Form Approved: OMB NO. 0910-0037; Expiration Date 11/30/2026 *(See PRA Statement on last page)*

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)"

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)

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

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.)

☐ 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., soy sauce (low sodium), fish sauce, caramel sauce, cheese sauce (with or without Jalapeno Peppers), 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 *(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.

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 *(If using a Process Mode of: Batch Agitating, Hydrostatic Retort, or Still Retort; continue to c.ii-c.iv; otherwise, continue to Section D).*

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) ☐ Not Applicable

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 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) ☐ Not Applicable

e) What is the maximum residual air? _ _ _ (enter in cubic centimeters) ☐ Not Applicable

5. ☐ Rigid Container (industrial size)

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) ☐ Not Applicable

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)

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

E. Processing Method: 1.c. Water Activity Control *(Continued)*

☐ 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.)**
(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.)

(Continue next page – Formulation Control)

E. Processing Method: *2. Formulation Control (Continued)*

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)*

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. ☐ Bath (Steam or Water)
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 below)***

_____

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 ☐ Lowest Hold Temp.	☐ Seconds ☐ Minutes		☐ 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:

Note: Under the terms and provisions of Title 18, Section 1001, United States Code, in any matter within the jurisdiction of the executive branch of the Government of the United States it is a criminal offense to falsify, conceal, or cover up a material fact; make any materially false, fictitious, or fraudulent statement or representation; or make or use any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.

If your process filing appears to be fabricated, the product on this form will not be in compliance with 21 CFR 108.35(c)(2). A process filing appears fabricated when it contains parameters that cannot be reconciled with one another, such that the filing does not describe a process that could actually be carried out. If we determine that your process filing appears fabricated, we will delete the filing from our system and notify you. We will not consider you to have complied with 21 CFR 108.35(c)(2) until you submit a completed process filing that does not appear to be fabricated.

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)
Human Foods Program
5001 Campus Drive
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.

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The time required to complete this collection of information is estimated to average 20 minutes 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:

FDA PRA Staff
Office of Operations
Food and Drug Administration
email to PRAStaff@fda.hhs.gov

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