CHAPTER 03 – FOOD MICROBIOLOGICAL HAZARDS

SUBJECT:	ACIDIFIED AND LOW-ACID CANNED FOODS PROGRAM – IMPORT & DOMESTIC
IMPLEMENTATION DATE:	Upon Receipt
PRODUCT CODES	INDUSTRY CODES: 02-41, 45-46, 50, 70, 72 PRODUCT CODES: Use appropriate product codes.
PRODUCT/ASSIGNMENT CODES (PACs)	REPORT PROGRAM ACTIVITIES UNDER THE FOLLOWING PACs: **03070A** Domestic Acidified Food (AF) Products **03070B** Domestic Low-Acid Canned Food (LACF) Products **03070C** Domestic Aseptic Low-Acid Canned Food (LACF) Products **03070F** Import Low-Acid Canned Food (LACF) Products **03070G** Import Acidified Food (AF) Products **03070J** Import Aseptic Low-Acid Canned Food (LACF) Products **71070** Domestic & Import Low-Acid Canned Food (LACF) Animal Food Products REPORT SAMPLE ANALYSIS UNDER THE FOLLOWING PACs: **03070A** Domestic Acidified Food (AF) Products **03070B** Domestic Low-Acid Canned Food (LACF) Products **03070C** Domestic Aseptic Low-Acid Canned Food (LACF) Products **03070F** Import Low-Acid Canned Food (LACF) Products **03070G** Import Acidified Food (AF) Products **03070J** Import Aseptic Low-Acid Canned Food (LACF) Products **71070** Domestic & Import Low-Acid Canned Food (LACF) Animal Food Products

FIELD REPORTING REQUIREMENTS:

1. Compliance

Submit all recommendations for compliance actions to CFSAN or CVM Division of Food Compliance (DFC) in the Compliance Management System (CMS) and follow the procedures outlined in the Regulatory Procedures Manual (RPM), Chapter 4, Advisory Actions.

2. Inspection

Establishment Inspection Reports (EIRs) must be completed in eNSpect per Investigations Operations Manual (IOM) subchapter 5.7 *Reporting*. Investigational Reports must be prepared per IOM subchapter 8.1.9 *General Investigation Reporting*. Corrective Actions taken during inspections must be documented in the Corrective Action Reporting (CAR) System within eNSpect as well as the Establishment Inspection Report (EIR), per IOM subchapter 5.7.3.7.17 *Voluntary Corrections*.

3. Sample Collections & Import Field Exams

Report all domestic sample collections in the Field Accomplishment Compliance Tracking System (FACTS).

Report all import sample collections and field/label exams in FDA import systems.

The analyzing laboratory will report results for each sample of low acid and acidified products into FACTS using PAF = ACD. **Exception**: for-cause samples collected for *C. botulinum* analysis; utilize PAF MIC for these samples.

Use the following Problem Codes:

AFD	Acid Food Analysis
ACF	Acidified Food Analysis
LAF	Low-Acid Canned Food Analysis

4. Analytical

A. Per FMD-147, ORA laboratories will communicate sample analytical findings to the appropriate compliance units.

B. All final results will be entered in FACTS and completed analytical worksheet packets will be uploaded to the Compliance Management System (CMS) as soon as possible following final result notification.

C. Per FMD-147 and the ORA Laboratory Manual, completed original analytical findings will be submitted electronically to the responsible party named in the Collection Remarks section of the Collection Report in an FDA 1551 Form, if applicable.

TABLE OF CONTENTS

PART I – BACKGROUND

In 2007, the Agency responded to an extensive class I recall by a large Low-Acid Canned Foods (LACF) manufacturer due to the risk of botulinum toxin. The source of the contamination was determined to be a malfunctioning crateless retort system. The firm involved was subsequently placed under Emergency Permit Control. As a follow-up to that inspection, a CFSAN issued survey assignment identified another firm with a large number of abnormal cans in their warehouse, serious control issues and positive *C. botulinum* laboratory findings. Inspectional findings identified malfunctioning equipment, a lack of control in the areas of container fill weights, can seam integrity problems, under-processed product, product accountability, product coding, and inadequate heat distribution studies and heat penetration documentation.

This event and others have raised additional awareness about the safety of Acidified Foods (AF) and LACF products and the state of control in the AF and LACF industry. Inadequate evaluation of aging equipment, changing formulations and processes, and failure to execute Good Manufacturing Practices (GMPs) could be industry wide problems. In addition, inadequate manufacturing, processing, or packing of thermally processed low-acid foods in hermetically sealed containers or acidified foods may result in the distribution in interstate commerce of processed foods that may be injurious to health. 21 CFR part 113 “Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers” and 21 CFR part 114 “Acidified Foods” describe requirements for manufacturing, processing, and packing foods to prevent an environment conducive to the growth of *Clostridium botulinum*, whose toxin causes the potentially fatal food poisoning known as botulism. The absence of oxygen, low acidity, normal room temperatures and adequate moisture/nutrients favor growth and toxin production by these bacteria. A failure to either destroy or control (by water activity, formulation, or acidification) the germination and growth of spores of *C. botulinum* due to improper manufacturing, processing, or packing may result in the production of a toxin which causes botulism.

In addition, 21 CFR part 108 “Emergency Permit Control” requires manufacturers of AF or LACF to register their processing plants, file their scheduled processes with FDA and to adhere to the mandatory requirements expressed in the GMPs.

A firm which does not comply with 21 CFR parts 108, 113 and 114 may be required to obtain an emergency permit as required under 21 CFR part 108 Subpart B “Specific Requirements and Conditions for Exemption from or Compliance with an Emergency Permit” before introducing its products into interstate commerce.

The requirements in 21 CFR part 108 (including the requirements for manufacturers of low-acid or acidified foods to register their processing plants and file scheduled processing information with FDA), and the requirements of 21 CFR parts 113 and 114 are intended to ensure safe manufacturing, processing and packing of thermally processed low-acid food in hermetically sealed containers, and acidified low-acid food, and to permit the Food and Drug Administration (FDA) to verify that the procedures are being followed.

This program is part of FDA's verification procedures to determine whether the industry implements adequate controls over the production and distribution of LACF and AF products.

This Compliance Program provides instructions and tools for FDA staff, including FDA investigators, laboratory analysts and compliance officers. It is a comprehensive approach to covering inspections, sample collections, sample analyses, and compliance activities to accomplish FDA's mission to ensure AF and LACF products in the U.S. food supply are safe and wholesome.

PART II – IMPLEMENTATION

1. Objectives

- Determine, by inspections and/or sample collections (and analyses), if AF and LACF manufacturers comply with 21 CFR part 108 “Emergency Permit Control”, 21 CFR part 113 “Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers”, 21 CFR part 114 “Acidified Foods”, and other requirements of the Food, Drug and Cosmetic (FD&C) Act, as applicable.

  NOTE: **Foreign AF and LACF manufacturers** that ship to the United States are also required to comply with the mandatory provisions of 21 CFR part 108 “Emergency Permit Control”, 21 CFR part 113, 21 CFR part 114, and other applicable requirements of the FD&C Act. Use the same instructions in this Compliance Program when conducting both foreign and domestic inspections.

- Determine if AF and LACF products are improperly processed or packaged through examination of lots, sample collection and analysis.

- Prevent the introduction of acidified and low-acid canned foods into interstate commerce, which are manufactured under conditions that do not comply with FDA requirements.

- Ascertain compliance and verify implementation of corrective actions are taken during and after an inspection.

- Document inspectional findings and initiate compliance action when warranted.

2. Program Management Instructions

A. General Information

- Because of the serious health hazards resulting from improperly processed AF and LACF and the occasional necessity for expert technical advice during investigations, inspections and sample collections, it is imperative that the CFSAN Office of Compliance Division of Enforcement be contacted immediately via DELACFandAFProduct@fda.hhs.gov when significant conditions are observed.

- Pet or animal food is covered under this program. Appropriate PAC and Product Codes shall be used for CVM products.

- For technical questions on this program, Investigators should contact CFSAN technical experts or ORA/OHAFO National Experts after concurrence with their District management.

B. Inspection Priorities

(1) Domestic Inspections

Inspectional priority should be governed by the following considerations:

- All newly registered AF and/or LACF manufacturers will be added to the FSMA inventory to be inspected within FSMA mandated timeframes.

  NOTE: Information on newly registered firms or changes to existing registrations will be handled with electronic mailing from the Center to the Director of Investigation Branch (DIB).

- All AF and/or LACF manufacturers operating under an Emergency Permit or classified "Official Action Indicated" (OAI) should be inspected within 3 months of the firm being issued the Emergency Permit or within 6 months of the OAI inspection. To verify corrective actions, regulatory follow-up inspections for facilities with inspection classifications of OAI and that were observed to have significant deficiencies according to FMD-86 and RPM Chapter 4, should be conducted by the divisions within 6 months of the compliance action being finalized. If there are critical deficiencies or a risk to public health, then follow-up must be conducted as soon as possible after the close of the inspection and completion of compliance action. If the follow-up inspection reveals that the firm continues to have conditions that are likely to lead to the adulteration of foods, the division should consider more severe enforcement action based on these repeat offenses. Divisions should initiate a call with CFSAN OC and ORA OHAFO program contacts within 24 hours of determining that an inspection revealed significant repeat observations.

- Manufacturers classified "Voluntary Action Indicated" (VAI) or EIs classified OAI and re-classified to VAI should be inspected within 12 months of the last inspection at the Division's discretion based on the type of violation to verify corrective action.

- All AF and/or LACF manufacturers classified as "No Action Indicated" (NAI) should be inspected within FSMA frequency mandate timeframes.

- Prior to conducting inspections in firms that are subject to dual jurisdiction with USDA, contact the USDA/FSIS management contact in your district and invite their participation in the inspection.

- Local and/or state regulatory agencies that perform AF/LACF inspections at the facility should be contacted prior to the inspection, to determine if they have any information and concerns regarding processing conditions.

(2) Foreign Inspections

Inspections of foreign manufacturers of LACF products and AF products to determine compliance with 21 CFR part 108 (Emergency Permit Control), 21 CFR part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers)

and 21 CFR part 114 (Acidified Foods) are accomplished under FDA's Foreign Inspection Program. Foreign human and animal food inspection EIRs are reviewed by ORA's Division of Foreign Human & Animal Food Operations (DFHAFO). This Division classifies most NAI and VAI inspections while CFSAN and CVM classify OAI inspections. Regulatory actions, such as Detention Without Physical Examination (DWPE) and/or placement on Import Alert, may be recommended by CFSAN if significant deviations from the regulations are revealed.

Foreign Remote Regulatory Assessment (RRA)
FDA can conduct voluntary RRAs at AF and LACF manufacturers. An RRA is examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs assist in protecting human and animal health, informing regulatory decisions, and verifying certain information submitted to the Agency (Attachment A). FDA utilizes RRAs to conduct oversight, mitigate risk, and meet critical public health needs when routine domestic and foreign surveillance inspections can't be conducted, or a remote assessment is more appropriate due to logistics.

RRAs are not considered inspections, conducted pursuant to section 704(a)(1) of the FD&C Act, and which involve duly designated officers or employees of the FDA physically entering (at reasonable times and in a reasonable manner), establishments subject to regulation under the FD&C Act to determine compliance with applicable FDA requirements. For this reason, RRAs do not satisfy statutory requirements that specify inspection under section 704 of the FD&C Act (e.g., section 510(h) or 503B(b) of the FD&C Act).

C. Interaction with Other Programs

(1) Preventive Controls and Sanitary Food Operations (7303.040)

LACF products are subject to the CGMP and PCHF rule (21 CFR part 117). However, subparts C and G do not apply to activities covered by 21 CFR part 113 *Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers*, which is intended to control microorganisms of public health significance (*C. botulinum* and most other microbiological hazards). Hazards that are not controlled by thermal processing requirements in 21 CFR part 113 and that require a preventive control are covered by 21 CFR part 117 subparts C and G (e.g., *Staphylococcus aureus* growth and toxin formation, chemical hazards and physical hazards).

Accomplishment hours for coverage of the CGMP & PCHF rule should be reported under the appropriate PAC (Part II(2)(C)(3) of that Compliance Program).

Report inspections of central distribution warehouses where unlabeled AF or LACF containers ("brites") are shipped for labeling and casing against PAC 03040.

Acidified foods are subject to the CGMP & PCHF rule. Refer to the PCHF Compliance Program for PCHF coverage of acidified foods. Regardless of the size of the operation,

inspectional focus for AF products should be on the regulatory requirements defined under 21 CFR parts 108 and 114.

Consult CP 7304.004A Pesticides & Industrial Chemicals in Food – Domestic & Import concerning pesticides/chemical contaminants and CP 7309.006 Domestic & Import Food Additives and Color Additives concerning food/color additives.

(2) Sampling for Foodborne Biological Hazards and Filth – Domestic and Import Compliance Program (7303.050)

Products labeled "Keep Refrigerated" are exempt from 21 CFR 113/114. These products should be covered under Compliance Program 7303.050.

(3) Comprehensive Animal Food Inspections (7371.000)

Some animal food manufacturers subject to 21 CFR part 507 are also subject to the requirements in 21 CFR part 113 for thermally processed low-acid foods packaged in hermetically sealed containers (LACF requirements). These facilities are exempt under 21 CFR 507.5 (b) from considering microbiological hazards in their hazard analysis; however, they would still have to consider physical and chemical hazards. In addition to the LACF requirements, a full comprehensive animal food inspection shall be conducted in accordance with the Comprehensive Animal Food Inspection Compliance Program. Accomplishment hours for coverage of the CGMP & PCAF rule should be reported under the appropriate PACs.

