CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:	**IMPLEMENTATION DATE**
DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS (FY 03/04/05)	UPON RECEIPT
	COMPLETION DATE
	9/30/05

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 LACF/AF products for filth only **NOTE:** Discontinue use of PAC 03F103 AF/ LACF Directed Inspections.
	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

FIELD REPORTS TO HEADQUARTERS

A. Send the following completed reports to:

FOOD AND DRUG ADMINISTRATION
CFSAN/ Domestic Branch, HFS-607
5100 Paint Branch Parkway
College Park, MD 20740-3835

1. Compliance

a. Entire Establishment’s Inspectional Report (EIR) and other correspondence relating to firms under **Emergency Permit**

Control.

b. Entire EIR and other correspondence relating to a firm that should be considered for a temporary emergency permit.

c. **Warning Letter Recommendation** - entire EIR and other correspondence with proposed Warning Letter attached for review.

d. *** Warning Letter Consideration** - memorandum summarizing areas of concern accompanied by the entire EIR. After review by CFSAN/Division of Enforcement/ Domestic Branch (HFS-607), the District will be provided with subjects to be covered under District issuance of Warning Letter. *

2. Analytical

a. Heat Resistance Studies

(1) Analyzing Laboratories: Immediately notify the Domestic Branch, HFS-607, by e-mail when cultures are sent to Southeast Regional Laboratory (SRL).

(2) Southeast Regional Laboratories (SRL) Analyzing Laboratory: Upon completion of the heat resistance studies, send:

(a) the original analytical worksheet (FDA Form 431) to the Home District

(b) a copy of the FDA Form 431 to the servicing laboratory if in a different District

3. Inspectional

*Send the following completed reports to:
FOOD AND DRUG ADMINISTRATION
CFSAN/Compliance Program Branch, HFS-636
ATTENTION: DOMESTIC LACF MONITOR
5100 Paint Branch Parkway
College Park, MD 20740-3835 *

a. * Entire EIR and information identified in PART III, A. 6., 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;

(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.

4. Training and Consulting
Better Process Control School Participation - See Part III, for further information

Send completed reports to:

FOOD AND DRUG ADMINISTRATION
CFSAN/ Domestic Branch, HFS-607
ATTENTION: BPCS Program Manager
5100 Paint Branch Parkway
College Park, MD 20740-3835

FACTS - DATA REPORTING

A. Investigations
Better Process Control Schools

Report resources expended by FDA personnel under Operations Code 83

B. Analytical

Report all analytical results for low acid, acidified and acid products using Problem Area Flag (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 I - BACKGROUND

Inadequate or improper 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 low-acid canned foods (LACF) or acidified foods (AF) to register their processing plants and file their 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 "shall" 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, 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 interstate marketing of acidified and low-acid canned foods manufactured under conditions that do not comply with these requirements.

*__NOTE:__ **Foreign LACF and Acidified Food Manufacturers** 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 foreign inspections. *

PROGRAM MANAGEMENT INSTRUCTIONS

A. **General Information**

1. Because of the serious health hazards resulting from improperly processed LACF/AF 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, HFS-607 must be notified immediately, per Attachment A.

2. **Do not cover** pet or animal food under this program.

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 covered containers; **and**

   b. 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 dill pickles are examples of naturally fermented products.

Low-acid foods are foods that purport to be "fermented" and have a pH after fermentation greater than 4.6 and water activity greater than 0.85. Foods partially fermented but requiring addition of acid to reduce the pH to 4.6 or below are considered **acidified foods**. If acid is added before or after fermentation, in an amount sufficient to reduce the pH to 4.6 or below, the product is an **acidified food**. Document pH after fermentation and after addition of acid, and inspect as an acidified processor.

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 sample the product for water activity and pH. Obtain a pH history at each processing step.

5. Domestic acidified and low-acid canned food 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/Compliance Program Branch, HFS-636 will issue a printout on all domestic producers of acidified/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.

B. **Priority Coverage**

Inspectional priority should be governed by the following considerations:

- All newly registered Acidified Food 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 Acidified Food and/or LACF manufacturers operating under an Emergency Permit or classified "Official Action Indicated" (OAI) should be inspected within 12 months of the last 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 Acidified Food and/or LACF manufacturers classified as "No Action Indicated" (NAI) should be inspected within 36 months of the last inspection.

