

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

**U.S. Department of Health and Human Services
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Table of Contents

I.	Introduction.....	5
II.	How to Submit Process Filing Form FDA 2541f by Paper	7
A.	General Information	7
B.	Step 1: Top of Form - Food Canning Establishment Number and Submission Identifier.....	8
1.	Food Canning Establishment (FCE) Number:	8
2.	Submission Identifier (SID):	8
C.	Step 2 – Section A. Product Information.....	10
1.	Food Product Group (Optional):	10
2.	Enter Product Name.	10
3.	What is the form of the product?.....	10
4.	What is the packing medium?	11
D.	Step 3 – Section B. Governing Regulation.....	11
E.	Step 4 – Section C. Container Type.....	11
1.	Aluminum/Tinplate/Steel Can.....	11
2.	Ceramic/Glass	12
3.	Flexible Pouch.....	13
4.	Retortable Paperboard Carton	15
5.	Rigid Container (10 pounds or more of product).....	16
6.	Semi-Rigid	17
7.	Other Container	19
F.	Step 5 – Section D. Container Size	19
1.	Dimensions:.....	20
2.	Volume:	20

3. Net Weight (Optional):.....	21
G. Step 6 – Section E. Processing Method.....	21
1. Water Activity Control.....	21
2. Formulation Control.....	22
H. Step 7 – Section F. Process Source	22
1. What is the Process Source?.....	22
2. What is the date of the Process Source Document?	23
I. Step 8 – Section G. Process Mode	23
J. Step 9 – Section H. Container and Container Closure Treatment	24
1. Aseptically Filled:	24
2. Heating Tunnel:.....	24
3. Hot Fill and Hold:	25
4. Water Spray:.....	25
5. Other:.....	25
K. Step 10 – Section I. Scheduled Process.....	25
1. Column 1. Process No.....	26
2. Column 2. Step.....	26
3. Column 3. Temperature.....	26
4. Column 4. Process Time	27
5. Column 5. Process Temperature	27
6. Column 6. F value	27
7. Column 7. Thruput (Containers per Minute)	27
8. Column 8. Headspace.....	28
9. Column 9a. Reel Speed.....	28
10. Column 9b. Reel Diameter.....	28

11. Column 9c. Steps per Turn of the Reel	28
12. Column 9d. Chain / Conveyor Speed.....	29
13. Column 9e. Cooker Capacity	29
14. Column 9f. Frequency Strokes per Minute (Oscillation Agitating ONLY)	29
15. Column 10. Maximum Fill Weight.....	29
16. Column 11. Other.....	29
L. Step 11 – Section J. Additional Information (Optional).....	30
1. Comments:	30
2. Full Name, Signature, Establishment Name and Date	30
III. How to Contact FDA or Obtain Help	30
IV. References.....	32
V. Appendix.....	32
A. Container Types and Shapes	32
B. Container Dimension Measurements.....	37
1. Cylindrical Measurement	38
2. Oval Shape Measurement.....	38
3. Rectangular Shape, Rectangular Tray and Low-Profile Measurement.....	39
4. Rectangular Shape Measurement	40
5. Rectangular Tray Measurement	40
6. Low-Profile Measurement.....	40
C. Abbreviations.....	40

Table of Figures

Figure 1 – Cylindrical Shape 2-Piece Aluminum Containers Depicting Double Seams..	32
Figure 2 – Low-Profile Rectangular Shape 2-Piece Aluminum Containers.....	33

Figure 3 – Cylindrical Shape 3-Piece Steel Containers with a Double Seam and Side Seam.....	33
Figure 4 – Cylindrical Shape 2-Piece Steel Containers with a Double Seam	34
Figure 5 – Flexible Pouch.....	34
Figure 6 – Glass Containers	35
Figure 7 – Semi Rigid Body, Oval Shape Containers with Heat Seal.....	35
Figure 8 – Semi Rigid Body, Rectangle Shape Containers	36
Figure 9 – Semi Rigid Body with an Aluminum Double Seam	36
Figure 10 – Semi Rigid Body, Cylinder Shape Containers with Induction Weld Seal. ...	37
Figure 11 – Semi Rigid Body with Heat Seal.....	37
Figure 12 – Measurement of a Cylindrical Shape Container.....	38
Figure 13 – Measurement of an Unusual Shape Cylindrical Container.	38
Figure 14 – Measurement of an Oval Shape Container	39
Figure 15 – Measurement of Outer Edges of Container	39
Figure 16 – Measurement of a Rectangular Shape Container	40
Figure 17 – Measurement of a Rectangular Tray Shape Container.....	40
Figure 18 – Measurement of a Low-Profile Container.....	40

I. Introduction

This document is intended for:

- Commercial processors who manufacture, process, or pack thermally processed low-acid foods packaged in hermetically sealed containers (historically referred to as “low-acid canned foods” or “LACF”)¹; and

¹ Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as “cans,” the term “low-acid canned foods” has been used for decades as a shorthand description for “thermally processed low-acid foods packaged in

- Persons who are authorized to act on behalf of such commercial processors².

Commercial processors who manufacture, process, or pack LACF are subject to the registration requirements of 21 CFR 108.35(c)(1), as well as the process filing requirements of 21 CFR 108.35(c)(2). These provisions require two basic types of submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using the following forms:
 - Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)
 - Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method)
 - Form FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems)

This document provides detailed instructions on how to submit process filings by using a *paper* Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method).

Form FDA 2541f is intended for:

- Low-acid food products where the growth of microorganisms is controlled through the amount of water available for microbiological growth (i.e. “water activity control” products) and the application of heat to foods; and
- Low-acid food products where the growth of microorganisms is controlled through multiple physical and/or physicochemical hurdles (i.e. “formulation control” products) and the application of heat to foods.

This document does not provide:

- Instructions for *electronic* submission of Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method);
- Instructions for submitting process filing Forms FDA 2541d (Food Process Filing for Low-Acid Retorted Method), and FDA 2541g (Food Process Filing for Low-Acid Aseptic Systems) in either electronic or paper format;
- Instructions for submitting Form FDA 2541e (Acidified Foods) in either electronic or paper format; or
- Instructions for submitting plant registration Form FDA 2541 in either electronic or paper format.

hermetically sealed containers,” and we continue to use that term (and its abbreviation, LACF) for the purposes of this document.

² Individuals who are authorized to act on behalf of commercial processors may do so for more than one commercial processor. Reference 1 addresses our electronic system for submitting process filing and identifies the responsibilities of each type of authorized user for that system.

For additional information about registration and process filing for commercial processors of LACF, see our guidance entitled “Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format” (Ref. 1 and the appendices in Reference 1.) For a list of abbreviations used in this document and other FDA documents relating to commercial processors who manufacture, process, or pack LACF and that are subject to 21 CFR Part 108, refer to Appendix C.

