

PRE-AUDIT QUESTIONNAIRE
(26 NOVEMBER 2019)
REQUIRED INFORMATION FOR INITIAL SANITATION AUDIT REQUESTS

I. ESTABLISHMENT NAME/ADDRESS

1. Establishment name.
2. Establishment's physical address (production facility).
3. Establishment's phone/fax number(s).
4. List any European (EU) establishment number(s) for your establishment.
5. Please provide any product codes that are listed under your establishment number.
6. List all products produced/processed at this establishment. Package sizes are not required for those products manufactured on the same processing line. List those products for which approval is requested.
7. Provide a copy of your company's letterhead.
8. Provide the business card of your establishment's audit representative.
9. Provide directions to your establishment. Include GPS coordinates and/or physical address

II. PERSONNEL/ADMINISTRATION

1. Provide the name and title of the establishment's primary Point-of-Contact for audits:
2. Provide the Establishment owner's name.
3. List the names of all "Key Personnel," preferably those that are English speaking, and their direct phone number and email address:

Plant Manager's Name:

Email address:

Phone number:

QA Manager's Name:

E-mail address:

Phone number:

Other - Name:

E-mail address:

Phone number:

III. GENERAL

1. Indicate the days and hours of operation for both production and administrative offices (i.e. M-F, shifts, etc.). List times for production, cleaning and administrative hours.
2. Indicate the number of employees (full, part-time or seasonal) that work in the establishment. Do you use a temporary agency for hiring employees? Who provides Food Safety and Food Defense training to the temporary employees?
3. If known and applicable, describe the specifics of the US Military/Department of Defense contract you have, or have had (contract number, type of product you supply, where you shipped to, volume, etc.).
4. Please list other inspection audit agencies (Government and civilian) and frequency of visits.
5. Indicate the output of product produced in your establishment, in either weight (average kilograms or tons per day) or number of products per day. Is this year round, or seasonal?

Code Dates:

6. What production code information is placed on your product?
7. If closed coded, what is the interpretation?
8. Which character(s) within the production code designate your establishment?
9. If no code is used, how is your product identified as being manufactured at your establishment?

Brand:

10. What are the brand names of products produced in your establishment?

Labeling:

11. Is there a special label for product sold to U.S. Forces?
12. Please describe and attach samples of the actual film/label.

Shelf-life:

13. What is the recommended shelf-life of your product(s)?
14. Under what conditions (e.g., temperature) should your product(s) be stored in order to maximize the shelf-life?
15. Describe the shelf-life studies performed on your product.

Traceability:

16. Describe your traceability/recall program.
17. Is there a recall team? Who are the members? Do you conduct mock recalls?

How often, and list the date of last mock recall?

IV. FACILITIES

1. Describe the location and the area surrounding your establishment.
2. What year was your establishment constructed?
3. What is the date of the most recent renovation? What was done? Are there any projected renovations?
4. Describe the building as well as the material(s) used in the construction of your establishment.
5. What is the square meters of your establishment?
6. What are the various areas that make up the production area?
7. What are the major pieces of equipment utilized in the production area?

V. FOOD PROTECTION AND SANITATION

HACCP and/or Food Safety Control Program:

1. What is your approach to controlling food safety?
2. Do you have a written Hazard Analysis Critical Control Point Program (HACCP) plan?
3. If yes, when was it developed and what was the date it was last reviewed?
4. If you have a HACCP plan, what are the Critical Control Points (CCPs)?
5. How is each CCP monitored?
6. What are the critical limits for each CCP?
7. What is the protocol when critical limits are exceeded?
8. If you do not have a HACCP plan, describe the Food Safety controls you have in place?

Raw Materials:

9. What is the source of water utilized in your establishment? Note: List all sources of water within the plant (specify if municipal, aqueduct, and/or artesian well).
10. What are the major raw ingredients in your product(s)? List all ingredients for each product for which approval is requested. Major components must be identified by material and manufacturing plant name and address. Provide European Economic Community (EEC) and United States Department of Agriculture (USDA) plant establishment number(s), if applicable.

11. Who are the suppliers? Who transports the materials?
12. What procedures/documentation are in place to ensure raw materials are safe, wholesome, and meet specifications?

Laboratory Testing:

13. What type of microbiological/chemical testing is performed on the water? Are samples pulled from within your establishment? How often?
14. What laboratory analyses are performed on raw materials? At what frequency and when/where are samples drawn? Are the results available for review?
15. What laboratory analyses are performed on finished product(s)? At what frequency and when/where are samples drawn? Are the results available for review?
16. What are the critical limits for each element/analyte tested?
17. What is the protocol when critical limits are exceeded?
18. Is product held pending laboratory results?
19. Describe the microbiological and environmental testing program within the establishment.
20. What is the name of the laboratory that performs the tests? Is it an internal or external lab?