INTERACTION WITH OTHER PROGRAMS

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

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

If one or more of the eight targeted food groups are used in the firm and the firm meets the criteria (designated in the Allergen Assignment Attachment G of 7303.803) for an allergen inspection then a full allergen inspection should be considered.

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 because these are already addressed under LACF. However, the processor's seafood HACCP plan must control other hazards associated with these canned seafoods. (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 firm 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/DFP. Attempt to "add-on" LACF inspections, if applicable. 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/DFP. Attempt to "add-on" LACF inspection, if applicable. Record both PACs **03803A and 21006** when both types of inspections are conducted.

E. **NLEA and General Food Labeling Requirements - Domestic** (7321.005)

This 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.

PART III - INSPECTIONAL

Consult the Domestic Food Safety Program (7303.803) concerning pesticides/ chemical contaminants and food/color additives.

A. **INSPECTIONAL**

1. Plant Registration/Scheduled Thermal Process Filing

NOTE: Lack of Plant Registration and/or failure to file processes are reportable items on FDA Form 483.

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 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 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.

Use the Low-Acid Canned Food (LACF) On-Line Computer System **to determine whether**:

- the manufacturer has registered/FCE number,
- a process(es) has been filed for the product(s), and/or
- to gain information about firm's thermal process in preparation for the inspection.

NOTE: A copy of the registration form should be obtained prior to and included in the inspection to ensure filing and registration. The Center's LACF Registration Coordinator provides each district with copies of all the firm's registered for that District. If the LACF system is down, the District can consult its own registration files. 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 FY 90. Personnel requiring access to this system located at the Division of Computer Research and Technology at the National Institute of Health (NIH) must obtain an account. Michelle Baucum at (301) 827-1537 is ORA's contact for new and existing accounts for Field Personnel. All Center for Food Safety and Applied Nutrition (CFSAN) users requiring an account should contact Kristine Krebs and existing CFSAN account users should contact Sharon Macuci, Celines Roberts, or Yanmei Liu. Once an ORA account is created, Ms. Baucum notifies CFSAN personnel and the additional requirements to gain access are granted by CFSAN personnel. Michelle contacts all ORA users with a follow up from CFSAN for account status upon completion.

NOTE: ORA personnel requiring a password fix contact Michelle Baucum; CFSAN staff, contact Sharon Macuci. For any other system problems, contact Sharon Macuci at (301) 436-1865.

a. If the FCE number is not provided, to determine if a manufacturer has registered, **select menu item 1)** for Registration file. The file may be searched using the manufacturer's name. Firms must register by 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 options should be followed as appropriate.

- **Select Menu item 4)** for Imports – to determine if the process is on file for the product, container type and container size.

- **Select Menu item 5)** for Domestic – to determine if the process is on file for the product, container type and container size.

- **Select Menu item 9)** to determine if the process is accepted for filing but not referenced under Menu item 4 or 5.

- **Select Menu item 3)** to determine if the process has been submitted to FDA but is:

  i. Still under review;
  ii. Has been returned to firm requesting more information; or
  iii. The manufacturer has complied with the filing requirement as evidenced by a date in the ready field but the information has not been updated to the Master File.

- **Select Menu item 6)** to determine import establishment product detentions.

c. If the firm to be inspected has no processes filed or the product of concern is not listed and all the referenced menu

items above have been checked, contact the LACF Registration Coordinator (HFS-618) for assistance at (301)436-2411. The Menu items listed above are updated continuously.

d. Contact Celines Roberts or Sharon Macuci to obtain an electronic copy of the firm's processes. All filed processes for the firm will be provided. Please allow at least one to two weeks notice prior to inspection to receive the filed processes for the firm. Please provide the FCE number, firm name and address and the FEI number. If the FCE number is not provided, this process may take longer to investigate whether the firm is listed in the database. CFSAN will notify the individual requesting the filings directly with all requested information.

e. If upon inspection, the firm has moved location, the manufacturer must notify CFSAN of the move and re-register and file process information for the new location.

f. For firms with no access to the Internet, provide copies of Forms FDA-2541 and FDA-2541a or FDA-2541c (as appropriate) along with the instruction booklet. Cite the requirements of 21 CFR 108.25(c)(1) "Acidified Foods - Registration" and 21 CFR 108.25(c)(2) "Acidified Foods – Process Filing" or 21 CFR 108.35(c)(1) "Thermal processing of low-acid foods packaged in hermetically sealed containers – Registration and process filing – Registration" and 21 CFR 108.35(c)(2) "Thermal processing of low acid foods packaged in hermetically sealed containers – Registration and process filing – Process filing" as appropriate. These forms, as well as the instruction book and regulations can be downloaded from CFSAN's Internet at http://www.cfsan.fda.gov/~comm/lacf-toc.html.

