CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

| **SUBJECT:** | **IMPLEMENTATION DATE** |
|---|---|
| IMPORT ACIDIFIED AND LOW-ACID CANNED FOODS COMPLIANCE PROGRAM (FY 06/07/08)<br><br>**This program has completed A Good Guidance Practices clearance by CFSAN's ORP and OC/DFP/CPB in July of 2006.** | 7/31/06 |
| | **COMPLETION DATE**<br>9/30/08 |

**DATA REPORTING**

| PRODUCT CODES | PRODUCT/ASSIGNMENT CODES |
|---|---|
| INDUSTRY CODES:<br><br>03, 04, 09 12-18,<br><br>20-25, 27, 29-31, 33-41<br>USE APPROPRIATE PRODUCT CODES:<br>(refer to Attachment A for an extended list) | REPORT INSPECTIONS UNDER THE FOLLOWING PACs:<br><br>03003 LACF Products<br><br>03003A Acidified Products |

**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**

Hard Copy Reporting to Headquarters

All hard copy reports are to be submitted by the analyzing laboratories, as listed in PART IV.

FACTS Reporting

The analyzing laboratory will report results for each sample of low acid and acidified products into FACTS using PAF = ACD.

Use the following Problem Codes:

AFD = Acid food Analysis

ACF = Acidified Food Analysis

LAF = Low-Acid Canned Food Analysis

OTHER Reporting

If there is any Entry Review or Filer Evaluation work, the following PAC Codes should also be included:

PAC 03R833 Entry Review (report as Import Investigation – Operation Code 14)
PAC 99R833 Filer Evaluations (report as Program Evaluation – Operation Code 95)

## 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. The absence of oxygen at normal room temperature storage conditions with adequate moisture and nutrients favor the growth of Clostridium botulinum (C. botulinum) in Low-Acid Foods. A failure to either destroy or control (by water activity or acidification) the germination and growth of spores of C. botulinum due to improper manufacturing, processing or packing may result in the production of a toxin which causes the potentially fatal food poisoning known as botulism.

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

This program is part of FDA's verification procedures to determine whether the foreign industry provides adequate controls over the production and distribution of LACF and acidified food (AF). FDA attempts to identify problems which may have broad implications such as commodities, industry segments from a particular region or country, faulty equipment, defective containers, etc.

Chinese mushrooms were implicated in four outbreaks of Staphylococcal Enterotoxin (SET) poisonings which occurred between February 13, 1989 and April 22, 1989. FDA’s testing of Chinese mushrooms detected SET in samples of mushrooms that were associated with the outbreaks. To prevent further SET outbreaks, on May 10, 1989, FDA initiated detention without physical examination (DWPE) of all #10 cans of People’s Republic of China (PROC) canned mushrooms and all other can sizes from PROC canneries whose mushrooms tested positive for SET. This DWPE was extended to all can sizes of mushrooms from all PROC canneries on October 17,1989. In 1995, the DWPE provisions were established for the “Lot by Lot” release program to allow entry of PROC mushrooms. *Import Alert 25-11 and the “Lot by Lot” release program was officially cancelled as of March 1, 2004. FDA and the Peoples Republic of China had a recent meeting and reached an agreement to cancel this import alert. The Chinese government has assumed responsibility for most of the firms currently shipping to the U.S. and recent visits and other information indicate that this alert is no longer supportable. Chinese mushrooms will now be covered under normal import surveillance.*

## PART II - IMPLEMENTATION

Objectives

- To determine whether products comply with the plant registration and process filing requirements as required by 21 CFR 108.
- To determine if AF and LACF products are improperly processed or packaged through examination of lots or analysis of samples.

Interaction with Other Programs

AF/LACF Foreign Inspections:
Inspections of foreign manufacturers of LACF products and acidified foods to determine compliance with 21 CFR 108 (Emergency Permit Control), 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) and 114 (Acidified Foods) (http://intranet.cfsan.fda.gov/OC/pages/industry.htm) are accomplished under FDA's Foreign Inspection Program. The Agency has been performing Foreign Inspections on a yearly basis and will continue to do so in the future. PAC Code 03R233 should be used for each Foreign Inspection. Investigators should refer to Compliance Program 7303.803a, Domestic LACF and Acidified Foods Compliance Program, for inspectional and regulatory guidance. CFSAN reviews foreign inspection EIRs and classifies each inspection. Regulatory actions, such as DWPE and/or placement on Import Alert, may be recommended by CFSAN if significant deviations from the regulations are revealed.

*Import Seafood Products Compliance Program, CP 7303.844:
Seafood hazards other than C. botulinum (e.g. histamine toxin formation, shellfish toxins, etc.) are to be reported under the Import Seafood Products Compliance Program, CP 7303.844, which provides additional coverage of fish and fishery products.

Import Foods – General Compliance Program, CP 7303.819:
Products labeled Keep Refrigerated, but are not are temperature abused, should be covered in the Import Foods – General Compliance Program, CP 7303.819.*

## PART III - INSPECTIONAL

**NOTES:**

1. The Import Alerts in FIARS list products and firms to be given intensified coverage.

2. Import Alert 99-04 lists products/firms to be detained without physical examination even if these firms have Food Canning Establishment (FCE) numbers or processes (SID's) on file. Therefore, this alert should be reviewed before release of an entry is considered.

3. If the listed manufacturer in the line entry is not the actual processor, the entry should not be released until the importer is contacted and the manufacturer's name determined and registration confirmed. If the manufacturer's name cannot be determined, the product should be detained.

### A. ENTRY REVIEW

Determine whether the product is LACF or an AF. Definitions for LACF and AF are found in 21 CFR 113.3 and 21 CFR 114.3.

