CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:	**IMPLEMENTATION DATE**
DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS	UPON RECEIPT
	COMPLETION DATE
	Continuing

DATA REPORTING

PRODUCT CODES	PRODUCT/ ASSIGNMENT CODES (PAC)
INDUSTRY CODES: 02-11, 13-41, 45-46, 50 USE APPROPRIATE PRODUCT CODES	REPORT INSPECTIONS UNDER THE FOLLOWING PACs: 03803A AF/LACF inspections 03803 Inspections of central distribution warehouses where unlabeled cans are shipped for labeling and casing; and follow-up inspections of AF/LACF products for filth. 71003E (CVM) Inspections of LACF pet food firms, Industry 72
	ADD-ON INSPECTIONS 03842 Add-on domestic fish or fishery products for GMPs 03842H Add HACCP portion of Seafood inspection 21002 Medical food add-on inspections 21005 NLEA (Label Review) 21006 Infant formula add-on inspections
	REPORT SAMPLE ANALYSIS UNDER THE FOLLOWING PACs: 03803A AF/ LACF

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

FIELD REPORTS TO HEADQUARTERS

1. Compliance

Do not send copies of domestic Establishment Inspection Reports (EIRs) to the Center for Food Safety and Applied Nutrition (CFSAN) unless a compliance action is recommended. Submit all

recommendations for compliance actions to CFSAN through Mission Accomplishments and Regulatory Compliance Services (MARCS) - Compliance Management System (CMS) and follow the procedures outlined in the Regulatory Procedures Manual (RPM), Chapter 4, Advisory Actions.

2. Inspectional

Send the following completed reports to:

FOOD AND DRUG ADMINISTRATION
CFSAN/Field Programs Branch (FPB), HFS-615
ATTENTION: DOMESTIC LACF MONITOR
5100 Paint Branch Parkway
College Park, MD 20740-3835

{Reports should only be sent to CFSAN if they meet the criteria listed below}.

a. Entire EIR and 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.

b. Entire EIR and any related materials for LACF inspections of any of the following technologies:

(1) Aseptically processed and packaged LACF products containing particulate food; e.g. clam chowder, chunky soups or stews, etc.

(2) Sterilization of aseptic packaging materials using media other than superheated steam, peroxyacetic acid/peracetic Acid or hydrogen peroxide;

(3) Digital thermometers in lieu of mercury-in-glass thermometers;

(4) Initial inspections of firms utilizing high pressure, microwave, pulsed light, ozone, pulsed electric fields, irradiation or technologies other than retorting used to process or aseptically package low acid canned food.

3. Training and Consulting

Better Process Control School Participation - See Part III, for further information.

Send completed reports to:

FOOD AND DRUG ADMINISTRATION
CFSAN/ Office of Food Safety
HFS-302
ATTENTION: BPCS Program Manager
5100 Paint Branch Parkway
College Park, MD 20740-3835

FACTS - DATA REPORTING

See Part III and Part IV for complete instructions for reporting inspectional and analytical results.

PART I - BACKGROUND

In 2007, the Agency responded to an extensive class I recall by a large 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/LACF industry. Inadequate evaluation of aging equipment, changing formulations and processes, and failure to execute 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 Parts 113 "Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" and 21 CFR Parts 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.

In addition to the other requirements, 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 Good Manufacturing Practices (GMPs).

A firm which does not comply with the mandatory provisions of 21 CFR Parts 108, 113 and 114 may be required to obtain an emergency permit as required in 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.

PART II - IMPLEMENTATION

OBJECTIVES

A. To determine, by inspections and sample collections (and analyses), if domestic acidified and low-acid canned food manufacturers comply with 21 CFR, Parts 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.

B. To prevent the introduction of acidified and low-acid canned foods into interstate commerce which are manufactured under conditions that do not comply with these requirements.

NOTE: **Foreign AF and LACF Manufacturers** that ship to the United States are also required to comply with the mandatory provisions of 21 CFR, Parts 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 FD&C Act. Use the same instructions in this Compliance Program when conducting both foreign and domestic inspections. *

PROGRAM MANAGEMENT INSTRUCTIONS

A. **General Information**

1. Because of the serious health hazards resulting from improperly processed AF/LACF and the occasional necessity for expert technical advice during an investigations and inspections, it is imperative that the Alert System procedures as defined in Attachment A be followed. During or **IMMEDIATELY** after an inspection in which significant deviations from the regulation are observed or where follow up to reports of product failures/recalls indicate a serious failure in a processing system or operating procedure, HFS-607 must be notified immediately, per Attachment A.

2. Pet or animal food should be covered under this program. Appropriate PAC and Product Codes should be used for CVM products.

3. 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)).

