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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Food Process Filing for Water Activity/Formulation Control Method (Form FDA 2541f)

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 2541f (Food Process Filing for Water Activity/Formulation Control 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.);

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.);

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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., soy sauce (low sodium), fish sauce, caramel sauce, cheese sauce (with or without Jalapeno Peppers), 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: (Refer to the precursor questions in the instructions)

Low-acid (21 CFR 108.35 and 21 CFR Part 113)

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

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? ___

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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)**

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))

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- 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)

Continue to Section E.

E. Processing Method: What method is used for processing this product? (Select one)

- 1. Water Activity Control
 - a) What is the finished equilibrium pH of the product after processing? ____
 - b) What is the maximum water activity? 0.____ (Attach documentation to support this value)
 - c) What is controlling the water activity? (Select all applicable factors)
 - % Salt (e.g., sodium chloride, potassium chloride) ____ (Select one) minimum maximum
 - Syrup Strength (degrees brix) ____ (Select one) minimum maximum
 - % Solids ____ (Select one) minimum maximum
 - % Moisture ____ (Select one) minimum maximum
 - % Other (Enter Name) _____ (Value) ____ (Select one) minimum maximum
 - d) Does the product contain microbial preservatives? Yes (Continue to d.i) No
 - i. Enter the preservative(s) and each minimum associated % (e.g., benzoate – 0.1%; sorbate – 0.2%): _____

- 2. Formulation Control (Identify all applicable critical factors and attach supporting challenge study)

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- a) What is the % (Sodium Chloride + Di-Sodium Phosphates)? ____ (Select one) minimum maximum
- b) What is the % moisture? ____ (Select one) minimum maximum
- c) What is the finished equilibrium pH of the product after processing? ____
- d) What is the % Catechins? ____ (Select one) minimum maximum
- e) What is the % Fat? ____ (Select one) minimum maximum
- f) What is the % Phosphates? ____ (Select one) minimum maximum
- g) What is the % Polyphenols? ____ (Select one) minimum maximum
- h) What is the % Microbial Preservatives (e.g. benzoate, sorbate)? _____
- i) What is the % Salt (e.g., sodium chloride, potassium chloride) ____ (Select one) minimum maximum
- j) What is the maximum water activity? 0.____ (Attach documentation to support this value)
- k) What is the % Solids? ____ (Select one) minimum maximum
- l) What is the Syrup Strength (degrees brix) ____ (Select one) minimum maximum
- m) Other (Enter Name) _____ (% Value) ____ (Select one) minimum maximum

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. Crateless Retort
- 6. Heating Tunnel – Steam or Water (water cascade, water immersion, water spray, or steam)
- 7. Hydrostatic Retort
- 8. Sterilmatic
- 9. Still Retort (Steam or Water)
- 10. Water Bath
- 11. Other: _____ (Attach support documentation)

When option 4-11 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:

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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: _ _ _ _ (enter in Fahrenheit).

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 / Conveyer Speed	e. Cooker Capacity	f. Frequency Strokes per Minute	Maximum Weight	Other	
		<input type="checkbox"/> Min. Initial <input type="checkbox"/> Fill	<input type="checkbox"/> Seconds <input type="checkbox"/> Minutes		<input type="checkbox"/> Fo (F18/250) <input type="checkbox"/> Other F Ref T _____ z: _____ (°F only)	Sterilmatic or Heating Tunnel – Steam or Water ONLY	Batch Agitating Retort or Sterilmatic ONLY	Sterilmatic or Batch Agitating Retort ONLY	Sterilmatic ONLY	Sterilmatic ONLY		Sterilmatic ONLY	Oscillation Agitating ONLY	<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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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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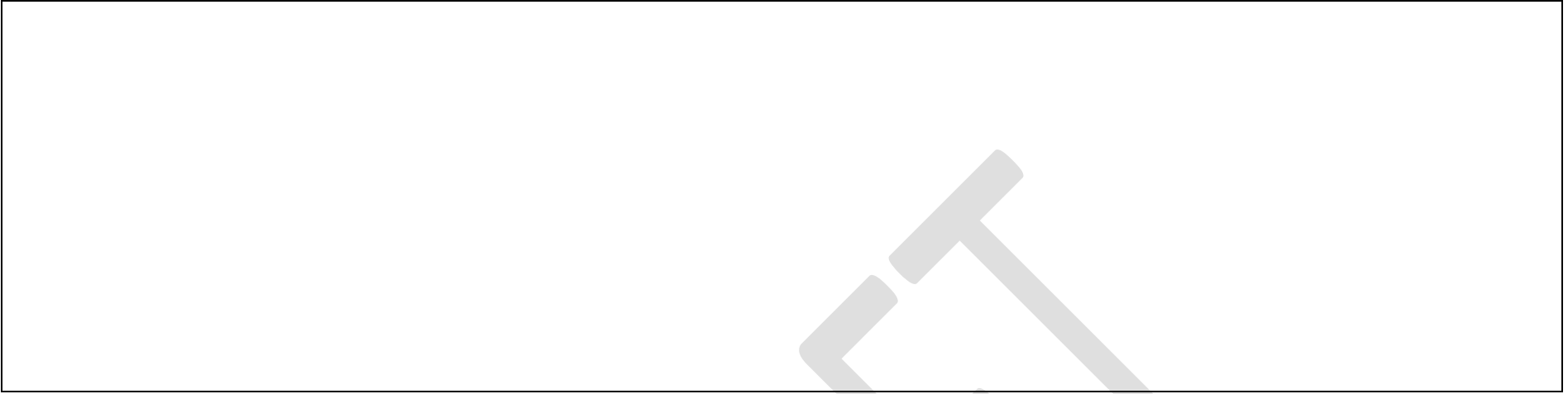
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