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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Food Process Filing for Acidified Method (Form FDA 2541e)

Note: There are separate process filing forms for each of the following: Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d); Food Process Filing for Acidified Method (Form FDA 2541e); Food Process Filing for Water Activity/Formulation Control Method (Form FDA 2541f); and Food Process Filing for Low-Acid Aseptic Systems (Form FDA 2541g).

USE FDA INSTRUCTIONS ENTITLED "Instructions for Paper Submission of Form FDA 2541e (Food Process Filing for Acidified Method)"

Date Received by FDA _ _ / _ _/ _ _ _ _ (MM/DD/YYYY) (FDA USE ONLY)

Food Canning Establishment (FCE) Number: _ _ _ _ _ _

Submission Identifier (SID) 20 _ _-_ _-_ _/_ _ _ (YYYY-MM-DD/SSS)

A. Product Information:
Note: Section A.1 (Food Product Group) requests optional information.

1. (Optional) Select one Food Product Group. If there is no single best Food Product Group that applies, select Other.
   - Aquaculture Seafood (e.g., farming of aquatic organisms including fish, mollusks, crustaceans, etc.);
   - Baby Food;
   - Beans, Corn, or Peas (Select one):
     - Beans or Peas - Dry or Mature Soaked;
     - Beans, Corn, Peas - Fresh Succulent;
   - Berry/Citrus/Core Fruit (Select one):
     - Berry/Citrus/Core Fruit;
     - Berry/Citrus/Core Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping;
   - Beverage Base;
   - Breakfast Foods (liquid form – ready-to-eat, such as porridge, gruel);
   - Cheese (does not include soy cheese or imitation dairy);
   - Cocoa;
   - Coffee/Teas (excluding herbal and botanical teas);
   - Crustacean (e.g., crab, shrimp, lobster, etc.);
   - Dairy (milk-based);
   - Dietary Supplement and/or herbal and botanical teas;
   - Dressings/Condiments (e.g., salad dressing, chutney, salsa, pepper sauce, etc.);
   - Engineered Seafood (e.g., shelf-stable imitation crab, surimi, etc.);
   - Exotic Meat (includes sausages such as vienna sausage, etc.);
   - Fishery (other aquatic (e.g., alligator, cuttlefish, frog legs, squid, etc.));
   - Fungi (e.g., mushrooms, pleurotus, truffles, etc.);
   - Gelatin, Pudding Filling for Pies, Pie Filling (liquid form ready-to-eat such as apple pie filling, etc.);
   - Imitation Dairy (includes soy-based products);
   - Fruit as a Vegetable (Select one):  - Fruit as a Vegetable (e.g., eggplant, pumpkin, etc.);
   - Fruit as a Vegetable Juice or Drink (e.g., eggplant juice, pumpkin juice, etc.);
   - Fungi (e.g., mushrooms, pleurotus, truffles, etc.);
   - Gelatin, Pudding Filling for Pies, Pie Filling (liquid form ready-to-eat such as apple pie filling, etc.);
   - Imitation Dairy (includes soy-based products);
   - Imitation/Pit/Mixed/Subtropical Fruit (Select one):
     - Imitation/Pit/Mixed/Subtropical Fruit;
     - Imitation/Pit/Mixed/Subtropical Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping;
   - Leafy/Stem Vegetables (Select one):
     - Leafy/Stem Vegetable;
     - Leafy/Stem Vegetable as a Juice or Drink (e.g., spinach juice, etc.);
   - Meal Replacement/Medical Foods (e.g., supplemental liquid nutrition, etc.);
   - Mixed Fishery (e.g., seafood salad, seafood bisque, etc.);
Mixed Vegetables (Select one): □ Mixed Vegetables (e.g., carrots and peas, etc); □ Mixed Vegetables as a Juice or Drink (e.g., carrot and green bean juice, etc.);
□ Multiple Food (one container with a separate compartment for each product item. e.g., lasagna dinner, chop suey dinner, etc.); □ Noodle/Pasta; □ Nut Spread and Nut Topping; □ Other Vegetables;
□ Pet Food (e.g., dog/cat food, etc.); □ Rice, Wheat, Oat or Grain (liquid form – ready-to-eat such as grits);

Root and Tuber Vegetables (Select one): □ Root/Tuber Vegetables (e.g., carrots, leeks, potatoes, etc.); □ Root/Tuber Vegetables as a Juice or Drink (e.g., carrot juice, etc.);
□ Shelled Eggs; □ Shellfish (e.g., clams, mussels, oysters, etc.); □ Soup (does not include seafood-type soups); □ Sweet Goods/Dessert (liquid form – ready-to-eat, such as pudding);

