Firm Name:	**FEI Number:**
City, State	**FCE Number:**
Inspection Date(s):	**Investigators:**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PROCESSING FORMULATION CONTROLLED PRODUCTS
(Retort Survey)

INSTRUCTIONS

Complete the question blocks below. Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted.

Before entering any confined space you must confirm with the firm that you are following the firm's Standard Operating Procedures designed to meet OSHA confined space requirements. If the firm insists that only plant personnel enter the retort, witness the measurement procedure and data collection. To obtain OSHA confined space information and safety procedures, see the confined space presentation on the FDA training web site. If the firm is not aware of the OSHA confined space requirements or does not have a confined space program, DO NOT ENTER THE RETORT.

If problems are found with the firm's retort equipment or processing system, refer the reader to the EIR for a narrative description of specific problems with supporting evidence, under "Objectionable Conditions and Management's Response." Submit the completed form as an EIR attachment.

PROCESS ESTABLISHMENT AND SCHEDULED PROCESSES - 21 CFR 108.35

1. Report the Product(s) and SID number(s) covered on this inspection.

Product(s)	SID(s)

2. Has the firm registered the facility with the FDA and filed a process for all LACF products manufactured? - *21 CFR 108.35 (c)* ☐ Yes ☐ No

3. Does the firm have a process letter or other process source documentation listing critical factors necessary to control in the attainment of commercial sterility? ☐ Yes ☐ No

Based on the processing authorities' evaluation critical factors are specific to an individual product or on occasion listed for a grouping of products.

4. Do critical factors or limits listed in source documents match critical factors or limits for selected products and processes filed with FDA? ☐ Yes ☐ No

PROCESSING DESCRIPTION

5. Pasteurization System Description ☐ Continuous ☐ Batch

6. Container Size(s)

7. Type of Heat Exchanger ☐ Swept Surface ☐ Plate Heat ☐ Tubular ☐ Other

8. Type of Filler ☐ Aseptic ☐ Hot Fill ☐ Can ☐ Other

9. Does a computer control any of the processor system functions? ☐ Yes ☐ No

10. Does the firm have documentation on hand which indicates that the computer system has been validated? ☐ Yes ☐ No

HEAT AND TEMPERATURE DISTRIBUTION - 21 CFR 113.87

11. Have there been any changes to the thermal processing system or filling system since the last temperature distribution study that could affect temperature distribution or container sterilization? ☐ Yes ☐ No

While reviewing the process authority's supporting documentation, compare the study parameters to actual operating conditions.

Pay attention to any changes during operating conditions that do not match the PA documentation. These could include (static cook vs. rotary cook; circulating water system turned off; changes to plumbing for the retort installation; different loading configurations, change in container size and other factors that can affect the attainment of temperature distribution or heat penetration in the retort.

If a change has been made in the thermal processing system that could affect temperature distribution, the firm must have on file documentation of the change, including the review and approval by a qualified process authority.

PRODUCT PREPARATION - 21 CFR 113.83

12. Are products prepared according to the method (rehydrating, drying, acidifying, blanching etc.) and / or formulation specified in the recommended scheduled process? ☐ Yes ☐ No

Be aware of changes in starches and other minor ingredients. If the wrong starch is used it can change the heat penetration inside the container.

13. When maintenance of pH (above 4.6) of a normally low acid food is a basis for a scheduled process does the firm ensure that the equilibrium pH of the finished product meets the value specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

In this case the firm must monitor pH as a critical factor at intervals of sufficient frequency and prepare maintain records the pH meter should be calibrated to ensure its accuracy. (113.81(e))

14. For water activity-controlled processes is the water activity (Aw) carefully controlled to ensure that the Aw of the finished product meets that of the scheduled process? ☐ N/A ☐ Yes ☐ No

When normally low-acid foods require sufficient solute to permit safe processing at low temperatures such as in boiling water there shall be careful supervision to ensure that the equilibrium water activity of the finished product meets that of the scheduled process 113.81(f)). In this case the firm must monitor water activity at intervals of sufficient frequency and prepare maintain records the water activity meter should be calibrated to ensure its accuracy (117.40(f)).