4. Naturally fermented products **are not** considered to be acidified foods. A naturally fermented product is one which:

   a. has been salted or held in a brine solution; **and**

   b. has been allowed to ferment for 1 or more weeks in containers; **and**

   c. 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.

5. Domestic AF and LACF inspections may be candidates for team inspections, especially as they relate to food processing and preservation, microbiological or electronic technologies.

6. CFSAN/Division of Field Program and Guidance/Field Programs Branch, HFS-615 will issue a printout on all domestic producers of AF/LACF. The Districts can use this printout for scheduling inspections using the following priority coverage. It is anticipated that this printout will be issued in late August of each fiscal year.

7. For technical questions on this program, Investigators should contact CFSAN technical experts or DFI National Experts after concurrence with their District management.

B. Priority Coverage

Inspectional priority should be governed by the following considerations:

- All newly registered AF and/or LACF manufacturers should be inspected within six months of notification.

  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 3 months of the OAI inspection. Manufacturers

classified "Voluntary Action Indicated" (VAI) should be inspected within 12 months of the last inspection at the Districts discretion based on the type of violation.

- All AF and/or LACF manufacturers classified as "No Action Indicated" (NAI) should be inspected within 36 months of the last inspection.

- 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.

INTERACTION WITH OTHER PROGRAMS

A. **Domestic Food Safety Program** (7303.803)

Report inspections of central distribution warehouses where unlabeled containers ("brites") are shipped for labeling and casing against **PAC 03803**. Cover container handling, equipment sanitation, and quality control procedures. If significant violations unrelated to the AF/LACF Program are revealed then a full inspection should be conducted in accordance with the Domestic Food Safety Program.

Consult the Domestic Food Safety Program concerning pesticides/chemical contaminants and food/color additives.

B. **Domestic Fish and Fishery Products Inspection Program** (7303.842)

The seafood Hazard Analysis and Critical Control Points (HACCP) regulations 21 CFR Part 123 "Fish and Fishery Products" became effective December 18, 1997. These regulations require, among other things, that all seafood be processed under a HACCP system. 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 these canned seafood. (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 7303.842 as appropriate). Attempt to "add-on" inspections of fishery product firms when conducting applicable LACF inspections. Record both PAC **03803A and the applicable Domestic Seafood PAC as per CP (7303.842)** when both types of inspections are conducted.

C. **Medical Foods - Import and Domestic** (7321.002)

Refer to the inspection schedule that is issued separately each year by CFSAN/DFPG. Where appropriate, include an LACF inspection. Record both PACs **03803A and 21002** when both types of inspections are conducted.

D. **Infant Formula Program – Import and Domestic (**7321.006) Refer to the inspection schedule that is issued separately each year by CFSAN/DFPG. Where appropriate, include an LACF inspection. Record both PACs **03803A and 21006** when both types of inspections are conducted.

E. **Food Labeling Compliance Program (**formerly NLEA and General Food Labeling) Requirements – Domestic (7321.005).

The Food Labeling Compliance program reflects the current NLEA instructions. Report all resources expended for NLEA under PAC 21005. Labeling issues regarding undeclared foods and allergens should be reported under this program accordingly.

F. Guidance For Use of pH Meters for Field Exams on Imported Acidified Food (ACF) Products and in Domestic Inspection at: http://inside.fda.gov:9003/ProgramsInitiatives/FieldOperations/FieldGuidance/default.htm

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

PART III – INSPECTIONAL

See "Implementation Section" for "Interactions With Other Programs".

A. **INSPECTIONAL**

1. Plant Registration/Scheduled Thermal Process Filing

As of June 2010 there is a new "exempt" category in the LACF Database to house products that have been reviewed by CFSAN and found to be exempt from filing. Products in this category do not file under 21 CFR 113 or 114 and therefore should not be included in inspectional activities under these regulations.

NOTE: Lack of Plant Registration and/or failure to file processes is 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. The firm should be informed by the investigator that the food has been determined after review to be an acidified food and that the firm should register and file the scheduled process for that product.
- 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.

Use the Low-Acid Canned Food (LACF) On-Line Computer System at **https://info1testtun.cfsan.fda.gov:8889/lacf/fda/default.cfm to:**

- Determine whether the manufacturer has registered for a Food Canning Establishment (FCE) number,

- Determine whether a process(es) has been filed and accepted for the product(s), and/or

- Gain information about firm's thermal process in preparation for the inspection.

  Note: A copy of the form FDA-2541, Food Canning Establishment Registration, should be obtained prior to and included in the inspection report to ensure filing and registration. The Center's LACF Registration Coordinator provides each DIB with a copy of form FDA-2541 for all the newly registered firms for their District. The DIB in return must provide the LACF Coordinator a copy of the form FDA-2541, indicating on each, the firm's assigned FEI number.