*Attachment A lists valid product codes for this program (not all inclusive).*

1. Examples of LACF and AF products (not all-inclusive):

   a. Low-acid canned foods (LACF)

      Bamboo shoots, bean sprouts, black olives, mushrooms, mussels, sardines, snails, tuna

   b. Water activity ($a_w$) and salt controlled LACF

      Bean paste, caviar, canned cake or bread, chutney, guava paste, lupini beans, salted fish, salted vegetables, some oriental cooking sauces, some soy sauces

   c. Acidified Foods (AF)

      Artichokes, hearts of palm, non-fermented pickles and pickled products, peppers, pimentos, papaya and other low-acid tropical fruits

   d. LACF where pH control at levels greater than 4.6 is a critical factor in the scheduled process.

      Clam sauces, gazpacho, okra and tomatoes, limas and corn, some potato salads, some spaghetti and other pasta in tomato sauces, shrimp in tomato sauce, turtle soup

   e. Mis-identified Fermented Products

      If it is suspected that the product is mis-identified as a fermented product, check the LACF database to determine if a process is on file, and if there is no process on file and resources exist, collect six subs and analyze for water

activity ($a_w$), salt content and pH. If after analyzing, the product falls within the parameters of an AF or LACF product (per 21 CFR 113.3 and 21 CFR 114.3), a recommendation should be made to DIOP to place the manufacturer/product under DWPE and to issue an advisory to the field and to CFSAN/Division of Enforcement/Imports Branch/HFS-606 alerting them of the situation. If processing procedures can be obtained from importer/filer, please include in recommendation package.

f. Other Products (including refrigerated products)

If products are unfamiliar to District personnel and cannot be readily classified as LACF, AF or fermented, and a check of the LACF database reveals no process information on file, then collect six subs and for $a_w$ and pH analyses. If the product falls under the parameters of a LACF or AF, follow the directions in 1e above. Consult CFSAN/Division of Enforcement/Imports Branch/HFS-606 for guidance and/or the Division of Import Operations/HFC-170 for guidance.

Also, refrigeration does not necessarily exempt a product from the regulations. For example, the small, extended shelf-life coffee creamers usually bear a "Keep Refrigerated" statement on the small peel-off foil top. Many times they are not held under refrigerated conditions (e.g. restaurant tables), so they are subject to the regulations.

2. *Example containers used for LACF and AF

a. Metal - tinplate, steel and aluminum (*usually LACF*)

Containers may be cylindrical, square, rectangular, or oval. Irregular shapes may be encountered.

b. Glass (*usually Acidified*)

Containers are generally cylindrical with a metal screw cap or pressed-on cap. There may also be unusually shaped containers.

c. Plastic

Rigid or semi-rigid cylindrical cans, trays, cups, or tubs with heat sealed or double seamed ends (*usually Acidified*)

Flexible - pouches heat sealed on two or more sides, tubes either heat sealed or closed with a metal crimp (*usually LACF*)*

d. Multilayer

These containers are usually flexible or semi-rigid and consist of multiple layers of various materials such as plastic, fiberboard and aluminum foil.

**B. REGISTRATION AND PROCESS FILING**

Determine whether the manufacturer has registered and filed processes for the product(s).

1. Obtain from import entry documents:

   - Country of origin
   - Product name
   - Name of the manufacturer
   - Food Canning Establishment (FCE) number and/or actual plant address of the site specific manufacturer.
   - SID number of the container dimensions

   If this information is not transmitted electronically or cannot be determined after review of the import documents from the importer, the product should be detained.

2. *The LACF Web Application System Website, available at # will assist in the determination of whether the manufacturer has registered and filed a process for the product(s) entered. ORA and District Office Personnel requiring access to this website may create their own accounts at # under the "Create New Accounts" link. Only FDA personnel who deal with LACF-related activities will be listed in the drop down list. Any FDA personnel who do not find their name in this list should contact the CFSAN Help Desk or send an e-mail to LACF@cfsan.fda.gov for assistance. There is a User's Guide available under the above referenced URL selecting the "LACF User Guide" link. If the Word version is selected to print, go to the bottom of the document to allow all graphics to load prior to printing the document.

   OASIS release 4.3.01 provides a link between OASIS and the information stored in the LACF database. Entry reviewers and other import staff are able to link directly from a line entry to the data stored for a specific FCE, manufacturer or scheduled process. They are also able to perform ad hoc queries of the data from within OASIS.

   a. If the FCE number is not provided, the FCE Registration Search/Update option may be used to search, using the manufacturer's or firm's name along with Country.

   b. If the manufacturer is registered, determine if there is a process on file for the product(s) and container size(s) being entered.

      i. The Generate Reports option in the LACF Website should be used:

         - Searches for LACF products and containers require two searches: **View Tracking Option** and **Products Report Option:**

           **View Tracking Option**: This option lists all forms which have been received by FDA and are in various stages of acceptance. For specifics on the information on this screen, refer to the LACF User's Guide. The dates on this screen are critical to determine the form(s) status of acceptance.

           **Products Report Option**: This option lists

process filing form(s) currently accepted and on file with FDA. It lists the firm information, FCE, SID, product name, governing regulation, i.e. whether filed as LACF or AF, water activity and pH (if critical), processing method, etc as well as container information.

- If a firm is on Import Alert #99-04, a reference to the product(s) on alert will appear in the report.

c. The LACF Registration Coordinator, HFS-618, should not be contacted, except in unusual circumstances, since the LACF Web Application Computer System is updated continuously.

d. The Import Alert option is a list of firms under Import Alert #99-04. It is advisable to check FIARS as well this option. Any discrepancies, please contact CFSAN/Division of Enforcement and Programs/Imports Branch/HFS-606 or the Division of Import Operations and Policy (DIOP)/HFC-170.*

3. Container Dimensions (see Attachment C)

Also note the following:

- Metal Containers

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

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

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

- Pouches

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

- Semirigid Containers

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

- Glass Containers

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

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

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

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

**C. OASIS Reporting Instructions**

Process the entry as a **DTR** (Detention Requests) if the following criteria are met:

1. The firm is not registered.

2. No process is on file.

3. Process filed but:

   - The container dimensions on file deviate by 2/16 inch or more in any dimension from those indicated on the file(for glass containers allow 3/16 or more). Therefore, conclude that a process has not been filed.

