility employees. Please check all that apply.
 Spanish
 Chinese
 Creole
 Korean
 Portuguese
 Vietnamese
 Thai
 Indigenous languages
 Other _____ [verbatim]
 None (We do not provide training in any language but English)

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Q214. Do you maintain the following records related to food safety and sanitation training received by your packing facility employees?

	a. <u>Permanent supervisors</u>		b. <u>Permanent packing line employees</u>		c. <u>Seasonal employees</u>	
	Yes	No	Yes	No	Yes	No
a. Documentation of administered training	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Documentation of the training content	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- c. Proof of management oversight
- d. Corrective actions
- e. Other _____[verbatim]

Q215. Which of the following methods do you use to assess the effectiveness of your food safety and sanitation training program? Please check all that apply.

- _____ Formal employee testing with records of such tests
- _____ Documented employee monitoring and performance evaluation
- _____ Other _____ [verbatim]
- _____ Do not formally evaluate training effectiveness

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SANITATION AND PERSONAL HYGIENE (Fresh Produce)

Q216. Do you have written *cleaning* procedures applicable to various areas of your packing facility?

- Yes
- No

Q217. Do you have written *sanitizing* procedures applicable to various areas of your packing facility?

- Yes
- No

Q218. Which of the following *best* describes the type of restroom facilities for your packing facility employees? Please check only one.

- Permanent restroom with a hand washing facility
- Permanent restroom without a hand washing facility
- Temporary restroom with a hand washing facility
- Temporary restroom without a hand washing facility
- Hand washing facility but no restroom
- No restroom or hand washing facility

Q219. Do you have written standard operating procedures and/or schedules for the following tasks associated with the upkeep of your restroom and hand washing facilities? Please check all that apply.

- Cleaning the restroom
- Cleaning the hand washing facility
- Stocking paper towels
- Stocking toilet paper
- Stocking liquid soap
- Stocking drinking cups
- Trash removal
- Sewage disposal
- Other _____ [verbatim]
- Do not have written procedures on restroom or hand washing facility upkeep

Q220. Which of the following are your employee hand-washing requirements? Please check all that apply.

- Hand washing at the start of work
- Hand washing after breaks (e.g., eating, drinking, or smoking)
- Hand washing after using the restroom
- Hand washing after touching something unclean

- Hand washing after touching body parts
- Do not have an employee hand washing policy

Q221.(*) Do you have written standard operating procedures and/or schedules for the following tasks? Please check all that apply.

- Container inspection [\[Go to Q222\]](#)
- Changing post harvest water in dump/wash tanks, if applicable [\[Go to Q223\]](#)
- Changing post harvest water in cooling units, if applicable [\[Go to Q224\]](#)
- Pest control
- None of the above [\[Go to Q225\]](#)

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Q226. For which of the following types of pests do you control? Please check all that apply.

- Insects
- Birds
- Rodents/small animals
- Reptiles/amphibians
- Other _____ [verbatim]
- None of the above

Q227. Do you periodically evaluate the effectiveness of your pest control policy *and* make changes as needed?

- Yes
- No

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Q228. Please indicate whether you have *written* policies addressing the following areas? Please check all that apply.

- Exclusion of domestic animals from the packing and storage areas
- Exclusion of children from the packing and storage areas
- Exclusion of ill workers from direct contact with fresh produce
- None of the above

Q229.(*) Please indicate from the following, the personal hygiene practices for your packing facility personnel. Please check all that apply.

- Employer-provided outer clothing (e.g., aprons or mocks)
- Employer-provided uniform
- Employer-provided footwear

- Hair nets or restraints for head and facial hair
- Sanitary gloves
- Hand dips
- Footbaths
- Other _____ [verbatim]
- None of the above

[Programmer Note 9: If Q230 = “Sanitary gloves”, go to Q231; otherwise go to Programmer Note 10]

[Programmer Note 11: If Q232 = “Field with some processing and water contact (e.g., significant trimming, coring, washing, and cooling)” or “Packing in a physical structure with some post harvest processing with water contact (e.g., trimming, coring, washing, waxing, and cooling),” go to Q233, otherwise go to END2]

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Q234. Which of the following characterizes the use of sanitary gloves at your packing facility? Please check all that apply.