  If the LACF system is down, the District can consult its own registration files to verify registration. The same does not hold true for process filing. Refer below for further instructions.

  This on-line computer system was implemented in the Field during Fiscal Year 2004. Personnel requiring access to this system will need to go to http://inside.fda.gov:9003/CFSAN/default.htm, then in the center of the page under "Title" choose "LACF". At this point you may request a new account by selecting the "Request Account" link on the LACF Login screen. The user will receive notification through FDA's email services when CFSAN has completed the account activation. The account activation should occur within one day, if the request is made on a regular business day.

  Complete instructions and definitions needed to use LACF online are available from the LACF Login Screen. Choose the Field Guide to print out a copy of this step by step guide. In addition, FAQs are available from the Login Screen. If additional assistance is needed please contact the LACF Registration Coordinator listed in Part VI of this program.

a. If the FCE number is not available, to determine if a manufacturer has registered, go to the LACF database, in **"Facility Section" select "search"**. The file may be searched using any combination of the manufacturer's name, street address, city, state/province, zip code/postal Code, and/or country. Firms must register by their actual processing plant name.

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

   - **Select "Product Report"** to determine if a process is on file for the product, container type and container size. Search using the FCE and Submission ID (SID).

c. 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 the LACF Registration Coordinator (HFS-303) for assistance at (301)436-2411. The Data Base is updated continuously.

d. If upon inspection, the firm has relocated, the manufacturer must notify CFSAN of the move and re-register and file process information for the new location. The District employee should notify the LACF Registration Coordinator in order to have the old FCE number put in an out of business status. **In addition, if the Districts 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 in order to update the LACF Database. The appropriate representative should submit an email to: LACF@fda.hhs.gov.**

e. All forms, as well as the instruction book and regulations can be downloaded from CFSAN's Internet at:

https://info1testtun.cfsan.fda.gov:8889/lacf/fda/default.cfm

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 facsimiles 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 District **must be destroyed**.

2. Inspections

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

The investigator must be prepared during inspections of AF/LACF manufacturers

to determine the firm's compliance with the AF regulations, 21 CFR Part 114; the LACF regulations, 21 CFR 113; Emergency Permit Control, 21 CFR 108; and GMP general standards regulation, 21 CFR Part 110.

Investigators should note that recent events such as confirmed botulism cases, Class I Recalls and serious investigational findings resulting in two firms being placed under Emergency Permit Control, have raised concerns about the safety of LACF products and the state of control in the industry. Problems identified included, malfunctioning equipment resulting in under processed product; a lack of control in the areas of container fill weights, can seam integrity, under processed product accountability and product coding; and inadequate heat distribution studies and heat penetration documentation. 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/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:

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

2) 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.

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 products internal temperature; increased risk of can damage during jams; and overcooling causing can 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 inspection include:

- 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 and the integrity of the containers.
- To review the firm's water quality and cooling water sanitation procedures/documentation.
- To conduct field exams of warehouse product and sample collections of suspect product.
- To determine how the firm identifies, handles and assesses spoiled product/abnormal cans, including finished product in storage.

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 or LACF training course where the concepts of retort design, vent size/configuration and drain location 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.

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 document full details in the EIR and on the appropriate forms. **NOTE: FDA-3511 forms were created to ensure complete inspectional coverage. Use FDA Form 3511 and the appropriate Retort Reporting Form (FDA Forms 3511a-i) as a guide to the conduct of the inspection.**

Report all AF/LACF inspections using the following forms, as appropriate. The Forms are available on ORA's forms site at http://www.fda.gov/opacom/morechoices/fdaforms/ora.html. The forms are in PDF format and can be electronically completed after downloading. The report forms are as follows:

a. FDA Form 3511 FDA LACF Inspection Report
b. FDA Form 3511 a-i Retort Reporting Forms - see below, as appropriate
c. FDA Form 3511-2 Acidified Food Inspection Report
d. FDA Form 3511-3 Aseptic Food Inspection Report (currently under final review). It will be available on the forms site upon completion.

Retort 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

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, 3511, 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 product:

- 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 amount of abnormal containers (greater than 1%)and 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

- LACF Products with pH of 4.7 – 5.4 held at ambient temperatures
- "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) Sample Chart 2, "SAMPLING SCHEDULE FOR CANNED AND ACIDIFIED FOODS" located at http://www.fda.gov/ICECI/Inspections/IOM/ucm127460.htm**

d. Scheduled Process

- Determine the Process Authorities 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 as necessary on the following when investigation reveals that major changes have been made in 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 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 no changes, a general visual inspection of the equipment to identify gross deviations from the regulations is sufficient.
  - 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-i) or FDA Form 3511 as necessary.
  - If significant deviations (e.g., broken MIG, etc.) are noted during the visual inspection, describe and document full extent of deviations using appropriate Retort Reporting Form (FDA Forms 3511a-i) or FDA Form 3511 as necessary.
  - Change in equipment could change parameters and 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 FDA Form 3511.