15. Is the formulation of the product and processing etc. conducted in a timely manner to prevent incipient spoilage? ☐ Yes ☐ No

CRITICAL FACTORS - 21 CFR 113.40(i)

16. Are all critical factors defined in the scheduled process measured and recorded at intervals of sufficient frequency to ensure the process is under control? ☐ Yes ☐ No

17. Is the minimum processing time and temperature and the fill temperature as specified in the scheduled process? ☐ Yes ☐ No

18. Is pH control of the product as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

19. Is moisture control of the product as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

20. Is water activity control of the product as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

21. Are percent salt and phosphate of the product as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

22. Are any antimicrobials included in the formulation of the product as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

23. Is the percent fat of the product as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

24. Are all instruments used for measuring critical factors accurate and properly calibrated? ☐ N/A ☐ Yes ☐ No

25. Are other product characteristics (formulation, particle size, viscosity, brix, etc.) as specified in the scheduled process? ☐ N/A ☐ Yes ☐ No

THERMAL PROCESSING ROOM OPERATIONS - 21 CFR 113.87

26. Is the system operated in the same state that was used during the last temperature distribution study? ☐ Yes ☐ No

27. Are scheduled processes and venting procedures (if applicable) posted in the production room or readily available to the retort operator? ☐ Yes ☐ No

21 CFR 113.87(a)

28. Are records maintained demonstrating that IT thermometers are properly calibrated? ☐ Yes ☐ No

29. Are thermal process timing devices (clocks, charts, stopwatches etc.) accurate? ☐ Yes ☐ No

Pocket or wristwatches are not considered satisfactory. Digital clocks that do not display seconds may be used if the operating process and the venting schedule have a 1-minute or greater safety factor over the scheduled process. - 113.87(d)

CONTAINERS - 21 CFR 113.60

30. For products covered during this inspection describe the method of filling containers (hand, vibration, pocket, etc.). If other, describe below. ☐ Hand ☐ Piston ☐ Vibration ☐ Other ☐ Pocket

31. Is this method the same as that used during process establishment tests? ☐ Yes ☐ No

32. Are container edges free of damage after filling? ☐ Yes ☐ No

33. Do product codes comply with part 113.60(c)? ☐ Yes ☐ No

The code shall be permanently visible to the naked eye and shall identify the packer product year day and period of packing describe the coding system including a code breakdown for products produced during this inspection.

34. Are regular observations performed during production for container defects? ☐ N/A ☐ Yes ☐ No

35. Are records of visual and destructive tests of containers performed and documented by qualified individuals? ☐ N/A ☐ Yes ☐ No

36. Are corrective actions for defects taken and recorded? ☐ N/A ☐ Yes ☐ No

37. For metal cans, are destructive tests performed on cans from each seaming head by qualified individuals and are all required measurements documented? ☐ N/A ☐ Yes ☐ No

Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing

38. For glass containers, are cold water vacuum tests for capper efficiency performed and recorded? ☐ N/A ☐ Yes ☐ No

Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing

39. For other containers, are appropriate tests and detailed inspections performed to ensure a consistently reliable hermetic seal? ☐ N/A ☐ Yes ☐ No

Collect supporting evidence for sealing closing parameters or specification values necessary for sealing/closing

40. What type of container testing is performed?

Identify all that apply. For additional details on package integrity, refer to the FDA BAM (Bacteriological Analytical Manual)

☐ Abuse	☐ Air leak	☐ Burst	☐ Conductivity	☐ Dye	☐ Electrolytic
☐ Etching	☐ Gas leak	☐ Incubation	☐ Light	☐ Machine Vision	☐ Pull Up
☐ Peel (Tensile)	☐ Proximity	☐ Seam scope	☐ Security	☐ Sound	☐ Squeeze
☐ Teardown	☐ Torque	☐ Vacuum	☐ Visual	☐ Other	

HEATING SYSTEM - 21 CFR 113.40(i)

41. Is the heating system equipped with at least one temperature-indicating device (TID) that accurately indicates the temperature during processing? ☐ Yes ☐ No

42. Is the TID installed where it can be accurately and easily read? ☐ Yes ☐ No

43. Is the TID used as the reference instrument during processing? ☐ Yes ☐ No

44. Are calibration records for the TID established and maintained? ☐ Yes ☐ No

45. Is the TID accurate to 1 °F (0.5 °C)? ☐ Yes ☐ No

Temperature Recording Device

46. Is the heating system equipped with a temperature recording device? ☐ Yes ☐ No

47. Is the temperature chart adjusted to agree as nearly as possible with but not higher than the known accurate TID during the processing period? ☐ Yes ☐ No

48. Does the temperature recording device record temperatures to a permanent record? ☐ Yes ☐ No

49. Is the appropriate chart paper used with the temperature recording device? ☐ Yes ☐ No

Chart paper must have both the appropriate range (2 °F or 1 °C) within a range of 10 °F (5 °C) of the process temperature and working scale (< 55 °F per inch or 12 °C per centimeter) within a range of 20 °F (10 °C) of the process temperature.