II. How to Submit Process Filing Form FDA 2541f by Paper

A. General Information

The paper Form FDA 2541f contains 10 sections (Sections A through J).

- All mandatory fields on Form FDA 2541f must be completed. Only three sections include optional information:
 - Section A, Question 1 (Food Product Group) is optional.
 - Section D, Question 3 (Net Weight (Optional)) is optional.
 - Section J, Additional Information (Optional) is optional.
- When you manufacture, process, or pack a product in more than one container size or type, you are required to submit a separate Form FDA 2541f for each container size and type.
- You may report multiple forms of the product (e.g., diced, chunks, cut, fillet) on the same Form FDA 2541f, provided that:
 - Other factors (e.g., container type or size) do not require separate filing; and
 - The process information you provide in Section I of Form FDA 2541f applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation of the product form must be filed. The comment section of the filing form should state which formulation product form heats the slowest.
- You may report multiple product packing mediums on the same Form FDA 2541f provided that:
 - Factors other than “product packing medium” (e.g., container type or size) do not require separate filing; and
 - The process information you provide in Section I of Form FDA 2541f applies to each product variation. If the heat transfer rates are different for each product variation, the process for the slowest heating formulation of the product packing medium must be filed. The comment section of the filing form should state which formulation packing medium heats the slowest.
- You may report multiple products with minor formulation changes (e.g., a shake base that you produce to have a strawberry-flavored version, and a shake base that you

produce to have a vanilla-flavored version) on the same Form FDA 2541f provided that:

- Other factors (e.g., container type or size) do not require separate filing; and
- The process information you provide in Section I of Form FDA 2541f applies to each formulation of the product. If the heat transfer rates are different for each product formulation variation, the process for the slowest heating formulation of the product must be filed. The comment section of the filing form should state which formulation heats the slowest.
- Brand names of products generally should not be part of the Product Name. However, you may need to include the brand name as part of the Product Name if it is necessary to distinguish products that are produced using different scheduled processes. You need not submit a separate Form FDA 2541f for each brand name of a product that is manufactured, processed, or packed under more than one brand name if the scheduled process for each brand is exactly the same.

When preparing separate forms that contain much of the same information (such as for a product that you manufacture, process, or pack in multiple container sizes), you may save time by using photocopying. Specifically, you may enter the information that applies to all the products, photocopy the form, and then complete the product-specific information on the photocopies. Each submitted form must be complete. Importantly, each submitted form must have a unique SID (see Step One) and must have an original (not photocopied) signature of an authorized company representative.

We recommend that the authorized representative make and keep a copy of each process filing form.

B. Step 1: Top of Form - Food Canning Establishment Number and Submission Identifier

Provide the FCE number and SID at the top of Form FDA 2541f, before Section A. Leave the “Date Received by FDA” blank (this is for FDA internal use only).

1. Food Canning Establishment (FCE) Number:

We assign a Food Canning Establishment (FCE) number to each physical processing facility that registers using Form FDA 2541 (Ref. 1). Enter the five digit FCE number we provide for the specific establishment (processing location) where the product(s) are manufactured, processed, or packed after you register that establishment using Form FDA 2541. If you are submitting a process filing at the same time as you are registering your establishment for the first time, you may leave the FCE number blank.

2. Submission Identifier (SID):

Each process filing is identified by a unique Submission Identifier (SID). The SID is a unique number associated with each new process filing. You assign the SID. The combination of the FCE number and the SID identifies a specific process filing form.

The SID is a combination of:

- (1) The date (i.e., year, month, and day of the month) that a process filing form is created; and
- (2) A sequence number that would distinguish multiple forms created on the same date. The sequence number starts with 001 and continues (002, 003) for as long as necessary to uniquely identify all forms created on the same date.

If you create multiple types of process filing forms on the same date (e.g., if you create three Forms FDA 2541f and three Forms FDA 2541d on the same date), the sequence number would increase by 001 for each created form rather than begin again at 001 for each type of form (see examples immediately below).

When you create paper forms, you assign the SID and include it on the form using the following format:

YYYY-MM-DD/SSS

Where:

YYYY represents the calendar year (e.g., 2013, 2014)

MM represents the month (e.g., 02 for February, 10 for October)

DD represents the day of the month (e.g., 02, 19, 30)

SSS represents the assigned sequence number (e.g., 001, 002, 003).

Examples of SIDs include:

2013-02-22/001: The first Form FDA 2541f created on February 22, 2013

2013-02-22/002: The second Form FDA 2541f created on February 22, 2013

2013-02-22/003: The third Form FDA 2541f created on February 22, 2013

2013-02-22/004: The fourth process filing form, this one a Form FDA 2541d created on February 22, 2013

2013-02-22/005: The fifth process filing form, this one a Form FDA 2541d created on February 22, 2013

2013-02-22/006: The sixth process filing form, this one a Form FDA 2541d created on February 22, 2013

C. Step 2 – Section A. Product Information

1. Food Product Group (Optional):

We request information about “Food Product Groups” to help us understand the nature of your products. The information you provide helps FDA prioritize which commercial processing facilities to inspect. The Food Product Group is optional information (i.e., you are not required to identify the Food Product Group.) If you choose to fill in this information and there is no single best Food Product Group applicable to the product, select “Other.”

2. Enter Product Name.

Describe the actual food commodity or formulated food in the container (e.g., eggplant spread; cheese sauce; black tea (ready to drink)).

- If the product is named in a foreign language, provide its English equivalent first and then provide the foreign language name in parentheses (e.g., sauce with cheese (salsa con queso)).

The product name may include scientific names. When a scientific name is in Latin, the product name should also include the common English translation or description of the scientific name (e.g., mushrooms (*Agaricus bisporus*) pieces and stems, in brine; Beans (*Phaseolus vulgaris*) in brine)

- Brand names should not be part of the product name unless a brand name is necessary to distinguish products that are produced using different scheduled processes.

Some product names may include qualifying terms that identify unique species, processing methods, or organoleptic or visual properties. Some products may be compartmentalized, and include multiple types of foods. For such products, specify these unique properties. If, however, you are submitting the same Form FDA 2541f for multiple products with minor formulation differences indicate those minor formulation differences with the product name. (See section II.A of these instructions.) For example, if you are submitting the same Form FDA 2541f for a shake base that you make using strawberry or vanilla flavoring, indicate those flavorings as part of the product name.

Some examples of product names:

- Enter “Shake Base (strawberry, vanilla)”
- Enter “Cheese Sauce (with Jalapeno Peppers),” not “Cheese Sauce”
- Enter “Soy Sauce (low sodium),” not “Soy Sauce”

3. What is the form of the product?

The product form relates to the shape or appearance of the product itself (e.g., cut, pieces and stems, whole) rather than the characteristics of the container.