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/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. 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.
- Bacterial spores are 10 to 1000 times more resistant to chlorine inactivation than are their corresponding vegetative cells. A contact time of 30 minutes is generally accepted as being an adequate amount of contact time for the inactivation of spores in cooling water at a specified chlorine level provided chlorine levels are adequate.

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 cumulate 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; at http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/Regulations/default.htm.

- 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, at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074992.htm

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 2 – Process/Procedures, at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074995.htm

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 3 – Containers/Closures, at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074999.htm

- FDA GUIDE TO INSPECTIONS OF ACIDIFIED FOOD MANUFACTURERS, at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm075003.htm

- FDA GUIDE TO THE INSPECTION OF ASEPTIC PROCESSING AND PACKAGING FOR THE FOOD INDUSTRY, at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074946.htm

- FDA GUIDE TO THE INSPECTIONS OF COMPUTERIZED SYSTEMS IN THE FOOD PROCESSING INDUSTRY, at http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074871.htm

- Better Processing Schools Manual; contact CFSAN Technical Expert.

- Various Publications available from GMA which if not available in your district can be purchased at http://www.gmabrands.com/index.cfm, including:
  - 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

- Reference: Attachment B, "Expanded LACF Establishment Inspection", May 2008, on CFSAN's (#)

- "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 DHRD because this document is no longer posted on the intranet.*

- ORAU Classroom Training

  - Basic Low Acid Canned Food, FD103
  - Advanced Low Acid Canned Food, FD3003
  - Acidified Foods, FD202
  - Aseptic Processing for Food, FD405
  - Canned Seam Analysis, LB221

- ORAU On-line Courses

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

- DFI Bulletins: Note – 2 proposed DFI bulletins have been written by Brian Hendrickson, DFI Technical Expert and sent to CFSAN for review and concurrence – (1) Venting & Operating Procedures For Continuous Agitating Retorts Processing in Steam, and (2) Heat Distribution vs. Temperature Distribution in Seam Retorts & Retorts Operating with Overpressure. After review and final concurrence by CFSAN, these bulletins should be distributed to the Field and referenced in this section of the compliance program.

4. Determination of Acidified Food

Acidified Foods are covered under 21 CFR Part 114.

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

- 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. The firm should be informed that the food has been determined after review to be an acidified food and that the firm should register and file the scheduled process for that product.

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.

To determine whether the small amounts of low-acid ingredient(s) result in a significant pH difference, obtain:

a. Quantitative formulation (obtain quantitative information using the same units of measurement or percentages). When determining the quantitative amounts of low acid ingredients, do not count sugar, salt or water. Do count powders such as onion powder, garlic powder, etc., as these ingredients can absorb acid and affect the finished equilibrium pH. 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.*

b. The pH of each ingredient in the quantitative formulation if feasible **OR** other evidence that determines whether ingredients being used are acid or low-acid components (i.e., raw chopped vegetables used as ingredient(s)).

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

d. The pH of the acid(s) and/or acid food(s)ingredients mixed together in the same proportion in which the acid(s)and/or acid food(s) ingredients appear in the product formulation. Relate these samples to the equilibrium pH of the finished product to determine if there is a significant shift in pH.

e. The pH (minimum of six units of finished product when obtaining information to determine if product is an acidified food). Obtain information from the firm, if available, or through sampling and testing with a calibrated pH meter. Finished products collected to determine pH by an FDA laboratory for the purpose of supporting regulatory action should be collected per IOM chapter 4 "Sample Schedule Chart 2" found at http://www.fda.gov/ICECI/Inspections/IOM/ucm127460.htm.

f. 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. Note – the firm should test a minimum of 6 jars of finished product. Collect the data

and submit with the EIR. If the firm determines through their own testing that a product is an acidified food and they have not registered and/or filed a scheduled process, consider citing the firm for their failure to register and/or file.

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).

5. 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 system:

- 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.

This information and the complete EIR should be submitted to CFSAN/Field Programs Branch, HFS-615 for review by CFSAN/ Food Processing Evaluation Team , HFS-302.

6. 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.

Districts at their option can 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 Canned and Acidified Foods" to determine the number of cans to examine in a lot.

B. SAMPLING

IOM, Sample Schedule Chart 2, "Sampling Schedule for Canned and Acidified Foods" (http://www.fda.gov/ICECI/Inspections/IOM/ucm127460.htm), lists sampling instructions. Routinely examine warehouse stock for evidence of abnormal containers.