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 factory 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

NOTE: CFSAN has discontinued the use of "targeted" or "directed" inspections due to "No Action Indicated" (NAI) firms no longer requiring annual inspections. Only these firms will be inspected on a three-year cycle. Report all LACF/ AF inspection using PAC 03803A. Form 3511-1, Targeted Inspection Report, is being removed from ORA's forms site.

Report all LACF/ AF 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 MS WORD format and can be electronically completed after downloading. The report forms consist of core pages that can be expanded to whatever length necessary. The forms are:

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
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

Use FDA Form 3511 and the appropriate Retort Reporting Form (FDA Forms 3511a-i) as a guide to the conduct of the inspection. Focus as necessary on the following when investigation reveals that major changes in the process or significant deviations from the scheduled process have occurred since the last inspection.

a. Scheduled Process

- Determine if the scheduled process (es) has changed since the most recent inspection.
  - Major changes include: Changes in processing methods (e.g., still to agitating, etc.), changes in container types (e.g., metal to semi-rigid, etc.), addition of new product lines, etc.
  - If the scheduled process (es) has changed, determine whether old processes have been canceled and new processes filed. Describe and document full extent of changes using FDA Form 3511.

b. 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 full extent of changes using 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.

c. 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.

d. Container Integrity

- Document whether or not the firm is conducting appropriate visual and destructive tests to assess container integrity.
- Audit container integrity examination records to ensure container seams or seals are within specifications.
- Audit container handling equipment and procedures (tracks, conveyors, crates, etc.) to ensure container integrity is not compromised.

e. 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.

3. For more information on the inspection of low-acid canned food and acidified food refer to:

- 21 CFR Parts 108, 113, 114; at http://www.cfsan.fda.gov/~comm/lacf-toc.html.

- 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 Processed, November 1996 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 Processed, November 1996 for specific guidance of use.

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 1- Administrative Procedures/Scheduled Processes, November 1996; at http://www.fda.gov/ora/inspect_ref/igs/lacfpt1/lacfpt101.html.

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 2 - Process/Procedures, April 1997; at http://www.fda.gov/ora/inspect_ref/igs/lacfpt2/lacfpt201.html.

- FDA GUIDE TO INSPECTIONS OF LOW ACID CANNED FOOD MANUFACTURERS, Part 3 – Containers/Closures, November 1998, only available in hard copy

- FDA GUIDE TO INSPECTIONS OF ACIDIFIED FOOD MANUFACTURERS, May 1998; at http://www.fda.gov/ora/inspect_ref/igs/acidfgde.htm

- FDA GUIDE TO THE INSPECTION OF ASEPTIC PROCESSING AND PACKAGING FOR THE FOOD INDUSTRY FEBRUARY 2001, only available in hardcopy

- FDA GUIDE TO THE INSPECTIONS OF COMPUTERIZED SYSTEMS IN THE FOOD PROCESSING INDUSTRY MARCH 1998; at http://www.fda.gov/ora/inspect_ref/igs/foodcomp.html

4. An acid food that contains a small amount of low-acid ingredient(s) and has an equilibrium pH that does not differ significantly from the pH of the predominant acid or acid food ingredient (i.e.,

formulated acid food) is not covered under 21 CFR 114 "Acidified Foods". Examples of formulated acid foods are some salsas, dressings, and condiment sauces.

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 acidified 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).

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 mixed acid ingredient's pH and the individual ingredient's pH levels.

e. The pH (minimum of six units when obtaining information to determine if product is covered) of the finished product (obtain from the firm, if available, or through sampling). Finished products collected to determine pH for the purpose of supporting regulatory action should be collected per IOM chapter 4 "Sample Schedule Chart 2" found at http://www.fda.gov/ora/inspect_ref/iom/contents/ch4_toc.html.

Submit the information to CFSAN/Division of Enforcement/ Domestic Branch (HFS-607) 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/Compliance Program Branch, HFS-636 for review by CFSAN/ Division of HACCP/Regulatory Food Processing and Technology Branch (HFS-617).