(4) Seafood Processor, Products and Importer Inspection Program (7303.842)

It is not necessary for a properly registered LACF processor of seafood to address controls for the hazard of *Clostridium botulinum* toxin in their HACCP plans when these are already addressed under LACF. However, the processor's seafood HACCP plan must control other hazards associated with canned seafood that are not eliminated through thermal process or acidification (e.g., the hazard of histamine toxin in canned tuna and other histamine forming species such as mackerel, sprats, anchovies, etc.). Investigators must complete the Seafood HACCP Inspection Report for the HACCP component of canned seafood inspections in addition to other required reports (see CP 7303.842 as appropriate). If the product selected for coverage during the inspection is a seafood LACF product, seafood HACCP coverage is a required component as the product is subject to both regulations. Record both the LACF PAC and the applicable Domestic Seafood PAC as per CP 7303.842 when both types of inspections are conducted.

(5) Medical Foods – Domestic and Import (7321.002)

When conducting inspections of medical foods under this program, CP 7321.002 should also be used as reference. Record the appropriate LACF PAC and 21002 when both types of inspections are conducted.

(6) Infant Formula Program – Inspection, Sample Collection and Examination (7321.006)

In addition to complying with 21 CFR parts 106 and 107, domestic and foreign manufacturers of low-acid and acidified liquid infant formulas must comply with the requirements specified in 21 CFR part 108 Emergency Permit Control, 21 CFR part 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers, and 21 CFR part 114 Acidified Foods as applicable. These regulations address manufacturing, processing, and packing of these products to control microorganisms including *Clostridium botulinum*. When conducting inspections of infant formula under this program, CP 7321.006 should also be used as reference. Use the appropriate LACF/AF PAC and 21006 when both types of inspections are conducted.

(7) NLEA, Nutrient Sample Analysis, and General Food Labeling Requirements – Domestic and Import (7321.005)

Report all resources expended for NLEA under PAC 21005. Thus, labeling issues regarding undeclared ingredients or major food allergens should be reported under PAC 21005 accordingly.

(8) Guidance For Use of pH Meters for Field Exams on Imported Acidified Food (ACF) Products and in Domestic Inspection

Refer to the field exam guide for instructions on conducting appropriate field exams in AF and LACF facilities.

PART III – INSPECTIONAL

1. Domestic and Foreign Operations

See “Part II – Implementation” for “Interactions with Other Programs”.

Firms Not Actively Manufacturing: While efforts are made to schedule inspections during active manufacturing periods, it's important to acknowledge that not all firms may be engaged in production at the time of the visit. In such instances, CSOs should proceed with the inspection as planned, conducting facility walkthroughs, employee interviews, obtaining information about processes and procedures, and covering all possible items detailed in Part III of the Compliance Program. **Additional considerations should be focused on the state of the processing equipment if process authorities conducted validation (heat distribution and heat penetration) studies and whether or not the firm filed the appropriate process for the retort equipment in the facility.**

Understanding of "Process Authority" by Foreign Firms: It has been noted that some foreign firms may not fully grasp the concept of "Process Authority." Determine the Process Authorities credentials as described in the Guide to LACF Inspections, Part 1. If the firm has misinterpreted or misunderstood the term and their Processing Authority is underqualified or misused, document this in your EIR and 483 (if necessary) and diplomatically explain the expected role of a Process Authority. In such cases, thorough documentation of their processes is crucial to show whether or not the firm is controlling for the critical factors identified in their filed processes.

Tomato and Tomato Products: Be aware of firms using some new varieties of tomatoes for processing which could result in tomatoes and tomato products being subject to coverage as low-acid or acidified foods, i.e., tomatoes with natural pH equal to or greater than 4.7 (21 CFR 114.3(d)).

Fermented Foods: Naturally fermented products **are not** considered acidified foods. A naturally fermented product is one which has been salted or held in a brine solution; **and**

- Has been allowed to ferment for one or more weeks in containers; **and**
- The product has reached a pH of 4.6 or below at the end of the fermentation period without the use of any added acid.

  NOTE: Some acids may be added before fermentation to control the fermentation.

The growth of microorganisms and their enzymes in the product are responsible for the biochemical changes that occur during food fermentation, including the lowering of the pH to 4.6 or below. This is often referred to as lactic acid fermentation. Sauerkraut, pickled cucumbers and cauliflower, and certain dill pickles are examples of naturally fermented products.

Foods that purport to be fermented foods are low acid foods if they have a pH after fermentation that is greater than 4.6, are not refrigerated and have a water activity greater than 0.85. If the pH of a food that purports to be a fermented food is below 4.6 only because of

its addition of acid, it is an acidified food and is subject to 21 CFR part 114, unless the water activity is below 0.85 and/or the product is refrigerated.

If a fermented product is subjected to a washing process (to remove the old salt brine), check the pH after the wash. If the pH is above 4.6, it is a low-acid food and must either be refrigerated, acidified, or thermally processed as a low-acid canned food, or given some other process to safely preserve it.

If questions arise as to whether the product is fermented, then it may be necessary to obtain a flow chart or document the flow of the fermentation process, and if necessary, sample the product for water activity and pH. The firm should have pH history at each processing step.

Inspections may encounter facilities in which a product appears to be an acidified food, but the firm has not had the product evaluated by a process authority to make this determination. It is ultimately the firm's responsibility to understand the food safety concerns associated with the manufacturing of their finished products.

Investigators may encounter:

- Instances where the food is easily recognized as an acidified food, (e.g., fresh pack peppers) and failure to register and file has occurred.

- Instances where the status of the food can be determined through contact with CFSAN, Supervisory, Compliance, or ORA experts to be AF or LACF prior to conclusion of the inspection.

- Cases where the status of the food may have to be determined through laboratory analysis or evaluation of the formulation.

In any of the above-mentioned events the firm should be informed that it is their responsibility to determine if the products they manufacture fall under the Acidified or Low-acid Canned Food regulations and file and register accordingly.

Apparent Acidified Foods
If an inspection encounters apparent acidified foods, information regarding the formulation should be collected and provided to CFSAN to make a product determination and to determine whether the small amounts of low-acid ingredient(s) result in a significant pH difference.

The following information should be collected on inspections and forwarded to CFSAN for their evaluation of the food product.

Formulation:
Complete description of the formulation process (how ingredients are processed and formulated together).

NOTE: All ingredients used for the determinations below (Steps 1 and 2) must be the same as those used in the finished product and must be combined in the same quantities or proportions as the finished product.

Provide a list of each ingredient, with the pH and % weight of each ingredient (including water).

Identify which ingredients are acid (i.e., pH value of 4.6 or below); and which are low acid (i.e., pH value above 4.6)

Obtain raw material pH information from the firm, if available, or through sampling and testing with a calibrated pH meter

STEP 1 – Determine the pH of the acid components of the food:

A. Combine all acid ingredients (these are ingredients with a ***pH value of 4.6 or below***) AND
B. Add all water used in the formulation of the product.
C. Determine the pH value of this mixture of these ingredients (acid ingredients and water).
D. Provide the pH of all the acid ingredients and water when combined.

STEP 2 – Determine the impact of the acid components on the pH shift of the finished product:

E. Combine mixture resulting from step 1 above (acid ingredients and water) AND
F. All low acid ingredients (these are ingredients with a ***pH value above 4.6***)
G. Grind or puree any solids into a smooth mixture using a blender or food processor.
H. Measure the pH value of this ground/pureed, smooth mixture (this mixture must have all the ingredients in the same proportion or quantity as the finished product). This value is called the "Maximum Equilibrium pH".
I. Provide the "Maximum Equilibrium pH"

STEP 3 - Submit the information to CFSAN Enforcement Contacts for review to determine if there is a significant difference between the pH of the finished product and the predominant acid(s) or acid food(s).

Alternatively, watch the firm determine the regulatory status of their own products – acidified or acid foods. This includes their quantification of ingredients – both low acid and acid/acid food ingredients to determine if the low acid food ingredients constitute "small amounts" and the pH testing of acid/acid food ingredients and finished product to determine if there is a significant shift in pH. Firms should test a minimum of 6 units of finished product when obtaining information to determine if product is an acidified food.

Laboratory Analysis
Finished products collected to determine pH by an FDA laboratory for the purpose of supporting regulatory action should be collected per IOM Chapter 4, "Sampling Schedule for Low-Acid Canned and Acidified Foods, Sample Schedule Chart 2".

If the investigator is unable to determine with certainty the status of the food product, then in addition to quantitative formulation, samples of all raw materials should be collected along with finished product. Enough raw materials should be collected to allow the formulation to be recreated in the lab, in the same proportion as the commercial product.

A. Inspectional

(1) Plant Registration/Scheduled Thermal Process Filing

Products listed as “exempt” in the LACF Database have been reviewed by CFSAN and found to be exempt from filing. Products in this category do not fall under 21 CFR 113 or 114 and therefore should not be included in inspectional activities under these regulations.

NOTE: Failure to register as a food canning establishment (FCE), failure to have product evaluated by a process authority and/or failure to file scheduled processes are reportable on the FDA-483, Inspectional Observations form.

Appropriate FDA-483 entries regarding failure to register and file include:

- Instances where the food is easily recognized as an acidified food or Low Acid Canned Food, and failure to register and file have occurred.
- Instances where the status of the food can be determined through contact with CFSAN, Supervisory, Compliance or ORA experts to be acidified or LACF prior to the conclusion of the inspection.
- Cases where the status of the food may have to be determined through laboratory analysis or evaluation of the formulation.
- For lack of registration, investigators should site section 21 CFR 108 Subpart B. In addition to other requirements, this section provides authority for establishments that fail to register, file or improperly train personnel.

In any of the above-mentioned events the firm should be informed that it is their responsibility to determine if the products they manufacture fall under the Acidified or Low-acid Canned Food regulations and file and register accordingly.

Utilize either Center Views or FURLS Acidified/Low-Acid Canned Foods Registration Process Filing to:

- Determine whether the manufacturer has registered for a Food Canning Establishment (FCE) number,
- Determine whether a process(es) has been filed and reviewed for the product(s), and/or
- Gain information about firm’s thermal process in preparation for the inspection.

Complete instructions needed to use LACF online are available from the LACF Main Menu. If additional assistance is needed, please contact the LACF Registration Coordinator (LACF@fda.hhs.gov).

- If the FCE number is not available to determine if a manufacturer has registered, go to the LACF database AF/LACF Main Menu, and select **"Search Establishment/Filing/Rep"**. Select **"Search Establishment/Filing"** and select **"Continue"**. The FCE may be searched using any combination of the manufacturer's name, street address, city, state/province, zip code/post code and/or country and selecting **"Submit"**. Firms must register by their actual processing plant name and actual manufacturing location.

    - Each manufacturer using a Shared-Use Facility is required to register and file per 21 CFR 108. The manufacturer will identify their company name on the FDA 2541 under the Establishment Name, the address location of the Shared-Use Facility under the Number and Street, City and State or Province, and under Establishment Contact Information Section, the individual's name who will communicate with FDA along with manufacturer's company information. Under the "Preferred Mailing Address" section of the FDA 2541, identify the manufacturer's contact information for communication to go directly to the manufacturer, and not the owner of the Shared-Use Facility.

- If the manufacturer is registered, the following steps should be followed, as appropriate, to determine if the process has been filed for the product(s), container type(s), and container size(s).

    - **Select "XX SIDs", where XX is the number of SIDs associated with the FCE,** to determine if a process is on file for the product, container type and container size. Search using the FCE and Submission ID (SID).

- If the firm to be inspected has no processes filed or the product of concern is not listed and all the referenced items above have been checked, contact LACFTechnical@fda.hhs.gov. The Database is updated continuously.

- If upon inspection, the firm has relocated, the manufacturer must notify CFSAN of the move and re-register and update file process information for the new location. The Division employee should notify the LACF Registration Coordinator to have the old FCE number put in an out of business status. In addition, if the Divisions find that firms within their Official Establishment Inventory have a change in operational status that would affect their registration, the LACF Coordinator must be notified to update the LACF Database. The appropriate representative should submit an email to LACF@fda.hhs.gov.

- All forms, as well as the instruction book and regulations can be downloaded from CFSAN's Internet at:
  Establishment Registration & Process Filing for Acidified and Low-Acid Canned Foods (LACF) | FDA

- **SID Status in LACF Online**: within the LACF Online system, there are SID flags associated with the different SID Status'.

SID Flag	Comment	SID Status
Not Reviewed	Filing passes "Smart Flow". It was not reviewed by a human.	Filed
Reviewed	Filing reviewed by a human.	Filed
Not Filed	Incomplete paper submission.	Considered **NOT ON FILE** with FDA.
Inquiry	FPET has questions regarding the filing and has contacted the processor.	Filed
Inquiry Response	Filer has responded to FPET questions.	Filed
Cancelled	Filing cancelled by firm.	Considered FILED with FDA for 3 years after the date of cancellation. NOTE: After 3 years, the system will ARCHIVE. Archive Reason becomes System Archive.
Voluntary	Fermented foods or foods with small amounts of low acid ingredients.	Filed
Archived	Under Archive, the Archive Reasons (listed in the next column) for SID Flag of Archive are acceptable.	Product exempt – acid food Product exempt – low water activity. Product exempt – refrigerated/frozen Product exempt - USDA

- Security of Information Provided in the Low-Acid Canned Food On-Line Computer System

  Due to the confidential information contained in the LACF Process File, special precautions must be taken to ensure security of the data generated from the system. The process filing PDF documents generated from this system must be handled with discretion, secured when not in use and destroyed in an appropriate manner when no longer needed, i.e.:

  - Only FDA employees and the firm being inspected can view their facsimiles and reports.