Select one or more product forms listed on the filing form. You may report multiple forms of the product on the same Form FDA 2541f with the caveats discussed in section II.A of this document. If none of the product forms listed on the form apply, select “Other” and enter the product form in the space provided.

4. What is the packing medium?

In general, “packing medium” refers to the liquid portion(s) of a product when the liquid is added over, or added to, the solid portion(s) of a product. You may report multiple product packing mediums on the same Form FDA 2541f with the caveats discussed in section II.A of this document.

Select one or more packing mediums listed on the form. If a product is all liquid, select “None (i.e., the product is all liquid).” If there is no packing medium, select “Solid (no packing medium).”

D. Step 3 – Section B. Governing Regulation

Form FDA 2541f only applies to Low-Acid Foods Controlled by Water Activity or Formulation, which are regulated pursuant to 21 CFR 108.35 and 21 CFR Part 113. Refer to Ref. 3 of this document. Therefore, Form FDA 2541f identifies these governing regulations and you do not need to add any information to Section B.

E. Step 4 – Section C. Container Type

Each different container type and each different size of the same container type should be filed as a separate Form FDA 2541f. Therefore, for any Form FDA 2541f that you submit, select a single container type. For additional technical information about container types, refer to Appendix – A, Container Types and Shapes.

1. Aluminum/Tinplate/Steel Can

The first container type listed on Form FDA 2541f is for a container of all non-flexible metal (i.e., aluminum,³ tinplate, or steel can). Do not select Aluminum/Tinplate/Steel Can if the container combines metal in one layer with other materials (e.g., paperboard or a polymer) in other layers.⁴

a) What is the shape of the container?

³ Note that we consider an aluminum can to be a non-flexible metal container rather than a semi-rigid container.

⁴ Note that we consider a combination of metal and other material containers to be a retortable paperboard or semi-rigid container.

Select the shape that best applies to the container. If the container is asymmetrical in shape, select “Irregular”, attach a picture or schematic, and in the space provided enter the document name for the attachment. If none of the shapes apply, select “Other”, attach a picture or schematic, and in the space provided enter the document name for the attachment.

b) How many pieces are used to construct the container?

A 2-piece container is a container where one end is made as part of the can body. There is no side seam and only one end is attached through the formation of a double seam.

A 3-piece container consists of a can body and two attached ends. A 3-piece container can be identified by the presence of a side seam. The side seam runs the length of the cylinder from one end to the other. Side seams are either cemented or welded.

You may select “2-piece container”, “3-piece container” or both, as applicable. Divider plates are any material used to separate layers of containers. If divider plates are used, select “Yes.” Otherwise, select “No.” For 3-piece containers, select “cemented” or “welded” to indicate how the side seam is sealed.

2. Ceramic/Glass

The second container type listed on Form FDA 2541f is for a container of ceramic or glass.

a) What is the shape of the container?

Select the shape that best applies to the container. If the container is asymmetrical in shape (e.g., boot, hat, tree), select “Irregular”, attach a picture or schematic, and in the space provided enter the document name for the attachment. If the shape choices listed on the form are not applicable, select “Other”, attach a picture or schematic, and in the space provided enter the document name for the attachment.

b) Do you use perforated divider plates?

Select “Yes” or “No.” Divider plates are any material used to separate layers of containers.

c) Is overpressure used during processing of the product to maintain container integrity?

Overpressure is the additional external pressure often used to maintain the hermetic seal during the processing cycle (heating and cooling). This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

If yes, continue to question c.i. If no, continue to c.ii through c.iv.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point and continue to Section D – Container Size.

Question c.ii: What is the percent (%) headspace?

Percent headspace is the fraction of volume of the void (where there is no food product) in the container divided by the volume of the entire container multiplied by 100. Enter the headspace using a maximum of two digits before the decimal point and one digit after the decimal point and continue to the next question.

Question c.iii: What is the minimum initial temperature?

Minimum initial temperature (IT) is the average temperature of the contents of the coldest container to be processed at the time the thermal process cycle begins. Enter the minimum initial temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point and continue to the next question.

Question c.iv: What is the vacuum?

Control of the internal pressure depends upon the vacuum in the container. Enter the minimum vacuum in inches of mercury (Hg) using a maximum of two digits before the decimal point and one digit after the decimal point.

3. Flexible Pouch

The third container type listed on Form FDA 2541f is for a container of flexible material.

A flexible pouch is a food container that has no fixed shape. Its final shape is defined by the product placed inside it during the filling and sealing process. It is constructed of flexible panels composed of laminated polymers. The composition of laminated polymers varies depending on the food product, the processing method, and the intended use. Some flexible pouches contain a foil layer.

a) What is the shape of the container?

Select the shape that applies to the container. For “Irregular” or “Other” shapes, attach a picture or schematic of the pouch, and in the space provided enter the document name for the attachment.

b) Is the container physically restricted during the processing of the product to control the container thickness?

During processing, the pressure inside the pouch often exceeds the pressure inside the processing vessel. In this instance, the pouch can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the pouch from expanding.

Select “Yes” or “No.” If yes, continue to question b.i to indicate how the container is restricted. If no, continue to question c.

Question b.i: Racks: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Pouches can be restrained by closely placed flat racks or racks that have indentations.

Other: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, select “Other”, attach a picture of the restraint used, and in the space provided enter the document name for the attachment.

c) Is overpressure used during the processing of the product to control container thickness?

With flexible pouches, some additional external pressure may be required to conform the container to its maximum dimensions for proper heat penetration and to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

Select “Yes” or “No.” If yes, continue to question c.i. If no, continue to question d.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point.

d) What is the maximum thickness during retort processing?

Maximum thickness of the container is the maximum thickness the container attains during the conditions of thermal processing. Enter the maximum thickness in inches using a maximum of two digits before the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and $\frac{1}{4}$ of an inch, 10.00 is a representation of exactly 10 inches).

e) What is the maximum residual air?

Residual air trapped inside a flexible pouch can cause significant package expansion during processing. If the package position (e.g., vertical, on edge, etc.) or physical restraint in the retort does not allow residual air to affect the heating rate, select “Not

Applicable.” Otherwise, enter the maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

4. Retortable Paperboard Carton

The fourth container type listed on Form FDA 2541f is for a container of retortable paperboard material.

Paperboard is a thick, paper-based material. While there is no rigid differentiation between paper and paperboard, paperboard is generally thicker than paper (usually more than 0.25 mm thicker (equal to 0.010 inches or 10 points)). A paperboard container is a container where the structure of the container is based on a wood pulp-based core which has the consistency of thick paper or cardboard.

a) What is the shape of the container?