   - The product name is not the same as that which is on file (with some exceptions). Therefore conclude that a process has not been filed. If there are questions about product names, then contact the LACF Registration Coordinator.

Process the entry as a **DER** (Detention Request without Exam) if:

The firm is identified for DWPE under a particular Alert such as Import Alert #99-04.

**DTR** and **DER** should include, if possible, copies of invoices, packing lists, and copies of labels, etc. since those documents may indicate the actual manufacturer.

**D. FIELD EXAMINATIONS AND PRODUCT SAMPLING**

***Reconciliation Exams:**

A comparison of records with the physical product to verify that the entry is consistent with declarations on product documents with regard to the type and quantity of product. These exams should be performed consistent with the guidance in the IOM and/or current Division of Import Operations/HFC-170 instructions. Refer to IOM 5.4.1.4 at:

http://www.fda.gov/ora/inspect_ref/iom/ChapterText/5_4.html#SUB5.4

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

1. Low-Acid Canned Foods

   a. Field Examination - See IOM, Sample Schedule 2 at:

      http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule2.html

      A "lot" should consist of only one production code and one product. If codes are commingled to the extent that sorting is impractical, consider the entry as one lot for the purpose of the field examination.

      Make a notation on the Collection Report (C/R), the codes observed, number of containers examined, and number of abnormal or defective cans by type of abnormality or defect, and relate to the can codes.

      When listing can codes, use a hyphen or a dash to denote a space between characters, and a slash "/" to denote separate lines.

   b. Sample Collection

      If abnormal or defective containers are found during the field examination, collect all abnormal (up to 24) and 12 normals. Include samples of each type of abnormal or container defect observed. If products may be partially preserved through control of $a_w$, collect 6 more normal containers. See IOM, Sample Schedule 2 at:

      http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule2.html

      *NOTE: When collecting swollen or leaking cans, place in plastic bags to prevent leakage before final packing for shipment to field laboratory for analysis.*

2. Acidified Foods (AF)

   Acidified foods not hermetically sealed in containers or not thermally processed are included under 21 CFR 114 (http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr114_02.html). Most acidified foods are in hermetically sealed

containers. Refer to "Investigator's Guide to Inspection of Acidified Foods" (http://www.fda.gov/ora/inspect_ref/igs/iglist.html#FOODS).

a. *Field examinations of acidified products should include checking for damaged or destructive container closures (non-destructive).*

b. Sample Collection - Collect samples for pH testing. Random sampling is essential to reveal pH variations.

1) For containers larger than 28 oz. net weight, select one normal container from each of 12 randomly selected cases.

2) For all other containers, 28 oz. net weight or less, select 2 normal containers from each of 12 randomly selected cases.

If abnormal containers are encountered, follow IOM, Sample Schedule 2 at:

http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule2.html

Collect all abnormal containers (up to 24) in addition to the normal containers collected for pH testing.

3) AF where pH is a critical factor in the scheduled process at pH greater than 4.6 should be treated according to instructions for LACF and sampled for pH to confirm the product pH is not higher than the maximum value specified in the scheduled process.

4) Questionable Products

a) When in doubt as to whether a product is LACF or AF, contact CFSAN/Division of Enforcement/Imports Branch/HFS-606 for guidance. Label ingredients listings may help identify acidified or partially acidified products and enable a regulatory decision to be made without laboratory analysis. When possible, obtain shipping documents, labels and other information to identify the actual manufacturer and the actual name of the product. Also attempt to obtain processing information. If a decision cannot be made based on this information, sampling for pH, water activity, and possibly water phase salt or soluble solids may be necessary. Samples to determine a product's status should consist of 3-6 containers.

b) 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. Examples of formulated acid foods are some salsas, dressings, and condiment sauces.

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

  1. Quantitative formulation (obtain quantitative information using the same units of measurement or percentages).

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

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

  4. pH of the acid(s) and/or 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.

  5. 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). Relate these samples to the mixed acid ingredients pH and the individual ingredient pH levels.

- Finished products collected to determine pH for the purpose of supporting regulatory action should be collected per IOM sample schedule chart 2.

- Submit the information to CFSAN/Division of Enforcement/Imports Branch/HFS-606 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).

c) If a shipment contains numerous questionable products (unclear whether many products are AF or LACF), call CFSAN/Division of Enforcement/Imports Branch/HFS-606 to arrange for a review of the invoice and guidance on product status and/or appropriate sample collection and analyses to determine product status.

5) Aseptically Packaged LACF/AF

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

Most of those products will be liquids or semi-solids, e.g., milk, soy bean products (drinks, TOFU), teas, puddings, fruit purees, etc. *If any products are encountered which appear to contain small pieces of food (e.g., cream of mushroom soup), collect documentary evidence for particulate size determination and photos of the suspect product and submit to CFSAN/Division of Enforcement/Imports Branch/HFS-606, 5100 Paint Branch Parkway, College Park, MD 20740. Hold the entry pending CFSAN, HFS-606 review.*

**NOTE:** The LACF Web Application System can be used to determine whether a product is LACF, AF, aseptically processed or $a_w$ controlled.

The "Process File Menu" link provides some of the information contained on the process filing forms and can be used to determine whether the process was filed as LACF or AF, the container type and sizes, the processing method and whether water activity or maximum pH are critical factors. Authorized FDA employees can obtain facsimiles of process filing forms directly from the LACF Web Application System.

**NOTE - SECURITY/CONFIDENTIALITY MEASURES**:
Due to the confidential information contained in the LACF Process File, special precautions should be taken to maintain the confidentiality and to ensure the security of the data generated from the system. The reports generated from this system should be handled with discretion, secured when not in use and destroyed in an appropriate manner when no longer needed, i.e.,

- Only FDA employees are to have access to these reports.
- These reports may not be reproduced or copied in any way.
- These reports should be secured in a locked cabinet when not in use or awaiting distribution.