  - These reports may not be copied, except to be provided to the inspected firm, if requested, during the inspection. Follow FDA's regulations and procedures regarding information disclosure when considering whether to disclose the information to a person outside FDA.

- These reports may be placed in the Official Establishment Inventory jacket, in the section that is identified "not for public information or distribution" if they are to remain as part of the official file.

- Reports generated in error or are no longer used by the Division **must be destroyed**.

(2) Inspections

To perform inspections under this program, Investigators must successfully complete the basic AF course to perform AF inspections, the basic LACF course to perform LACF inspections and the Aseptic Processing course to perform LACF Aseptic inspections.

The investigator must be prepared during inspections of AF and LACF manufacturers to determine the firm's compliance with the AF regulations, 21 CFR part 114; the LACF regulations, 21 CFR part 113; Emergency Permit Control, 21 CFR part 108; and Preventive Controls and food CGMPs, 21 CFR part 117. If inspecting an animal food LACF facility, the investigator must also be prepared to cover the Preventive Control for Animal Food regulation, 21 CFR part 507.

Investigators should note that events such as confirmed botulism cases, Class I Recalls and serious investigational findings have raised concerns about the safety of LACF products and the state of control in the industry. At one firm, defective containers (swollen, buckled, and exploding cans) were routinely disposed of, or put on hold, without a determination of the severity or cause of the problem. In one case, problems were related in part to economic pressure from a new parent corporation to "cut corners", resulting in poor equipment maintenance, poor labor- management relations, and complacency.

These findings have led to a reassessment of inspectional methods and focus during inspections of AF and LACF manufacturers. In the past a large part of the inspection focused on record review. The recent inspections have shown that in many cases records covering processing, can seam integrity and other operations, may not reveal problems that exist. An expanded, multiple angle inspectional method is more likely to reveal problems and deviations that exist at a firm.

This updated program stresses among other issues the following:

- The need to perform field exams, review of process deviation files and QC hold logs early in the inspection to identify possible problems and;

- Investigation into whether equipment malfunctions, process deviations, or lack of an assessment of changes made to equipment, product and processes may have adversely affected the process/product safety.

Objectives of the Acidified Foods Inspection

- To determine if the firm is adhering to the filed scheduled process.

- To assure that the firm's Process Authority has established a scheduled process identifying critical factors related to the acidification and thermal processing of acidified foods.

  NOTE: Thermal processing operations may include but are not limited to operations such as boiling water baths, hot fill hold, cold fill hold, vat pasteurization, and tunnel pasteurization.

- To review formulation/filling method changes and any corresponding evaluation records.

- To observe the acidified food processing operations and to look for possible under-processing, improper acidification procedures and equipment malfunctions.

- To evaluate how the firm ensures that the container suitably protects the contents from recontamination and review any container integrity testing that is performed.

- To conduct field exams of warehouse products and sample collections of suspect products.

- To determine how the firm identifies, handles, and assesses spoiled product/abnormal cans, including finished product in storage.

- To determine how the firm's process authority reviews any deviations where critical factors are not met or achieved.

Objectives of the LACF inspection include:

- To determine if the firm is adhering to the filed scheduled process.

- To assure that the firm's Process Authority has had an active role in temperature distribution and heat penetration studies, and deviation evaluation.

- To observe the retort processing line while in operation and to look for possible malfunctions.

- To review maintenance records (for each system) for changes to equipment or process, and any corresponding evaluation records (i.e., temperature distribution studies).

- To review formulation/filling method changes and any corresponding evaluation records.

- To evaluate the firm's container integrity testing procedures, container integrity records and the seam/seal integrity of the containers themselves.

- To review the firm's water quality and cooling water sanitation procedures/documentation.

- To conduct field exams of warehouse products and sample collections of suspect products.

- To determine how the firm identifies, handles, and assesses spoiled product/abnormal cans, including finished product in storage.

During these inspections it is important to focus on the occurrence of unusual events that may have affected the delivery of the process or introduced post-process contamination. They may include potential for the filler to overfill cans; risk of incipient spoilage if the line is down for several hours; reduction of the product's internal temperature; increased risk of can damage during jams; and overcooling can cause seams to remain wet and increase the risk of leaker spoilage. In cases where process deviations result in "still cooks" of a lot in a continuous agitating retort, unprocessed cans in the in-feed track should be properly accounted for and reprocessed or destroyed. The disposition of these unprocessed cans should be documented. Because a firm may file numerous alternate processes, not all unusual events may be documented in a deviation file. QC hold logs may also identify unusual occurrences.

Objectives of the Aseptic LACF inspection include:

- To determine if the firm is adhering to the filed scheduled process and Supplementary Submission (SUP-SID).

- To ensure that the firm has established conditions for achieving commercial sterility of the aseptic processing system and all product contact surfaces downstream of the hold tube. These conditions could include clean in place (CIP) or sterilize in place (SIP) studies.

- To ensure that the firm's Process Authority has conducted aseptic processor sterilization studies, tank temperature distribution and / or aseptic container sterilization studies and is actively involved in deviation evaluation.

- To review any CIP studies to ensure that the products assessed are applicable and relevant to current products manufactured by the firm in order to achieve a condition of commercial sterility in the aseptic processing system.

- To review formulation changes that may have an impact on product flow characteristics and any corresponding evaluation records.

- To observe the aseptic processing, aseptic storage tanks and aseptic fillers while in operation and to look for possible malfunctions.

- To review and assess aseptic processing operations and records against critical factors in the SID and Supplemental SID.

- To review maintenance records and change control documents to ensure that any changes to the aseptic product or processing equipment or process were reviewed by a processing authority.

- To evaluate the firm's container integrity testing procedures and records related to the integrity of the containers.

- To conduct field exams of warehouse products and sample collections of suspect products.

- To determine how the firm identifies, handles, and assesses spoiled product/abnormal containers, including finished product in storage.

Inspectional Considerations:

It is important to be fully prepared before initiating the inspection, to use critical thinking skills and be flexible and open-minded in your approach. A team approach should be considered for these inspections, dividing the workload into process evaluation and field exam/sampling duties. Lead CSOs should be experienced investigators who routinely conduct LACF inspections, and have attended the FDA AF, LACF or Aseptic LACF training course where specific concepts such as retort design, vent size/configuration and drain location or aseptic processing operations are covered. When necessary and feasible, an experienced Lab Analyst should also be included on a team inspection to evaluate the firms can seam teardown and evaluation procedures. Investigators should also familiarize themselves with the potential safety hazards and special safety situations of inspecting a retort (IOM S.12.5 Thermal Processing/Retorts).

Inspections should occur when the firm is operating (which may require some advance planning) and should include observations of retort processing lines while in operation, to look for possible malfunctions. (This may involve the inspection team **being at the firm for early or late shifts and overtime**.)

Inspections should be thorough and include use of reporting forms 3511. The forms have been updated to capture critical information during the inspection that is essential to determining an establishment's state of control. Investigators should continue to document relevant details in the EIR and on the appropriate forms. **NOTE: FDA-3511 forms were created to ensure inspectional coverage of different LACF processing systems. Use the appropriate Retort Reporting Form (FDA Forms 3511a-j) as a guide to the conduct of the inspection.**

Report all AF and LACF inspections using the following forms, as appropriate. The Forms are available on ORA's forms site. The forms are in PDF format and can be electronically completed after downloading. The report forms are as follows:

- FDA Form 3511 a-j LACF Retort Reporting Forms - see below, as appropriate
- FDA Form 3511-2 Acidified Food Inspection Report
- FDA Form 3511-3 Aseptic Food Inspection Report

LACF Retort Specific Reporting Forms:

- 3511a Processing in Steam in Still Retorts
- 3511a-1 Processing in Steam in Crateless Retorts
- 3511b Processing in Water in Still Retorts
- 3511c Processing in Steam in Continuous Agitating Retorts
- 3511d Processing in Steam in Discontinuous Agitating Retorts
- 3511e Processing in Water in Discontinuous Agitating Retorts
- 3511f Processing in Steam in Hydrostatic Retorts
- 3511g Processing in Cascading/Spray Water Retort
- 3511h Processing in Steam-Air Retorts
- 3511i Processing in Other Unique Retort Systems
- 3511j Processing Formulation Controlled Products

(a) Inspection Preparation

- Determine firm status: e.g., initial, routine, compliance follow-up, etc. Contact appropriate individuals as required prior to the inspection for guidance e.g., compliance officer, other investigators, national and program experts via district management as needed.

- Review previous inspection reports.

- Review references such as “Guide to Inspection of…” as listed below in the “Reference” section.

- Obtain equipment and all required forms (482, 482a, 482b, 3511s, etc.).

- Investigators should choose a product and production line that represents one of the most difficult to control.

(b) Inspectional Approach

At the on-set of the inspection look for unusual events and defective products:

- Review deviation files and QC hold logs

- Visually examine the firm’s warehouse stock

- Examine QC hold areas, determine why lots are on hold and document lot numbers. These areas may also be called “distressed goods”, “morgue”, “quarantine”, etc.

- Examine product for signs of leaking, swollen, and damaged containers or containers with any abnormalities.

- Examine off-site storage areas concurrent with other areas if more than one FDA Investigator is on-site.

- Determine if lots are on hold and why.

(c) Field Exams

Field examination of warehouse stock is stressed. Any of these issues would prompt field exams:

- Visual observation of warehoused product that shows a significant number of abnormal containers (greater than 1%) where the firm has not conducted a spoilage diagnosis to determine the cause of the spoilage and if the lot is safe for distribution.

- Record review and/or observation of processing equipment and unexpected events such as excessive delays resulting from frequent stoppages in the production line that could cause or contribute to incipient spoilage and under-processing.

- Inadequate maintenance of seaming equipment combined with evidence of loose seams and poor-quality cooling water.

- Products which have had changes in formulation/fill, with no evaluation of scheduled process by a Process Authority.

- Product manufactured on equipment which has been modified or received maintenance (changing functional parameters) with no subsequent temperature distribution studies by a Process Authority.

- "Not for Cause" flat can sampling of green beans, peas, and beets should be discussed with CFSAN Enforcement Contact, prior to initiation.

NOTE: If any observations noted during review of the maintenance records have the potential to affect the proper processing of products on the retort line, the investigator must conduct a field examination of two production lots immediately prior to the maintenance and two production lots immediately after the maintenance, based on availability of products in storage at the facility.

If your findings indicate abnormal product may have been distributed contact the CFSAN Enforcement Contact to determine if the observations noted warrant additional field examination to be performed at consignees.

NOTE: For detailed information on Field Exams refer to the guidance document "Requests for Additional pH Meters and Updated Guidance for Their Use" and the Investigations Operations Manual (IOM) Chapter 4, Sample Chart 2, **"**SAMPLING SCHEDULE FOR CANNED AND ACIDIFIED FOODS"**.**

(d) Scheduled Process

- Determine the Process Authority's credentials (knowledge, training, and experience, etc.).

- Determine if the Process Authority is actively involved in conducting temperature distribution studies, heat penetration studies and evaluating process deviations.

- Determine if product or process changes have occurred since the most recent inspection and if so, determine whether the Process Authority has evaluated the scheduled process in relationship to these changes.

- Focus inspectional activities on any major changes that have been made to the process or product. Major changes include:

  - Change in product formulation
  - Change in ingredient specification
  - Ingredient substitutions
  - Change in product form or cut
  - Change in processing and filler equipment
  - Change in blending procedure
  - Change in processing methods (e.g., still to agitating, etc.)
  - Change in container types (e.g., metal to semi-rigid, traditional can to self-heating can, etc.
  - Addition of new product lines, etc.

- If the scheduled process(es) have changed, Investigators should determine if the changes were reviewed by the firm's Process Authority. Investigators should determine whether old processes have been canceled and new processes filed. Describe and document full extent of changes using the appropriate FDA Form 3511.

(e) Delivery of the Scheduled Process

Determine if the retorts, retort control systems, container filling and handling equipment, and venting conditions have remained the same since the last inspection.

- If the retort system and/or other critical equipment have changed significantly, describe, and document the full extent of changes using the appropriate Retort Reporting Form (FDA Forms 3511a-j) as necessary.

- If significant deviations (e.g., broken Mercury in Glass (MIG), etc.) are noted during the visual inspection, describe and document full extent of deviations using appropriate Retort Reporting Form (FDA Forms 3511a-j) as necessary.

- Changes in equipment could change processing parameters and the associated scheduled process requiring review by the Process Authority.

(f) Documentation of Process Delivery

- Determine that records to document delivery of the scheduled process and control of critical factors are being created and maintained.

- Conduct a random audit of the records to determine that the scheduled process is being delivered and that critical factors are under control.

- If an audit reveals deviations from the scheduled process or lack of control of critical factors, audit the separate process deviation log or file. If the deviation log or file indicates improper handling of deviations, describe and document firm's failure to comply in complete detail using the appropriate FDA Form 3511 (a – j).

(g) Process Controls and Concerns

The following are some process concerns which may not be evident by normal record review but have proved to be problematic during past inspections. Be sure to focus on the occurrence of unusual events that may affect processing.