Vine/Other Fruit (Select one): □ Vine/Other Fruit; □ Vine/Other Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping; □ Wine Cooler; □ Other

2. Enter Product Name (e.g., salsa (mild, medium, hot), artichokes (marinated), peppers (red or green), etc.).

3. What is the form of the product? □ Chunks (e.g., chunks, nuggets, etc.) □ Cut □ Diced □ Fillet □ French Cut □ Liquid (i.e., all liquid no solids) □ On the Cob □ Paste/Puree □ Pieces □ Round/Spheres □ Shredded/Julienne □ Sliced (e.g., slices, quarters, strips, etc.) □ Spears/Stalks □ Whole □ Other _______________________

4. What is the packing medium? □ Brine □ Cream/Sauce/Gravy □ Oil □ Solid (no packing medium) □ Syrup □ Water □ None (i.e., the product is all liquid) □ Other _______________________

Continue to Section B.

B. Governing Regulation: (Select one)

1. □ Acidified (Product is an acidified food and is governed by 21 CFR 108.25 and 21 CFR Part 114)
2. □ Voluntary (The processor has concluded that the product is not an acidified food. The processor is voluntarily submitting process information about the product to facilitate FDA determinations regarding the regulatory status of the product.) If you select this option, attach documentation to support the determination that the product is not an acidified food. If the product appears to be a fermented food, include a detailed process flow diagram of fermentation processes, including the pH at each step.

Continue to Section C.

C. Container Type: (Select one)

Note: If the product is not packaged in one of the container types identified below, select “Other” option.

1. □ Aluminum/Tinplate/Steel Can
   a) What is the shape of the container? (Select one) □ Cylindrical □ Irregular (Attach a picture or schematic) □ Oval □ Rectangular □ Other ________________________ (Attach a picture or schematic)
   b) How many pieces are used to construct the container? (Select one)
      i. □ 2-pieces – Do you use perforated divider plates? □ Yes □ No
      ii. □ 3-pieces – Do you use perforated divider plates? □ Yes □ No □ How is the side seam sealed? (Select one) □ Cemented □ Welded
2. ☐ Ceramic/Glass
   a) What is the shape of the container? (Select one) ☐ Cylindrical ☐ Irregular (Attach a picture or schematic) ☐ Rectangular ☐ Other __________________________ (Attach a picture or schematic)
   b) Do you use perforated divider plates?  ☐ Yes ☐ No
   c) Is overpressure used during the processing of the product to maintain container integrity?  ☐ Yes (Continue to c.i) ☐ No (Continue to c.ii-c.iv)
   i. What is the total overpressure used during processing? __ _ _ _ _ (enter in pounds per square inch gauge (psig)) (Continue to Section D)
   ii. What is the percent (%) headspace? __ _ _ _
   iii. What is the minimum initial temperature? __ _ _ _ (enter in Fahrenheit)
   iv. What is the vacuum? __ _ _ _ (enter in inches of mercury (Hg))

3. ☐ Flexible Pouch
   a) What is the shape of the container? (Select one) ☐ Flat pouch ☐ Gable top ☐ Gable top/side gusseted ☐ Gusseted ☐ Irregular (Attach a picture or schematic)
      ☐ Other __________________________ (Attach a picture or schematic)
   b) Is the container physically restricted during the processing of the product to control container thickness? ☐ Yes (Continue to b.i) ☐ No (Continue to c)
      i. Racks ☐ Other __________________ (Attach a picture)
   c) Is overpressure used during the processing of the product to control container thickness? ☐ Yes (Continue to c.i) ☐ No (Continue to d)
      i. What is the total overpressure used during processing? __ _ _ _ (enter in pounds per square inch gauge (psig))
   d) What is the maximum thickness during retort processing? __ _ _ _ (enter in inches)
   e) What is the maximum residual air? __ _ _ _ (enter in cubic centimeters)

4. ☐ Retortable Paperboard Carton
   a) What is the shape of the container? (Select one) ☐ Rectangular ☐ Other __________ (Attach a picture or schematic)
   b) Is the container physically restricted during the processing of the product to control container thickness? ☐ Yes (Continue to b.i) ☐ No (Continue to c)
      i. Racks ☐ Other ________________ (Attach a picture)
   c) Is overpressure used during the processing of the product to control container thickness? ☐ Yes (Continue to c.i) ☐ No (Continue to d)
      i. What is the total overpressure used during processing? __ _ _ _ (enter in pounds per square inch gauge (psig))
   d) What is the maximum thickness during retort processing? __ _ _ _ (enter in inches)
   e) What is the maximum residual air? __ _ _ _ (enter in cubic centimeters)