Employee Hygiene and Sanitation:

21. Do employees receive a medical examination prior to employment?
22. What are the employees tested for and what is the frequency of the exam?
23. Are employees trained in sanitation and hygiene (CGMPs)? How often, by whom, and is it documented?
24. Are training, signage, and other pertinent instructions available in all applicable languages? If not, does your establishment have a translator?

Plant Sanitation:

25. What is the make-up of the personnel that perform sanitation functions (production employees, sanitation team, contractor, etc.)? Indicate whether company employees or an external contractor performs the cleaning and sanitizing.
26. Is there a written and documented master sanitation schedule and/or program? Provide a copy (translated in English) of your written and documented cleaning & sanitation program.
27. What is the name of the sanitation team leader? Is there an alternate? Who provides sanitation training? Are records of training available for review?
28. Who is your chemical supplier? What type of support do they provide at your establishment? How often do they provide that support? Do you retain

documentation locally to demonstrate this support and is it available for review?

29. When are the master sanitation tasks conducted?

30. Is there a system in place to keep sanitation employees/equipment on the raw material side separate from sanitation employees/equipment on the finished product side?

31. What chemicals are utilized and how are they stored in the establishment?

32. How are chemical sanitizer concentrations verified? How often? Are results documented and available for review?

33. Are there pre operation and post operation checklists/procedures in place? Are they documented and available for review?

34. Are environmental and rapid method detection procedures in place to monitor sanitation?

35. If so, are environmental and rapid method detection results reviewed by sanitation personnel?

36. How are chemicals dispensed into other containers labeled?

37. What other chemicals, other than those required for production, sanitation, and maintenance functions are stored at your establishment?

Pest Control:

38. Who performs the pest control functions at your establishment?

39. Is the pest control technician licensed?

40. What services are provided? Are records of the services retained locally for review?

41. How often are the pest control services provided?

42. Describe the key components of your pest control system (bait stations, traps etc.).

43. Is there a pest control diagram of all the pest control devices utilized at your establishment?

44. Does the pest control provider store extra equipment or pest control chemicals at your location? If so, how and where are they stored?

Waste Management:

45. Who provides waste management services for your establishment?

46. How often is waste picked-up?

47. Are the waste collection area(s) (interior and exterior) included in your sanitation program and under surveillance of the pest control provider?

VI. PROCESS

1. Describe the processing steps from receipt of raw materials to the finished product. Specify time, temperature, pressure, kill steps, etc. List major processing equipment in use at each processing step, test control(s) (thermometers, testing strips, etc.), and quality control program(s) (e.g., Statistical Process Control (SPC), In-line Inspection Points, etc.). If there is a HACCP in place, indicate the CCP's in the narrative. Please provide a copy of the process flow diagram (in English) from receipt of raw materials to the distribution of the finished product(s), with all CCP's clearly annotated.

VII. STORAGE

1. Describe the raw and finished product storage areas (purpose, location, quantity, temperature requirement, and humidity).
2. How often are these areas cleaned and sanitized? Are they on the master sanitation schedule or included in the sanitation program?

VIII. DISTRIBUTION

1. Describe the product distribution and transportation system. Include whether or not product is shipped directly from the manufacturing plant or whether it is routed through distribution centers before delivery to US military customers.
2. Indicate how finished product gets from the production establishment to U.S. Forces.
3. Indicate how often the transportation assets are cleaned and sanitized.

IX. FOOD DEFENSE*

1. Does your establishment have an implemented *Food Defense Policy* that adequately reduces food defense vulnerabilities?
2. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from *Outside Grounds and Roof* areas?
3. Does your establishment have an *Employee and Visitor* program in place and implemented to adequately reduce food defense vulnerabilities?
4. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from the *Material Receiving* area(s)?

5. Does your establishment have processes within the *Facility Operations* that adequately reduce food defense vulnerabilities?

6. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from the *Finished Goods Storage/Shipping* area(s)?

*Food Defense Plan/Program - A written document or approach that uses established risk management procedures for preventing intentional food tampering and responding to threats or actual incidents of intentional tampering. Developed by an establishment to assess and mitigate the vulnerabilities within the food system or infrastructure to an attack from deliberate or intentional acts of food destruction, contamination or tampering.