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/ora/inspect_ref/iom/contents/ch4_toc.html), 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 important 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 container defects.

   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.

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 LACF/AF 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, HFS-607 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 Food Processors Institute (FPI) and the FDA. FDA participants should be experienced LACF/ AF investigators and familiar with the LACF and Acidified Food 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 video taped introduction for BPCS some time ago by Division of Field Investigations (DFI). If you cannot locate this tape in your district and would like a copy please contact DFI.

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 were 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 NLEA compliance program (CP 7321.005) for complete

guidance.

21006 Infant formula add-on inspections

NOTE: Discontinue use of PAC 03F103 AF/ LACF Directed Inspections.

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

3. Hard copy reporting to CFSAN/Compliance Program Branch, HFS-636

   a. Entire EIR and information identified in PART III, A. 6., 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;

      3. Digital thermometers in lieu of mercury-in-glass thermometers;

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

PART IV - ANALYTICAL

ANALYZING LABORATORIES

Consult the Servicing Laboratories Table, Appendix III, and ORA Field Workplan for laboratory capability/servicing area in performing the following analyses:

pH Determination

Microbiological and Physical Examination of Container

Staphylococcal enterotoxin

Heat Resistance Determination

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 *Plant and Dairy Foods and Beverages, * Division of Microbiological Studies/Microbiological Methods Development Branch, HFS-516

- Staphylococcal enterotoxin confirmation - CFSAN/Office of *Plant and Dairy Foods and Beverages, Division of Microbiological Studies/Microbiological Methods Research Branch, * HFS-516 [or] (see memo to field Guidance for Staphylococcal Enterotoxin Testing in Foods issued August 1, 1997).

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., LACF or Acidified Food). 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), 8th Ed., Revision A (1998) or most current version at http://www.cfsan.fda.gov/~ebam/bam-toc.html

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 8th Ed., Revision A, 1998 (http://www.cfsan.fda.gov/~ebam/bam-toc.html), 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.cfsan.fda.gov/~ebam/bam-toc.html), 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.cfsan.fda.gov/~ebam/bam-toc.html) 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. It is possible to use a rubber mallet to tap the buckle down thereby enabling leak testing to be performed. Leak tests for oddly shaped containers can be accomplished by creating a gasket using tar-based or flexible gasket compounds. 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 the appropriate servicing laboratory for *C. botulinum* confirmation:

Arkansas Regional Laboratory (ARL), Northeast Regional Laboratory (NRL) and Denver District Laboratory (DEN-LAB) should be sent to Southeast Regional Laboratory (SRL),

San Francisco District Laboratory (SAN-LAB) and Pacific Regional Laboratory Southwest (PRL-SW) should be sent to Pacific Regional Laboratory Northwest (PRL-NW). *

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

All *C. botulinum* testing preformed and cultured toxins must be confirmed by CFSAN/Office of Plant, Dairy Foods and Beverages, Division of Microbiological Studies/Microbiological Methods Development Branch, Attn: H.M. Solomon, HFS-516.

d. Heat Resistance Studies

If examination shows gram positive or gram variable rods typical of either the *Bacillus* or *Clostridium* genus, in the absence of other morphological types and micro-leaks, and if no defective can seams are found, or if no seam measurements are outside of the can manufacturers' specifications, then heat resistance studies may be necessary since this is suggestive of under-processing. Follow this procedure:

(1) Immediately call CFSAN/Division of Enforcement/ Domestic Branch, HFS-607 with a summary of the cultural findings as well as can seam and micro-leak data. CPB will instruct the District if heat resistance studies are needed.

*(2) Submit the culture(s) to SRL if heat resistance studies are necessary ensuring that on the LACF Screen summary that the "sent slant heat rest" box is triggered and that the FDA lab is equal to SRL. *

(3) SRL should start analysis of the cultures immediately upon receipt. If closer worksheet review by HFS-607 reveals that heat resistance studies are not needed, SRL will be told to stop analysis.

NOTE: The Home District will notify SRL to destroy the cultures.

2. Water Activity (a_w) or Salt Control

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

Where the product status is in doubt (i.e., LACF or acidified) 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 "b)" 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 AOAC, 17th Ed. or the most current Ed., 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 (AOAC, 17th Ed. or

most current Ed., 978.18, section 42.1.03, B. Instruments and Systems).