- These reports may be placed in the case files, in the section which is not for public information or distribution.

- These reports should be destroyed after use, including reports generated in error.

6) Reporting

a. Products Released Without Field Examination or Sample Collection.

*Report time spent determining that a product meets registration and filing requirements, including measuring containers, as "Entry Review" and ensure that the appropriate PAC is used (e.g. 03003 for Import LACF or 03003A for Import AF)*

b. LACF/AF or Samples Collected for Abnormal Containers

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

Report the number of each type of abnormal (hard swell, etc., refer to IOM, Sample Schedule 2 at: http://www.fda.gov/ora/inspect_ref/iom/ChapterText/sschedule2.html or defective containers observed (leaker, seam defects or other abnormalities).

**E. Fraudulent Entries**

*Entry reviewers should look for suspicious entries; for example, mushrooms from one country shipped by an exporter in another country. Fraudulent entries of other mushroom products, bamboo shoots, and water chestnuts have also been found. If fraud is suspected, it should immediately be brought to the attention of the district compliance branch via supervisory channels. Appropriate evidence needs to be collected such as documents, product samples and interviews of involved personnel. OCI should be consulted early in the investigation. Any suspicious entries should also be brought to the attention of CFSAN/Division of Enforcement/Imports Branch/HFS-606 for further instructions.

Report time under OASIS Activity Code #23 – Field Exam (FEX) when conducting review of can codes to verify the actual manufacturer and use the appropriate PAC (e.g. 03003 or 03003A).*

## PART IV - ANALYTICAL

### I. ANALYTICAL LABORATORIES

A. pH Determination - Normal servicing laboratories

B. Microbiological and Physical

1. Initial Analysis - Normal servicing laboratories

2. C. botulinum confirmation - SRL for NE, CR, and SE Regions, PRL-NW for SW, and PA Regions.

C. Toxin Confirmation - Division of Microbiological Studies, HFS-515.

D. Cover chemical contaminants and food additives under CP 7309.006, Import Food and Color Additives, not under the AF/LACF program.

E. Heat Resistance - SRL for all Districts.

F. Filth and Extraneous Matter - Normal servicing laboratories

G. Headspace Gas Analysis by Gas Chromatograph (GC) - Normal servicing laboratories

H. Water Activity ($a_w$) - Normal servicing laboratories

### II. ANALYSIS

A. Low-Acid Canned Foods (LACF)

1. Microbiological and Physical: Refer to Bacteriological Analytical Manual for Foods (BAM), Rev A, 8th Ed. or most current (http://www.cfsan.fda.gov/~ebam/bam-toc.html).

- Districts so equipped and trained should use the gas chromatography (GC) method for headspace gas provided in the BAM, *8th Ed.*

- Laboratories that do not have the necessary equipment (GC) should perform headspace gas analysis according to the BAM, *8th Ed.*

- Perform teardown seam evaluations on abnormal cans (to the extent that the data obtained are meaningful) and on a representative number of normal cans (see CPG 7120.16) (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg520-200.html). Perform microleak examinations where appropriate. Perform vacuum tests aseptically (LIB No. 2723) on the normal cans selected for culturing and seam teardown exams.

- Send sample portions and cultures to the appropriate servicing laboratory for C. botulinum confirmation.

  All preformed C. botulinum tests for toxin in samples and

production of toxin by cultures should be confirmed by CFSAN.

**NOTE:** 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 microleaks, and if no defective can seams are found, or if no can seam measurements are outside of can manufacturers' specifications, heat resistance studies may be required. Follow this procedure:

a. Immediately notify CFSAN/Low-Acid and Acidified Canned Foods Team, HFS-617 with a summary of the cultural findings as well as can seam and microleak data. RFPTB will instruct the District if heat resistance studies are needed.

b. Submit a completed Heat Resistance Report (Attachment B) and the culture(s) to SRL if heat resistance studies are necessary. Also, send copy of analytical worksheet and collection report.

c. SRL should start analysis of the cultures immediately upon receipt. If closer worksheet review by HFS-617 reveals that heat resistance studies are not needed, SRL will be told to stop the analysis.

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

2. Water Activity ($a_w$)

*Please refer to the most current AOAC Methods available, unless stated otherwise.*

In products having a pH above 4.6, when $a_w$ may be a part of the preservation means, determine $a_w$ using "Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC)," *16th Edition (1995) 42.1.03 (978.18)*.

- Where the product status is in doubt (i.e., LACF/AF or exempt) it may be necessary to determine the $a_w$ 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 should always be used.

- If sugar may be controlling $a_w$, determine the percent sucrose (Brix) or soluble solids. If salt content may be controlling $a_w$, 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 method described in the AOAC, *16th Ed., 35.1.18 (937.09)*, under "Volumetric Method - Official Final Action," which is incorporated by reference, multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished products as

determined by the method described in AOAC, *16th Ed., 35.1.13 (952.08)*, under "Total Solids for all Marine Products, Except Raw Oysters - Official Final Action."

a. Initial Screening: For all size containers, determine the $a_w$ of 3 units using the Abbeon $a_w$ Value Analyzer or other approved analyzer (AOAC, 16th Ed., 42.1.03 (978.18B)*. The Decagon Aqualab Hygrometer is faster than the Abbeon analyzer. NRL, SRL, and SAN will also determine the $a_w$ for samples receiving an initial $a_w$ screening in their laboratories by measurement of microcrystalline cellulose weight change. Standardize the instrument using salt slush, AOAC, *16th Ed., 42.1.03(978.18D, E)*.

b. Confirmation: Determine the $a_w$ of 3 containers using the:

- Beckman Hygroline Moisture/Humidity Meter,
- Decagon Aqualab Hygrometer,
- Weather Measure Relative Humidity System, or
- Rotronic AG.

If $a_w$ is confirmed at or above 0.90, refer the results of analysis to the District Compliance Branch of the collecting District. The Lab or District Compliance Branch may contact the to Low-Acid and Acidified Canned Foods Team, HFS-617, for any direct questions concerning analysis of foods in which water activity or salt content may be at least in part a means of preservation.