- Employees handling fresh produce wear gloves
- Company provides and maintains disposable gloves
- Company provides and maintains non-disposable gloves
- Non-disposable gloves are maintained by the employee

[Programmer Note 12: If Q235 = “Field with some processing and water contact (e.g., significant trimming, coring, washing, and cooling)” or “Packing in a physical structure with some post harvest processing with water contact (e.g., trimming, coring, washing, waxing, and cooling),” go to Q236, otherwise go to END2]

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PROCESS CONTROLS (Fresh Produce)

Water Quality

Q237. What is the source for your post harvest processing water? Please check only one.

- Municipal water
- Well water
- Surface water
- Other _____ [verbatim]

Q238. How frequently do you test your post harvest processing water for the following indicator organisms and/or pathogens?

	<u>Never</u>	<u>Less than once per year</u>	<u>Annually</u>	<u>Quarterly</u>	<u>Monthly</u>	<u>Daily</u>
Total coliform bacteria	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fecal coliform bacteria	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Generic <i>E. coli</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>E. coli</i> O157:H7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Salmonella spp.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cryptosporidium parvum	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q239. Do you have backflow and vacuum breaker valves to prevent backflow and contamination of your water supply?

- Yes
- No

Q240.(*)What type of disinfectant do you use for your post harvest processing water? Please check only one.

- Chlorine (sodium hypochlorite, calcium hypochlorite, or chlorine gas)
- Chlorine dioxide
- Peroxyacetic acid [\[Go to Q241\]](#)
- Ozone [\[Go to Q242\]](#)
- Other _____ [verbatim] [\[Go to Q243\]](#)
- None of the above [\[Go to Q244\]](#)

[\[“Previous Page” and “Next Page” buttons\]](#)

Q245. How frequently do you monitor the following during post harvest processing?

	<u>Not applicable</u>	<u>Never</u>	<u>Weekly</u>	<u>Daily</u>	<u>Hourly</u>	<u>Continuously</u>
a. Total chlorine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- | | | | | | | | |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| b. Free chlorine | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| c. Oxidation reduction potential (ORP) | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| d. PH | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| e. Temperature | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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Q246. Which of the following methods do you use for maintaining the disinfectant concentration of your post harvest processing water? Please check all that apply.

- | | <u>Automatic</u> | <u>Manual</u> |
|--|-----------------------|-----------------------|
| a. Disinfectant concentration monitoring | <input type="radio"/> | <input type="radio"/> |
| b. pH monitoring | <input type="radio"/> | <input type="radio"/> |
| c. Addition of disinfectant to water | <input type="radio"/> | <input type="radio"/> |
| d. pH adjustment | <input type="radio"/> | <input type="radio"/> |

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RECORDKEEPING

Q247. Please indicate whether you maintain a log or other records for the following?

	<u>Not applicable</u>	<u>Yes</u>	<u>No</u>
a. Wash water disinfectant concentration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Wash water oxidation reduction potential (ORP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Wash water pH	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Wash water temperature	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Cooling water disinfectant concentration	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Cooling water oxidation reduction potential (ORP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Cooling water pH	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Cooling water temperature	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q248. Do you keep the following records about your incoming materials?

	<u>Yes</u>	<u>No</u>
a. Field	<input type="radio"/>	<input type="radio"/>
b. Harvest date	<input type="radio"/>	<input type="radio"/>
c. Type of produce	<input type="radio"/>	<input type="radio"/>
d. Volume of produce	<input type="radio"/>	<input type="radio"/>

Q249. Do you label your outgoing produce with lot codes or other marks that could facilitate traceback and recall in the event of a problem?

- _____ Yes
- _____ No

Q250. If FDA were to modernize the GMPs, on average, how much total management time would be necessary to review the new FDA requirements for training, SSOPs, process controls, and recordkeeping to determine whether your existing procedures are adequate or whether modifications/additions might be necessary?

- _____ Less than 1 day
- _____ 1 day to 1 week
- _____ 1 week to 2 weeks
- _____ 2 weeks to 4 weeks
- _____ 4 weeks or more

[\["Previous Page" button and "Next Page" button that goes to END2\]](#)

SURVEY EXIT

END1: Given your operations, we have determined that the remaining questions are not applicable to your facility. [\[Go to END2\]](#)

[\[“Previous Page” and “Next Page” buttons\]](#)

END2: Thank you very much for your time. Please click on the “Submit Survey” button to submit your survey. If you would like to make changes to your responses before submitting, please use the “Previous Page” button.