Select the shape that best applies to the container. If the container is rectangular (e.g., juice box, soup box) in shape, select “Rectangular.” Otherwise, select “Other”, attach a picture or schematic, and in the space provided enter the document name for the attachment.

b) Is the container physically restricted during the processing of the product to control the container thickness?

During processing, the pressure inside the retortable paperboard carton often exceeds the pressure inside the processing vessel. In this instance, the retortable paperboard carton can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the retortable paperboard carton from expanding.

Select “Yes” or “No.” If yes, continue to question b.i to indicate how the container is restricted. If no, continue to question c.

Question b.i: Racks: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Retortable paperboard cartons can be restrained by closely placed flat racks or racks that have indentations.

Other: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, then select “Other”, attach a picture of the restraint that is used, and in the space provided enter the document name for the attachment.

c) Is overpressure used during the processing of the product to control container thickness?

Overpressure is extra external pressure to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

Select “Yes” or “No.” If yes, continue to question c.i. If no, continue to question d.

Question c.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point.

d) What is the maximum thickness during retort processing?

Maximum thickness of the container is the maximum thickness the container attains during the conditions of thermal processing. Enter the maximum thickness in inches using a maximum of two digits before the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and $\frac{1}{4}$ of an inch, 10.00 is a representation of exactly 10 inches).

e) What is the maximum residual air?

Residual air trapped inside a retortable paperboard carton can cause significant package expansion during processing. If the package position (e.g., vertical, on edge, etc.) or the physical restraint in the retort does not allow residual air to affect the heating rate, select “Not Applicable.” Otherwise, enter the maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

5. Rigid Container (10 pounds or more of product)

The fifth container type listed on Form FDA 2541f is for a commercial size container of rigid material that contains 10 pounds or more of product.

A rigid container is a large, industrial sized container that maintains its shape with 10 pounds per square inch (PSI) or less of pressure. A rigid container may have a liner that may be either removable or non-removable.

a) What is the shape of the container?

Select the shape that best applies to the container. If none of the shapes apply, select “Other”, attach a picture or schematic, and in the space provided enter the document name for the attachment.

b) What kind of rigid container is used?

Select one of the referenced containers that best describes the container (i.e., drum, pail, or tote) and select the material that makes up the kind of container. If none of the listed

materials make up the container, select “Other” and enter the name of the material. If none of the referenced containers are applicable, select “Other”, enter the name of the container, attach a picture or schematic, and in the space provided enter the document name for the attachment.

6. Semi-Rigid

The sixth container type listed on Form FDA 2541f is for a container of semi-rigid material.

A semi-rigid container is a container where the shape of the container is not altered by filling of product at atmospheric pressures---but can be altered by additional external pressure.

a) What is the shape of the container?

Select the shape that best fits the container. For “Irregular” or “Other” shapes, attach a picture or schematic, and in the space provided enter the document name for the attachment.

b) Is this a compartmentalized container?

Compartmentalized containers are containers that hold more than one food product (e.g., chickpea spread (hummus) and crackers where chickpea spread and crackers are held in separate sections within a single container) and the food is processed in the single container.

If the container consists of more than one compartment and the compartments contain different food products, select “Yes” and identify the number of compartments. Otherwise, select “No.”

c) What is the predominant material used to make the body of the container?

Select the material that, based on weight, is the predominant material used to make the container stock. If you select “Other,” enter the information next to “Other.”

d) What is the predominant material used to make the lid of the container?

Select the material that, based on weight, is the predominant material used to make the lid stock. If you select “Other,” enter the information next to “Other.” If the container is a web fed paperboard brick pack, without a lid, select “Not Applicable.”

e) How is the lid sealed to the body of the container?

Select the appropriate mechanism for how the lid is sealed to the body of the container. If you select “Other,” enter the information next to “Other.” If the container is a web fed paperboard brick pack, without a lid, select “Not Applicable.”

f) Is the container physically restricted during the processing of the product to control container thickness?

During processing, the pressure inside the semi-rigid container often exceeds the pressure inside the processing vessel. In this instance, the semi-rigid container can expand---resulting in under processing from poor heat penetration or rupturing from structural stresses. In place of overpressure, physical restraints can be used to inhibit the semi-rigid container from expanding.

Select “Yes” or “No.” If yes, continue to question f.i to indicate how the container is restricted. If no, continue to question g.

Question f.i: Racks: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by racks. Semi-rigid containers can be restrained by closely placed flat racks or racks that have indentations.

Other: For containers that are physically restricted during the processing of the product to control container thickness, this field provides a place to indicate whether the container is restricted by means other than racks. If racks are not used, then select “Other”, attach a picture of the restraint that is used, and in the space provided enter the document name for the attachment.

g) Is overpressure used during the processing of the product to control container thickness?

Overpressure is extra external pressure to avoid structural stresses on the sealing surfaces. This additional pressure is generated by the addition of compressed air into the processing vessel or by steam when using a Rotomat type cooker.

Select “Yes” or “No.” If yes, continue to question g.i. If no, continue to question h.

Question g.i: What is the total overpressure used during processing?

The total overpressure used during processing is the total gauge pressure (psig) during heating and cooling. Enter the overpressure in pounds per square inch gauge (psig) using a maximum of two digits before the decimal point and one digit after the decimal point.

h) What is the maximum thickness during retort processing?

Maximum thickness of the container is the maximum thickness the container attains during the conditions of thermal processing. Enter the maximum thickness in inches using a maximum of two digits before the decimal point and two digits after the decimal point (e.g., 1.25 is a representation of 1 inch and $\frac{1}{4}$ of an inch, 10.00 is a representation of exactly 10 inches).

i) What is the maximum residual air?

Residual air trapped inside a semi-rigid container can cause significant package expansion during processing. If the package position (e.g., vertical, on edge, etc.) or the physical restraint in the retort does not allow residual air to affect the heating rate, select “Not Applicable.” Otherwise, enter maximum residual air in cubic centimeters (cc) using a whole number with a maximum of three digits and no decimal point.

7. Other Container

The seventh container type listed on Form FDA 2541f is for a container of a type other than the ones listed above.

Select “Other” when none of the container types listed on the form applies and enter the container type.

a) Attach a schematic or picture of the container and in the space provided enter the document name for the attachment.

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. If the container does not have a lid, specify Not Applicable.

F. Step 5 – Section D. Container Size

Section D includes information on Container Size. You are required to complete either D.1 (Dimensions) or D.2 (Volume). You may complete D.2 only if you intend to select the thermal process mode in Section G (Process Mode) of Form 2541f as: 1) High Temperature Short Time (HTST); 2) Hot Fill and Hold; or 3) Steam Jacketed Kettle.