- Failure to contact Process Authority when a change warrants notification which may result in changes to processing parameters

- Failure to recognize and correct process deviations

- Inadequate corrective steps taken to address deviations

- Inadequate delivery of scheduled process

- Overfilling of containers

- Risk of incipient spoilage due to processing delays

- Reduction of products internal temperature

- Container damage

- Overcooling

- Loose can seams

- Inadequate container closure

- Inadequate vacuum

- Low initial temperatures

- Low brine fill temperatures

- Excessive headspace
- Product codes not synchronized with the retort time clock, missing or not complete
- Timing delays
- Inadequate equilibrium pH

(h) Container Integrity

- Document whether or not the firm is conducting appropriate visual and destructive tests to assess if the container seaming operation is adequate.
- Interview employees that evaluate or inspect seams and/or closures of AF and LACF products. Determine if these employees have had adequate training.
- Audit container examination records to ensure container seams or seals are within specifications.
- Audit container handling equipment and procedures (tracks, conveyors, crates, etc.) to ensure the container closing operation is not compromised.
- Determine how the firm handles, investigates and documents abnormal containers.
- Is finished product exposed to elevated temperatures during storage or shipment that could cause thermophilic growth and spoilage?
- Determine if the firm's containers are protected from post processing contamination.
- Determine if container closures are examined and if results are recorded.

(i) Water Supply

- Recent inspections have shown container cooling water sanitation to be a problematic area. Below are areas to examine.
  - Determine the source of the firm's water supply.
  - If non-municipal, examine well design, maintenance and records.
  - If pre-treated, determine by what method.
  - Determine if the water is disinfected, the method used and how it is monitored.
  - Determine water analysis and the frequency conducted.
  - Determine if the water used is re-circulating or single pass.

- Free chlorine kills bacterial cells and spores more rapidly as the pH decreases from pH 7.0. Above pH 7.0, the antimicrobial effect diminishes rapidly. Plant cooling water should have a pH between 6.5 and 8.5. Below pH 6.5, the water is highly corrosive and may degrade equipment; above pH 8.5, the antimicrobial effect is negligible.

- Chlorine and chlorine compounds are the most commonly used water sanitizers. Other sanitizers such as bromine may be used and sometimes in combination with chlorine. Determine how the firm provides for a measurable residual of sanitizer and frequency of residual sanitizer testing on container cooling water.

    - Container cooling water should be breakpoint chlorinated such that there is a measurable amount of free chlorine, ideally 2-7 ppm.

    - Determine if there are problems that would lead to the water being contaminated.

    - Municipal water can vary greatly in microbiological quality. The most common source of water system contamination is due to line breaks with infiltration of soil bacteria. Check points in the distribution system farthest from the treatment plant.

      NOTE: If the quality of the firm's containers and the source cooling water quality are suspect, contamination may be introduced in the container during cooling. In such cases be prepared to trace water lines and collect water samples. Samples must be collected aseptically and analyzed within 24 hours of collections. See IOM Chapter 4 for instructions on collecting water samples and sodium thiosulfate usage.

      For more information regarding inspectional coverage of water supply in AF and LACF see "Reference" section below.

(j) Equipment

A thorough review of the firm's equipment condition, maintenance and related documents should be performed.

- Determine when the last major overhaul or maintenance was performed on firm equipment.

- Determine if the firm conducts a retort survey after a major overhaul or after maintenance is performed on critical equipment which helps ensure compliance with the regulations.

- Determine how often temperature distribution studies are conducted on retorts, who evaluates the data, what procedures are used, and if there is documentation such as a retort diagram and parameters used to validate the test.

- Does the Process Authority conduct heat distribution tests on one or all retorts?

- Determine if the boiler(s) supply sufficient steam to the retorts and if the header pipe supplies steam to the retorts especially when more than one retort is being vented simultaneously.

- Determine if the Process Authority is advised when additions/revisions to the retort or boiler configuration occur. Determine if contact with the Process Authority has been documented.

- Review maintenance records to determine if the equipment is adequate to ensure that the scheduled process is delivered. Focus on maintenance of equipment used to measure critical factors such as scales, thermometers, gauges, and consistency meters or devices; replacement of equipment found to be out of specifications; and modification of any equipment critical to controlling time/temperature parameters of the firm's scheduled process.

- Determine if proper calibration procedures are used to assure the accuracy of MIGs used on retorts.

- Determine if the firm's thermometers are accurate (dial or MIG).

- Determine if the firm has pH meters and if they are used properly.

- Determine what type of changes have been made since the temperature/heat distribution study was last done. Many small plumbing changes can have an overall significant cumulative impact on the process delivery.

(k) General

- Determine if appropriate plant personnel have been to a Better Process Control School (BPCS).

- Document whether or not the firm has a recall plan on file.

- Complete a review of the firm's consumer complaint file. Focus on reports of spoilage, swollen containers, inadequate pH, etc., frequency of such reports and action taken if any.

(3) References

For more information on the inspection of acidified food and low-acid canned foods refer to 21 CFR Parts 108, 113, 114.

FORMS

- Form FDA 482a – Written Demand for Records. Refer to the FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 1 – Administrative Procedures/ Scheduled Processes, for specific guidance of use.

- Form FDA 482b – Written Request for Information. Refer to the FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 1 – Administrative Procedures/ Scheduled Processes, for specific guidance of use.

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 1- Administrative Procedures/Scheduled Processes

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 2 - Process/Procedures

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 3 – Containers/Closures

- PCHF DRAFT GUIDANCE FOR INDUSTRY, CHAPTER 16: ACIDIFIED FOODS

- FDA GUIDE TO THE INSPECTION OF ASEPTIC PROCESSING AND PACKAGING FOR THE FOOD INDUSTRY

- FDA GUIDE TO THE INSPECTIONS OF COMPUTERIZED SYSTEMS IN THE FOOD PROCESSING INDUSTRY

- Better Processing Schools Manual; contact CFSAN Technical Expert.

- Various Publications available from the Consumer Brands Association which, if not available in your division, can be purchased:
  - AOAC Classification of Can Defect Poster
  - NFPA Bulletins 26-L & 30L (Thermal Processes-Low Acid in Metal Containers).
  - NFPA Bulletin # 43-L Validated Guidelines for Automated Control

- "Requests for Additional pH Meters and Updated Guidance for Their Use DFI Memorandum issued 12/5/08"

- Low Acid Canned Foods Webinar, May 2008: *Please request through OTED because this document is no longer posted on the intranet.*

OTED Classroom Training

- Conducting Acidified Food Inspections, FD202
- Conducting Low Acid Canned Food Inspections - FD304
- Aseptic Processing and Fill, FD405
- Canned Seam Analysis, LB221

OTED On-Line Courses

- FD6040 - Food Microbiological Control 7A: Control by Thermal Processing (MIC08)
- FD6042 - Food Microbiological Control 7C: Control by Retorting (MIC10)

(4) Computer Controls

When retorting systems use microprocessors or computers to generate records of processing and/or to control thermal critical factors, collect the following data and information on the systems:

- Information on equipment specifications (software and hardware),
- What critical factor(s) are controlled and recorded
- How critical factor(s) are controlled and recorded,
- How the firm ensures that the microprocessor or computer are indicating the correct information,
- How often the equipment is calibrated and/or checked for accuracy.

(5) Contract Packers

Be aware of the firm's use of a contract or off-site packaging operation (e.g., shrink wrap sleeves). Container damage in the form of container "slits, splits, holes, punctures" may occur to the containers during handling at these packers. This type of damage can occur as the result of opening "master" container cartons with sharp case knives rather than using case paddles. Two (2) piece "light metal cans" (e.g., thin gauge tin/steel; or aluminum are more susceptible to this type of container damage than sturdier metals.

Divisions may perform can examinations of the product manipulated by the identified contract or off-site packager using IOM, Chapter 4, Sample Schedule Chart 2, "Sampling Schedule for Low-Acid Canned and Acidified Foods" to determine the number of cans to examine in a lot.

B. Domestic Sampling

IOM, Chapter 4, Sample Schedule Chart 2, "Sampling Schedule for Low-Acid Canned and Acidified Foods" lists sampling instructions. Routinely examine warehouse stock for evidence of abnormal containers. Follow Special Sample Handling instructions for abnormal container collections in IOM referenced above.

If abnormal containers are found, the Investigator **must** report lot size, number of containers examined, and number of abnormal containers found by the type (e.g., hard swells, etc.). Estimate the percentage of abnormal containers in the lot. These abnormalities should be recorded on form FDA 483 per IOM, Chapter 5, Establishment Inspection, Reportable Observations.

(1) LACF Products: If under-processing or critical container integrity problems are found or suspected, conduct warehouse examinations of suspect codes. If both thermal processing deviations and container integrity problems exist, give priority to examining lots involving thermal processing deviations. Collect examples of all types of abnormal containers and all critical container defects along with a control.

For products preserved through control of water activity (a_w) or salt, collect an additional six normal containers from suspect codes when record review or inspectional evidence indicates a failure to adequately control a_w or salt. Examples of a_w or salt-controlled foods are bean paste, salted fish or vegetables, some oriental sauces and Lupini beans.

(2) Acidified Products: If evidence indicates failure to adequately control pH, collect samples of suspect codes for pH determination per IOM Sample Schedule Chart 2, "Sampling Schedule for Low-Acid Canned and Acidified Foods". For containers larger than 795 grams (e.g., 28 ounces) net weight, use the sample size for #10 cans. (603 x 700 size cans). For all others, use the sample size for #2 1/2 cans. If there is any doubt whether the product is acidified, collect information as per “Determination of Acidified Food” (page 12).

In addition, if the firm appears to have deviations from its scheduled process, which could result in pH levels above 4.6, collect samples from several suspect lots. (See Part V – Regulatory/Administrative Strategy if high pH is found).

(3) LACF and Acidified Products: If problems are suspected, but no abnormal containers are found and there is no evidence/history of spoilage or evidence/history damaged containers do not collect flat containers for analysis.

C. Domestic Investigations of Imported Goods

Imported products cross all program areas and our regulation of them does not stop at the border. Please be alerted to imported products whenever you are conducting an inspection. During inspections of domestic firms, if you encounter counterfeit imported products, returned imported products, rejected imported products, or otherwise suspect an imported product should not have been allowed to enter the country, take some time to investigate the source of the imported products. Determine the Customs entry number, port of entry, and /or the importer if possible. Obtain copies of the entry paperwork, and through Supervisory channels, notify ORA/OIO/Division of Import Operations (DIO) immediately. It is possible that other domestic firms have imported the same product and DIO can determine the nationwide scope of the problem. In addition, it is critical to determine the complete name and address of the foreign supplier or at a minimum the importer or consignee of record for dissemination to DIO. (Reference: IOM Chapter 6, Imports)

D. Better Process Control Schools

The Better Process Control School (BPCS) program is a cooperative training program between FDA, the Consumer Brands Association (CBA) and the universities that have been approved by the Commissioner for giving BPCS instruction. FDA participants should be experienced AF/LACF investigators and familiar with the AF and LACF regulations. FDA

participants are expected to be in attendance and available throughout the BPCS. From the beginning FDA has been responsible for providing an FDA participant to:

- Present an introduction that generally focuses on:
  - The importance of the course, and
  - Highlights of the regulations.
- Answer questions
- Provide support to the university manager and instructors.
- When necessary, provide some of the information necessary for FDA to determine approval of a new university that proposes to begin offering the BPCS training program.
- Provide feedback to CFSAN in the form of a written report:
  - The kinds of questions that arise,
  - New information that might arise from class discussion,
  - Any unanticipated problems.

2. Import Operations

Import activities may include examination and/or sample collection to verify imported LACF/AF products meet FDA regulatory requirements. In the absence of specific instructions outlined in an assignment or other directive, use the information below. Detailed descriptions for reporting these activities are in Part III, Item 3B, Imports Reporting.

A. Summary of Admissibility Requirements:

Verify the following requirements at the time of import in accordance with 21 CFR parts 108, 113 & 114:

- foreign canning establishment (FCE) registration
- process filing (SID)

(1) Import Entry Review

Conduct entry review in accordance with IOM section 6.2 Entry Review and the Summary of Admissibility Requirements section above.

FDA import systems will cross reference any Affirmations of Compliance (AofC) transmitted with the entry, including the FCE and the SID, with information contained in the LACF/AF database.

If AofCs are not transmitted or the import system cannot verify the AofCs, proceed as follows:

(a) Determine whether the product is LACF or an AF. Definitions for low-acid foods and acidified foods are found in 21 CFR 113.3 and 21 CFR 114.3, respectively. Attachment A lists common product codes that indicate a product may be an LACF or AF (not all-inclusive). If unable to determine whether the product is LACF or AF solely with information transmitted electronically, request entry documents (DRQ).

(b) For products that appear to be LACF/AF foods, determine if the product meets LACF/AF admissibility requirements (listed above) or are exempt from LACF / AF regulations.

- If FCE and SID are transmitted and the entry/line failed the system lookup, determine reason for failure and verify manually. Utilize the LACF/AF option under the CFSAN tab within Center Views (CV).

(c) Manual Check for a valid FCE.

- If the firm is in CV and the address transmitted matches the address on file, proceed to (d) to verify the SID.
- If the firm is in CV but the address transmitted does not match the address on file, verify the address with the broker or importer.
- If the address cannot be verified or the addresses are confirmed to not match, recommend the entry/line for detention (DTR).

