

# 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 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 (infant/junior foods including infant formula);
- Bakery Products (canned brown bread, bakery glazes); **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.);
- 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.);
- Gravies/Sauces (spaghetti sauce, mushroom gravy);  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;

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**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.);  Meat Products (Exotic Meat (emu, elk, etc.));  Mixed Fishery (e.g., seafood salad, 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 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 (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 (Enter product form) \_\_\_\_\_

**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 (Enter packing medium) \_\_\_\_\_

**Continue to Section B.**

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**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.**

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**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  Irregular (Attach a picture or schematic) \_\_\_\_\_  Oval  
 Rectangular  Other (Attach a picture or schematic) \_\_\_\_\_

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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  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)  Not Applicable

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)  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)** \_\_\_\_\_

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)** \_\_\_\_\_

6.  Semi-Rigid

a) What is the shape of the container? **(Select one)**  Bowl  Cylindrical  Irregular **(Attach a picture or schematic)** \_\_\_\_\_  Oval

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- 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 (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 terephthalate)  
 Other (Enter material) \_\_\_\_\_  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 (Enter seal type) \_\_\_\_\_  
 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)  Not Applicable
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 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

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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) \_\_\_\_\_

- 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. 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)

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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.  Crateless Retort
6.  Heating Tunnel – Hot Air, Steam or Water (water cascade, water immersion, water spray)
7.  Hydrostatic Retort
8.  Sterilmatic
9.  Still Retort (Steam or Water)
10.  Water Bath
11.  Other (**Attach support documentation**) \_\_\_\_\_

When process mode 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:
  - 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.)



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Comments:

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

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## LACF Contact Information

For more information, contact the LACF Registration Coordinator by e-mail at [LACF@FDA.HHS.GOV](mailto: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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