In your response to D.2, you may only select “Not Applicable” if 1) your product is a cheese product under section A.1, 2) you have identified “Other” under Step 3 (Section C) (Container Type) of Form FDA 2541f, and 3) you intend to select HTST, Hot Fill and Hold or Steam Jacketed Kettle. In all other circumstances, you may not select “Not Applicable” in your response to D.2.

For all other circumstances, complete D.1. Section D.3 (net weight) is optional information.

Products come in a variety of container shapes (see section II.E of this document for information about container shapes). For cylindrical (including bowl and oval) shapes, select “a” to report the container size. For rectangular (including trays) shapes, irregular shapes, or pouches, select “b” to report the container size. Report container dimensions

in English units (number of whole inches and sixteenths of an inch). When reporting volume in D.2 instead of dimensions in D.1, report the volume using a maximum of three digits before the decimal point and one digit after the decimal point.

Refer to Appendix B - Container Dimension Measurements for examples.

1. Dimensions:

a) Diameter and Height.

Enter information for Diameter and Height only for cylindrical (including bowl and oval) shaped containers.

b) Length, Width and Height/Thickness.

Enter information for Length, Width, and Height/Thickness for container shapes other than cylindrical.

When entering dimensions for diameter, length, width, and height/thickness, express the dimensions by creating a round number that is a code reflecting the dimensions in inches. The first part of the code represents the whole number of inches and the last two digits represent the fraction of an inch in sixteenths. For example:

- If the dimension is 12 and 8/16 inches, create the code from 12 and 08 – i.e., 1208.
- If the dimension is 5 and 15/16 inches, create the code from 5 and 15 - i.e., 515.
- If the dimension is 3 and $\frac{3}{4}$ inches, first express the $\frac{3}{4}$ inches in sixteenths - i.e., 12/16. Then create the code from 3 and 12 - i.e., 312.
- If the dimension is 4 inches, create the code from 4 and 00 - i.e., 400.
- If the dimension is 4 and 1/8 inches, first express the 1/8 inches in sixteenths - i.e., 2/16. Then create the code from 4 and 2 - i.e., 402.

Rounding may be necessary for sizes that are less than one sixteenth of an inch. Rounding can be up or down depending on the measurement. If the measurement is closer to the “higher” sixteenth, round up; if the measurement is closer to the “lower” sixteenth, round down. For example:

- If the diameter is 3 and 7/16 inches and the width is 2 inches and 1/4 of one 16th inches, the rounded dimensions will be 307 x 200
- If the diameter is 4 5/16 inches, the width 3 and 1/16 inches, and height is 0.906 (14/16ths and 1/2 of one 16th of an inch), the rounded dimensions will be 405 x 301 x 015

2. Volume:

Enter the volume using a maximum of three digits before the decimal point and one digit after the decimal point and select the applicable units.

3. Net Weight (Optional):

This question provides the opportunity for you to include the net weight of your product. Although you are not required to enter this information on this filing form, entering the information can help FDA inspectors examining product in matching a product under examination to the product described in this filing form.

Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food.

Enter the net weight in ounces if you choose to provide this optional information using a maximum of three digits before the decimal point and two digits after the decimal point.

G. Step 6 – Section E. Processing Method

Processing method is a general description of how the product and the container are treated.

The Water Activity Control process method controls the amount of water available for microbiological growth in a food product. As water activity is reduced, and less water is available, microorganisms are inhibited from growing. Some products prevent the growth of microorganisms solely through control of water activity. If your product prevents the growth of microorganisms solely through control of water activity, select E.1 “Water Activity Control” as the processing method.

Other products prevent the growth of microorganisms through a combination of other intrinsic and extrinsic qualities, such as percent salt, pH, fat content, and/or preservatives. Products that prevent the growth of microorganisms through multiple physical and/or physicochemical hurdles are often referred to as “formulation control” (and sometimes also “multiple hurdle technology”) products. If your product prevents the growth of microorganisms through multiple physical and/or physicochemical hurdles, select E.2 “Formulation Control” as the processing method.

1. Water Activity Control

a) What is the finished equilibrium pH of the product after processing?

Enter the representative pH of the product after processing using a maximum of two digits before the decimal point and two digits after the decimal point. We consider this pH value to be an average of a range between the low and high pH of the standard product. In instances where there is no decimal value, the decimal portion will be two zeros.

b) What is the maximum water activity?

Water activity (a_w) is defined as $a_w = P/P_o$ where P is the vapor pressure of the food and P_o is the vapor pressure of pure water.

Enter the water activity value of the food product at a reference temperature of 77 degrees Fahrenheit using a zero before the decimal point and three digits after the decimal point. Attach the documentation to support this value and in the space provided enter the document name for the attachment.

c) What is controlling the water activity?

Select all applicable factors used to control the water activity, attach supporting documentation where referenced on the form, and in the space provided enter the document name for the attachment. Enter percent values using a maximum of two digits before the decimal point and two digits after the decimal point for all factors---with the exception of “Syrup Strength,” which is reported using a maximum of two digits before the decimal point and one digit after the decimal point. If “Other” is selected, enter the name and value in percent using a maximum of two digits before the decimal point and two digits after the decimal point. For each selected factor, select either “Minimum” or “Maximum” next to the factor.

d) Does the product contain microbial preservatives?

If microbial preservatives are added, select “Yes” and continue to question d.i. to enter each preservative and the minimum amount in percent weight of total product. Otherwise, select “No.”

2. Formulation Control

Select the critical variables that are necessary to control the formulation of the product, attach supporting documentation where referenced on the form, and in the space provided enter the document name for the attachment. Provide the critical limit of each selected variable using a maximum of two digits before the decimal point and two digits after the decimal point **for all factors**---with the exception of “Syrup Strength,” which is reported using a maximum of two digits before the decimal point and one digit after the decimal point. If a necessary variable is not listed, select “Other” and provide information about the variable. When applicable to a selected variable, select “Minimum” or “Maximum.” Attach a challenge study (refer to Ref. 2 for detailed explanation of what is needed in a challenge study) to support the critical factors and filed process and in the space provided enter the document name for the attachment.

H. Step 7 – Section F. Process Source

1. What is the Process Source?

The process source is the individual or entity (e.g., organization, company, individual, university, or other entity) that establishes the scheduled process. Scheduled processes for low-acid foods must be established by qualified persons having expert knowledge of

thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations.

Enter the name of the process source who scientifically established the scheduled process(es), attach the support documentation containing the process recommendations (e.g., letter, bulletin, scientific paper) , and in the space provided enter the document name for the attachment. You may refer to 21 CFR 113.83 for more detailed requirements concerning establishing scheduled processes. Below, we provide some examples of how to name the process source.

- If the process was established by your facility, enter the facility's name.
- If the process was established by an organization, individual, university or other entity, enter the name of that entity (followed by the name of an individual, as appropriate).
- If the process was established by a reference source document or publication, enter the reference source document.