NRL, SRL, and SAN-LAB will also determine a_w for samples receiving initial a_w screening in their laboratories by measurement of microcrystalline cellulose weight change. Standardize the instrument using salt slush, AOAC, 17th Ed., 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,
- 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.

b. If sugar may be controlling a_w, determine the percent sucrose (Brix), or soluble solids, AOAC, 17th Ed. or 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.

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, 17th Ed. or most current Ed., section 35.1.13 (952.08),

  NOTE: Substitute pumice or sand for asbestos.

- Water Phase Salt - AOAC, 17th Ed. or 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:

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

d. 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 Compliance/ Division of Field Program / Regulatory Food Processing and Technology Branch, HFS-617, *(301) 436-2411*.

C. **Acidified Foods - pH Analysis**:

1. Use normal containers. Refer to AOAC, 17th Ed. or 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, e.g., 4.40.

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, send a portion of the product and the subculture enrichment along with copies of the analyst worksheets, collection report, etc. to:

CFSAN/Office of Plant, Dairy Foods and Beverages,
Division of Microbiological Studies/
Microbiological Methods Development Branch, HFS-516,
Attn: H. M. Solomon,
5100 Paint Branch Parkway
College Park, MD 20740-3835

2. Staphylococcal Enterotoxin Confirmation

See memos to field, Guidance for Staphylococcal Enterotoxin Testing in Foods.

- Dated December 5, 1995 issued by the Division of Field Program Planning and Evaluation, HFS-635

- Dated May 16, 1997 issued by the Division of Enforcement, HFS-605 (revises one part of 12/5/95 memo)*

E. **Container Integrity/Abnormal Containers**

1. 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 seafoods are involved. Seam or seal 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). Upon receipt 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 Field Programs/Division of HACCP Programs/Regulatory Food Processing and Technology Branch (HFS-617) at 301/436-2411. 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. Heat Resistance Studies

1. Analyzing Laboratories: Immediately notify CFSAN/DOE/DB, HFS-607 when cultures are sent to SRL specifying sample number. Copies of the analytical worksheets and other pertinent documents (labels, etc.) should be sent as hard copy.

2. SRL Analyzing Laboratory: Upon completion of the heat resistance studies, send:

   a. the original analytical worksheet (FDA Form 431) to the Home District

   b. a copy of the FDA Form 431 to the servicing laboratory if in a different District

B. 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 analysis to the District's Compliance Branch.

NOTE: Never average the two analysts' results together.

C. 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/ Domestic 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/DOEP/CPB, HFS-607 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

2. Analysis confirms adulteration or progressive decomposition 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 (District Initiated and/or CFSAN Review) and other Actions**

District Compliance Branch will submit:

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

NOTE: Proposed Warning Letters concerning LACF and acidified food violations must be reviewed and receive concurrence from CFSAN prior to the District Director issuance of the Warning Letter. The Agency established "Supplemental Procedures for Clearing Warning Letters and Untitled Letters", dated March 5, 2002, which is 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/DOE/DB (HFS-607), District will be provided with subjects to be covered under District issuance of Warning Letter.

Attachment C contains proposed model language for Warning Letters and Untitled Letters.

The following guidance applies whenever we find evidence of failure of a firm to comply 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 center will support an Untitled Letter rather than a Warning Letter. However if the evidence demonstrates that the firm has a chronic history of failure to comply or unwillingness or inability to comply with the mandatory provisions of 21 CFR 108.25 and 114, CFSAN would be willing to consider further warning 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. Solicit their written response, 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 deviations 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 noncompliance with significant requirements of the regulations with little or no improvement, stronger 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 low-acid canned food and acidified food operations and policy, and discuss their findings with HFS-607.

The type and seriousness of observed deviations from the mandatory provisions of the regulations will dictate the type and nature of the appropriate regulatory action. The significance of the deviations relative to the degree of potential public health hazard that exists must be made and/or confirmed by Center experts. Once their evaluation is made, several courses of action are preferred by the Center:

- If there is no evidence of an immediate danger to health and the deviations are significant, a Warning Letter is appropriate.

- If the nature of the deviation is such that the Center experts can technically support the conclusion that continued operation by the firm could result in the distribution of potentially hazardous products, then emergency permit action is the regulatory action of choice over injunction or prosecution. This action is administrative in nature and does not go through the normal legal channels (refer to 21 CFR 108.5).