50. If the chart is a multipoint plotter, does it record at intervals that assures that the parameters of the process time and process temperature were met? ☐ N/A ☐ Yes ☐ No

51. Does the digital temperature recorder record data at sufficient intervals to assure that the parameters of the process time and process temperature were met? ☐ N/A ☐ Yes ☐ No

POST PROCESS HANDLING - 21 CFR 113.60

52. Are container handling procedures and conveyance equipment adequate to protect container bodies and seals from damage that could result in leakage and post-process contamination? ☐ Yes ☐ No

Conveyor tracks should be maintained in a clean sanitary dry way. These conveyors are often neglected and contain build-up of food and dirt residues. The seams are most vulnerable to post-process leakage at this time because of the negative pressure developing inside the container as the contents cool. Conveyor tracks should not contain sharp edges or projections that could dent and damage can bodies and seams. Conveyors should be designed so that excessive heavy contact between cans does not occur and the double seams do not roll on or contact the conveyor during conveyance.

53. Are lots containing spoiled or swollen containers properly investigated? ☐ Yes ☐ No

Note that an acceptable level for can food spoilage in the LACF industry is 0.01% or 1 abnormal container per 10,000 containers - at levels above this the firm should perform a spoilage diagnosis including microbiological analysis to determine the cause of the spoilage. In addition, the firm should determine the cause of the problem and document this and any corrective action taken to prevent the problem from reoccurring.

PROCESS DEVIATIONS - 21 CFR 113.89

54. Does the firm maintain a separate file or log for documenting process deviations? ☐ Yes ☐ No

55. Did the firm properly handle all scheduled process deviations? ☐ Yes ☐ No

RECORDS - 21 CFR 113.100

56. Are all lots that are shipped in interstate commerce free from instances of public health significance and otherwise not injurious to health? ☐ Yes ☐ No

A commercial processor shall promptly report to the FDA any instances of spoilage or process deviations which indicate potential health significance when the lot of food has in whole or in part entered distribution.

57. Do operators document processing and production information on forms that include the product, code number, date, retort or processing system, container size, approximate number of containers, initial temperature, actual processing time, TID readings, temperature recorder device readings and other appropriate processing data?	☐ Yes	☐ No
58. Is processing and production information recorded at the time it is observed by the processing system operator?	☐ Yes	☐ No
59. Are recording thermometer charts (analog, graphical or digital) identified by date, processor system number, and other data as necessary so that they can be correlated with the written record of lots processed?	☐ Yes	☐ No
60. Are processing and production records signed or initialed by the operator and reviewed for completeness and signed or initialed and dated by plant management within 1 working day after the actual process to assure that the product received the scheduled process?	☐ Yes	☐ No
61. Are all operators of thermal processing systems and container closure inspections under the operating supervision of a person who has attended a school approved by FDA?	☐ Yes	☐ No
62. Does the firm have recall procedures on file that comply with 108.35(f)?	☐ Yes	☐ No
63. Does the firm maintain initial distribution records per 113.100(f)?	☐ Yes	☐ No
Food Preservation Records - 113.100(a)(6)		
64. Are records of time, temperature or other processing information measured with accurate instruments to ensure the scheduled process is met?	☐ Yes	☐ No
65. Are records maintained showing adherence to the product formulation, the scheduled processed used and all critical factors?	☐ Yes	☐ No
TID and Reference Device Records -113.100(c) and 113.100(d)		
66. Do the TID calibration records include: A reference to the tag or seal, the name of the manufacturer, the ID of the reference device, NIST traceability, ID of the person who performed the test, the date and results of the testing including adjustments, and the date the next test is to be performed?	☐ Yes	☐ No
67. Do the reference device calibration records include: A reference to the tag or seal, the name of the manufacturer, the ID of the reference device, NIST traceability, ID of the person who performed the test, the date and results of the testing including adjustments, and the date the next test is to be performed?	☐ Yes	☐ No
Container Integrity Records - 113.100(e)		
68. Do container closure records include the product code, date, time, measurements and corrective actions taken?	☐ Yes	☐ No
69. Are container integrity records signed and dated by the inspector and reviewer?	☐ Yes	☐ No
70. Are container integrity records reviewed with sufficient frequency to ensure containers are hermetically sealed?	☐ Yes	☐ No

COMMENTS