2. What is the date of the Process Source Document?

Enter the date of the process source document that is attached in month/day/year format.

I. Step 8 – Section G. Process Mode

Part 113 requires that the processing of low-acid canned foods be done in a manner that ensures that commercial sterility is achieved. Processing of low-acid food products controlled by water activity or formulation can occur inside or outside of the product container or a combination of both. If processing of the product occurs outside the container and the product is subsequently placed in the container, processors must nonetheless assure that the products are commercially sterile. Contaminated containers may prevent commercial sterility.

Select a single process mode. The process mode you select should be the primary processing mode.

- In a High Temperature Short Time (HTST) and Steam Jacketed Kettle process mode, the product is thermally processed outside of the container.
- In a Hot Fill and Hold process mode, the product is thermally processed outside the container and the container is filled with the hot, processed product. The product contact surface of the container is subsequently thermally treated by introduction of the heated product.
- For process modes listed in sections G.4-G.10, the food is placed in the container and the container is heated with the food inside, treating both the food and the container simultaneously.

If none of the listed process modes fit the process mode for your product, select “Other”, attach the support documentation, and in the space provided enter the document name for the attachment.

If you select either HTST, Steam Jacketed Kettle, or Hot Fill and Hold, you must complete Section H of the form about container and container closure treatment.

If you select Batch Agitating Retort, Crateless Retort, Heating Tunnel, Hydrostatic Retort, Sterilmatic, Still Retort, Water Bath, or Other, you do not need to complete Section H of the form. Instead, continue to Section I of the form.

J. Step 9 – Section H. Container and Container Closure Treatment

This section only applies to process modes of: 1) High Temperature Short Time (HTST), 2) Hot Fill and Hold, and 3) Steam Jacketed Kettle. If you selected any other process mode in Section G of the form, skip Section H of the form and continue to Section I.

Select a single container and container closure treatment. The treatment you select should be the primary treatment.

In completing Section H of the form, describe how the container, headspace, and interior surface (i.e., surfaces that are in contact with the food) of the container closure are treated by selecting one of the treatments listed on the form. If none of the listed treatments apply, select “Other” and enter the information adjacent to “Other.”

1. Aseptically Filled:

If the container is treated in an aseptic environment before being filled with a chemical sterilant, heat, or some other means (e.g., radiation) and the food is filled into the container and sealed in an aseptic environment, select aseptically filled as your container treatment.

a) What is the filler name and model?

Enter the name of the filler and model of the filler used.

2. Heating Tunnel:

The heating medium in the tunnel can be hot air, steam, or water.

a) What is the process time?

If you select “Minutes,” enter the time using a maximum of two digits before the decimal point and one digit after the decimal point. If you select “Seconds,” enter the time using a maximum of two digits before the decimal point and zero as the decimal portion.

b) What is the temperature in the heating tunnel?

Enter the temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

3. Hot Fill and Hold:

In addition to being a process mode under Section G of the form, Hot Fill and Hold can function as a method for container and container closure treatment in Section H of the form---both for processors that select Hot Fill and Hold as a process mode under Section G, and for processors that select High Temperature Short Time (HTST) or Steam Jacketed Kettle under Section G.

a) What is the temperature of the product in the container at the end of the hold time?

Enter the temperature of the product in the container at the end of the hold time in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

Question a.i: Select one of the container closure and treatments.

Select one of the available choices listed and, when applicable, complete the information next to the selected choice. If none of the choices apply, select “Other” and enter the information next to “Other.”

4. Water Spray:

a) What is the process time?

If you select “Minutes,” enter the time using a maximum of two digits before the decimal point and one digit after the decimal point. If you select “Seconds,” enter the time using a maximum of two digits before the decimal point and zero as the decimal portion.

b) What is the temperature of the water spray?

Enter the temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

5. Other:

Select “Other” when none of the treatments listed on the form apply. Enter a description of how the container, headspace, and interior surface of the container closure are treated in the area next to “Other.”

K. Step 10 – Section I. Scheduled Process

Under 21 CFR 113.3(r), scheduled process means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. The scheduled process, which is the process established by a

qualified process source as described in section II.H.1 of this document, may be in excess of what is necessary to ensure destruction of microorganisms of public health significance.

List each process on a single line, except for a multiple-step process. In a multiple-step process, only list the minimum initial temperature for the first step. In addition, only list the cumulative lethality value (i.e., total F value for all steps) for the last step.

In the instructions, we identify the processing systems that require data entry in the applicable columns.

1. Column 1. Process No.

Each process has its own process number. Enter the number 1 in the first row, the number 2 in the second row, and continue entering numbers in increments of 1 for each scheduled process that you list. The process number increases by increments of 1 regardless of the number of steps in each scheduled process.

2. Column 2. Step

A process may have one or more steps. For a single-step process, enter the number 1 in column 2. When the process has multiple steps, enter the number 1 for the first step, the number 2 for the second step, and continue entering numbers in increments of 1 for each subsequent step.

3. Column 3. Temperature

If you selected HTST or Steam Jacketed Kettle as your process mode in Section G of the form, skip this column. This information applies to all other process modes. There are two choices available under the column heading, and you should only select one of these choices: 1) Minimum Initial; or 2) Fill.

Minimum Initial temperature (IT) is the lowest initial temperature permitted in the scheduled process. IT is the average temperature of the contents of the coldest container to be processed at the time the thermal process cycle begins. This may be calculated by agitating/shaking the filled, sealed container to mix the contents before obtaining this value.

Fill Temperature is the temperature at the end of the hold time for a Hot Fill and Hold process mode. Only select Fill Temperature if you selected Hot Fill and Hold as a process mode in Section G.

Enter the value in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

4. Column 4. Process Time

There are two choices available under the column heading, and you should only select one of these choices: 1) Seconds; or 2) Minutes.

Enter the duration of the process time based on the choice selected above using a maximum of three digits before the decimal point and two digits after the decimal point. If the duration is a whole minute, enter the number of minutes and two zeros for the decimal portion.

Examples of how to enter process time:

- If the process time is 15 minutes and 30 seconds, enter 15.50 and select “Minutes.”
- If the process time is 150 minutes and 0 seconds, enter 150.00 and select “Minutes.”
- If the process time is 45 seconds, enter 45.00 and select “Seconds.”

5. Column 5. Process Temperature

If you selected Hot Fill and Hold as your process mode in Section G of the form, skip this column. This information applies to all other process modes. Enter the temperature of the step in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point.

6. Column 6. F value

There are two choices available under this column heading: “Fo,” and “Other F.” Select one of these choices, based on the scheduled process.

