

## **PRE-AUDIT QUESTIONNAIRE - REQUEST THE INFORMATION BELOW**

### **ESTABLISHMENT NAME/ADDRESS**

- Provide the establishment name?
- Provide the establishments' physical address (production facility)?
- Provide the establishments' phone/fax number(s)?
- Provide the Federal, Foreign (EU), and/or State plant number(s) for your establishment?
- Provide any product codes that are listed under your plant number (e.g., USDA plant# 43-1123)?
- Provide a copy of your company's letterhead.
- Provide directions to your establishment.
- If the establishment is doing business as (DBA) another company, indicate the other business name.

### **PERSONNEL/ADMINISTRATION**

- What are the names of the key personnel along with their position (title), phone number, and email addresses?
- Provide the business card of your establishment's POC / audit representative.
- Provide the name(s) of the company owner(s) or entity.

### **PRODUCTS**

- List all products produced, stored, or distributed at this establishment.
- List the product(s) that you are requesting to be listed in the *Worldwide Directory*.

### **OTHER INSPECTION AGENCIES/AUDING ORGANIZATIONS**

- Provide other (Governmental or Civilian) inspection/auditing agencies reports and certificates.

### **BRAND NAMES AND POINT OF ORIGIN CODE(S)**

- List all brand names for the type(s) of products approved for directory listing.
- Provide the production code information on the product.
- If a closed code is used, provide the interpretation.
- Provide the character(s) within the production code designate your establishment.
- If no code is used, how is your product identified as being manufactured at your establishment?
- Provide the location (landmark) on the primary container where the point of origin code or other identifying information are located.
- Provide samples of actual film/labels used for products listed in the *Worldwide Directory*.

### **GENERAL**

- Indicate the hours and days of operation for production, sanitation, and administrative offices (M-F, shifts, etc.)?
- Indicate the number of employees for each employment status (full, part-time, temporary, or seasonal) that work in the establishment.
- Do you use a temporary agency for hiring employees?
- Who provides Food Safety and Security training to the temporary employees?

- If known and applicable, describe the specifics of the Department of Defense contract you have, or have had (contract number, type of product you supply, where you shipped to, volume, etc.).

#### Production Sizes:

- Provide common size of finished products (500 g packages, 1 L bottles, 3 lbs. containers)
- Indicate the average output of product produced in your establishment. Is this year round, or seasonal?

#### Recall & Traceability:

- Describe your recall and traceability programs.
- Identify how finished products are traced forward.
- Identify how raw products are traced backward.
- Describe the last traceability exercise to include the date, product traced, results, and corrective actions taken if needed.
- Is there a recall team? Who are the members? Do you conduct mock recalls? How often, and list the date of last mock recall?
- Identify for mock recall and any actual recalls:
  - Issue (reason for recall)
  - Date of Recall
  - Start/End Time
  - Product Involved
  - Amount Produced
  - Amount in Inventory
  - Amount Shipped
  - Amount Recalled in time IAW facility standard
  - Total Amount Recalled
  - Corrective actions taken if recall was not IAW standard or not fully recalled.

#### Shelf-life:

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

### **FACILITIES**

- Identify the geographical location of the establishment. Specify if the location is residential, commercial, or rural.
- Describe the location and the area surrounding your establishment.
- What year was your establishment constructed?
- What is the date of the most recent renovation? What was done? Are there any projected renovations?
- Describe the building as well as the material(s) used in the construction of your establishment.
- Identify the square footage of the establishment by area (i.e. production, raw storage, finished product storage, laboratory, admin).
- What are the various areas that make up the production area?

### **MAJOR EQUIPMENT AND CALIBRATION**

- List all major equipment deemed pertinent to food production and food safety operations. Include equipment used to control or verify a critical control point, control point, and/or other food safety controls.

- Identify for each list piece of equipment:

- Who calibrates the equipment? (internal or external)

- What is their certification? (ISO 17025, ISO 9001:2008)

- Is the calibrator certified to calibrate that piece of equipment?

- How often equipment is calibrated? i.e. calibration plan

- Critical limits of calibration. i.e. thermometers are calibrated to  $\pm 0.01^{\circ}\text{F}$ .

- Actions taken when equipment is out of calibration.

## **FOOD PROTECTION AND SANITATION**

HACCP and/or Food Safety Control Program:

- Include a complete copy of your HACCP or Food Safety Control Program.
- What is your approach to controlling food safety?
- Do you have a written Hazard Analysis Critical Control Point Program (HACCP) plan?
- If yes, when was it developed and what was the date it was last reviewed?
- If you have a HACCP plan, what are the Critical Control Points (CCPs)?
- How is each CCP monitored?
- What are the critical limits for each CCP?
- What is the protocol when critical limits are exceeded?
- What is the protocol for process deviations?
- If you do not have a HACCP plan, describe the Food Safety controls you have in place?

Raw Materials:

- What is the source of water utilized in your establishment? · What are the major raw ingredients in your product(s)?
- Who are the suppliers? Who transports the materials?
- Identify any laboratory testing or certifications included with the procurement of raw material.
- What procedures/documentation is in place to ensure raw materials are safe, wholesome, and meet specifications?