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Drop-down 1

-Select-

- Animal Slaughtering & Processing
- Bakeries & Tortilla Manufacturing-Retail Bakeries
- Bakeries & Tortilla Manufacturing-Commercial Bakeries
- Bakeries & Tortilla Manufacturing-Frozen Cakes, Pies, & Other Pastries Manufacturing
- Bakeries & Tortilla Manufacturing-Cookie & Cracker Manufacturing
- Bakeries & Tortilla Manufacturing-Flour Mixes & Dough Manufacturing from Purchased Flour
- Bakeries & Tortilla Manufacturing-Dry Pasta Manufacturing
- Bakeries & Tortilla Manufacturing-Tortilla Manufacturing
- Beverage Manufacturing-Soft Drink Manufacturing
- Beverage Manufacturing-Bottled Water Manufacturing
- Beverage Manufacturing-Ice Manufacturing
- Beverage Manufacturing-Breweries
- Beverage Manufacturing-Wineries
- Beverage Manufacturing-Distilleries
- Dairy Product Manufacturing-Fluid Milk Manufacturing
- Dairy Product Manufacturing-Creamery Butter Manufacturing
- Dairy Product Manufacturing-Cheese Manufacturing
- Dairy Product Manufacturing-Dry, Condensed, & Evaporated Dairy Product Manufacturing
- Dairy Product Manufacturing-Ice Cream & Frozen Desert Manufacturing
- Fruit & Vegetable Preserving & Specialty Food Manufacturing-Frozen Fruit, Juice, & Vegetable Manufacturing
- Fruit & Vegetable Preserving & Specialty Food Manufacturing-Frozen Specialty Food Manufacturing
- Fruit & Vegetable Preserving & Specialty Food Manufacturing-Fruit & Vegetable Canning
- Fruit & Vegetable Preserving & Specialty Food Manufacturing-Specialty Canning
- Fruit & Vegetable Preserving & Specialty Food Manufacturing-Dried & Dehydrated Food Manufacturing
- Grain & Oilseed Milling-Flour Milling
- Grain & Oilseed Milling-Rice Milling
- Grain & Oilseed Milling-Malt Manufacturing
- Grain & Oilseed Milling-Wet Corn Milling
- Grain & Oilseed Milling-Soybean Processing
- Grain & Oilseed Milling-Other Oilseed Processing
- Grain & Oilseed Milling-Fats & Oils Refining & Blending
- Grain & Oilseed Milling-Breakfast Cereal Manufacturing
- Postharvest Crop Activities
- Seafood Product Preparation & Packaging-Seafood Canning

Seafood Product Preparation & Packaging-Fresh & Frozen Seafood Processing
Sugar & Confectionery Product Manufacturing-Sugarcane Mills
Sugar & Confectionery Product Manufacturing-Cane Sugar Refining
Sugar & Confectionery Product Manufacturing-Beet Sugar Manufacturing
Sugar & Confectionery Product Manufacturing-Chocolate & Confectionery Manufacturing from Cacao Beans
Sugar & Confectionery Product Manufacturing-Confectionery Manufacturing from Purchased Chocolate
Sugar & Confectionery Product Manufacturing-Nonchocolate Confectionery Manufacturing
Other Food Manufacturing-Roasted Nuts & Peanut Butter Manufacturing
Other Food Manufacturing-Other Snack Food Manufacturing
Other Food Manufacturing-Coffee & Tea Manufacturing
Other Food Manufacturing-Flavoring Syrup & Concentrate Manufacturing
Other Food Manufacturing-Mayonnaise, Dressing, & Other Prepared Sauce Manufacturing
Other Food Manufacturing-Spice & Extract Manufacturing
Other Food Manufacturing-Perishable Prepared Food Manufacturing
Other Food Manufacturing-All Other Miscellaneous Food Manufacturing

Drop-down 2

-Select-

None

Animal Slaughtering & Processing
Bakeries & Tortilla Manufacturing-Retail Bakeries
Bakeries & Tortilla Manufacturing-Commercial Bakeries
Bakeries & Tortilla Manufacturing-Frozen Cakes, Pies, & Other Pastries Manufacturing
Bakeries & Tortilla Manufacturing-Cookie & Cracker Manufacturing
Bakeries & Tortilla Manufacturing-Flour Mixes & Dough Manufacturing from Purchased Flour
Bakeries & Tortilla Manufacturing-Dry Pasta Manufacturing
Bakeries & Tortilla Manufacturing-Tortilla Manufacturing
Beverage Manufacturing-Soft Drink Manufacturing
Beverage Manufacturing-Bottled Water Manufacturing
Beverage Manufacturing-Ice Manufacturing
Beverage Manufacturing-Breweries
Beverage Manufacturing-Wineries
Beverage Manufacturing-Distilleries
Dairy Product Manufacturing-Fluid Milk Manufacturing
Dairy Product Manufacturing-Creamery Butter Manufacturing
Dairy Product Manufacturing-Cheese Manufacturing