- If you are using a z value of 18 degrees and a reference temperature of 250 degrees Fahrenheit to achieve commercial sterility, select “Fo.”
- If the F value used is not based on a z value of 18 degrees Fahrenheit and a reference temperature of 250 degrees Fahrenheit, select “Other F”.

Enter the reference temperature in degrees Fahrenheit using a maximum of three digits before the decimal point and one digit after the decimal point and enter the z value in degrees Fahrenheit using a maximum of two digits before the decimal point and one digit after the decimal point.

Enter the number of minutes using a maximum of two digits before the decimal point and two digits after the decimal point for each process.

7. Column 7. Thruput (Containers per Minute)

Answer this question if you selected “Sterilmatic” or “Heating Tunnel” in Section G of the form.

Enter the number of food containers going through the processing system per minute using a whole number with a maximum of four digits and no decimal point. The value entered should be the maximum number of containers per minute that provides the basis for the filed process time.

8. Column 8. Headspace

Answer this question only if you selected “Batch Agitating Retort” or “Sterilmatic” in Section G of the form. Select one of the following: 1) Net, 2) Gross, or 3) NA.

Net headspace is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the lowest inside surface of the lid. Gross headspace is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

If you select net or gross headspace, enter the value in inches using one digit before the decimal point and four digits after the decimal point. If you enter a zero as the digit before the decimal point, you must follow the zero with a decimal value (e.g., 0.125). If you select “NA,” do not enter any numerical values in this column.

9. Column 9a. Reel Speed

Answer this question only if you selected “Batch Agitating Retort” or “Sterilmatic” in Section G of the form.

Enter the reel speed in rotations per minute (rpm) of the agitation that provides the basis for the filed process time and report the value using a maximum of two digits before the decimal point and two digits after the decimal point.

10. Column 9b. Reel Diameter

Answer this question only if you selected “Sterilmatic” in Section G of the form.

Enter the diameter of the reel in inches using a whole number with a maximum of three digits and no decimal point.

11. Column 9c. Steps per Turn of the Reel

Answer this question only if you selected “Sterilmatic” in Section G of the form.

Enter the number of containers held in a 360 degree rotation of the reel that provides the basis for the filed process time using a whole number with a maximum of two digits and no decimal point.

12. Column 9d. Chain / Conveyor Speed

If process time relies on chain or conveyor speed, select one of the following: 1) Feet; 2) Carriers; or 3) Flights.

In this column, enter the value for the speed per minute using a maximum of three digits before the decimal point and three digits after the decimal point.

13. Column 9e. Cooker Capacity

Answer this question only if you selected “Sterilmatic” in Section G of the form.

Enter the maximum number of containers that each cooker shell holds that provides the basis for the filed process time, using a whole number with a maximum of four digits and no decimal point. Do not include infeed or discharge valves. For processes with multiple shells in a multiple step process, enter the cooker capacity for each step on the appropriate step.

14. Column 9f. Frequency Strokes per Minute (Oscillation Agitating ONLY)

A stroke is the single movement in any direction up or down or side to side. The frequency is the number of strokes per period of time. Oscillating Agitating includes rocking or planar agitation. Answer this question only if you selected “Batch Agitating Retort” in Section G of the form and the agitating is by oscillation.

Enter the strokes per minute using a maximum of three digits before the decimal point and two digits after the decimal point.

15. Column 10. Maximum Fill Weight

There are two choices available under this column heading: “Fill” and “NA.” Select one of these choices.

If “Fill” is selected, the maximum fill weight includes the weight of the entire product in the container, including brine or sauce, but does not include the weight of the container. The maximum fill weight is recorded before processing. Enter the maximum fill weight in ounces using a maximum of three digits before the decimal point and two digits after the decimal point.

If the process authority determines that maximum weight is not critical to the process, select “NA” under the column heading and do not enter any numerical values in this column.

16. Column 11. Other

If there are any other critical factors whose values have been specified by the process source as critical to the delivery of the scheduled process, enter them in the column

heading and provide the applicable values for each scheduled process. If no additional critical factors have been identified by the process source, leave this column blank.

Example for Other:

Cooling Water Temperature – 100 degrees F

L. Step 11 – Section J. Additional Information (Optional)

Under this section of the form, you may provide optional attachments. Select one or more choices and identify the document name adjacent to the appropriate choice(s).

1. Comments:

Enter any additional information you consider pertinent to the product and/or the scheduled process critical factor(s). Comments are optional unless you report multiple forms of the product, multiple packing mediums, or multiple product variations, in which case comments may be required in some circumstances as discussed under section II.A (General Information) in this document.

If you report multiple forms of a product (e.g., diced, chunks, cut, fillet), multiple packing mediums, or multiple products with minor formulation changes on a single form, the heat transfer rates may differ for each product variation. In such cases, the process for the slowest heating formulation of the product or its packing medium must be filed and you should use the comment box section to specify which formulation packing medium heats the slowest.

If you consider any additional information pertinent to the product and/or the scheduled process critical factor(s), enter that information in the comment box and/or attach one or more documents containing the additional information as discussed in section II.J.

2. Full Name, Signature, Establishment Name and Date

Print the first and last name of the person authorized to represent the facility, as well as the FCE facility name, state (for US) or province (for foreign countries), and country. The person authorized to represent the facility must sign and date the form and provide the authorized person's telephone number.

III. How to Contact FDA or Obtain Help

You may contact us:

- By email at LACF@fda.hhs.gov;
- By telephone at 240-402-2411; and
- By mail at the address immediately below.

Food and Drug Administration

LACF Registration Coordinator (HFS-303)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

IV. References

1. [Guidance for Industry: Submitting Form FDA 2541 \(Food Canning Establishment Registration\) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g \(Food Process Filing Forms\) to FDA in Electronic or Paper Format](#)
2. [National Advisory Committee on Microbiological Criteria for Foods, 2010. Parameters for determining inoculated pack/challenge study protocols. *Journal of Food Protection* 73 \(1\): 140–202.](#)
3. LACF/AF Precursor Questions

V. Appendix

A. Container Types and Shapes

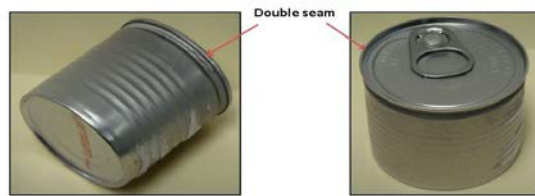


Figure 1 – Cylindrical Shape 2-Piece Aluminum Containers Depicting Double Seams



Figure 2 – Low-Profile Rectangular Shape 2-Piece Aluminum Containers

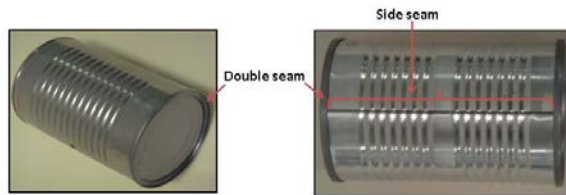


Figure 3 – Cylindrical Shape 3-Piece Steel Containers with a Double Seam and Side Seam