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 (6) 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: bread, 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. 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 III.A.3.

   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, collection of normal containers for surveillance samples is optional.

C. ALERT SYSTEM

Because of the serious health hazards resulting from improperly processed AF/LACF and the occasional necessity for expert technical advice during an investigation, it is imperative that the Alert System procedures as defined in Attachment A be followed. During or **IMMEDIATELY** after an inspection in which significant deviations from the regulation are observed or where follow-up to reports of product failures/recalls indicate a serious failure in a processing system or operating procedure, CFSAN Enforcement Contacts, must immediately be called, per Attachment A.

D. BETTER PROCESS CONTROL SCHOOLS

The Better Process Control School (BPCS) program is a cooperative training program between the universities that have been approved by the Commissioner for giving BPCS instruction, the Grocery Manufacturers Association (GMA) and the FDA. 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:

1. Present an introduction that generally focuses on:
   a. The importance of the course, and
   b. Highlights of the regulations.

2. Answer questions

3. Provide support to the university manager and instructors.

4. 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.

5. Provide feedback to CFSAN in the form of a written report:
   a. The kinds of questions that arise,
   b. New information that might arise from class discussion,
   c. Any unanticipated problems.

NOTE: All districts were provided with a BPCS video tape by the Division of Field Investigations (DFI). If you need a copy in your district please contact The DFI Technical Contacts listed in Part VI.

E. REPORTING

1. FACTS REPORTING

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

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 and/or add-on inspections:

PAC	Description
03803A	AF/LACF full inspections
03803	Inspections of central distribution warehouses where unlabeled cans are shipped for labeling and casing; and follow-up inspections of LACF/AF products for filth, only
03842	Add-on domestic fish or fishery products for GMPs
03842H	Add-on Seafood HACCP portion of an inspection
21002	Medical food add-on inspections

21005	NLEA: Coverage of NLEA will be accomplished during ALL routine inspections conducted under the Domestic Acidified and Low Acid Canned Foods program for firms that are manufacturing and/or labeling or re-labeling food products at the site being inspected. Do not report inspections under NLEA. See current Food Labeling Compliance Program (CP 7321.005) for complete guidance.
21006	Infant formula add-on inspections
71003E	LACF pet food inspections

2. Better Process Control Schools. Report resources expended by FDA personnel under Operations Code 83.

3. Hard copy reporting to CFSAN/Field Programs Branch, HFS-615

   a. Entire EIR and 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.

   b. Entire EIR and any related materials for LACF inspections of any of the following technologies:

      1. Aseptically processed and packaged LACF products containing particulate food, e.g., clam chowder, chunky soups or stews, etc.;

      2. Sterilization of aseptic packaging materials using media other than superheated steam or hydrogen peroxide;

   c. Any new canning technology being inspected for the first time.

F. **INVESTIGATING IMPORTED GOODS IN DOMESTIC COMMERCE**:

Imported products cross all program areas and our regulation of them does not stop at the border. Please be alert to imported products whenever you make 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/ORO/Division of Import Operations and Policy (DIOP) immediately. It is possible that other domestic firms have imported the same product and DIOP 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 DIOP. (Reference: IOM Chapter 6, Imports) http://www.fda.gov/ICECI/Inspections/IOM/ucm123337.htm

PART IV - ANALYTICAL

ANALYZING LABORATORIES

Consult the National Sample Distributor (NSD) or your District management for laboratory capability/servicing area in performing the following analyses:

pH Determination

Microbiological and Physical Examination of Container

Staphylococcal enterotoxin

Headspace Gas Analysis by GC

Water Activity (a_w) Determination

Chemical Contaminants and Food Additives

Filth and Extraneous Matter

NOTE: Cover chemical contaminants, food additives and filth/extraneous matter under CP 7303.803, Domestic Food Safety, not under the AF/LACF Program.

CFSAN Laboratory Confirmation:

- *Clostridium botulinum* toxin confirmation - CFSAN/Office of Regulatory Science, Division of Microbiology, Molecular Methods & Subtyping Branch, HFS-712, 5100 Paint Branch Parkway, College Park, MD 20740-3835. Note: Confirmation by CFSAN is performed when initial analytical results are inconclusive and as necessary.

- Staphylococcal enterotoxin confirmation - CFSAN/Office Regulatory Science, Division of Microbiology, Molecular Methods Development Branch, HFS-711, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

ANALYSIS

A. General Information

It may be necessary to determine the a_w and pH to classify the product where the product status is in doubt (i.e., AF or LACF). Products with a_w values at or below 0.85 are neither LACF nor Acidified Food. All samples collected for microbiological analysis must also be examined for container integrity.