Dairy Product Manufacturing-Dry, Condensed, & Evaporated Dairy Product Manufacturing
Dairy Product Manufacturing-Ice Cream & Frozen Desert Manufacturing
Fruit & Vegetable Preserving & Specialty Food Manufacturing-Frozen Fruit, Juice, & Vegetable Manufacturing
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Fruit & Vegetable Preserving & Specialty Food Manufacturing-Fruit & Vegetable Canning
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Grain & Oilseed Milling-Rice Milling
Grain & Oilseed Milling-Malt Manufacturing
Grain & Oilseed Milling-Wet Corn Milling
Grain & Oilseed Milling-Soybean Processing
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Grain & Oilseed Milling-Breakfast Cereal Manufacturing
Postharvest Crop Activities
Seafood Product Preparation & Packaging-Seafood Canning
Seafood Product Preparation & Packaging-Fresh & Frozen Seafood Processing
Sugar & Confectionery Product Manufacturing-Sugarcane Mills
Sugar & Confectionery Product Manufacturing-Cane Sugar Refining
Sugar & Confectionery Product Manufacturing-Beet Sugar Manufacturing
Sugar & Confectionery Product Manufacturing-Chocolate & Confectionery Manufacturing from Cacao Beans
Sugar & Confectionery Product Manufacturing-Confectionery Manufacturing from Purchased Chocolate
Sugar & Confectionery Product Manufacturing-Nonchocolate Confectionery Manufacturing
Other Food Manufacturing-Roasted Nuts & Peanut Butter Manufacturing
Other Food Manufacturing-Other Snack Food Manufacturing
Other Food Manufacturing-Coffee & Tea Manufacturing
Other Food Manufacturing-Flavoring Syrup & Concentrate Manufacturing
Other Food Manufacturing-Mayonnaise, Dressing, & Other Prepared Sauce Manufacturing
Other Food Manufacturing-Spice & Extract Manufacturing
Other Food Manufacturing-Perishable Prepared Food Manufacturing
Other Food Manufacturing-All Other Miscellaneous Food Manufacturing

Definition 1: By **food safety and sanitation training**, we mean training to teach employees concepts and practices for keeping food free of biological, chemical, and physical hazards, including allergenic ingredients and materials. By definition, this training does not include other types of training, such as job-specific and health and safety training that you may provide hourly personnel upon hire.

Definition 2: By newly hired hourly personnel, we mean any production line employee who has worked at the facility for less than four (4) weeks.

Definition 3: By refresher training, we mean training designed to refresh and/or enhance the initial food safety and sanitation training provided to newly hired personnel.

Definition 4: By continuing training, we mean training designed to refresh and/or enhance the initial food safety and sanitation training provided to newly hired personnel. This includes the time spent in conferences and workshops, if any.

Definition 5: By cross-training, we mean training an employee in another activity related to their current work.

Definition 6: By pay-for-skills program, we mean relating the pay of an employee to the acquisition of various job-related skills, thereby rewarding employees for enhancing their value to the organization.

Definition 7: By industry short courses, we mean such courses offered by organizations, such as the American Institute of Baking (AIB), Food Processors Institute (FBI), and others.

Definition 8: By validation, we mean the process of ensuring that a defined set of control measures is capable of achieving appropriate control over a specific hazard or hazards associated with an activity. Validation is typically conducted prior to the initiation of an activity, such as cleaning, and repeated only infrequently when significant changes are instituted, such as changes in cleaning agents. Validation is *not* the ongoing process of monitoring whether an activity is being carried out properly.

Definition 9: By production areas, we mean those areas where food contact equipment is located, including the floors, walls, drains, etc.

Definition 10: By environmental sampling and testing, we mean a systematic collection and testing of swab samples for pathogens, such as Listeria and Salmonella, for the purpose of monitoring the quality of one's production areas, including food contact surfaces and non contact surfaces such as floors, drains, equipment, walls ceilings and more.