5. ☐ Rigid Container (10 pounds or more of product)
   a) What is the shape of the container? (Select one) ☐ Cylindrical ☐ Rectangular ☐ Other __________ (Attach a picture or schematic)
   b) What kind of rigid container is used? (Select the description that best applies to the container (i.e., drum, pail, or tote) and select the material that makes up that container)
      ☐ Drum (Large industrial cylinder container) (Select one) ☐ Aluminum/Steel ☐ Fiberboard ☐ Plastic ☐ Other __________________________ (Attach a picture or schematic)
      ☐ Pail (Select one) ☐ Aluminum/Steel ☐ Fiberboard ☐ Plastic ☐ Other __________________________
      ☐ Tote (Large industrial rectangular container) (Select one) ☐ Aluminum/Steel ☐ Fiberboard ☐ Plastic ☐ Other __________________________
      ☐ Other __________________________ (Attach a picture or schematic)

6. ☐ Semi-Rigid
   a) What is the shape of the container? (Select one) ☐ Bowl ☐ Cylindrical ☐ Irregular (Attach a picture or schematic) ☐ Oval ☐ Rectangular ☐ Tray ☐ Other __________________________ (Attach a picture or schematic)
   b) Is this a compartmentalized container?  ☐ Yes  How many compartments? __ _ _ _ ☐ No
   c) What is the predominant material used to make the body of the container? (Select one) ☐ HDPE (high-density polyethylene) ☐ HDPP (high-density polypropylene) ☐ Paperboard ☐ PET (polyethylene teraphthalate) ☐ Other __________________________
   d) What is the predominant material used to make the lid of the container? (Select one) ☐ HDPE (high-density polyethylene) ☐ HDPP (high-density polypropylene) ☐ Nylon ☐ PET (polyethylene teraphthalate) ☐ Other __________________________ ☐ Not Applicable
   e) How is the lid sealed to the body of the container? (Select one)
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- Double Seam □ Heat Seal □ Induction Weld □ Press Twist □ Snap On □ Threaded Closure □ Ultrasonic Seal □ Other ________________________________ □ Not Applicable

f) Is the container physically restricted during the processing of the product to control container thickness? □ Yes (Continue to f.i) □ No (Continue to g)

i. Racks □ Other ________________________ (Attach a picture)

- Overpressure used during the processing of the product to control container thickness? □ Yes (Continue to g.i) □ No (Continue to h)

i. What is the total overpressure used during processing? _ _._ (enter in pounds per square inch gauge (psig))

h) What is the maximum thickness during retort processing? _ _._ (enter in inches)

i) What is the maximum residual air? _ _ _ (enter in cubic centimeters)

- Other (Enter container type) ______________________________

a) Attach schematic or picture of container.

b) Specify the material that, based on weight, is the predominant material used to make the container stock. This is the material that constitutes the highest weight value of the container stock. ___________

c) Specify the material that, based on weight, is the predominant material used to make the lid stock. This is the material that constitutes the highest weight value of the lid stock. If the container does not have a lid, specify Not Applicable _________________

d) Specify the method used to seal the lid to the body of the container. If the container does not have a lid, specify Not Applicable __________________________

Continue to Section D.

D. Container Size:
Note: You are required to complete either D.1 (Dimensions) or D.2 (Volume). You may complete D.2 if the thermal process mode in Section G is identified as: 1) High Temperature Short Time (HTST); 2) Hot Fill and Hold; or 3) Steam Jacketed Kettle.

If you are completing D.2 because you selected HTST, Hot Fill and Hold, or Steam Jacketed Kettle, and if 1) your product is a cheese product under Section A.1, and 2) you have identified “Other” under Section C, you may indicate “Not Applicable” in your response to D.2. In all other circumstances, if you are completing D.2 in accordance with the directions in paragraph 1, you may not select “Not Applicable.”

For all other circumstances, complete D.1. Section D.3 (net weight) is optional information.

1. Dimensions:
   a) _ _ _ _ Diameter _ _ _ _ Height (Use for cylindrical shapes) (see accompanying instructions for proper coding)
   b) _ _ _ _ Length _ _ _ _ Width _ _ _ _ Height (Use this option for container shapes other than cylindrical) (see accompanying instructions for proper coding)

2. Volume: _ _ _ _ (Select one) □ Fluid Ounces □ Gallons □ Liters □ Milliliters □ Not Applicable

3. Net Weight (Optional): _ _ _ _ (enter in ounces)

Submissions for Acidified Foods: Continue to Section E.

