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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

ACIDIFIED FOODS INSPECTION REPORT

This inspection report is available in PDF on the forms site: http://www.fda.gov/opacom/morechoices/fdaforms/ora.html. Narrative responses to each item can be entered in the item's "comments" area or where otherwise prompted. Complete documentation of deficiencies, including deviations from Part 114, should be narrated with reference to photos, exhibits, etc., in the EIR under "Objectionable Conditions and Management's Response." When necessary, refer the reader to the appropriate section of the EIR for a full explanation of details.

This form should be downloaded from the forms site to a computer drive prior to completion and copying. Submit the finished report as an attachment to the EIR.

PROCESS ESTABLISHMENT AND SCHEDULED PROCESSES – 21 CFR 108.25

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

Product(s)	SID(s)

2. Have processes been established by a processing authority for all acidified foods processed at this facility? ☐ Yes ☐ No

3. Has the firm registered with FDA and filed a process for all acidified foods processed at this facility? ☐ Yes ☐ No

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

Compare maximum equilibrium pH and other critical factors listed on process filing forms with similar information listed in process letters or other process source documentation. Critical factors may exist that the firm controls but have not been identified in the process filing. Critical factors may also exist that have or have not been identified and are not controlled.

PROCESSING OPERATIONS – 21 CFR 114.80

5. Are products acidified according to the method and/or formulation specified in the recommended scheduled process? ☐ Yes ☐ No

6. Is the product thermally processed to destroy vegetative cells of public health concern and spoilage organisms capable of growing in the food? ☐ Yes ☐ No

A thermal process may also include cold/fill/hold procedures if the firm has documentation that the appropriate pathogens are destroyed in the product.

7. Are minimum initial temperatures and process temperatures achieved as recommended by the process authority and filed with FDA? ☐ Yes ☐ No

8. If the finished equilibrium pH is greater than 4.0, does the firm use accurate instruments to measure the pH? ☐ N/A ☐ Yes ☐ No

If the equilibrium pH is >4.0, firms must use a pH meter and relate any in-process titration or colorimetric measurements to the finished equilibrium pH.

9. Is the firm's pH testing done on enough representative samples and with sufficient frequency to ensure that equilibrium pH is less than 4.6? ☐ Yes ☐ No

10. Does the firm adequately control pH to ensure that the equilibrium pH of finished products is achieved and maintained as specified in the scheduled process? ☐ Yes ☐ No

CONTAINER INTEGRITY 21 CFR 114.80(a)(4)

11. Do testing and examination of containers occur often enough to ensure that containers suitably protect the food from leakage and contamination? ☐ Yes ☐ No

21 CFR Part 114 does not require that the firm prepare and maintain container integrity monitoring records. Encourage the firm to document its container integrity testing activities. If subject to Subparts C and G, 21 CFR Part 117 requires firms to ensure container integrity if they identify post process contamination as a hazard requiring a process preventive control

12. Is each container identified with a visible code that specifies the packer, the product, the year, day and period of packing? ☐ Yes ☐ No

13. Is the packing period code changed often enough to assure ready identification of lots during their sale and distribution? ☐ Yes ☐ No

The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically as follows - after intervals of 4-5 hours after personnel shift changes or after each batch as long as one batch does not represent more than one personnel shift. - 114.80(b)

PROCESS DEVIATIONS – 21 CFR 114.89

14. Does the firm identify and maintain a separate log or file containing process deviations? ☐ Yes ☐ No

15. When a process deviation occurred did the firm fully reprocess the product, thermally process as a low-acid food under 21 CFR 113, or set aside for further evaluation as to any potential public health significance? ☐ N/A ☐ Yes ☐ No

For example failure to achieve the minimum process time and / or temperature and/or maximum equilibrium pH as listed in the filed scheduled process.

16. If the deviation was set aside for further evaluation was it evaluated by a competent processing authority in accordance with procedures recognized as being adequate to detect any potential hazard to public health? ☐ N/A ☐ Yes ☐ No

RECORDS – 21 CFR 114.100

17. Does the firm maintain records for examination of incoming raw materials? ☐ Yes ☐ No

18. Does the firm maintain records for incoming packaging materials? ☐ Yes ☐ No

19. Does the firm maintain records for finished product evaluations? ☐ Yes ☐ No

20. Are records of all critical factors (time/temperature/pH etc.) prepared and maintained showing adherence to the scheduled process? ☐ Yes ☐ No

21. Do processing and production records include sufficient additional information (such as product, code, production date, container size etc.) to permit a health hazard evaluation of processes applied to each lot? ☐ Yes ☐ No

RECORDS – 21 CFR 108.25

22. Have appropriate plant personnel attended and completed a school approved by FDA? ☐ Yes ☐ No

23. Do the firm's records identify initial distribution of production lots? ☐ Yes ☐ No

24. Does the firm have a recall plan on file? ☐ Yes ☐ No

25. Were all production lots shipped in commerce free from instances of public health concern? ☐ Yes ☐ No

If a firm ships product in commerce that is of public health concern, they are required to notify FDA.

COMMENTS