- If the product has reached distribution channels and the Center concludes that a potential danger to health exists. Present the

responsible firm with the case facts and the position of the Center. Determine if the firm intends to initiate a voluntary recall of the product(s) involved. If this fails, state embargo, FDA initiated recall, or FDA seizure should be considered, in that order.

D. **Industry Education**

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

At the District's request, CFSAN/Office of Constituent Operations/ Industry Activities Staff, HFS-565, 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
Attachment C - Proposed Model Language for Warning Letters and Untitled Letters

REFERENCES

FDA Guide to Inspections of Low Acid Canned Food Manufacture

Part 1 - Administrative Procedures/Scheduled Processes, November 1996
(http://www.fda.gov/ora/inspect_ref/igs/lacfpt1/lacfpt101.html)

Part 2 - Process/Procedures, April 1997
(http://www.fda.gov/ora/inspect_ref/igs/lacfpt2/lacfpt201.html)

Part 3 - Containers/Closures, November 1998

FDA Guide to Inspections of Aseptic Processing and Packaging for the Food Industry, February 2001

FDA Guide to Inspections of Acidified Food Manufacturers, May 1998
(http://www.fda.gov/ora/inspect_ref/igs/acidfgde.htm)

FDA Guide to Inspections of Computerized Systems in the Food Processing Industry, March 1998
(http://www.fda.gov/ora/inspect_ref/igs/foodcomp.html)

FDA Investigations Operations Manual (most current issue)
(http://www.fda.gov/ora/inspect_ref/iom/iomtc.html**)**

PROGRAM CONTACTS

General Program Directions:	Karen Swajian, CFSAN/ *Office of Compliance/ Division of Field Program/ Compliance Program Branch *, HFS-636, (301/436-1616), FAX (301/436-2657), Kswajian@CFSAN.FDA.Gov
Regulatory, compliance matters or interpretation of regulations/ what products are covered:	Dennis Dignan, Ph.D. CFSAN/*Office of Compliance/ Division of Enforcement/ Domestic Branch *, HFS-607, (301/436-2051), Ddignan@CFSAN.FDA.GOV Don Greaves, CFSAN/*Office of Compliance/ Division of Enforcement/ Domestic Branch *, HFS-607, (301/436-2057), Dgreraves@CFSAN.FDA.GOV

LACF Registration Control Coordinator (Plant registration and filed scheduled processes):	Nathaniel L. Murrell, Jr., CFSAN/ Office of Compliance/ Division of Field Programs/ Regulatory Food Processing and Technology Branch , HFS-618, (301/436-2132), Nmurrell@CFSAN.FDA.GOV
Obtaining accounts for the On-Line LACF Registration and Process File:	Michele Baucum, ORA/Office of Resource Management/Division of Information Systems, HFC-30, (301/827-1573), Mbaucum@ORA.FDA.GOV.
Questions regarding the preservation, processing or packaging of LACF/AF or analysis of foods in which pH, water activity, or salt content may be at least in part a means or preservation:	Stephen Spinak, CFSAN/Office of Compliance/ Division of Field Programs/ Low-Acid and Acidified Canned Foods Team, HFS-617 (301/436-2411), SSpinak@CFSAN.FDA.GOV
Confirmation of Preformed and/or Cultured *C. botulinum* toxin:	Haim M. Solomon, CFSAN/Office of *Plant and Dairy Foods and Beverages, * Division of Microbiological Studies/ Microbiological Methods Development Branch, HFS-516 (301/436-2013), HSolomon@CFSAN.FDA.GOV
Confirmation of Staphylococcal enterotoxin:	Reginald Bennett, CFSAN/Office of *Plant and Dairy Foods and Beverages, *, Division of Microbiological Studies/ Microbiological Methods Research Branch, HFS-516, (301/436-2009), Rbennett@CFSAN.FDA.GOV
Industry Education:	John Tisler, CFSAN/Office of Constituent Operations/ Industry Activities Staff, HFS-565, (301/436-1727), JTisler@CFSAN.FDA.GOV
Inspectional Inquiries:	Barbara Marcelletti, ORO/ Division of Field Investigations, HFC-132, to (301/827-5635), BMarcell@ORA.FDA.GOV
Analytical Methods Inquiries:	Marsha Hayden, ORO/ Division of Field Science, HFC-140, (301/827-1039), MHayden@ORA.FDA.GOV

PART VII - CENTER RESPONSIBILITIES

1. **Botulinum Toxin Confirmation**

Confirmation of preformed and cultured botulinum toxin, CFSAN/Office of Special Research Skills/Division of Microbiological Studies/Microbiology Methods Development Branch, HFS-516

2. **LACF Registration and Process Files**

Maintenance of the LACF Registration and Process Files, CFSAN/Office of Compliance/Division of Field Programs, HFS-618

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 Program, 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/ Division of Enforcement, Domestic Branch, HFS-607, Branch Chief, at phone number (301) 436-1611.

