Form Approved: OMB NO. 0910-0037; Expiration Date 9/30/2017 *(See PRA Statement on last page)*

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)"

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

Food Canning Establishment (FCE) Number *(Enter number assigned by FDA)*	Submission Identifier (SID) *(YYYY-MM-DD/SSS)*
_____	20 _ _ - _ _ - _ _ / _ _ _

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 (infant/junior foods including infant formula)
- ☐ Bakery Products (canned brown bread, bakery glazes)

Beans, Corn, or Peas

- ☐ Beans or Peas - Dry or Mature Soaked ☐ Beans, Corn, Peas - Fresh Succulent

Berry/Citrus/Core Fruit

- ☐ 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.) ☐ Fishery (finfish)
- ☐ Fishery (other aquatic (e.g., alligator, cuttlefish, frog legs, squid, etc.)

Fruit as a Vegetable

- ☐ Fruit as a Vegetable (e.g., eggplant, pumpkin, etc.)
- ☐ Fruit as a Vegetable Juice or Drink (e.g., eggplant juice, pumpkin juice, etc.)

A.1 (Food Product Group) *(Continued)*

- ☐ 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.)
- ☐ Gravies/Sauces (spaghetti sauce, mushroom gravy)
- ☐ Imitation Dairy (includes soy-based products)

Imitation/Pit/Mixed/Subtropical Fruit

- ☐ Imitation/Pit/Mixed/Subtropical Fruit
- ☐ Imitation/Pit/Mixed/Subtropical Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

Leafy/Stem Vegetables

- ☐ 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.)
- ☐ Meat Products (Exotic Meat (emu, elk, etc.)) ☐ Mixed Fishery (e.g., seafood salad, etc.)

Mixed Vegetables

- ☐ 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

- ☐ Root/Tuber Vegetables (e.g., carrots, leeks, potatoes, etc.)
- ☐ Root/Tuber Vegetables as a Juice or Drink (e.g., carrot juice, etc.)

A.1 (Food Product Group) *(Continued)*

☐ Shelled Egg ☐ Shellfish (e.g., clams, mussels, oysters, etc.) ☐ Soup
☐ Sweet Goods/Dessert (liquid form – ready-to-eat, such as pudding)
☐ Vegetable Protein Products (e.g., imitation meat analog)

Vine/Other Fruit
☐ Vine/Other Fruit
☐ Vine/Other Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

☐ Wine Cooler
☐ Other ***(Specify below)***

_____

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? ***(Select all that are applicable)***

☐ Chunks (e.g., chunks, nuggets, etc.) ☐ Cut ☐ Diced ☐ Filet ☐ 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 ***(Enter product form)***

_____

4. What is the packing medium? ***(Select all that are applicable)***

☐ Brine ☐ Cream/Sauce/Gravy ☐ Oil ☐ Solid (no packing medium)
☐ Syrup ☐ Water ☐ None
☐ Other ***(Enter packing medium)***

_____

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 choice, 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.

   (Attach document. Provide name or a brief description of attachment below.)

   _____

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.

1. ☐ Aluminum/Tinplate/Steel Can

   a) What is the shape of the container? ***(Select one)***

   ☐ Cylindrical ☐ Oval ☐ Rectangular
   ☐ Irregular ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

   _____

   ☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

   _____

   b) How many pieces are used to construct the container? ***(Select one or more choices, as applicable)***

   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 ☐ Rectangular
   ☐ Irregular ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

   _____

   ☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

   _____

   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))

C. Container Type (Continued)

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. Provide name or a brief description of attachment below.)***

_____

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

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. Provide name or a brief description of attachment below.)***

_____

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) ☐ Not Applicable

4. ☐ Retortable Paperboard Carton

a) What is the shape of the container? ***(Select one)*** ☐ Rectangular

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

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. Provide name or a brief description of attachment below.)***

_____

C. Container Type: 4. Retortable Paperboard Carton *(Continued)*

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) ☐ Not Applicable

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. Provide name or a brief description of attachment below.)***

_____

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 ***(Enter material)***

_____

☐ Pail ***(Select one)***

☐ Aluminum/Steel ☐ Fiberboard ☐ Plastic

☐ Other ***(Enter material)***

_____

☐ Tote (Large industrial rectangular container) ***(Select one)***

☐ Aluminum/Steel ☐ Fiberboard ☐ Plastic

☐ Other ***(Enter material)***

_____

☐ Other ***(Enter rigid container)***

_____

(Attach a picture or schematic. Provide name or a brief description of attachment below.)

_____

C. Container Type *(Continued)*

6. ☐ Semi-Rigid

a) What is the shape of the container? ***(Select one)***

☐ Bowl ☐ Cylindrical ☐ Oval ☐ Rectangular ☐ Tray

☐ Irregular ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

☐ Other ***(Attach a picture or schematic. Provide name or a brief description of attachment below.)***

_____

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 ***(Enter material)***

_____

d) What is the predominant material used to make the lid of the container? ***(Select one)***

☐ Aluminum/Steel ☐ HDPE (high-density polyethylene)

☐ HDPP (high-density polypropylene) ☐ Nylon

☐ PET (polyethylene teraphthalate)