(d) Verify the SID. Compare the transmitted information with the container dimensions, product name and filing status within CV. If deviations exist, conduct a field examination (as resources permit), or recommended the entry/line for detention (DTR).

- Transmitted container dimensions must not deviate by 2/16 inch or more in any dimension from those indicated on the file (for glass containers allow 3/16 or more).
- Product name should be the product name on file. Contact the LACF coordinator with questions on product names.
- Valid filing statuses are “not reviewed”, “reviewed”, “inquiry”, or “inquiry response”.

(2) Import Examinations

(a) Examinations should be conducted in accordance with IOM 6.3 Field Examination and IOM Chapter 4, Sample Schedule Chart 2.

A "lot" should consist of one product and one production code. If codes are commingled to the extent that sorting is impractical, consider the entry/line as one lot for the purpose of the field examination and put the onus back on the importer to clarify the product(s) and lot(s) in the entry.

(3) Import Sample Collection

Samples should be collected for cause (e.g., due to a class 3 field exam, inability to determine the product is an LACF/AF, or other directive).

(a) Abnormal containers: collect in accordance with IOM 6.4 Import Sample Collection and IOM Chapter 4, Sample Schedule Chart 2.

(b) LACF and Acidified Products: Unless directed by assignment or screening, do not collect flat (i.e., normal) containers for analysis. Please document reason for collection, in the “Reason for Collection” field on the Collection Report.

(c) Finished products collected to determine pH for the purpose of supporting regulatory action should be collected per IOM Chapter 4, Sample Schedule Chart 2, "Sampling Schedule for Low-Acid Canned and Acidified Foods".

(d) Any product that appears to be an AF, with a pH greater than 4.6, should be treated as an LACF and sampled for pH to confirm the product pH is not higher than the maximum value specified in the SID.

i. For questions on whether a product is LACF or AF, contact DELACFandAFProducts@fda.hhs.gov

- include any evidence (e.g., shipping documents, labels and other information) to identify the actual manufacturer, actual name of the product, and processing information. If CFSAN is unable to determine if product is LACF or AF, CFSAN may request a sample (SAM/ACD) for pH, water activity, and water phase salt or soluble solids. To determine a product's status, collect the appropriate number of subsamples according to the IOM requirements based on container and lot size.
- If a shipment contains numerous questionable products (unclear whether many products are AF or LACF), contact CFSAN/Division of Enforcement/Imports Branch/HFS-606 to arrange for a review of the invoice and guidance on product status and/or appropriate sample collection and analyses to determine product status.
    - If a determination cannot be made based upon the shipping records and labels, please contact CFSAN/Office of Food Safety/ Food Processing Evaluation Team, LACFtechnical@fda.hhs.gov[1].

ii. When a sample is collected for water activity, utilize the FURLS option under the CFSAN tab within CV to assess whether a process was filed or the maximum water activity value filed. Include this information in the collection report as the reason for analyses (e.g., "analyze to determine if LACF" or if known to be LACF: "confirm compliance with a filed maximum water activity value").

NOTE: Submit all samples as directed in Part IV, Item I, Analytical Laboratories.

3. Reporting

A. Domestic Reporting

(1) Field Exams

Report warehouse stock examinations conducted during inspections as part of the inspection not as a "Field Exam".

[1] LACF@fda.hhs.gov should not be contacted, except in unusual circumstances, since the LACF database is updated continuously.

Report as a “Field Exam", only if examination of suspected lots was conducted **at consignees** and no samples were collected.

Use the following PACs for specific operations:

PAC	Description
03070A	Domestic Acidified Food (AF) Products
03070B	Domestic Low-Acid Canned Food (LACF) Products
03070C	Domestic Aseptic Low-Acid Food (LACF) Products
03040	Field exams at central distribution warehouses where unlabeled cans are shipped for labeling & casing; and f/u inspections of LACF/AF products for filth only
71070	Domestic and Import Low Acid Canned Food (LACF) Animal Food Products

(2) Better Process Control Schools

Report resources expended by FDA personnel under Operations Code 83.

(3) Establishment Inspection Report (EIR)

EIRs for both domestic and foreign inspections should be reported in eNSpect.

- For EIRs sent to CFSAN for review, include the information identified in PART III, A(5), Computer Controls, for review of retorting systems using microprocessors or computers to control and generate records of thermal processing or critical factors.
- For LACF inspections, fully report any of the following technologies:
  - Aseptically processed and packaged LACF products containing particulate food, e.g., clam chowder, chunky soups or stews, etc.
  - Sterilization of aseptic packaging materials using media other than superheated steam or hydrogen peroxide.
- Fully detail any new canning technology being inspected for the first time.

(4) Domestic Sample Collections

Report all domestic sample collections in the Field Accomplishment and Compliance Tracking System (FACTS). Utilize the following PAC/PAF combinations:

PAC	PAC Description	PAF	PAF Description
03070A	Domestic Acidified Food (AF) Products	ACD	Low-Acid/Acidified Canned Foods
03070B	Domestic Low-Acid Canned Food (LACF) Products	ACD	Low-Acid/Acidified Canned Foods

PAC	PAC Description	PAF	PAF Description
03070C	Domestic Aseptic Low-Acid Canned Food (LACF) Products	ACD	Low-Acid/Acidified Canned Foods
71070	Domestic & Import Low-Acid Canned Food (LACF) Animal Food Products	ACD	Low-Acid/Acidified Canned Foods
Varies	**NOTE**: Samples collected explicitly for C. botulinum analysis should be for-cause only and appropriately assigned PACs should be used, as applicable (e.g. consumer complaint, outbreak or illness related).	MIC	Microbiological Analysis

NOTE: Please always specify the analyses being requested on the Collection Report when known.

B. Imports Reporting

(1) Products Released Without Field Examination or Sample Collection.

Report time spent determining that a product meets registration and filing requirements, including measuring containers, as “Entry Review” and ensure that the appropriate PAC is used (e.g. 03070F for Import LACF or 03070G for Import AF).

(2) LACF/AF or Samples Collected for Abnormal Containers

Report the total number of containers examined and estimate the percentage of abnormal in the lot.

Report the number of each type of abnormal (hard swell, etc., refer to IOM Chapter 4, Sample Schedule Chart 2, “Sampling Schedule for Low-Acid Canned and Acidified Foods”), or defective containers observed (leaker, seam defects or other abnormalities).

(a) Report all import sample collections and field examinations in the appropriate import system.

Part IV – ANALYTICAL

1. Analyzing Laboratories

NOTE: Please always specify the analyses being requested on the Collection Report when known.

ORA ORS OHAFLO applies a sample triage strategy for AF and LACF related collections and specifically with requests for *Clostridium botulinum* analysis. Consult the ORA LST Dashboard for laboratory capacity and capability with the following caveats:

A. Routine Compliance or Surveillance sample collections, sample collections **NOT related to a *Clostridium botulinum* illness investigation** (low priority, i.e., routine "canned food" analysis such as pH, water activity, progressive decomposition and/or product cultural analysis, container integrity)

(1) Normal containers – Send to any lab on the ORA LST Dashboard (PAF ACD)

(2) Abnormal containers OR when metal container integrity analysis is also being requested – Send only to labs NOT designated as "Normal cans only" on the ORA LST Dashboard (PAF ACD)

(3) When cultural ***Clostridium botulinum* analysis is requested** – Send to any lab on the ORA LST Dashboard with capacity (PAF MIC)

NOTE: PAF ACD cultural analysis can recover *Clostridium botulinum* or spoilage microorganisms, if present, from both normal or abnormal containers of AF & LACF product and should be the default (PAF) assignment selection for most low priority sample collections when cultural "micro" analysis is requested. PAF MIC should be reserved for for-cause *C. bot* collections when pathogen specific analysis is requested.

B. Sample collections **related to a *Clostridium botulinum* investigation, but not directly linked to the patient** (medium priority, i.e., similar product but not the same lot consumed by patient, not usually associated with *C. bot* related illness)

- **Normal and abnormal containers when only cultural *Clostridium botulinum* analysis is requested** – Send to any lab on the ORA LST Dashboard (PAF MIC)
- **If pre-formed toxin testing is being requested in addition to cultural *Clostridium botulinum* analysis** – Send to Arkansas Human and Animal Food Laboratory (ARLHAF via PAF MIC)
- **If metal container integrity analysis is requested in addition to *Clostridium botulinum* analysis** – Send only to labs NOT designated as "Normal cans only"

NOTE: Pre-formed toxin testing requires advanced resource planning and is generally to be avoided for medium priority samples. If desired, contact both ARLHAF

ORAORSHAFARKLMicroSupesTeamLeaders@fda.hhs.gov and ORA ORS OHAFLO IO oraorsoffloiomicro@fda.hhs.gov in advance of collection to help facilitate resource planning.

Sample collections directly related to a confirmed case of botulism are classified as high priority, especially if they involve items consumed by the patient, are associated with a previous *Clostridium botulinum* illness, or suggest potential intentional contamination. If a medical professional strongly suspects that the illness is due to *C. botulinum* and we have samples directly linked to the patient, these samples should be sent immediately to Arkansas Human and Animal Food Laboratory (ARLHAF via PAF MIC) labs for analysis. This prompt action is essential, as even a single case of foodborne botulism is considered a public health emergency, and timely testing can facilitate accurate diagnosis, effective treatment, and the prevention of further outbreaks.

NOTE: Because of the high priority nature of these samples, contact both ARLHAF ORAORSHAFARKLMicroSupesTeamLeaders@fda.hhs.gov and ORA ORS OHAFLO IO oraorsoffloiomicro@fda.hhs.gov in advance of collection to help facilitate resource planning.

CFSAN Laboratory Confirmation when original ORA ORS analytical results are inconclusive and or as necessary or requested for *Clostridium botulinum* toxin confirmation:

CFSAN/Office of Regulatory Science,
Division of Microbiology,
Molecular Methods & Development Branch, HFS-711,
Attention: Shashi Sharma,
5001 Campus Drive,
College Park, MD 20740-3835

Chemical Contaminants and Food Additives are covered under CP 7309.006, Domestic and Import Food Additives and Color Additives, NOT under the AF/LACF program.

Filth and Extraneous Matter are covered under CP 7303.050, Sampling for Foodborne Biological Hazards, and Filth – Domestic and Import, NOT under the AF/LACF program.

2. Analyses to be Conducted

A. General Information

Upon sample receipt in the laboratory, the lab will review the collection report and any other documentation submitted with the sample to determine the required analyses. The product's filed process may help determine the appropriate course for analysis.

Where the product status is in doubt (i.e., AF or LACF) it may be necessary to determine a_w and pH to classify the product.

Products with a_w values at or below 0.85 are **neither** LACF nor Acidified Food.
When it is necessary to establish the pH as well as a_w, follow instructions below under "3", – Acidified Foods – pH Analysis.

B. Low-Acid Canned Food (LACF)

Normal, flat, routine (not for-cause), compliance or surveillance sample collections (with a filed process) rarely, if ever, result in violative regulatory findings, much less pose a significant public health risk. If such samples are received fitting this description, the laboratory only needs to spend minimal resources in evaluating the sample.

"Minimal resources" are defined as examination of six (6) normal LACF containers for the following: visual and organoleptic evaluation of product; visual evaluation of the exterior and interior container; and pH evaluation (no check analysis required). Only if significant observations are found will additional analyses be necessary.

Follow the respective instruction from Bacteriological Analytical Manual (BAM) Chapter 21A: Examination of Canned Foods

Abnormal containers, whether collected/received as abnormal or resulting from 14-day progressive decomp incubation, and or for-cause collections will necessitate additional analyses as indicated below and or upon request.

Abnormal containers should be opened as soon as possible upon laboratory receipt. Related normal containers should be incubated and observed for a 14-day progressive decomp evaluation. If all normal containers remain flat, open six (6) containers and perform microscopic, physical, and organoleptic examinations.

Only when microbiological activity is observed during analysis, will container integrity analysis be warranted. Further culture examination is only required when vegetative cells or spores are observed. However, when characteristic cultural and microscopic findings for spore-forming Gram-positive or Gram-variable rods is observed, test the culture for botulinum neurotoxin and/or *C. botulinum according* to Chapter 17 - *Clostridium botulinum*.

(1) Microbiological and Physical

NOTE: for routine compliance or surveillance (low priority) samples that are not implicated or suspected in *C. bot* illnesses, laboratories should follow BAM Chapter 21A: Examination of Canned Foods for microbiological cultural analysis.

(a) Headspace Gas Analysis (Performed for-cause only, i.e., when abnormal cans are present)

Laboratories so equipped and trained should use either gas chromatography method specified in BAM Chapter 21A section Headspace Gas Determination by Gas-Liquid Chromatography or BAM Chapter 21B: Modification of Headspace Gas Analysis Methodology | FDA

Laboratories that do not have the necessary equipment should perform hydrogen pop test as described in BAM Chapter 21A Section D.2.a.

(b) Seal Integrity Examination and Container Evaluation (Performed for-cause only, i.e., when abnormal cans are present)

Perform seal integrity examination and evaluation on abnormal containers (to the extent that the data obtained are meaningful) and on a representative number of normal containers as specified in BAM Chapters 21A and 22A through 22D as applicable.

Perform micro-leak examinations before destructive testing. Vacuum leak testing is preferred. If leak testing does not appear possible (i.e. because of buckling, or because unusually shaped containers are encountered), seek guidance. Regardless of what procedures are utilized, record all information to how the test was performed.