Definition 11: Spelt is a sub-specie of common wheat grown mostly in Europe.

Definition 12: By allergen free, we mean a finished food product that does not contain any of the following eight (8) allergens or proteins from them: soybean or soybean-based ingredients, peanuts or peanut-based ingredients, fish, crustacea, tree nuts, milk, eggs, and wheat.

Definition 13: By allergen control plan, we mean a systematic *and* documented method for identifying and controlling allergens at a food processing facility.

Definition 14: By rework, we mean clean, unadulterated food that has been (1) removed from processing for reasons other than insanitary conditions or (2) successfully reconditioned by reprocessing and that is suitable for use as food.

Definition 15: By label review, we mean a formal review of product label for conformance to current labeling regulations regarding product name, net weight, ingredient listing, manufacturer/distributor name and address, nutrition information, any health claims, product coding, and any statements related to product storage.

Definition 16: By batch, we mean a production run that can be isolated from other runs and identified with a specific set of material, production facility, and process characteristics. A batch may consist of one or more production lots each of which having a unique code (i.e., lot code).

Definition 17: By Hazard Assessment and Critical Control Point (HACCP) system, we mean a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles: (1) Conduct a hazard analysis. (2) Determine the critical control points (CCPs). (3) Establish critical limits. (4) Establish monitoring procedures. (5) Establish corrective actions. (6) Establish verification procedures. (7) Establish record-keeping and documentation procedures.

Definition 18: By in-process testing, we mean inline testing of materials during manufacturing, such as the continuous monitoring of throughput for metal particles with a metal detector incorporated into a processing or packaging line.

Definition 19: By finished-product testing, we mean systematic laboratory testing of the finished product according a predefined plan for pathogens, allergens, chemicals, and/or physical contaminants.

Definition 20: By food safety control system audit, we mean a thorough assessment of all food safety systems in a facility, including but not limited to administrative procedures, operational procedures, allergen control program, personnel, equipment, calibration, material resources, environmental conditions of processing areas, processes, product conformance, documentation and recordkeeping, and consumer complaints.

Definition 21: By newly hired personnel, we mean any employee who has worked at the facility for less than four (4) weeks.

Definition 22: By plant design review records, we mean routine and non-routine service logs and pest control service records.

Definition 23: By environmental monitoring records, we mean environmental sampling and testing records.

Definition 24: By equipment maintenance records, we mean maintenance logs, maintenance work and repair orders, equipment calibration master logs, and calibration compliance reviews.

Definition 25: By equipment cleaning and sanitation records, we mean equipment cleaning and sanitation logs, cleaning schedules, sanitation plans and procedures.

Definition 26: By supplier qualification records, we mean supplier certification records, supplier guarantees, certificates of analyses, and records of on-site supplier inspections.

Definition 27: By incoming raw material inspection records, we mean material review records (net-weight verification, label-to-product conformance checks, lot numbers, expiration dates), ingredient examination and testing records, sampling records (for testing purposes), packaging and supplies labeling reviews, disposition records (quarantine, approve, or reject), and records of non-conforming materials.

Definition 28: By plant personnel records, we mean employee background records, employee training records, employee training audits, and employee performance reviews.

Definition 29: By consultant/contractor records, we mean records of consultant and/or contractor qualifications.

Definition 30: By production process records, we mean master manufacturing records, production batch records, records of manufacturing process parameters (time, temperature, pressure, humidity, light), and CCP monitoring records.

Definition 31: By sampling and testing records, we mean in-process sampling and testing records for identity and for contamination.

Definition 32: By planned and unplanned process deviation records, we mean records of routing changes, corrective actions, and reprocessing and rework records.

Definition 33: By analytical testing records, we mean test method protocols, sampling plans, sample receipt protocol and checklists, test data for incoming ingredients, in-process materials, and finished products, test result review logs, and records of product deviations from standards.

Definition 34: By verification records, we mean internal and/or third-party audit records, document review logs, annual product reviews, material and ingredient reviews, and product recall reviews.

Definition 35: By consumer complaints, we mean consumer complaint data and records of records of corrective actions in response to complaints.

Definition 36: By equipment validation records, we mean equipment design, installation, operation, and performance qualification records.

Definition 37: By process validation records, we mean records of CCP determinations and manufacturing process scientific and technical documentation.

Definition 38: By cleaning validation records, we mean records of cleaning validation protocols for equipment, utensils, cleaning agents, and facility.