B. Acidified Foods

pH Analysis

1. Use normal containers. Refer to AOAC *16th Ed., 42.1.04 (981.12)* except:

Determine the pH on the container mixture only, by opening the container, inserting the electrode(s) and measuring the pH. Do not make separate pH 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.

- Carry out all pH determinations to two decimal places, e.g., 4.40.

2. Number of containers for pH analysis:

The total sample size for containers 28 oz. net weight or smaller is 24 containers. The total sample size for all others is 12 containers.

a. One analyst will determine the pH of half of the sample containers and record the name, model and serial number of the pH meter on the Analyst Worksheet.

b. 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 should 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.

c. 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.

d. 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.

C. Acidified and LACF

Toxin Confirmation

For confirmation of preformed and/or cultured C. botulinum toxin, send a portion of the product and the subculture enrichment to the CFSAN/ Office of Plant and Dairy Foods/ Division of Microbiological Studies/ Microbiological Methods Development Branch, HFS-516, along with copies of the analyst worksheets, collection report, etc.

D. Container Integrity/Abnormal Containers

Container Integrity

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

In examining canned foods for container integrity, the analyst should examine each can for visible can seam defects and describe these defects. Guidance in describing visible defects is available in the AOAC chart, 2000, Classification of Visible Can Defects (Exterior).

When visible can seam defects are found, the analyst should attempt to determine the severity of the defects. This is done by determining the amount of overlap remaining in the seam at the point of the defect. The defect rating procedure provided below was devised as a means to judge the severity of "droops" and "vees" encountered in the cover hook of can double seams:

Rate the defects in the cover hook ("droops", "vees") in the same manner as the juncture on cylindrical cans. Defects should be rated on a percentage scale, in ten (10) percent increments, from 100 to 0%. If the cover hook at the defect is even with the rest of the cover hook on the torn-down seam, it is given a 100% rating. If the cover hook is reduced by 70% the defect is given a 30% rating. When the cover hook at the defect is reduced to a point where it is even with or below the bottom of the seam and there would be no overlap between the cover hook and body hook, the defect is given a 0% rating.

- Abnormal Containers

  Conduct the following additional analyses on the abnormal containers: gas, odor and appearance, net weight, drained weight, can seam teardown and condition of container interior. If the pH of abnormal containers is greater than 4.65, analyze for C. botulinum toxin.

- Glass containers and Semirigid and Flexible Packaging

  Perform visual examinations, microleak examinations and destructive testing where appropriate. Refer to the BAM, Chapter 22B (http://www.cfsan.fda.gov/~ebam/bam-22b.html), "Examination of Containers for Integrity", pages 22.35 - 22.85, for methods of analysis. When necessary, questions should be referred to CFSAN, Office of Compliance, Low-Acid and Acidified Canned Foods Team (HFS-617), phone (301) 436-2411.

E. *Staphylococcal Enterotoxin In Canned Mushrooms

General Instructions:

Perform enterotoxin testing if:

1. Product abuse (e.g. temperature, outbreaks, etc.) is suspected.

OR

2. Instructed by Compliance Program or Field Assignment to analyze the sample for *Staphylococcus*.

If viable *Staphylococcus sp.* colonies are observed by:

- most probable number (MPN) when performed as directed per BAM Chapter 12 (http://www.cfsan.fda.gov/~ebam/bam-12.html)where the results are >11,000

AND

- direct plate counts when performed as directed per BAM chapter 2 (http://www.cfsan.fda.gov/~ebam/bam-2.html)indicates a level of 10,000/ gram

*Enterotoxin Analysis:

Follow the methodology outlined in BAM 8th Ed., Revision A, 1998 or most current Ed., Ch. 13, "Staphylococcal Enterotoxins" (http://www.cfsan.fda.gov/~ebam/bam-toc.html), beginning on page 13.01.

The laboratory will individually test each sub-sample using the TECRA™ ELISA with proper procedures followed accordingly.

**NOTE:** Under **no** circumstances should positive TECRA™ ELISA results be conveyed to a regulated firm or consumer without confirmation. The TECRA™ ELISA is intended as a screening method only.

**NOTE**: The total contents of each subsample should be retained until the original analyses are completed to ensure that a sufficient amount of product is available for subsequent additional and confirmation tests, if necessary.

TECRA™ ELISA Test Results

1. Negative result - the laboratory need not conduct further analysis for enterotoxin. The sample is considered "negative" and no other regulatory or follow-up action is warranted. The laboratory should classify this particular analysis as lab class 1, in compliance.

2. Positive result – the laboratory should analyze the original sample using the VIDAS method for confirmation refer to BAM 8th Ed., Revision A, 1998 or most current Ed., Ch. 13A, "Staphylococcal Enterotoxins: Micro-slide Double Diffusion and ELISA Based Methods"(i.e., VIDAS)". See (http://www.cfsan.fda.gov/~ebam/bam-toc.html)

TECRA™ ELISA **and** the VIDAS Tests Results

1. When the TECRA™ ELISA **and** the VIDAS Tests are **positive**, the following **should be sent to CFSAN for re-confirmation analysis**:

   (a) The remaining portion of the original TECRA™ ELISA positive tested extract(s)

   (b) The remaining portion of the positive tested extract(s) from the VIDAS System

(c) If possible, send at least 100 grams of the remaining reserve portion of the positive subsample(s)

(d) A copy of the analytical worksheets

(e) A copy of the collection report

to

FDA/ CFSAN/ Microbiology Methods Research Branch
Attention: Reginald Bennett, HFS-516
5100 Paint Branch Parkway
College Park, MD 20740.

**NOTE**: If additional information concerning sample preparation, handling or shipping to CFSAN is needed contact Reginald Bennett at (301) 436-2009.

Confirmation analyses will be performed on the extract and reserve subsample(s) as appropriate.