Measurement systems specified in B.2.a should always be used.

B. Low-Acid Canned Food (LACF)

1. Microbiological and Physical:

Refer to Bacteriological Analytical Manual (BAM), the most current on-line version at http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/Bacterio

logicalAnalyticalManualBAM/default.htm

Chapter 13 - Staphylococcal enterotoxin

Chapter 17 - *Clostridium botulinum*

Chapter 21 - A. Examination of Canned Foods
B. Modification of Headspace Gas Analysis, using the SP4270 Integrator

Chapter 22 - Examination of Containers for Integrity

a. Headspace Gas Analysis

Districts so equipped and trained should use BAM, the most current on-line version at (http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm), Chapter 21, Section B, for headspace gas analysis.

Laboratories that do not have the necessary equipment should perform headspace gas analysis according to BAM 8th Ed., Revision A, 1998 (http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm), Chapter 21, Section A.

b. Seal Integrity Examination and Evaluation

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 (see BAM 8th Ed., Revision A, 1998, (http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm) Chapter 22,C.3. and Compliance Policy Guide 7120.16 Section 520.200 at http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg520-200.html). 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 aseptically (LIB No. 2723) on the normal containers selected for culturing and appropriate seal examinations.

c. *Clostridium botulinum*

Send sample reserve and cultures to Arkansas Regional Laboratory (ARL),for *C. botulinum* confirmation.

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

All *C. botulinum* testing preformed and cultured toxins that will be confirmed by CFSAN should be forwarded to CFSAN/Office of Regulatory Science, Division of Microbiology, Molecular Methods & Subtyping Branch, HFS-712, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Attn: Shashi Sharma. Note: C. botulinum toxin confirmation analysis is initially performed by Arkansas Regional Laboratory (ARL). CFSAN will perform confirmation as necessary.

2. Water Activity (a_w) or Salt Control

When it is necessary to establish the pH as well as a_w, follow instructions below under "C", – Acidified Foods – pH Analysis.

Where the product status is in doubt (i.e., AF or LACF) it may be necessary to determine a_w to classify the products. Products with a_w values at or below 0.85 are **neither** LACF nor acidified. **Measurement systems specified in "a" below for a_w should always be used.**

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 using the AOAC (most current on-line version, 978.18, section 42.1.03).

(1) Initial Screening: For all size containers, determine the a_w of three (3) units using the Abbeon a_w Value Analyzer or other approved analyzer (see AOAC, most current on-line version, 978.18, section 42.1.03, B. Instruments and Systems).

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).

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.

(2) Confirmation: Determine the a_w of three (3) containers using the:

- Decagon Aqualab Hygrometer, or
- Rotronic AG.

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

(4) Do not classify as lab class "3", unless it is known that a_w values exceed the maximum value filed by the firm.

a. 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.

b. 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, (301) 436-2411.

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.

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.

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

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

c. 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.

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

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:

CFSAN/Office of Regulatory Science
Division of Microbiology
Molecular Methods & Subtyping Branch, HFS-712,
Attn: Shashi Sharma
5100 Paint Branch Parkway
College Park, MD 20740-3835

Note: C. botulinum toxin confirmation analysis is initially performed by Arkansas Regional Laboratory (ARL). CFSAN will perform confirmation as necessary.

2. Staphylococcal Enterotoxin Confirmation

The procedures for the assay for Staphyloccal Enterotoxin in canned foods are referenced in the FDA Bacteriological Analytical Manual (BAM), 8th Edition, Revision A, 1998, Chapter 13, Introduction (last paragraph). The online version is located at http://www.cfsan.fda.gov/~ebam/bam-toc.html. All positive samples and samples suspected to have caused a Staphylococcal food poisoning outbreak should be submitted for confirmation to CFSAN/Office of Regulatory Science, Division of Microbiology, Microbial Methods Development Branch, HFS-711, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

E. Container Integrity/Abnormal Containers

1. Container Integrity

Container integrity problems, especially seam or seal defects are significant with acidified and low-acid canned foods. All can defects and out of specifications seams can be of importance to public health. For example, Tilly-Lewis was canned tomatoes with a can defect that allowed an organism B. licheniformis to grow and change the pH and allow C. botulinum to grow which caused a fatal incident.

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.

2. 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 *C. botulinum* toxin.

3. Glass Containers and Semi-rigid and Flexible Packaging

Perform visual examinations, microleak examinations and destructive testing where appropriate. Refer to BAM, Chapter 22, "Examination of Containers for Integrity", 8th Ed., Revision A (1998) for methods of analyses. Questions should be referred to CFSAN/Office of Food Safety/ Food Processing Evaluation Team, HFS-302 at 301/436-2411, lacf@fda.hhs.gov. Guidance in describing visible defects for flexible packages is available in the AOAC chart, "Classification of Visible Exterior Flexible Package Defects".