Definition 39: By warehousing and storage records, we mean records of storage procedures, warehouse temperature and humidity control records, and inventory logs.

Definition 40: By shipment and distribution records, we mean procedures and records for forward and backward tracing of products, salvaged product records, and food product examination and reprocessing records.

Privacy and Security Statement

Your responses to this survey will be kept strictly confidential. All data you provide is being collected and compiled by Eastern Research Group, Inc. (ERG), an independent consulting firm contracted by the U.S. Food and Drug Administration (FDA). ERG will provide FDA personnel only with a summary of the data compiled in the course of the study. In keeping with longstanding FDA practice, ERG will not provide FDA with identifiers that would permit the association of specific responses with a given respondent.

ERG has provided for the security of your Food Industry Practices Survey data, ensuring that your information is handled in the safest and most confidential manner. Our data security measures include the following.

Upon entering the Food Industry Practices Survey Web Site, you'll be asked to provide a log-in password. This password is provided for your exclusive use. A password is provided only to those facilities that have registered with the FDA in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and supplied a valid email address.

Also, the information exchanged between your Web browser and ERG is encrypted for your protection. The encryption process converts the information being transmitted into uninterruptible machine code and then back into readable information once it is safely received.

The survey requires the use of Microsoft Internet Explorer 4.02 or higher or Netscape 4.08 or higher. These are two popular Web browsers that support the 128-bit encryption key used by the Food Industry Practices Survey Web Site to provide the security measures mentioned above. With over a trillion possible key combinations, it is the highest level of data encryption possible. Each time you sign in to the Food Industry Practices Survey Web Site, your computer is assigned a different key combination. Anyone who attempts to break that code would have to start over every time they entered the site.

Frequently Asked Questions

1. How will my data be kept secure if I submit my responses to the Food Industry Practices Survey via the Internet?

ERG has provided for the security of your survey data, ensuring that your information is handled in the safest and most confidential manner. ERG security measures include the following.

Upon entering the survey Web Site, you will be asked to provide a password. This password is provided for your exclusive use by ERG. A password is provided only to those companies scheduled to participate in the survey.

Also, the information exchanged between your Web browser and ERG is encrypted for your protection. The encryption process converts the information being transmitted into uninterruptible machine code and then back into readable information once it is safely received.

The ERG survey requires the use of Microsoft Internet Explorer 4.02 or higher or Netscape 4.08 or higher. These are two popular Web browsers that support the 128-bit encryption key used by the survey Web Site to provide the security measures mentioned above. With over a trillion possible key combinations, it's the highest level of data encryption possible. Each time you sign in to the survey Web Site, your computer is assigned a different key combination. Anyone who attempts to break that code would have to start over every time they entered the site.

2. I have forgotten my password. What should I do?

Contact the ERG survey helpline at surveyhelp@erg.com. Upon contact, we will send your password to the email address that you provide upon logging into the survey.

3. Can I make changes to the survey data that I submit?

Changes are permitted to any/all data submitted prior to the final submission of the survey. However, once you have reached the end of the survey and submitted the data, you cannot make any modifications.

4. What are the standards used for creation of the survey web pages?

The survey pages were designed in accordance with Section 508. Section 508 requires that Federal agencies' electronic and information technology is accessible to people with disabilities, including employees and members of the public.

In addition, the default screen size used in the creation of these pages is 800 x 600. This is the industry standard for normal default screen sizes used on 17-inch and higher monitor displays. You may adjust the viewing area of your monitor either by changing the text size settings of your browser or changing the screen size properties of your monitor.

5. What happens when I click on the “Next Page” button?

When you click on the “Next Page” button, all data entered will be automatically saved, and you will advance to the next page of survey. Please note that saving your data may take a few minutes, during which you will not be able to work further in the browser window.

6. What happens when I click on the “Previous Page’ button?

When you click on the “Previous Page” button, the previous page of the survey will be presented. Please note that all data entered on the page where you clicked the “Previous Page” button will be not automatically saved, unless you have clicked the “Next Page” button on that page previously.

7. What happens when I click on the “Submit Survey” button at the end of the survey?

When you click on the “Submit Survey” button, the entire contents of your survey are transmitted directly to ERG’s survey data collection database. Confirmation of your submission will then appear on your screen. Once you have submitted your survey, you will no longer be able to make changes to the data that you have entered online.

8. Who can I contact if I have questions about the survey?

You may send an email to surveyhelp@erg.com.