Figure 4 – Cylindrical Shape 2-Piece Steel Containers with a Double Seam



Figure 5 – Flexible Pouch



Figure 6 – Glass Containers



Figure 7 – Semi Rigid Body, Oval Shape Containers with Heat Seal



Figure 8 – Semi Rigid Body, Rectangle Shape Containers

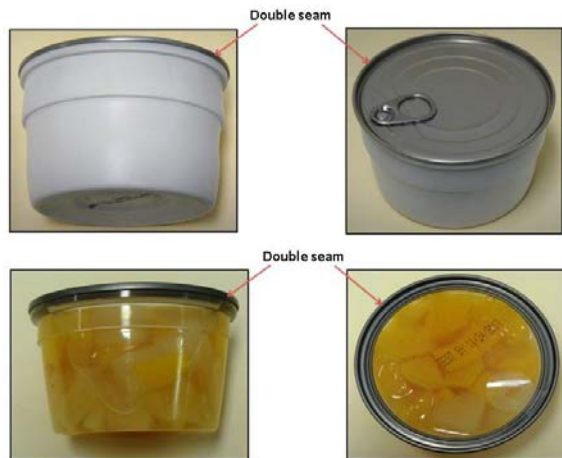


Figure 9 – Semi Rigid Body with an Aluminum Double Seam



Figure 10 – Semi Rigid Body, Cylinder Shape Containers with Induction Weld Seal.



Figure 11 – Semi Rigid Body with Heat Seal

B. Container Dimension Measurements

Container dimension measurements should always be measured from the outside edge of the container. Below, we list different types of materials and descriptions of how to properly measure the dimensions of the container.

1. Cylindrical Measurement

Measure the diameter from the outside of the double seam on the container. Measure the height from the top of the double seam to the opposing double seam top. If the can is a two piece can, measure from the top of the double seam to the furthest point on the other end. For glass bottles or unusually shaped cylindrical containers, always measure the widest part of the container.

For heat-sealed, semi-rigid containers, do not measure the sealing flange as part of the container dimensions. Only measure from the inner edge of the flange where the seal edge meets the chamber holding the food.

When measuring cylindrical shaped containers, list diameter x height (e.g., 0211 x 0400 for a 2 11/16 inch x 4 inch container).

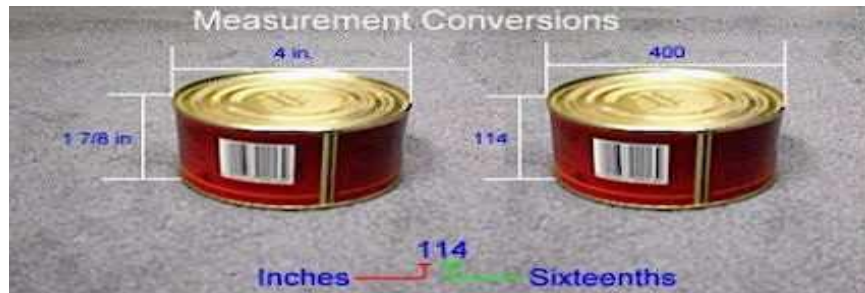


Figure 12 – Measurement of a Cylindrical Shape Container.

When measuring unusually shaped cylindrical containers, always measure the widest part of the container.



Figure 13 – Measurement of an Unusual Shape Cylindrical Container.

2. Oval Shape Measurement

When measuring unusually shaped oval containers, always measure the widest part of the container.



Figure 14 – Measurement of an Oval Shape Container



Figure 15 – Measurement of Outer Edges of Container

3. Rectangular Shape, Rectangular Tray and Low-Profile Measurement

For all rectangular containers (including trays), list length (longest dimension) x width (second longest dimension) x height; for example, list 0405 x 0301 x 0014 for a container that is 4 5/16 inches long, 3 1/16 inches wide, and 14/16 of an inch.

For a rectangular can, measure the length and width from outside of the double seam. When measuring the height of the container, measure from the top of the double seam to the furthest point on the bottom.

For a rectangular pouch, measure from the inner edge of the seams for the length and width. For the height, measure the thickness at the thickest point.

For paper board rectangular containers, measure the length, width, and height from the outside edge of the container.

4. Rectangular Shape Measurement

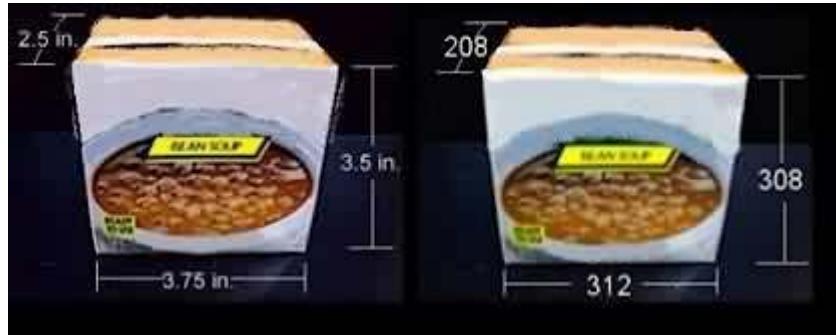


Figure 16 – Measurement of a Rectangular Shape Container

5. Rectangular Tray Measurement

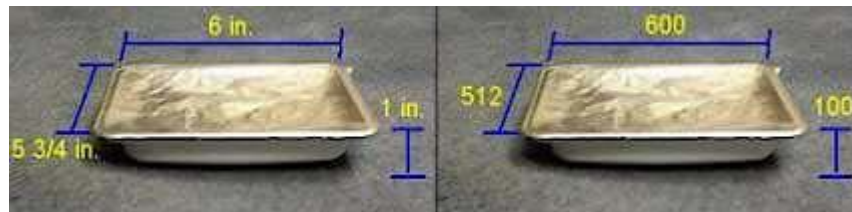


Figure 17 – Measurement of a Rectangular Tray Shape Container

6. Low-Profile Measurement



Figure 18 – Measurement of a Low-Profile Container

C. Abbreviations

Abbreviation	Full Term
AF	Acidified Food
AR	Authorized Representative

ECP	Establishment Contact Person
FCE	Food Canning Establishment
FFR	Food Facility Registration
FIS	FDA Industry System
FURLS	FDA Unified Registration and Listing Systems
LACF	Low-Acid Canned Foods
ROAR	Read Only Authorized Representative
SID	Submission Identifier
SUPER AR	Super Authorized Representative