Districts should wait for Center confirmation before finalizing any regulatory action.

2. When the result of the TECRA™ ELISA is **positive** and the VIDAS is **negative** then:

Check for presence of peroxidase.

**NOTE**: Some foods contain peroxidase which can cause a false-positive reaction with the TECRA™ ELISA; therefore if this scenario presents itself the analyst should inactivate the peroxidase and retest.

To determine peroxidase presence, refer to the method outlined in BAM chapter 13A "Staphylococcal Enterotoxins: Micro-slide Double Diffusion and ELISA-based Methods", Section "Extraction of Enterotoxins from Foods for ELISA Assays", A. General Precautions. If peroxidase is present, inactivate the peroxidase using the methods outlined in the General Precautions section and retest.

**NOTE:** Under **no** circumstances should positive TECRA™ ELISA results be conveyed to a regulated firm or consumer without confirmation. The TECRA™ ELISA is intended as a screening method only.

If the TECRA™ ELISA retest remains positive, send the extract used for the TECRA™ ELISA and the reserve portion for all of the original sub-samples to:

FDA/ CFSAN/ Microbiology Methods Research Branch
Attention: Reginald Bennett, HFS-516
5100 Paint Branch Parkway
College Park, MD 20740.*

Methods Contact

- Reginald Bennett, CFSAN/Office of Plant and Dairy Foods/ Division of Microbiological Studies/ Microbiological Methods Research Branch/HFS-516, (301) 436-2009, RBennett@CFSAN.FDA.GOV

- Marsha Hayden, ORO/Division of Field Science/HFC-140, (301) 827-1039, MHayden@ORA.FDA.GOV

CFSAN's Microbiological Methods Research Branch will provide results to CFSAN/Office of Compliance/Division of Enforcement. The Division of Enforcement will contact the District's Compliance Branch with the results for appropriate follow-up.*

## III. REPORTING

pH Determination

If any normal container of acidified product has a pH at or above 4.65 or the mean plus two standard deviations (as determined by either analyst's total result(s) is at or above 4.65, immediately refer the results of analysis to the District Compliance Branch. Do not average the two analysts' pH results.

FACTS Reporting

The analyzing laboratory will report results for each sample of low acid and acidified products into FACTS using PAF = ACD.

The following Problem Area Flags should be used:

AFD = Acid Food Analysis

ACF = Acidified Food Analysis

LAF = Low-Acid Canned Food Analysis

## PART V - REGULATORY/ADMINISTRATIVE STRATEGY

If the Center for Food Safety and Applied Nutrition determines that a health hazard exists, determine the disposition of the lot after it has been refused admission and inform, CFSAN, HFS-606. If the lot has been re-exported, HFS-606 will inform the International Affairs Staff (HFY-50), who will notify appropriate authorities of the countries to which the lot was shipped.

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

1. LACF Products Based on Microbiological Findings

   Advise HFS-606 of any detentions. Follow instructions in the Regulatory Procedures Manual (Import Alerts) (http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9dirs.html) and Compliance Policy Guide Section 520.200 "Canned Foods - Seam Defects" (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg520-200.html).

2. Water Activity Controlled Products Based on pH and $a_w$ Findings

   *When analysis identifies a water activity controlled product with pH above 4.6 for which there is no process filing or the water activity is confirmed above the maximum $a_w$ listed in the filed scheduled process, contact HFS-606 for further instructions.

   In addition, when a sample is collected for water activity, the district import branches should either check the LACF Web Application System to determine whether a process has been filed or the maximum water activity value filed should be reported to the laboratory with the collection information. The reason for analyses should be noted either “analyses to determine if LACF” or if known “to confirm compliance with a filed maximum water activity value”.*

3. Acidified Products Based on pH Findings

   *Consult “CPG Section 520.300 Acidified Low-Acid Canned Foods – Adulteration Due to High pH (CPG 7120.25)” (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg520-300.html).*

   If sample results meet criteria stated in CPG Section 520.300, send all pertinent documents, such as the analytical worksheets, collection report, entry package and complete labeling, to HFS-606 along with Detention Request. List the FCE number on the documents.

4. Abnormal Containers (Acidified, LACF, and $a_w$ controlled Products)

   - If the abnormal rate is 1% or greater, send a Detention Request in addition to all pertinent documents as listed above to CFSAN, HFS-606. (IOM Sample Schedule Chart 2 describes the different types of abnormal containers).

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

5. Firm's Failure to Register or to have Process on File

   In most cases, this decision will be based on a **DTR** or **DER**, rather than a physical sample.

a. Detain the shipment if the steps in PART III, pages 1 and 2 have been completed and the firm has not registered and has not filed the necessary processing information with FDA.

Consider providing the importer with:

- The FDA Importer's Guide/Low Acid Canned and Acidified Foods, and/or
- Importing Foods into the United States.
- Also refer them to the Center's Webpage "Acidified and Low-Acid Canned Foods" at http://vm.CFSAN.fda.gov/~comm/Lacf-Toc.html. At this site, they can download the regulations, registration and process filing forms, instructions for completing the forms and there are links to FDA inspection Guides, Import Alerts, Import Procedures and Importer's Guide.

These publications are available in each District or on-line at the above site. Additional copies may also be obtained through HFS-565 (301) 436-1727.

b. While evaluating the disposition of an entry, check the LACF Web Application System. If the process filing form has been accepted as indicated in the tracking file or the LACF Process File, the entry may be released. An accepted form in the tracking file will have a date in the "Ready" slot.

6. Import Alerts, Including #99-04

Follow the criteria, instructions, and guidance contained in the Import Alerts. Release of products should only be given with concurrence of CFSAN/Imports Branch, HFS-606 and DIOP HFC-170 should also be notified.

Import Alert # 99-04 "Detention Without Physical Examination Of Manufacturers of Low-Acid Canned Foods and Acidified Foods" was designed only for companies that have already registered with FDA (have an FCE number). Do not recommend firms/products for inclusion in this alert if the firm does not have an FCE number.