Voluntary Filing: Stop here and go to the signature section at the bottom of the form.

E. Processing Method: Acidification:

1. What is natural pH of the product before acidification? _ _ _ _

2. What is the finished equilibrium pH of the product after acidification? _ _ _
3. What is the maximum time it takes for the product to achieve the finished equilibrium pH of 4.60 or lower?  _ _ _   Minutes   Hours
4. Method of Acidification (Select one)  □  Addition of Acid Foods  □  Blanch  □  Direct Batch  □  Direct In Container  □ Immersion  □ Other ________________________________________________________________________________________________
5. Acidifying Agent(s): (Select all that apply)  
□  Acetic Acid  □  Acid Food(s)  □  Apple Product(s) (other than vinegar)  □  Citric Acid  □  Fruit Juice(s)  □  Fumaric Acid  □  Gluconic Acid  □  Hydrochloric Acid  □  Lactic Acid  □  Malic Acid  □  Phosphoric Acid  □  Sodium Acid Sulfate  □  Tamarind Product(s)  □  Tartaric Acid  □  Tomato Product(s)  □  Vinegars (All Types)  □  Wine  □ Other ________________________________________________________________________________________________
6. Microbial Preservative(s): (Select all that apply and enter percent concentration(s))

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<th>Microbial Preservative</th>
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<td>Potassium Metabisulphite</td>
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<td>Sodium Sorbate</td>
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<td>Potassium Sorbate</td>
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<td>Sodium Sulfite</td>
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<td>Propylparaben</td>
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<td>Sorbic Acid</td>
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<td>Calcium Propronate</td>
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Continue to Section F.

F. Scheduled Process Source:


b) What is the date of the Process Source (mm/dd/yyyy)? _ / _ / _ _ _ _

 Continue to Section G.

G. Process Mode: (Select one)

1.  □  High Temperature Short Time (HTST)
2.  □  Hot Fill and Hold
3.  □  Steam Jacketed Kettle

When option 1, 2, or 3 is selected, continue to Section H.

4.  □  Batch Agitating Retort
5.  □  Cold Fill and Hold (Attach support documentation)
6.  □  Crateless Retort
7.  □  Heating Tunnel – Steam or Water (water cascade, water immersion, water spray, or steam)
8.  □  Hydrostatic Retort
9.  □  Sterilmatic
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10. □ Still Retort (Steam or Water)
11. □ Water Bath
12. □ Other: _______________________________  (Attach support documentation)

When option 4-12 is selected, continue to Section I.

H. Container and Container Closure Treatment: (Complete this section ONLY for Process Modes: 1) High Temperature Short Time (HTST); 2) Hot Fill and Hold; 3) Steam Jacketed Kettle)

Describe how the container, headspace, and interior surface (the surfaces that are in contact with the food) of the container closure are treated. (Select one)

1. □ Aseptically Filled:
   a) What is the filler name and model? __________________________________________________________________________

2. □ Steam Tunnel:
   a) What is the process time? _ _ _ (Select one) □ Seconds □ Minutes
   b) What is the temperature in the steam tunnel? _ _ _ (enter in Fahrenheit)

3. □ Hot Fill and Hold:
   a) What is the temperature of the product in the container at the end of the hold time? _ _ _ (enter in Fahrenheit)
      i. Select one of the container closure treatments.
         □ Inversion/Laydown of Container: How long is the product inverted/laid-down? _ _ _ (Select one) □ Seconds □ Minutes
         □ Steam Flow Closure
         □ Other __________________________________________________________________________
   What is the exposure time? _ _ _ (Select one) □ Seconds □ Minutes

4. □ Water spray:
   a) What is the process time? _ _ _ (Select one) □ Seconds □ Minutes
   b) What is the temperature of the water spray? _ _ _ (enter in Fahrenheit)

5. □ Other (Specify) __________________________________________________________________________

Continue to Section I.

I. Scheduled Process: (Do not write in shaded areas -- Check appropriate box under column heading, when applicable, and enter numerical values on dashed lines.)

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<td>Process No</td>
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<td>Thruuput (Containers per Minute)</td>
<td>Sterilmatic or Heating Tunnel – Steam or Water ONLY</td>
<td>Headspace</td>
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Comments:

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<th>Country (other than U.S.)</th>
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LACF Contact Information

For more information, contact the LACF Registration Coordinator by e-mail at LACF@FDA.HHS.GOV or phone: 240-402-2411

For paper submissions, send completed forms to:

Food and Drug Administration  
LACF Registration Coordinator ((HFS-303)  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.*

The burden time for this collection of information is estimated to average .333 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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