Perform vacuum tests, when abnormal containers are present, on normal containers selected for culturing and appropriate seal examinations.

(c) BAM Chapter 13B - Staphylococcal Enterotoxin Detection Methods (Performed for-cause and upon request only, i.e., only when SET is implicated or suspected in illness)

NOTE: only used for Staphylococcal Enterotoxin implicated or suspected illness related, or for-cause collected samples

(d) *Clostridium botulinum* (Performed for-cause and upon request only, i.e., only when *C. botulinum* is implicated or suspected in illness)

When *C. botulinum* is implicated in an illness, investigation, or suspected in the product, laboratories shall follow BAM Chapter 17 *Clostridium botulinum* for cultural analysis.

If *C. botulinum* is not implicated or suspected, laboratories should follow BAM Chapter 21A for cultural analysis.

For FDA ORA Laboratories:

If typical clostridial isolates are recovered (from either BAM Chapter 17 or 21A), laboratories should perform whole genome sequencing (WGS) and submit the sequencing data to CFSAN SMEs for toxin gene evaluation.

If WGS is pointing toward *Clostridium botulinum* identification (or further testing is recommended by CFSAN SMEs based upon toxin gene evaluation), laboratories should send isolates (AND details of the testing performed at ORA and analytical worksheet, AND only when requested, reserve sample for preformed toxin testing) to ARLHAF for confirmation testing via mouse bioassay (MBA) and or other approved methodology.

Remember to follow all applicable procedures and regulations when shipping suspect *C. botulinum* isolates to ARLHAF (or confirmed isolates CFSAN).

NOTE: Retain sufficient reserve of product (1/2 of #10 cans, all of other cans) in case additional confirmation is required by CFSAN.

If an original food sample submitted for *C. botulinum* confirmation is identified or verified as a select agent or toxin, the confirmatory testing lab must follow the Federal Select Agent Program requirements (including but not limited to reporting using

APHIS/CDC Form 4). See the Select Toxin Guidance for more detail. Further, the lab must adhere to any additional agency, center, and or organizational reporting requirements and procedures as applicable.

(e) BAM Chapter 14 - *Bacillus cereus*, Section 8 Test for cereulide, emetic toxin (Performed for-cause and upon request only, i.e., only when emetic toxin is implicated or suspected in illness related to LACF product)

NOTE: only used for *Bacillus cereus* emetic toxin implicated or suspected illness related, or for-cause collected samples.

(2) Water Activity (a_w)

(a) For products having a pH above 4.6, and when maximum a_w is a critical factor in the scheduled process, determine a_w.

NOTE: Please refer to the most current AOAC Official Method available (AOAC 978.18, section 42.1.03) or ISO 18787 (2017 Determination of Water Activity).

- Initial Screening: For all size containers, determine the a_w of three (3) units using approved instrumentation (see AOAC, most current on-line version, 978.18, section 42.1.03, B. Instruments and Systems, or use equivalent, verified, modern instrumentation per ISO 18787).

  If applicable, standardize the instrument using salt slush (see AOAC, most current on-line version, 978.18, section 42.1.03, D. Preparation of Reference Salt Slushes), or verify instrument calibration and function utilizing water activity standards per instrument manual instruction and ISO 18787.

- Check Analysis: When initial screening shows a_w at or above 0.90, or a wide range of a_w values, including one or more above 0.93, confirm using a different instrument (if available) on the same three (3) container (subsamples).

  If a_w is confirmed at or above 0.90, refer the results of analysis to the Compliance Branch of the Collecting District.

Do not classify as lab class “3”, unless it is known that a_w values exceed the maximum value filed by the firm.

(b) Sugar Control and Salt Content (Performed for-cause and upon request only)

NOTE: These two analyses are rarely performed and if requested, advanced notice is required to identify and ready the testing laboratory. Inquire with ORA ORS OHAFLO IO oraorsoffloiomicro@fda.hhs.gov for additional information.

- If sugar may be controlling a_w, determine the percent sucrose (Brix), or soluble solids, AOAC, most current edition, 932.14-section 44.1.04, C. Solids in

Syrups By Means of Refractometer, Page 1011. Use Tables 990.35 and 990.36, Appendix C.

- If salt content may be controlling a_w or the growth of microorganisms, determine and report the percent salt as water phase salt.
    - "Water phase salt" means the percent salt (sodium chloride) in finished product as determined by the following methods:
        - Moisture Content (**Total Solids**) - AOAC, most current Ed., section 35.1.13 (952.08),

          NOTE: Substitute pumice or sand for asbestos.
        - Water Phase Salt - AOAC, most current Ed., section 35.1.18 (937.09), volumetric method.

          NOTE: Formula for calculating water phase salt, i.e., salt concentration expressed as percent of salt in aqueous phase:

$$\% \text{ salt (aqueous phase)} = \frac{\% \text{ salt} \times 100}{\% \text{ water} + \% \text{ salt}}$$

Direct questions concerning analysis of foods in which water activity or salt may be, at least in part, a means of preservation, to CFSAN/Office of Food Safety/ Food Processing Evaluation Team/, HFS-302, LACF@fda.hhs.gov .

C. Acidified Foods – pH Analysis

(1) Use normal containers

Refer to AOAC, most current Ed., section 42.1.04 (981.12), **except**: Determine the pH on the container contents only, by opening the container, inserting the electrode(s) and measuring the pH. **Do not** make determinations on both the liquid and the solid. (If the product is freshly packed and not in equilibrium, blend entire contents of can and test pH.

(2) Number of containers for pH analysis:

The total sample size for containers 795 grams (i.e., 28 oz.) net weight or smaller is 24 containers. The total sample size for all others is 12 containers.

- One analyst will determine pH of half of the sample containers and record the name, model and serial number of the pH meter on the Analyst Worksheet.
- If one or more containers have pH values equal to or greater than 4.40, or if the mean pH plus 2 standard deviations is equal to or greater than 4.40, a second analyst must promptly (same day) re-determine the pH values of the

same containers using a different pH meter, and record the name, model and serial number of the pH meter on the Analyst Worksheet.

- If one or more containers have pH values above 4.65, or if the mean pH plus 2 standard deviations (as determined separately from either analyst's results) is above 4.65, both analysts will analyze the remaining half of the sample using the same respective pH meters as were used on the first half of the sample.

- When the analysis is complete, regardless of whether it was necessary to analyze all containers in the sample or only half of them, consider all of the pH values determined by the first analyst together as the "original analysis." If a second analyst was required, consider all of the pH values determined by the second analyst together as the "check analysis." Never average the two analysts' results together.

- Carry out all pH determinations to two (2) decimal places, with reproducibility at ±0.05 pH., e.g., 4.40 or 4.45.

NOTE: pH is a logarithmic measure for the acidity of an aqueous solution. Since pH represents the negative logarithm of a number, it is not mathematically correct to calculate simple averages or other summary statistics. Instead, all pH calculations* should be converted to hydrogen ion concentrations, calculation performed, then re-converted to pH value(s).
**Average pH value of duplicate subsample readings, mean pH value of the range of subsamples, and mean plus 2 standard deviations of the range of subsamples.*

The following guidance is provided:

- Convert each pH value to hydrogen-ion activity (H+), using the equation: Activity = 10^{-pH}
  In Excel, the formula is: =10^(-pH number)

- Calculate the mean of the activity values by adding the values and dividing the sum by the total number of values. Calculate the standard deviation also from the activity values.

- Convert the calculated mean activity back to pH units, using the equation: pH = (-)($\log_{10}$)(mean H^+ activity). Also convert the standard deviation to pH units.
  In Excel, the formula is: = -LOG10(number)

The mean pH plus 2 standard deviations calculation may be calculated as a pH value smaller than the mean. This is normal because of the nature of logarithmic pH calculations.

When the pH values correspond closely, there is not a significant difference between the mathematical mean and the logarithmic mean. As the pH values

spread further apart from each other, or there is an outlier pH value, the difference between the two means becomes more significant.

(3) pH of Emulsified (High Fat/Oil) Products

Some sauces high in fat/oil (such as Hollandaise, Béarnaise and other condiment sauces) when tested for pH will give erratic pH readings because the fat/oil content will plug the pH electrodes. Since the growth of microorganisms is dependent on the pH of the water phase, it is necessary to determine the pH of the water phase portion of the sauce. To do this, the emulsion must be broken, and the oil/fat phase removed by putting the product through a freeze thaw cycle and decanting the oil layer in a multi-step process.

- Transfer the sample into a beaker and place the beaker in a freezer for at least 4 hours.

- Remove the butter/oil phase, warm sample to room temperature, and insert the pH electrodes into the aqueous phase. Record the pH readings.

  NOTE: This step may be sufficient to get stabilized readings and analysis can end here. The AOAC Official Method also includes other methods for overcoming oily products.

- Optionally, transfer the aqueous phase to a suitable size separatory funnel. Add a suitable amount (e.g., half the volume of the sample) of ether. Shake the funnel to provide a thorough mixing of contents.

  NOTE: Ether is an oxidizer and peroxide former. If utilized, all laboratory hazard and safety measures must be followed. Spent waste must be disposed of as hazardous waste according to local procedure.

- Separate the oil and aqueous phase again. Collect the defatted aqueous portion and take pH readings.

  NOTE: If readings are taken after BOTH freezing AND ether treatments, then both sets of readings must be submitted and notated accordingly in final worksheet package.

D. Acidified and LACF

(1) *C. botulinum* Toxin Confirmation

For confirmation of preformed and/or cultured *C. botulinum* toxin, please contact CFSAN prior to submission. Send a portion of the product and the subculture enrichment along with copies of the analyst worksheets, collection report, etc. to the CFSAN *C. botulinum* confirmation laboratory listed in the Analyzing Laboratories section.

NOTE: *C. botulinum* toxin confirmation analysis is initially performed by Arkansas Human and Animal Food Laboratory (ARLHAF). CFSAN will perform confirmation as necessary.

(2) Container Integrity/Abnormal Containers

(a) Container Integrity

Container integrity problems, especially seam defects, are most significant with low-acid canned foods. They are of primary importance from a public health standpoint when canned seafood is involved. Seam defects are less important from a public health standpoint with acidified foods unless contamination has resulted in elevated pH levels at or above 4.75.

In examining canned foods for container integrity, the analyst should examine each container for visible defects and describe these defects. Guidance in describing visible defects is available in the AOAC chart; Classification of Visible Can Defects (Exterior).

The Bacteriological Analytical Manual (BAM), most current version (on-line), can also be used as guidance in describing visible defects. All visible defects, as well as their location on the container, should be noted. Make a comparison to the collection report and identify and record any abuse related defects not identified during sample collection.

When visible can seam or seal defects are found, the analyst should attempt to determine the severity of the defects.

(b) Abnormal Containers

Conduct the following additional analyses or other appropriate destructive tests on the abnormal containers: gas, odor and appearance, net weight, drained weight, visual defects, leak testing, can seam teardown or other appropriate destructive tests, and condition of container interior.

It is particularly important to examine unopened abnormal containers (flippers, springers, soft swells, hard swells, leakers) and compare them to the condition reported at the time of sample collection (see the collection report). Changes in abnormal classification from the time of sample collection to the start of analyses must be recorded.

If the pH of abnormal containers is greater than 4.75, and microbiological tests confirm the presence of viable mesophilic Gram-positive anaerobic spore formers, analyze for botulinum neurotoxin and *C. botulinum* by PCR.

(c) Glass Containers and Semi-Rigid and Flexible Packaging

Perform visual examinations, microleak examinations and destructive testing where appropriate. Refer to BAM, Chapter 22B "Examination of Glass Containers for Integrity" or Chapter 22C “Examination of Flexible and Semirigid Food Containers for Integrity” for methods of analyses.

Questions should be referred to CFSAN/Office of Food Safety/ Food Processing Evaluation Team, lacftechnical@fda.hhs.gov .

Guidance in describing visible defects for flexible packages is available in BAM Chapter 22C.

(d) Photograph visible defects with a digital camera or scan pictures for submission to CFSAN.

3. Methodology

A. Refer to the following Bacteriological Analytical Manual (BAM) Chapters, online edition:

Chapter 13B - Staphylococcal Enterotoxin Detection Methods

Chapter 14 – Bacillus cereus

Chapter 17 - *Clostridium botulinum*

Chapter 21 - A. Examination of Canned Foods

Chapter 21 - B. Modification of Headspace Gas Analysis, using the SP4270 Integrator

Chapter 22A - Examination of Metal Containers for Integrity

Chapter 22B - Examination of Glass Containers for Integrity

Chapter 22C - Examination of Flexible and Semirigid Containers for Integrity

Chapter 22D – Examination of Containers for Integrity; Glossary and References

B. Refer to the following Official Methods of Analysis of AOAC International, online edition:

Chapter 35, Subchapter 1, Section 13 (35.1.13) AOAC Official Method 952.08, Solids (Total) in Seafood: Gravimetric Method

Chapter 35, Subchapter 1, Section 18 (35.1.18) AOAC Official Method 937.09, Salt (Chlorine as Sodium Chloride) in Seafood: Volumetric Method

Chapter 42, Subchapter 1, Section 03 (42.1.03) AOAC Official Method 978.18, Water Activity of Canned Vegetables

Chapter 42, Subchapter 1, Section 04 (42.1.0) AOAC Official Method 981.12, pH of Acidified Foods

Chapter 44, Subchapter 1, Section 04 (44.1.04) AOAC Official Method 932.14, Solids in Syrups

C. Refer to the following International Organization for Standardization (ISO) method, online edition:

ISO 18787:2017 – Determination of water activity

4. Reporting

A. pH Determinations

If even one normal container of acidified product has a pH at or above 4.75 or the mean plus two (2) standard deviations (as determined by either analyst's total result(s)) is at or above 4.75, **immediately** refer the results of the analysis to the District's Compliance Branch.