Laboratory Testing:

- Identify for each raw material, finished product, water, and environmental test:
  - What laboratory is conducting the testing? (internal or external)
  - What is laboratory accreditation/certification?
  - Is the lab accredited/certified to perform tests that they establishment is utilizing?
  - What tests is the laboratory performing?
  - What are the critical limits for each test?
  - What actions are taken when critical limits are exceeded?
- Is product held pending laboratory results?

Employee Hygiene and Sanitation:

- Do employees receive a medical examination prior to employment?
- How often are employees examined?
- What are employees tested for?

- Describe the employee training program. Include:
  - What type of training is provided to employees?
  - Who oversees the training program?
  - Who conducts the training, internal employees or external organization?
  - Provide the accreditation/certification of the training provider.
  - How often is the training conducted?
  - Is the training documented?
  - How is the training documented?
  - Are training, signage, and other pertinent instructions available in all applicable languages?
  - If not, does your establishment have a translator?
  - Who provides Food Safety and Security training to the temporary employees?

#### Plant Sanitation:

- Is sanitation performed by internal employees or an external organization?
- What is the make-up of the personnel that perform sanitation functions (production employees, sanitation team, contractor, etc.)?
- Provide the master sanitation schedule and/or program. Ensure complete steps for CIP and COP are included for each piece of equipment that is pertinent to food production and food safety operations.
- What is the name of the sanitation team leader? Is there an alternate? Who provides sanitation training? Are records of training available for review?
- 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?
- When are the master sanitation tasks conducted?
- 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?
- What chemicals are utilized in the establishment?
- At what concentration, temperature, and contact time is each chemical used.
- How are chemicals stored at the establishment?
- How are chemical sanitizer concentrations verified? How often? Are results documented and available for review?
- Are there pre operation and post operation checklists/procedures in place? Are they documented and available for review?
- Are environmental and rapid method detection procedures in place to monitor sanitation?
- If so, are environmental and rapid method detection results reviewed by sanitation personnel?
- How are chemicals dispensed into other containers labeled?
- What other chemicals, other than those required for production, sanitation, and maintenance functions are stored at your establishment?

#### Pest Control:

- Who performs the pest control functions at your establishment?
- Provide the pest control technician and company applicator license.
- What services are provided? Are records of the services retained locally for review?
- How often are the pest control services provided?

- Describe the key components of your pest control system (bait stations, traps etc.)
- Is there a pest control diagram of all the pest control devices utilized at your establishment?
- Does the pest control provider store extra equipment or pest control chemicals at your location? If so, how and where are they stored?
- List the target pests identified by the pest control plan and the controls implement to mitigate their risks.

#### Waste Management:

- Who provides waste management services for your establishment?
- How often is waste picked-up?
- Are the waste collection area(s) (interior and exterior) included in your sanitation program and under surveillance of the pest control provider?

### **PROCESS**

- Describe the processing steps from receipt of raw materials to the finished product. Specify time, temperature, pressure, kill steps, etc. List major processing equipment at each 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. Provide a copy of the process flow diagram with all CCP's clearly annotated.

### **STORAGE**

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

### **DISTRIBUTION**

- Describe the product distribution and transportation system.
- Indicate how finished product gets from the production establishment to U.S. Forces.
- Indicate how often the transportation assets are cleaned and sanitized.

### **FOOD DEFENSE**

Describe the Food Defense /FORM or equivalent program.

- Describe procedures used to investigate possible intentional contamination issues.
- Describe how customer complaints are maintained, investigated, and resolved.

Describe how the facility is able to respond to a product contamination threat or event.

- Describe how facility operations prevent unauthorized access by people or entry of unapproved materials into the facility and onto the facility grounds.
- Describe who provides security (in-house or contracted).
- Describe physical and procedural boundaries used.
- Describe the security systems in place inside and outside the facility.
- Describe how employee personal belongings are monitored and stored within the facility.
- Describe how areas are identified as sensitive to storage or production of foods.

Describe how products are protected from intentional contamination throughout receiving, production, storage, and delivery.

- Describe how supplier's ingredient and packing is verified safe from intentional contamination.
- Describe how material and delivery drivers are verified.
- Describe how unloading is conducted and verified, to include equipment used (i.e. hoses, pipes, augers).
- Describe how damaged, suspected tampered, counterfeit, or rejected materials are handled.
- Describe how the water supply is protected from intentional contamination.
- Describe how finished goods are packaged to prevent intentional contamination.
- Describe how finished goods are stored, secured, and tracked within the facility prior to distribution.
- Describe how products being distributed are verified before leaving the facility and to include multiple stops or delivery.

Describe how authorized personnel are identified and procedures used to exclude unauthorized personnel, to include facility employees in sensitive areas.

- Describe pre-hiring screening program for all employees (i.e. temporary, contract, part-time, full-time).
- Describe positive identification and recognition systems used for employees and visitors.
- Describe visitor program.
- Describe uniform or required clothing requirements and procedures.

Describe employee food defense training.

Identify members and positions of the Food Defense (crisis management) Team.

List dates of the last assessment and validation of the Food Defense /FORM plan.