

Draft Issued for Comment Only. Do Not Use to Submit a Process Filing to FDA

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

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.);

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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 Egg; 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

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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 _____
- 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 terephthalate) Other _____
- d) What is the predominant material used to make the lid of the container? (**Select one**)
 Aluminum HDPE (high-density polyethylene) HDPP (high-density polypropylene) Nylon PET (polyethylene terephthalate) 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**)

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)

7. 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? ____

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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))

Microbial Preservative	Concentration (%)	Microbial Preservative	Concentration (%)	Microbial Preservatives	Concentration (%)
<input type="checkbox"/> Alcohol	-----	<input type="checkbox"/> Potassium Benzoate	-----	<input type="checkbox"/> Sodium Metabisulfite	-----
<input type="checkbox"/> Ascorbic Acid	-----	<input type="checkbox"/> Potassium Bisulfate	-----	<input type="checkbox"/> Sodium Polyphosphate	-----
<input type="checkbox"/> Benzoic Acid	-----	<input type="checkbox"/> Potassium Metabisulfite	-----	<input type="checkbox"/> Sodium Propionate	-----
<input type="checkbox"/> Butylated Hydroxyanisole	-----	<input type="checkbox"/> Potassium Propionate	-----	<input type="checkbox"/> Sodium Sorbate	-----
<input type="checkbox"/> Butylated Hydroxytoluene	-----	<input type="checkbox"/> Potassium Sorbate	-----	<input type="checkbox"/> Sodium Sulfite	-----
<input type="checkbox"/> Calcium Chloride	-----	<input type="checkbox"/> Potassium Sulphite	-----	<input type="checkbox"/> Sorbic Acid	-----
<input type="checkbox"/> Calcium Propionate	-----	<input type="checkbox"/> Propylparaben	-----	<input type="checkbox"/> Trisodium Citrate	-----
<input type="checkbox"/> Calcium Sorbate	-----	<input type="checkbox"/> Salt	-----	Other: _____	-----
<input type="checkbox"/> Erythorbic Acid	-----	<input type="checkbox"/> Sodium Benzoate	-----	_____	-----
<input type="checkbox"/> Ethanol	-----	<input type="checkbox"/> Sodium Bisulfate	-----	_____	-----
<input type="checkbox"/> Gucono Delta Lactone	-----	<input type="checkbox"/> Sodium Chloride	-----	<input type="checkbox"/> None	-----
<input type="checkbox"/> Polysorbate	-----	<input type="checkbox"/> Sodium Erythorbate	-----		-----

Continue to Section F.

F. Scheduled Process Source:

1. Process Source: a) What is the Process Source? _____ (**Attach support documentation**)
- 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.)

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 / Conveyor Speed	e. Cooker Capacity	f. Frequency Strokes per Minute	Maximum Weight	Other
								Sterilmatic or Batch Agitating Retort ONLY	Sterilmatic ONLY	Sterilmatic ONLY		Sterilmatic ONLY	Oscillation Agitating ONLY		

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		<input type="checkbox"/> Min. Initial <input type="checkbox"/> Fill	<input type="checkbox"/> Seconds <input type="checkbox"/> Minutes <input type="checkbox"/> Hours		<input type="checkbox"/> Fo (F18/250) <input type="checkbox"/> Other F Ref T _____ Z: _____ (°F only)		<input type="checkbox"/> Net <input type="checkbox"/> Gross <input type="checkbox"/> NA				<input type="checkbox"/> Feet <input type="checkbox"/> Carriers <input type="checkbox"/> Flights (per minute)			<input type="checkbox"/> Fill <input type="checkbox"/> NA	
Number	Number	°Fahrenheit	See above	°Fahrenheit	Minutes	Number	Inches	RPM	Inches	Number	Number	Number	Number	Ounces	
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Comments:

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

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

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

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