NOTE: Never average the two analysts' results together.

When an outlier pH value(s) is present, that causes the mean plus two (2) standard deviations calculation to be significantly skewed, add a note to the sample summary acknowledging this finding. Additionally, include any unique findings that may have contributed to the outlying subsample pH reading.

B. Analytical Data Reporting

Report all analytical results for low acid, acidified and acid products using the ACD PAF except for samples collected for *C. botulinum* analysis; utilize MIC PAF for *C. bot* samples.

Completed laboratory report (worksheet package) will be uploaded to the Compliance Management System (CMS) and or other applicable system according to ORA Laboratory Manual and or other applicable laboratory guidance.

Laboratory classification of AF and LACF sample analysis will follow the ORA Laboratory Manual and or other applicable laboratory guidance. The following are suggested laboratory classifications for specific examples of AF or LACF sample types and or analytical results that may be encountered.

- Import samples analyzed with normal result findings (normal containers, normal product odor and appearance, and otherwise normal pH (less than or equal to 4.6) and or water activity values (greater than 0.85)); but without an apparent Food Canning Establishment (FCE) number or Schedule Identifier (SID) number; should be given a laboratory classification two (2 – Regulatory Action not Established/Defined).

- Import samples analyzed with abnormal result findings including either a pH (greater than 4.6) and or water activity values (less than or equal to 0.85); and without an apparent Food Canning Establishment (FCE) number or Schedule Identifier (SID) number; should be given a laboratory classification three (3 - Adverse Findings).

- Import samples where container integrity analysis indicates seam defects are present; but without any other adulteration (swollen, leaking, contains viable

microorganisms or is decomposed) found pursuant to CPG Sec 520.200; should be given a laboratory classification one (1 – In Compliance).

PART V – REGULATORY/ADMINISTRATIVE STRATEGY

1. When to Notify the Center

A. Acidified Products – Analysis Results
Recommend actions to CFSAN/Division of Enforcement, HFS-607 via CMS if one or more containers analyzed are found to have a measured pH value of 4.75 or above by both the original and check analysis. See CPG 7120.25; section 520.300, "Acidified Low-Acid Canned Foods - Adulteration Due to High pH".

B. Please submit the following situation to CFSAN/Office of Compliance/ Division of Enforcement via CMS:

(1) Any measured pH value is less than 4.75, but greater than or equal to 4.65, or if the mean pH plus 2 standard deviations (as determined from either analyst's total results) is 4.65 or above;

or

(2) Analysis identifies a water activity controlled LACF product with pH above 4.6 **and** water activity confirmed at 0.90 or above the maximums listed in the filed scheduled process;

or

(3) Analysis confirms adulteration or progressive spoilage in abnormal container in at least 1% of the lot. (If findings do not indicate suspected health hazards, recommendations for legal action may be submitted in the usual manner without first discussing findings.);

or

(4) A firm has not registered and filed its processes within 60 days of being notified of these requirements.

2. Compliance Actions

A. Warning Letters Based upon Facility Inspections (Domestic and Foreign)

Division Compliance Officers or Foreign Case Reviewers will submit all correspondence through CMS:

(1) Entire EIR and other correspondence relating to firms under Emergency Permit.

NOTE: Proposed Warning Letters concerning AF and LACF food deficiencies must be reviewed and must receive concurrence from CFSAN prior to the Division Director issuance of the Warning Letter. Refer to the Agency established Regulatory Procedures Manual, Chapter 4, 4-1-1. For proposed AF Warning Letters please also see CFSAN Enforcement Bulletin #3 Acidified Foods.

(2) Warning Letter Recommendations - entire EIR, exhibits, attachments, firm response, and other correspondence with proposed Warning Letter attached for review. CFSAN/DE/FAAB will draft Warning Letters for foreign facilities as the Compliance Branch for OHAFO Foreign Operations.

NOTE: Domestic Warning Letter Considerations – recommendation memorandum-summarizing areas of concern to accompany entire EIR, exhibits, and attachments. Upon review by CFSAN/DE/ FAAB(HFS-607), Division will be provided with subjects to be covered under District issuance of a Warning Letter.

Unless the evidence establishes that the firm produces acidified foods with insufficient pH control (e.g., evidence of pH values in excess of 4.6 in finished products) the Division should recommend to CFSAN issuance of the appropriate action. However, if the inspection demonstrates that the firm has a chronic history of failure, unwillingness or inability to adhere to the mandatory provisions of 21 CFR 108.25 and 114, CFSAN would be willing to consider further action and ultimately an Order of Need to obtain and hold a permit.

Encourage the responsible individuals of a firm to take the initiative in correcting observed deficiencies. This should be accomplished at the conclusion of an inspection and with a Warning Letter. If necessary, solicit for a written response from the firm observations noted, delineating corrective action to be taken and timetables for completion as discussed in FMD-86. The Division should review the firm's responses promptly for enforcement consideration per RPM Chapter 4.

When deficiencies from the mandatory provisions of 21 CFR 108, 113 or 114 appear to be of a serious nature, which could result in the production of potentially hazardous product or where there has been a continuous history of non-compliance with significant requirements of the regulations with little or no improvement, notify CFSAN OC/DE immediately via DELACFandAFProducts@fda.hhs.gov.

The type of deficiencies from the mandatory provisions of the regulations will dictate the type and nature of the appropriate regulatory action. The significance of the deficiencies relative to the degree of potential public health hazard that exists must be made and/or confirmed by Center experts.

B. Import Compliance Actions

(1) Detention

Products which meet the following criteria shall be considered for detention by the import division:

(a) LACF Products Based on Microbiological Findings

Follow instructions in the Regulatory Procedures Manual Chapter 9 - Import Operations and Actions and Compliance Policy Guide Section 520.200 "Canned Foods - Seam Defects".

(b) Water Activity Controlled Products Based on pH and a_w Findings

When analysis identifies a water activity-controlled product with pH above 4.6 for which there is no process filing or the water activity is confirmed above the maximum a_w listed in

the filed scheduled process, submit a detention recommendation (DTR) case via CMS to CFSAN/Division of Enforcement /Food Adulteration Assessment Branch.

(c) Acidified Products Based on pH Findings

Consult "CPG Section 520.300 Acidified Low-Acid Canned Foods – Adulteration Due to High pH (CPG 7120.25)".

Information can be submitted to CFSAN/Division of Enforcement via CMS WA task for review to determine if there is a significant difference between the pH of the finished product and the predominant acid(s) or acid food(s).

If sample results meet criteria stated in CPG Section 520.300, send all pertinent documents, such as the analytical worksheets, collection report, entry package and complete labeling, with detention recommendation (DTR) request via CMS to CFSAN Division of Enforcement/Food Adulteration Assessment Branch.

(d) Abnormal Containers (Acidified, LACF, and a_w controlled Products)

i. If the abnormal rate is 1% or greater, send a detention recommendation (DTR) request in addition to all pertinent documents as listed above to CFSAN Division of Enforcement/Food Adulteration Assessment Branch. (IOM Chapter 4, Sampling Schedule for Low-Acid Canned and Acidified Foods, Chart 2, describes the different types of abnormal containers.

ii. When submitting any collection reports or analytical worksheets always send copies of labels, invoices/packaging lists or other documents which may identify the manufacturer.

(e) Firm's Failure to Register or to have Process on File

Detain the shipment if the firm has not registered and has not filed the necessary processing information with FDA.

i. Consider providing the importer with:

- Importing Human Foods.
- Importing Animal Foods
- Food Industry resource page
- Inspection Guides
- Instructions about registration and other guidance
- Information about Import Alert Procedures & RPM Chapter 9 Information regarding Import Alerts.

ii. While evaluating the disposition of an entry, check the FURLS database for valid FCE and SID information.

(f) Import Alerts, Including #99-37 and #99-38

i. Import Alert # 99-37 “Detention Without Physical Examination of Low-Acid Canned Foods and Acidified Foods Without Filed Scheduled Processes” was created to allow detention and refusal of entries of products that are determined to be LACF or AF and that lack a filed scheduled process. This import alert provides a mechanism to identify LACF and AF products for DWPE if the firm has not filed a scheduled process for the product (including in situations where the firm has not registered as a LACF or AF commercial processor) **when FDA determines such action is necessary for efficient and effective protection of the public health** (e.g., an unfiled process for a product that FDA has determined is an LACF or AF product when FDA's examination of the product indicates a potential public health risk; evidence of recidivism by a firm trying to circumvent the scheduled process filing requirements; or other similar situations warranting such DWPE action)*.

***Do not recommend firm/products for an Import Alert/DWPE solely based on firm/product not registered and/or filed processes with FDA since all LACF and acidified foods should be checked for registration and process filing.**

ii. Import Alert # 99-38 “Detention Without Physical Examination of Low-Acid Canned Foods and Acidified Foods Due to Inadequate Process Control” was created to allow detention and refusal of entries of products that the firm has already determined to be LACF or AF based on their submission of scheduled processes to FDA. This import alert provides a mechanism to add a firm and product to DWPE when FDA determines the product(s) were not properly manufactured to control growth and toxin production from *Clostridium botulinum* or other microorganisms of significance to public health.

Recommendations for additions to the Red List should be forwarded to the Division of Import Operations (DIO) via CMS. Recommendations for DWPE should include documentation of Center concurrence when the action is not covered by direct reference authority.

(g) Fraudulent Entries

Entry reviewers should look for suspicious entries; for example, mushrooms from one country shipped by an exporter in another country or multiple manufacturing facilities using the same FCE/SID.

When fraud is suspected, it should immediately be brought to the attention of the division compliance branch via supervisory channels. Appropriate evidence needs to be collected, including documents, product samples, and interviews of involved personnel. OCI should be consulted early in the investigation. Regulatory actions that can be taken for fraudulent entries include refusal or may proceed after consultation with the district compliance branch, CFSAN and OCI.

If CFSAN determines that a health hazard exists, the import division will be notified by a decision memo uploaded into the CMS case. The import division will then determine the

disposition of the lot after it has been refused admission and inform CFSAN/Division of Enforcement. The lot can be destroyed or re-exported. Additional options can be considered upon further review by CFSAN. If the lot is/will be re-exported, CFSAN/Division of Enforcement will inform the Office of International Engagement, who will notify appropriate authorities of the countries to which the lot was shipped.

PART VI – REFERENCES, ATTACHMENTS & PROGRAM CONTACTS

1. References

A. FDA Guides to Inspections of Low-Acid Canned Food Manufacturers

Part 1 - Administrative Procedures/Scheduled Processes, November 1996

Part 2 - Processes/Procedures, April 1997

Part 3 - Containers/Closures, November 1998

FDA Guide to Inspections of Aseptic Processing and Packaging for the Food Industry, February 2001 PCHF Draft Guidance for Industry, Chapter 16: Acidified Foods

FDA Investigations Operations Manual (most current issue)

Regulatory Procedures Manual (most current issue)

21 CFR Parts 108, 113, 114

INDUSTRY EDUCATION INFORMATION

Acidified & Low-Acid Canned Foods Guidance Documents & Regulatory Information | FDA

2. Attachments

Attachment A – Import Product Code List

Attachment B – Import Heat Resistance Form

Attachment C – Import Can Sizes

3. Program Contacts

CFSAN Program Contacts

Compliance Program Contact
Krista Whitten, CFSAN/OC/DFPG/Program Assignment & Monitoring Branch
Phone: 615-366-7842
Email: krista.whitten@fda.hhs.gov

Division of Enforcement Contact
(Regulatory, compliance matters or interpretation of regulations/covered products)
Email: DELACFandAFProducts@fda.hhs.gov

CFSAN Technical Expert/Better Process School Coordinator
(Questions regarding preservation, processing or packaging of AF/LACF; and/or analysis of foods in which pH, a_w, or salt content may be at least in part a means of preservation)
Email: LACFTechnical@fda.hhs.gov

LACF Registration Control Coordinator
(Questions regarding the LACF online system, and plant registration and filed scheduled processes)
Email: LACF@fda.hhs.gov

Intranet LACF Web Application System accounts
Obtain from AF/LACF Main Menu (fda.gov)

Confirmation of Preformed and/or Cultured *C. botulinum* Toxin
Shashi Sharma, CFSANORS/DM/MMDB
Phone: 240-402-1570
Email: Shashi.sharma@fda.hhs.gov

Confirmation of Staphylococcal Enterotoxin
Sandra Tallent, CFSAN/ORS/DM/MMDB
Phone: 240-402-1619
Email: Sandra.tallent@fda.hhs.gov

International Inquiries
CFSAN/OCD/International Affairs
Email: FDA-CFSAN-International-Engagement@fda.hhs.gov

CVM Program Contact

Isaac Carney, Division Director, CVM/OSC/ Division of Food Compliance
Phone: 802-868-4725 x1107
Email: Isaac.carney@fda.hhs.gov

ORA/OIO Program Contacts

ORA OIO DIO CFSAN Liaisons
Email: oraoeiodiocfsanliaisons@fda.hhs.gov

ORA/OHAFO Program Contacts

Analytical Method Inquiries, ORA LST Dashboard or Lab Capacity Questions
Darcy Brillhart, ORA/ORS/Office of Human and Animal Food Laboratory Operations
Phone: 404-253-2294
Email: darcy.brillhart@fda.hhs.gov

Inspectional Inquiries
Rupa Pradhan, ORA/OHAFO
Phone: 781-281-4843
Email: rupa.pradhan@fda.hhs.gov

National Experts

Bob Neligan
Phone: 706-485-2725
Email: Robert.neligan@fda.hhs.gov

Brian Yaun
Phone: 240-402-2922
Email: brian.yaun@fda.hhs.gov

PART VII – CENTER RESPONSIBILITIES

1. Botulinum Toxin Confirmation

Confirmation of preformed and cultured botulinum toxin, CFSAN/ORS/Division of Microbiology, HFS-711
Shashi Sharma, shashi.sharma@fda.hhs.gov

SEB Confirmation
Confirmation of preformed and cultured SEB toxin, CFSAN/ORS/Division of Microbiology/ Microbiological Methods and Subtyping Branch,
Sandra Tallent, 240-402-1619 sandra.tallent@fda.hhs.gov

2. LACF Registration and Process Files

Maintenance of the LACF Registration and Process Files, CFSAN/Office of Food Safety/ Food Processing Evaluation Team, HFS-302.
LACF@fda.hhs.gov

3. Foreign Inspection Program

Upon the receipt of violative conditions or inspectional findings from the foreign inspection program (Division of Foreign HAF Operations, HFC-130), the Center may modify an FCE/SID filing, submit a recommendation to DIO for placement of the firm(s) on Import Alert, or initiate other appropriate enforcement action (such as a warning letter) based on the findings.