☐ Not Applicable

☐ Other ***(Enter material)***

_____

e) How is the lid sealed to the body of the container? ***(Select one)***

☐ Double Seam ☐ Heat Seal ☐ Induction Weld ☐ Press Twist

☐ Snap On ☐ Threaded Closure ☐ Ultrasonic Seal

☐ Not Applicable

☐ Other ***(Enter seal type)***

_____

C. Container Type: 6. Semi-Rigid *(Continued)*

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. Provide name or a brief description of attachment below.)***

_____

g) Is 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) ☐ Not Applicable

7. ☐ Other ***(Enter container type)***

_____

a) Attach schematic or picture of container. ***(Provide name or a brief description of attachment below.)***

_____

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 you intend to select the thermal process mode in Section G 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 intend to select 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/Thickness ***(Use 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 the 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 ***(Enter acidification method)***

   _____

E. Processing Method: Acidification: (Continued)

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 ***(Enter one or more agents not listed)***

   _____

6. Microbial Preservative(s) critical to the scheduled process: ***(Select all that apply and enter percent concentration(s))***

Microbial Preservative	Concentration (%)
☐ Alcohol	_ _._ _
☐ Ascorbic Acid	_ _._ _
☐ Benzoic Acid	_ _._ _
☐ Butylated Hydroxyanisole	_ _._ _
☐ Butylated Hydroxytoluene	_ _._ _
☐ Calcium Chloride	_ _._ _
☐ Calcium Propronate	_ _._ _
☐ Calcium Sorbate	_ _._ _
☐ Erythorbic Acid	_ _._ _
☐ Ethanol	_ _._ _
☐ Gucono Delta Lactone	_ _._ _
☐ Polysorbate	_ _._ _
☐ Potassium Benzoate	_ _._ _
☐ Potassium Bisulphate	_ _._ _
☐ Potassium Metabisulphite	_ _._ _
☐ Potassium Propionate	_ _._ _
☐ Potassium Sorbate	_ _._ _
☐ Potassium Sulphite	_ _._ _
☐ Propylparaben	_ _._ _
☐ Salt	_ _._ _
☐ Sodium Benzoate	_ _._ _
☐ Sodium Bisulphate	_ _._ _
☐ Sodium Chloride	_ _._ _
☐ Sodium Erythorbate	_ _._ _
☐ Sodium Metabisulfite	_ _._ _
☐ Sodium Polyphosphate	_ _._ _
☐ Sodium Propionate	_ _._ _

(Continue next page – Microbial Preservative(s))

E. Processing Method: *6. Microbial Preservative(s) (Continued)*

Microbial Preservative	Concentration (%)
☐ Sodium Sorbate	_ _._ _
☐ Sodium Sulfite	_ _._ _
☐ Sorbic Acid	_ _._ _
☐ Trisodium Citrate	_ _._ _

☐ Other: (Enter preservative) _____

(Enter preservative) _____

(Enter preservative) _____

☐ None

Continue to Section F.

F. Process Source

1. What is the Process Source?

_____

(Attach support documentation)

_____

2. What is the date of the Process Source Document (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 process mode 1, 2, or 3 is selected, continue to Section H.

4. ☐ Batch Agitating Retort
5. ☐ Cold Fill and Hold ***(Attach support documentation. Provide name or a brief description of attachment below.)***

   _____
6. ☐ Crateless Retort
7. ☐ Heating Tunnel - Hot Air, Steam or Water (water cascade, water immersion, water spray)
8. ☐ Hydrostatic Retort
9. ☐ Sterilmatic
10. ☐ Still Retort (Steam or Water)
11. ☐ Water Bath
12. ☐ Other ***(Attach support documentation). Provide name or a brief description of attachment below.***

    _____

When process mode 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. ☐ Heating Tunnel
   a) What is the process time? _ _._ ***(Select one)***
      ☐ Seconds ☐ Minutes
   b) What is the temperature in the heating 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 (Enter container closure treatment)

         _____

         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.)

In the section below, please do NOT enter decimal points. They are already on the form. No blank spaces are allowed, therefore, enter leading zeros, where necessary.

Col. 1	Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7	Col. 8	Col. 9						Col. 10	Col. 11
Process No	Step	Temperature	Process Time	Process Temperature	F value (only one)	Thruput (Containers per Minute)	Headspace	a. Reel Speed	b. Reel Diameter	c. Steps per Turn of Reel	d. Chain/ Conveyer Speed	e. Cooker Capacity	f. Frequency Strokes per Minute	Maximum Fill Weight	Other
		☐ Min. Initial ☐ Fill	☐ Seconds ☐ Minutes ☐ Hours		☐ Fo (F18/250) ☐ Other F Ref T _____ z: _ _._ (°F only)		☐ Net ☐ Gross ☐ NA				☐ Feet ☐ Carriers ☐ Flights (per minute)			☐ Fill ☐ NA	
Number	Number	°Fahrenheit	See above	°Fahrenheit	Minutes	Number	Inches	RPM	Inches	Number	Number	Number	Number	Ounces	
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J. Additional Information (Optional)

☐ Heat Penetration Study ***(Attach document. Provide name or a brief description of attachment below.)***

_____

☐ Temperature Distribution Study ***(Attach document. Provide name or a brief description of attachment below.)***

_____

☐ Other ***(Attach document. Provide name or a brief description of attachment below.)***

_____

Comments:

Full Name (Please Type or Print)			Signature	
Establishment Name	State or Province	Country (other than U.S.)	Date	Telephone No.

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

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