4. Photograph visible defects with a digital camera or scan pictures for submission to CFSAN.

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.

B. ANALYTICAL DATA REPORTING

Report all analytical results for low acid, acidified and acid products using PAF **"ACD"**.

In addition to reporting the analytical results, data requested under the "violative sample data screen" for samples which are determined to be lab class "3", must be completed.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

A. Acidified Products - Analysis Results

Recommend actions to CFSAN/ Division of Enforcement/ Manufacturing and Storage Adulterations Branch, HFS-607 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. Contact CFSAN Enforcement Contacts for further instructions if:

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.

C. Warning Letters and other Actions

District Compliance Branch will submit all correspondence through MARCS-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 District Director issuance of the Warning Letter. Refer to the Agency established "Supplemental Procedures for Clearing Warning Letters and Untitled Letters", dated March 5, 2002, available on FDA's ORA Intranet Website at http://web.ora.fda.gov/oe/warningletters/TRKLET116R.htm.

2. Warning Letter recommendations - entire EIR and other correspondence with proposed Warning Letter attached for review.

3. Warning Letter considerations - memorandum-summarizing areas of concern to accompany entire EIR. Upon review by CFSAN/DE/ MSAB (HFS-607), District will be provided with subjects to be covered

4. under District issuance of a Warning Letter.

The following applies when an inspection determines failure of a firm to adhere to with all of the mandatory provisions of 21 CFR 108.25 and 114. 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 District 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. The District should review the firm's responses promptly [refer to FMD 120 - Follow Up to a Firm's Response to an FDA 483(This form is not yet available on ORA's Intranet.)].

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, other regulatory action may be necessary.

Attachment A describes procedures for using the "Alert System." At any time during an investigation when it becomes apparent that public health may be at risk, districts are encouraged to evaluate the significance of the deviations, using personnel familiar with AF/LACF and operations and policy, and discuss their findings with CFSAN Enforcement Contacts.

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.

D. **Industry Education**

Materials developed by the Center (see Attachment B) which explain many of the FDA requirements for processing AF and LACF may be useful in responding to industry inquiries or requests for assistance in solving compliance problems.

At the District's request, CFSAN/Office of the Center Director/ International Affairs Staff, HFS-550, will assist the District in developing and conducting industry education workshops concerning recalls or other topics deemed appropriate by the District.

PART VI - ATTACHMENTS, REFERENCES AND PROGRAM CONTACTS

ATTACHMENTS

Attachment A - Details of Alert System
Attachment B - Industry Education Publications

REFERENCES

FDA Guide to Inspections of Low Acid Canned Food Manufacture

Part 1 - Administrative Procedures/Scheduled Processes, November 1996 Low Acid Canned Food Manufacturers Part 1 - Administrative Procedures/Scheduled Processes

Part 2 - Process/Procedures, April 1997
Low Acid Canned Food Manufacturers Part 2 - Processes/Procedures

Part 3 - Containers/Closures, November 1998
Low Acid Canned Food Manufacturers Part 3 - Container/Closures (11/98)

FDA Guide to Inspections of Aseptic Processing and Packaging for the Food Industry, February 2001
http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074946.htm

FDA Guide to Inspections of Acidified Food Manufacturers, May 1998
http://www.fda.gov/ICECI/InspectionGuides/ucm075003.htm

FDA Guide to Inspections of Computerized Systems in the Food Processing Industry, March 1998
http://www.fda.gov/ICECI/InspectionGuides/ucm074955.htm

FDA Investigations Operations Manual (most current issue)
http://www.fda.gov/ICECI/Inspections/IOM/default.htm

PROGRAM CONTACTS

CFSAN Program Contact:	Edette J. Newby, CFSAN/ Office of Compliance/ Division of Field Program Guidance/ Field Programs Branch, HFS-615, (301/436-2068), FAX (301/436-2657), Edette.Newby@fda.hhs.gov
CVM Program Contact:	Neal Bataller, Center for Veterinary Medicine, Office of Surveillance and Compliance, Division of Compliance,HFV-230, (240/276-9201), FAX (240/276-9241), Neal.Bataller@fda.hhs.gov