4. Evaluation Requirements

The Office of Food Safety (OFS) will provide subject matter expertise in the maintenance and evaluation of the compliance program and provide guidance to the Office of Compliance (OC) with regard to program priorities, relevant evaluation questions and recommended program changes. The OC will lead the effort and work in conjunction with OFS to prepare routine compliance program evaluations. Evaluation will be conducted on a periodic basis and outline the program office's current objectives, general and specific program evaluation questions, list recommendations for process improvement, and highlight data patterns and trends for better targeting and resource allocation. The OC will make these evaluations available internally to FDA. In addition, the OC will prepare an annual summary report of this compliance program which will be available for internal use only at Compliance Program Summaries.

ATTACHMENT A – IMPORT ACIDIFIED AND LOW-ACID CANNED FOODS PROGRAM PRODUCT CODE LIST

The following product codes include both LACF and acidified products. These codes are not all inclusive for LACF and Acidified products. Additionally, some of the codes can be used for products which are either LACF or Acidified foods.

PRODUCT DESCRIPTION	INDUSTRY CODE	PRODUCT CLASS
Bakery Products, dough, mixes and icings	03	A, T, U, Y
Macaroni and noodle products	04	C
Milk, Butter and Dried Milk Products	09	C, D, E, F, G, Y
Cheese and Cheese Products	12	B, C, Y
Ice Cream and Related Products	13	G
Milk Substitutes and Imitation Milk Products	14	All
Egg and egg products	15	All but A
Fishery/ Seafood Products	16	All
Meat, Meat Products and Poultry (include only game animals and birds, NOT APHIS inspected products)	17	All
Vegetable Protein Products (Simulated meats)	18	All
Fruits and Fruit Products (Limited to avocado, banana, black olives, exotic fruits, guava, melon, papaya and other low-acid fruits)	20 – 22	All
Nuts and Edible Seeds	23	D, E, F, Y
Vegetables and Vegetable Products (Exclude high acid tomatoes, sauerkraut, fermented salt stock pickles)	24 - 25	All
Dressing & Condiments (e.g. chili, puree, chutney, pepper sauce, etc)	27	Y
Soft Drinks and Water (Only banana, chocolate, coconut and other low-acid beverages)	29	A, Y
Beverages Bases, Concentrates and Nectars (Only banana, coconut and other low-acid products)	30	B, G, K, P, Y
Coffee and Tea (liquids only)	31	A, E, K, P
Toppings, Non-fruit or Nut Origin	33	T, Y
Chocolate and Cocoa Products	34	H, J, Y
Gelatin, Rennet, Pudding Mixes and Pie fillings (Only low-acid products)	35	C, D, E, F
Food sweeteners (syrups, molasses & imitation syrups, molasses & Honey)	36	B, D, Y
Multiple Food Dinners, Gravies, Sauces and Specialties	37	A, B, C, D, G, J, Y
Soups	38	All
Prepared Salad Products	39	All
Baby (Infant and Junior) Food Products	40	All but X
Dietary Conventional Foods and Meal Replacements	41	All
Non-medicated animal feed	70	All
Pet and Laboratory animal food	72	All

ATTACHMENT B – HEAT RESISTANCE REPORTING FORM

DIVISION	SAMPLE NUMBER	DATE SENT

PRODUCT	MANUFACTURER AND/OR DISTRIBUTOR

	SUBSAMPLE #	CODE	CULTURE #	TYPE OF CULTURE	VERIFICATION	D_{240}

ATTACHMENT C – CAN SIZES & CONTAINER DIMENSIONS

In the canning trade can sizes are commonly referred to by symbols and common names, e.g. 307 x 409 = No. 2 can. The actual size is measured in whole inches and fractions of 1/16th inches in diameter and height. In the 307 x 409 example, the 3 = 3 inches & the 07 = 7/16th of an inch; the 4 = 4 inches & the 09 = 9/16th of an inch, the 307 x 409 can is 3 7/16 inches in diameter & 4 7/16 inches in height.

Can Number	Inches	Can Dimensions in Millimeters (Diameter x Height)	Common Name
202 x 202	2 2/16 x 2 2/16	54.0 x 54.0	None
202 x 204	2 2/16 x 2 4/16	54.0 x 57.2	2oz Mushroom
202 x 214	2 2/16 x 2 14/16	54.0 x 73.0	5oz Baby food
202 x 308	2 2/16 x 3 8/16	54.0 x 88.9	6oz Jitney
202 x 314	2 2/16 x 3 14/16	54.0 x 98.4	6oz
211 x 109	2 11/16 x 1 9/16	68.3 x 39.7	¼ lb tuna
211 x 200	2 11/16 x 2	68.3 x 50.8	4oz Pimiento – 211 Baby Food
211 x 210	2 11/16 x 2 10/16	68.3 x 66.7	6oz Junior Food
211 x 212	2 11/16 x 2 12/16	68.3 x 69.9	4oz Mushroom
211 x 214	2 11/16 x 2 14/16	68.3 x 73.0	None
211 x 300	2 11/16 x 3	68.3 x 76.2	8oz Short
211 x 304	2 11/16 x 3 4/16	68.3 x 82.5	8oz Tall
211 x 400	2 11/16 x 4	68.3 x 101.6	No.1 (Picnic)
211 x 414	2 11/16 x 4 14/16	68.3 x 123.8	No.211 Cylinder
211 x 600	2 11/16 x 6	68.3 x 152.4	Pint Olive
300 x 109	3 x 1 9/16	76.2 x 39.7	None
300 x 206	3 x 2 6/16	76.3 x 60.3	7oz Pimiento
300 x 308	3 x 3 8/16	76.2 x 88.9	None
300 x 400	3 x 4	76.2 x 101.6	8oz Mushroom
300 x 407	3 x 4 7/16	76.2 x 112.7	No. 300
300 x 409	3 x 4 9/16	76.2 x 115.9	None
301 x 106	3 1/16 x 1 6/16	77.8 x 34.9	¼lb Salmon
301 x 208	3 1/16 x 2 8/16	77.8 x 63.5	8oz Pimiento
301 x 408	3 1/16 x 4 8/16	77.8 x 114.3	No.1 Tall
301 x 411	3 1/16 x 4 11/16	77.8 x 119	No.1 Tall
303 x 406	3 3/16 x 4 6/16	81.0 x 111.1	No. 303
303 x 509	3 3/16 x 5 9/16	81.0 x 141.3	No. 303 Cylinder
307 x 113	3 7/16 x 1 13/16	87.3 x 46.0	1/2 lb Tuna
307 x 200.25	3 7/16 x 2 1/64	87.3 x 51.2	½ lb Salmon

307 x 202	3 7/16 x 2 2/16	87.3 x 54.0	None
307 x 203	3 7/16 x 2 3/16	87.3 x 55.6	No.1 Flat
307 x 208	3 7/16 x 2 8/16	87.3 x 63.5	None
307 x 214	3 7/16 x 2 14/16	87.3 x 73.0	Kitchenette
307 x 306	3 7/16 x 3 6/16	87.3 x 85.7	No. 2 Vacuum
307 x 400	3 7/16 x 4	87.3 x 101.6	No.95
307 x 409	3 7/16 x 4 9/16	87.3 x 115.9	No. 2
307 x 509	3 7/16 x 5 9/16	87.3 x 141.3	None
307 x 510	3 7/16 x 5 10/16	87.3 x 142.9	Jumbo
307 x 512	3 7/16 x 5 12/16	87.3 x 146.1	No. 2 Cylinder
307 x 704	3 7/16 x 7 4/16	87.3 x 184.2	Quart Olive
307 x 710	3 7/16 x 7 10/16	87.4 x 193.7	32oz (Quart)
401 x 205.5	4 1/16 x 2 11/32	103.2 x 59.5	No. 1 Tuna
401 x 206	4 1/16 X 2 6/16	103.2 x 60.3	No.1¼ (Veg.)
401 x 207.5	4 1/16 x 2 15/32	103.2 x 62.7	No.1¼
401 x 211	4 1/16 x 2 11/16	103.2 x 68.3	No.1 Flat
401 x 411	4 1/16 x 4 11/16	103.2 x 119.1	No. 2½
404 x 307	4 4/16 x 3 7/16	108.0 x 87.3	No. 3 Vac.
404 x 414	4 4/16 x 4 14/16	108.0 x 123.8	No. 3
404 x 700	4 4/16 x 7	108.0 x 177.8	No. 3 Cylinder (46oz)
502 x 510	5 2/16 x 5 10/16	130.2 x 142.9	No. 5
603 x 405	6 3/16 x 4 5/16	157.2 x 109.5	None
603 x 408	6 3/16 x 4 8/16	157.2 x 114.3	No. 5 Squat
603 x 700	6 3/16 x 7	157.2 x 177.8	No. 10
603 x 812	6 3/16 x 8 12/16	157.2 x 222.3	No. 12 (Gal.)

A. Metal Containers

Some countries incorrectly file a "plug diameter" measurement (diameter inside double seam) for cans. It may be necessary to measure the plug diameter to determine process filing. The plug diameter will be approximately 2/16 smaller than the outside diameter.

Cylindrical (round) cans have two dimensions - diameter and height. Square, rectangular and oval cans have three dimensions - length, width and height.

Measurement of can diameter (round) or length and width (square and oval) should be measured from the outside of the end or lid seam. Side-to-side measurement of can height should be from the top of one end seam to the top of the other in 3-piece round, square, or oval cans, or from the top of the seam to the bottom of the container in 2-piece cans.

B. Pouches

Measurement of length and width in pouches should be made from the inside edge of the seal area, side-to-side. Pouch thickness should be determined by placing the container horizontally on a flat surface and measuring the thickness approximately halfway down its length. Pouches have three dimensions - length, width and thickness. The actual pouch thickness should be less than or equal to the thickness listed in the filed scheduled thermal process. Thickness listed in the filed scheduled thermal process represents the maximum thickness during thermal processing and is not necessarily the pouch thickness dimension.

C. Semirigid Containers

Measure heat-sealed containers using procedures similar to that described under pouches. For plastic bowl-shaped containers with metal lids that are double seamed, measure the diameter of the double seamed end, the height, and the dimension of the plastic bottom. Plastic bottles are measured similar to procedures described for glass containers.

D. Glass Containers

The widest body diameter or the neck diameter is often given on filing forms.

Measurement of the diameter of a glass jar may be facilitated by using a flexible measuring tape to measure the circumference, then dividing by π (3.1416) to obtain the diameter.

Height is usually measured from the lip to the bottom. Accurate measurements will not be possible on jars in a shipment because of the presence of the cap.

Manufacturers are permitted to file container capacity for irregularly shaped containers. The filed weight should be the weight declared on the label.

E. Aseptically Packaged LACF/AF

Aseptic packaging systems may use high temperature for a relatively short period of time to render the product commercially sterile and use various means (chemicals, irradiation, etc.) for container sterilization. Containers used for these products are usually flexible or semi-rigid cartons which cannot tolerate high temperature (e.g., multi-layer, fiberboard, laminated boxes; molded form/fill/seal cups).

Most of those products will be liquids or semi-solids, e.g., milk, soybean products (drinks, TOFU), teas, puddings, fruit purees, etc. *If any products are encountered which appear to contain small pieces of food (e.g., cream of mushroom soup), collect documentary evidence for particulate size determination and photos of the suspect product, then submit this information to CFSAN/Division of Enforcement/Imports Branch/HFS-606, via CMS case. Hold the entry pending CFSAN review.*

NOTE: The FURLS Acidified/Low-Acid Canned Foods Registration & Process Filing System can be used to determine whether a product is LACF, AF, aseptically processed or a_w controlled.

The LACF database search functionality provides some of the information contained on the process filing forms and can be used to determine whether the process was filed as LACF or AF, the container type and sizes, the processing method and whether water activity or maximum pH are critical factors. Process filings can be obtained from the LACF database.