DAIRY PRE-AUDIT QUESTIONNAIRE INITIAL FOOD PROTECTION AUDIT

The information requested in this questionnaire is required to process an initial food protection audit of your establishment. Please provide the information in English. Failure to provide requested information may cause a delay in processing this request. All information provided is considered confidential and is used for official purpose to plan and conduct a food protection audit.

| Data | |
|------|--|
| Date | |

Products Requested for Approval:

I. ESTABLISHMENT NAME / ADDRESS

- 1. Establishment name:
- 2. Establishment's physical address of the production facility, to include GPS coordinates:
- 3. Company Website:
- 4. List all products produced/processed at this establishment:
- 5. Official EU Number or Equivalent:

II. PERSONNEL/ADMINISTRATION

- 6. Establishment owner's name:
- 7. Name of the primary and alternate points-of-contact (POC) and their direct phone numbers and email addresses:

Primary POC Name:

Email address:

Phone number:

Alternate POC Name:

Email address:

Phone number:

8. Name of key personnel and their Email addresses:

Site Director:

Quality Systems Leader:

HACCP Team Lead:

Laboratory Manager:

Other:

9. Please identify where the auditor will report to gain access to the facility and if there are any codes or extension numbers to contact to gain access. For security purposes, you may wish to withhold this information until you are contacted by the auditor for the purpose of setting up the audit.

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III. GENERAL

- 10. Indicate the days and hours of operation for production (M-F, shifts, etc...).
- 11. Indicate the days and hours of operation for administrative offices (M-F, shifts, etc...).
- 12. Indicate the days and hours of operation for cleaning and sanitation (M-F, shifts, etc...).

Shelf-life:

- 13. Recommended shelf-life of products being requested for approval:
- 14. Recommended storage condition for finished products to achieve maximum shelf-life:

Recall/Traceability:

- 15. Date / Version of formal program:
- 16. Explain how product coding relates to traceability of finished goods and raw materials:

IV. FOOD PROTECTION AND SANITATION

HACCP and/or Food Safety Control Program:

- 17. Date / Version of formal program:
- 18. Please provide a copy of the CCP summary page for products being requested for approval. Show what the CCPs are, how they are monitored, who monitors, critical limits and the prescribed corrective action(s) when critical limits are not acceptable:

Raw Materials:

- 19. List all sources of water utilized in your establishment and specify if from a municipal source or an artesian well:
- 20. Describe how the company sources raw materials / ingredients:
- 21. Do any raw ingredients arrive with certificates of analysis, and, if so, which ones:
- 22. Do milk products purchased for use in production arrive at the plant with an accompanying certificate of analysis for pesticides and antibiotic testing?

Laboratory Testing:

- 23. Indicate whether services are performed by an in-house, an external laboratory, or both:
- 24. Describe what testing is performed for raw ingredients, in-process, and finished products:

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- 25. Is there an environmental monitoring program? If yes, explain target organisms, frequency of testing and which laboratories perform those tests:
- 26. Are laboratories ISO 17025 certified? If yes, please ensure copies of their accreditation are available for review:

Plant Sanitation:

- 27. Is there a written and documented master sanitation schedule and/or program in place:
- 28. Which company supplies the cleaning chemicals, and describe how employees are trained to handle these chemicals safely and effectively:
- 29. Are there pre-operation and post-operational checklists / procedures in place? Are they documented and available for review?

V. PROCESS

- 30. 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.
- 31. Describe how many processing lines are utilized in the facility and if specific products are assigned to those lines:

VI. FOOD DEFENSE

- 32. Does your establishment have an implemented *Food Defense Policy* that adequately reduces food defense vulnerabilities?
- 33. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from *Outside Grounds and Roof* areas?
- 34. Does your establishment have an *Employee and Visitor* program in place and implemented to adequately reduce food defense vulnerabilities?
- 35. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from the *Material Receiving* area(s)?
- 36. Does your establishment have processes within the *Facility Operations* that adequately reduce food defense vulnerabilities?
- 37. Does your establishment have a system in place and implemented to adequately reduce food defense vulnerabilities from the *Finished Goods Storage/Shipping* area(s)?

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VII. ADDITIONAL INFORMATION FOR DAIRIES ONLY

A certified dairy auditor will be tasked to perform the audit. A significant amount of time will be applied to understand the design, function, and maintenance of the pasteurizers. We will only evaluate the pasteurizers used to produce products destined for US Forces. If possible, please Email detailed pasteurizer schematics along with this questionnaire to allow for a preview. In addition, the auditor will attempt to calculate the holding time requirements. The auditor will require actuate measurements for the holding tube "length" and "inner diameter." Please ensure there is a certification for the holding tube length and inner diameter, either from the manufacture or qualified third party. Also have current calibration records for the pasteurizer, to include (thermometers / pressures / flow rates /pressures in plate heat exchangers / divert valve functions / etc...).

- D1. Indicate the number of pasteurizers on-site as well as the number of pasteurizers intended to be evaluated during the audit:
- D2. Indicate the type of pasteurizers: HTST / HHST / UHT
- D3. Indicate the operating parameters for each pasteurizer:
 - Normal operating temperature
 - Cut-in temperature
 - Cut-out temperature
 - Normal flow rates
 - Maximum flow rates
 - What is the measured or calculated holding time
 - If using regenerative heating, is proper pressure differential maintained
 - Is a daily divert check performed
- D4. Copies of all schematics for pasteurizers used in production of products being requested for approval:
- D5. Who performs calibrations / testing of pasteurizer equipment and at what frequency? A thorough review of records will be made during the audit:
- D6. Source of incoming dairy: (farms / other dairies). How is herd health monitored in the areas of the source milk?
- D7. What conditions trigger a diverted or recirculated flow: (loss of temp / loss of pressure / excessive flow rate / other)
- D8. Who has access rights to change pasteurizer settings that involve time, temperature, pressure set points?
- D9. Describe the sequence of events (system logic) from system start and moving to forward flow:
- D10. Describe the sequence of events (system logic) after recovery from a diverted flow:
- D11. During the audit, technical questions may be asked that require in-depth knowledge of the

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design and operation of the pasteurizer(s).

Additional information for the supplier:

Please note: Once this pre-audit questionnaire has been completed, please return to the agency you received it from; along with your request letter for your facility to be audited. Once all the required forms have been reviewed, the auditor will be tasked to contact the primary contact via Email to schedule the audit. The auditor will outline the audit requirements and may request additional information to better prepare for the audit. Failure of the supplier to provide the required documentation in English may result in the failure of the supplier to be listed in the Directory of Sanitarily Approved Food Establishments for Armed Forces Procurement.

For questions or more information, contact Pubic Health Command - Europe, Veterinary Services Division at: +49 (0)6371 9464 9903 / +49 (0)6371-9464 9748, or by Email: usarmy.landstuhl.medcom-ph-e.mbx.veterinary-services-division@mail.mil