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

DOMESTIC ACIDIFIED AND LOW-ACID CANNED FOODS PROGRAM

INDUSTRY EDUCATION INFORMATION

FDA:

1. Copies of the publication, **A Processor's Guide to Establishment Registration and Process Filing for Acidified and Low-acid Canned Foods** can be obtained from CFSAN/Office of Compliance/ Division of Field Program/ Regulatory Food Processing and Technology Branch, Nathaniel L. Murrell, Jr.; HFS-618, (301) 436-2132 or CFSAN's web page at: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 Constituent Operations/Industry Activities Staff, HFS-565, John Tisler, (301) 436-1727.

Food Processors Institute:

A number of publications and audiovisuals are available from:

Food Processors Institute
*1350 I Street, N. W.
Suite 300 *
Washington, D. C. 2005 (202) 393-0890

The audiovisuals include:

1. **Can Seam Formation and Evaluation**

   Part I explains the basis for construction can seams

   Part II discusses evaluation methods used to rate can seams

2. **For the Retort Operator**

   Discusses still retorts and pH differences between low-acid and high acid foods (slide show)

***Proposed Model Language for Warning Letters and Untitled Letters ***

Model Untitled Letter (open electronic file with these changes already incorporated)

We inspected your firm located at (*address*) on (*date*). The inspection was conducted to determine your compliance with FDA's [select as appropriate, (Low-acid Canned Food (21 CFR Part 108 and 113), and (Acidified Food (21 CFR Part 108 and 114)] regulations. The [select as appropriate, (Low-acid Canned Food), and (Acidified Food)] regulations were issued, in part, pursuant to Sections 404 of the Federal Food, Drug and Cosmetic Act (the Act)(21U.S.C. 344). A temporary emergency permit may be required for [acidified] [low-acid canned] foods whenever a processor has failed to fulfill the requirements of [21 CFR 108.25][21 CFR 108.35, including registration and filing of process information, and the mandatory requirements of 21 CFR [113][114]. In addition, based upon certain criteria in Part [114][113], [acidified][low-acid canned food] may be adulterated within the meaning of section 402(a)(3) of the Act (21 U.S.C. 342(a)(3)) in that it may have been manufactured under such conditions that it is unfit for food, or within the meaning of section 402(a)(4)(21 U.S.C. 342(a)(4)) in that it may have been prepared, packed , or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find the Act and the [select as appropriate, (Low-acid Canned Food), and (Acidified Food)] regulations through links in FDA's home page at http://www.fda.gov.

Model Warning Letter (open electronic file with these changes already incorporated)

On (*date*) we inspected your [select as appropriate, (Low-acid Canned Food), and (Acidified Food)] located at (*address*). We found that you have serious deviations from the [select as appropriate, (Low-acid Canned Food (21 CFR Parts 108 and 113), and (Acidified Food (21 CFR Parts 108 and 114)] regulations. Failure to comply with all of the requirements of 21 CFR [part 108.25] [108.35] and the mandatory portions of part [113] [114] constitutes a prima facie basis for the immediate application of the emergency permit

control provisions of section 404 of the Act. In addition, such failure renders your [select as appropriate, (Low-acid Canned Food), and (Acidified Food)] adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your (identify product(s)) is adulterated in that (identify product(s)) has been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health. You can find the Act and the [select as appropriate, (Low-acid Canned Food), and (Acidified Food)] regulations through links in FDA's home page at <http://www.fda.gov>.

The above violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure, injunction and/ or issuance of an Order of Need to obtain and hold a Temporary Emergency Permit. **

NOTE: To the District: **Issuance of an Order of Need to obtain and hold a Temporary Emergency Permit is normally the action of choice rather than injunction. However, an Order of Need is appropriate only when the firm ships its finished product(s) in interstate commerce.

NOTE: Notification from the firm of specific steps taken to correct the noted violations should be received within fifteen (15) working days of receipt of the Warning Letter as per the Regulatory Procedures Manual (RPM), chapter 4, Format.