***Do not recommend firm/products for an Import Alert/DWPE solely based on firm/product not registered and/or filed processes with FDA since all LACF and acidified foods should be checked for registration and process filing. However, it may be appropriate to recommend to CFSAN/DIOP an Alert or Import Bulletin for non-registration and/or process filing if the product may not readily be identified as a LACF or an acidified food. It may also be appropriate to recommend a separate Import Alert/DWPE of an LACF or acidified product if the violation involves a health hazard and it does not fit into the criteria for being included in Import Alert # 99-04. Recommendations may be made directly to CFSAN/Import Branch (HFS-606) and an info copy sent to DIOP, HFC-170. Follow the procedures in Chapter 9 of the Regulatory Procedures Manual***

7. *Fraudulent Entries

When fraud is suspected, it should immediately be brought to the

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

## PART VI - ATTACHMENTS, REFERENCES, AND PROGRAM CONTACTS

ATTACHMENTS

Attachment A - Product Code List
Attachment B - Heat Resistance Report Form
Attachment C - Can Sizes

PROGRAM CONTACTS

| | |
|---|---|
| General Program Directions: | *Robyn Jones, CFSAN/ Office of Compliance/ Division of Field Program/ Compliance Program Branch, HFS-636, (301) 436-2575, Fax (301) 436-2657, Robyn.Jones@FDA.HHS.GOV* |
| Regulatory, compliance matters or interpretation of regulations/ what products are covered: | *Angel Suarez, CFSAN/ Office of Compliance/ Division of Enforcement/ Import Branch, HFS-606, (301) 436-2146, ASuarez@FDA.HHS.GOV; |
| LACF Registration Control Coordinator (Plant registration and filed scheduled processes): | CFSAN/ Office of Compliance/ Division of Field Programs/ Regulatory Food Processing and Technology Branch , HFS-618, (301) 436-2411, LACF@FDA.HHS.GOV |
| Accounts for the Intranet LACF Web Application System can be obtained from http://intranet.cfsan.fda.gov/LACF/login.cfm If there are any problems, contact: | *Sharon Macuci, CFSAN/ Office of Management System, HFS-676, (301) 436-1865, SMacuci@FDA.HHS.GOV<br><br>Celines Roberts, CFSAN/ Office of Management System, HFS-676, (301) 436-1476, CRoberts@FDA.HHS.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: | Susan Brecher, CFSAN/Office of Compliance/ Division of Field Programs/ Low-Acid and Acidified Canned Foods Team, HFS-617, (301) 436-1781, SBrecher@FDA.HHS.GOV |
| Import Procedures, Joint BCBP Compliance Enforcement Actions and Coverage: | ORO/ Division of Import Operations and Policy, HFC-170, (301) 443-6553 |
| Inspectional History: | ORO/ Division of Field Investigations, HFC-130, (301) 827-6691 |
| Confirmation of Preformed and/or Cultured *C. botulinum* toxin: | *Richard C. Whiting, CFSAN/Office of Plant and Dairy Foods, HFS-301, (301) 436-1925, Rwhiting@FDA.HHS.GOV |

| | |
|---|---|
| Confirmation of Staphylococcal enterotoxin: | *Reginald Bennett, CFSAN/Office of Plant and Dairy Foods/ Division of Microbiological Studies/ Microbiological Methods Research Branch, HFS-516, (301) 436-2009, Rbennett@FDA.HHS.GOV * |
| Industry Education: | CFSAN/Office of Constituent Operations/ International Policy in Industry Outreach Branch, HFS-585, (301) 436-1714 |
| Analytical Methods Inquiries: | *Marsha Hayden, ORO/ Division of Field Science, HFC-140, (301) 827-1039, MHayden@FDA.HHS.GOV* |

## PART VII - CENTER RESPONSIBILITIES

1. Center Analyses for Program Support

*Confirmation of preformed toxin samples and toxin production by culture isolates and Staphylococcal Enterotoxin, CFSAN, Office of Plant and Dairy Foods/ Division of Microbiological Studies/ Microbiological Methods Research Branch, HFS-516, R.C. Whiting, S. Sharma, and R.W. Bennett (SET).*

2. Evaluation Requirements

The Office of Compliance has the responsibility to prepare periodic formal evaluations of this compliance program. When completed and cleared, the evaluations will be available for Agency personnel on CFSAN's OC Intranet site (http://intranet.cfsan.fda.gov/OC/pages/panda.htm). Additionally, the evaluations should appear on CFSAN's Internet website.

3. Foreign Inspection Program

On receipt of information from the foreign inspection program (Division of Field Investigational, HFC-130), of noncompliant firms, the Center will modify the lists of registered firms with filed processes and/or submit a recommendation to DIOP to revise Import Alert #99-04 and reflect the findings.

## Import Acidified and Low-Acid Canned Foods Program

### PRODUCT CODE LIST

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

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

| | | |
|---|---|---|
| Multiple Food Dinners, Gravies, Sauces and Specialties | 37 | A, B, C, D, G, J, Y |
| Soups | 38 | All |
| Prepared Salad Products | 39 | All |
| Baby (Infant and Junior) Food Products | 40 | All but X |
| Dietary Conventional Foods and Meal Replacements | 41 | All |

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## HEAT RESISTANCE REPORTING FORM

| DISTRICT | SAMPLE NUMBER | DATE SENT |
|---|---|---|
| | | |

| PRODUCT | MANUFACTURER AND/OR DISTRIBUTOR |
|---|---|
| | |

| SUBSAMPLE # | CODE | CULTURE # | TYPE OF CULTURE | VERIFICATION | $D_{240}$ |
|---|---|---|---|---|---|
| | | | | | |
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## CAN SIZES