CFSAN Enforcement Contact:	Donald Greaves, CFSAN/ Office of Compliance/ Division of Enforcement/MSAB, HFS-607, (301/436-2057), Donald.Greaves@fda.hhs.gov Bill Correll, CFSAN/ Office of Compliance/ Division of Enforcement/MSAB, HFS-607, (301)/436-1611 William.Correll@fda.hhs.gov
DIOP Contact:	If Districts encounter issues with imported products, contact your DIOP Operations and Policy Branch Regional Activities Managers.
CFSAN Technical Expert; Better Processing Control School Coordinator; questions regarding the preservations; 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:	Michael Mignogna, CFSAN/ OCD/ Office of Food Safety, Food Processing Evaluation Team, HFS-302, (301/ 436-1565), Michael.Mignogna@fda.hhs.gov
DFI Technical Expert:	Brian Hendrickson, Office of Regulatory Affairs/ ORO/ Division of Field Investigations, HFR-CE756, (317/226-6500, ext. 104), Brian.Hendrickson@fda.hhs.gov
LACF Registration Control Coordinator, questions regarding the LACF online system, and plant registration and filed scheduled processes:	Brenda Pinkney, CFSAN/ Office of Food Safety/ Food Processing Evaluation Team, HFS-303, 301/436-2411, LACF@fda.hhs.gov
Confirmation of Preformed and/or Cultured *C. botulinum* toxin:	Shashi Sharma, CFSAN/OCD/ORS/DM/MMSB, HFS-712, (301/436-1570), Shashi.Sharma@fda.hhs.gov
Confirmation of Staphylococcal enterotoxin:	Reginald Bennett, CFSAN/OCD/ORS/DM/MMSB, HFS-711, (301/436-2009), Reginald.Bennett@fda.hhs.gov
Industry Education:	Kenneth Nieves, CFSAN/OCD/International Affairs Staff HFS-550, (301/436-1179), Kenneth.Nieves@fda.hhs.gov

Inspectional Inquiries:	Norman Fogg, Office of Regulatory Affairs, ORO/ Division of Field Investigations, HFC-130, (301/827-5645), Norman.Fogg@fda.hhs.gov
Analytical Methods Inquiries:	Marilyn Khanna, Office of Regulatory Affairs/ ORO/ Division of Field Science/SCRRB, HFC-141, (301/827-4659), Marilyn.Khanna@fda.hhs.gov
DFS NSD Contact:	Todd Bozicevich, Office of Regulatory Affairs/ ORO/ Division of Field Science, HFC-140, (301/ 827-9552), Todd.Bozicevich@fda.hhs.gov

PART VII - CENTER RESPONSIBILITIES

1. **Botulinum Toxin Confirmation**

Confirmation of preformed and cultured botulinum toxin, CFSAN/Office of Regulatory Science/Division of Microbiology, HFS-712 Shashi Sharma, shashi.sharma@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. Brenda Pinkney, lacf@fda.hhs.gov

3. **Evaluation Requirements**

During the course of this program, but no later than thirty (30) days after the expected date of final data receipt, any deficiencies in the conduct of Field operations or program quality should be identified by the Director, Division of Field Programs and Guidance, Office of Compliance, HFS-615, so that necessary corrective action may be initiated. An annual evaluation of this program will also be provided.

DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS PROGRAM

ALERT SYSTEM

1. If the District determines at any time during an investigation that the public health may be at risk, the Director, Investigations Branch, with the Supervisor and Investigator will call CFSAN/ DE, MSAB, HFS-607, Branch Chief, at phone number (301) 436-1611.

2. If the MSAB, HFS-607, concurs that a serious potential health hazard is possible, complete the report as soon as possible and submit it via a one-day delivery service to HFS-607.

3. On issues involving imported product, CFSAN should determine if the responsible district has notified DIOP of the issues. If CFSAN determines that the responsible district has not notified DIOP, CFSAN will engage DIOP immediately.

4. The District may recommend specific regulatory action, but should not delay submitting the EIR while awaiting such recommendation from the District's Compliance Branch.

5. The District should alert the Center for Veterinary Medicine, Office of Surveillance and Compliance, Division of Compliance, HFV-230, when problems arise regarding canned animal food.

DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS PROGRAM

INDUSTRY EDUCATION INFORMATION

FDA:

1. Copies of publications can be obtained from the CFSAN internet website: http://VM.CFSAN.FDA.GOV/~comm/LACF-TOC.html.

2. Copies of the publication, **pH Control - Why the concern?**, which explains why the food processing employee must be concerned with properly controlling the acidification and determining the pH of foods can be obtained from CFSAN/Office of the Center Director/ International Affairs Staff, HFS-550, Kenneth Nieves, (301) 436-1179, Kenneth.nieves@fda.hhs.gov.

Food Processors Institute:

A number of publications and audiovisuals are available from:

Grocery Manufacturers Association (GMA)
*1350 I Street, N. W.
3rd Floor *
Washington, D. C. 2005
(202) 639-5900

Website for GMA is www.GMAonline.com