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

| Can Number | Inches | Can Dimensions in Millimeters (Diameter x Height) | Common Name |
|---|---|---|---|
| 202 x 202 | 2 2/16 x 2 2/16 | 54.0 x 54.0 | None |
| 202 x 204 | 2 2/16 x 2 4/16 | 54.0 x 57.2 | 2oz Mushroom |
| 202 x 214 | 2 2/16 x 2 14/16 | 54.0 x 73.0 | 5oz Baby food |
| 202 x 308 | 2 2/16 x 3 8/16 | 54.0 x 88.9 | 6oz Jitney |
| 202 x 314 | 2 2/16 x 3 14/16 | 54.0 x 98.4 | 6oz |
| 211 x 109 | 2 11/16 x 1 9/16 | 68.3 x 39.7 | ¼ lb tuna |
| 211 x 200 | 2 11/16 x 2 | 68.3 x 50.8 | 4oz Pimiento – 211 Baby Food |
| 211 x 210 | 2 11/16 x 2 10/16 | 68.3 x 66.7 | 6oz Junior Food |
| 211 x 212 | 2 11/16 x 2 12/16 | 68.3 x 69.9 | 4oz Mushroom |
| 211 x 214 | 2 11/16 x 2 14/16 | 68.3 x 73.0 | None |
| 211 x 300 | 2 11/16 x 3 | 68.3 x 76.2 | 8oz Short |
| 211 x 304 | 2 11/16 x 3 4/16 | 68.3 x 82.5 | 8oz Tall |
| 211 x 400 | 2 11/16 x 4 | 68.3 x 101.6 | No.1 (Picnic) |
| 211 x 414 | 2 11/16 x 4 14/16 | 68.3 x 123.8 | No.211 Cylinder |
| 211 x 600 | 2 11/16 x 6 | 68.3 x 152.4 | Pint Olive |
| 300 x 109 | 3 x 1 9/16 | 76.2 x 39.7 | None |
| 300 x 206 | 3 x 2 6/16 | 76.3 x 60.3 | 7oz Pimiento |
| 300 x 308 | 3 x 3 8/16 | 76.2 x 88.9 | None |
| 300 x 400 | 3 x 4 | 76.2 x 101.6 | 8oz Mushroom |
| 300 x 407 | 3 x 4 7/16 | 76.2 x 112.7 | No. 300 |
| 300 x 409 | 3 x 4 9/16 | 76.2 x 115.9 | None |
| 301 x 106 | 3 1/16 x 1 6/16 | 77.8 x 34.9 | ¼lb Salmon |
| 301 x 208 | 3 1/16 x 2 8/16 | 77.8 x 63.5 | 8oz Pimiento |
| 301 x 408 | 3 1/16 x 4 8/16 | 77.8 x 114.3 | No.1 Tall |
| 301 x 411 | 3 1/16 x 4 11/16 | 77.8 x 119 | No.1 Tall |
| 303 x 406 | 3 3/16 x 4 6/16 | 81.0 x 111.1 | No. 303 |
| 303 x 509 | 3 3/16 x 5 9/16 | 81.0 x 141.3 | No. 303 Cylinder |
| 307 x 113 | 3 7/16 x 1 13/16 | 87.3 x 46.0 | 1/2 lb Tuna |
| 307 x 200.25 | 3 7/16 x 2 1/64 | 87.3 x 51.2 | ½ lb Salmon |
| 307 x 202 | 3 7/16 x 2 2/16 | 87.3 x 54.0 | None |
| 307 x 203 | 3 7/16 x 2 3/16 | 87.3 x 55.6 | No.1 Flat |
| 307 x 208 | 3 7/16 x 2 8/16 | 87.3 x 63.5 | None |
| 307 x 214 | 3 7/16 x 2 14/16 | 87.3 x 73.0 | Kitchenette |
| 307 x 306 | 3 7/16 x 3 6/16 | 87.3 x 85.7 | No. 2 Vacuum |
| 307 x 400 | 3 7/16 x 4 | 87.3 x 101.6 | No.95 |
| 307 x 409 | 3 7/16 x 4 9/16 | 87.3 x 115.9 | No. 2 |
| 307 x 509 | 3 7/16 x 5 9/16 | 87.3 x 141.3 | None |
| 307 x 510 | 3 7/16 x 5 10/16 | 87.3 x 142.9 | Jumbo |
| 307 x 512 | 3 7/16 x 5 12/16 | 87.3 x 146.1 | No. 2 Cylinder |
| 307 x 704 | 3 7/16 x 7 4/16 | 87.3 x 184.2 | Quart Olive |
| 307 x 710 | 3 7/16 x 7 10/16 | 87.4 x 193.7 | 32oz (Quart) |

| | | | |
|---|---|---|---|
| 401 x 205.5 | 4 1/16 x 2 11/32 | 103.2 x 59.5 | No. 1 Tuna |
| 401 x 206 | 4 1/16 X 2 6/16 | 103.2 x 60.3 | No.1¼ (Veg.) |
| 401 x 207.5 | 4 1/16 x 2 15/32 | 103.2 x 62.7 | No.1¼ |
| 401 x 211 | 4 1/16 x 2 11/16 | 103.2 x 68.3 | No.1 Flat |
| 401 x 411 | 4 1/16 x 4 11/16 | 103.2 x 119.1 | No. 2½ |
| 404 x 307 | 4 4/16 x 3 7/16 | 108.0 x 87.3 | No. 3 Vac. |
| 404 x 414 | 4 4/16 x 4 14/16 | 108.0 x 123.8 | No. 3 |
| 404 x 700 | 4 4/16 x 7 | 108.0 x 177.8 | No. 3 Cyl (46oz) |
| 502 x 510 | 5 2/16 x 5 10/16 | 130.2 x 142.9 | No. 5 |
| 603 x 405 | 6 3/16 x 4 5/16 | 157.2 x 109.5 | None |
| 603 x 408 | 6 3/16 x 4 8/16 | 157.2 x 114.3 | No. 5 Squat |
| 603 x 700 | 6 3/16 x 7 | 157.2 x 177.8 | No. 10 |
| 603 x 812 | 6 3/16 x 8 12/16 | 157.2 x 222.3 | No. 12 (Gal.) |