

Instructions for Electronic 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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I. Introduction

A. Purpose of this Document

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
- 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 an *electronic* 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 control” products); and
- Low-acid food products where the growth of microorganisms is controlled through multiple physical and/or physicochemical hurdles (i.e. “formulation control” products).

This document does not provide:

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 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.

- Instructions for *paper* 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;
- Instructions for submitting plant registration Form FDA 2541 in either electronic or paper format; or
- Instructions on how to use the *electronic* system for acidified foods (AF) and LACF (which we call the AF LACF Online System).

B. 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

C. Additional Resources

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.)

See instructions entitled “How to Use AF/LACF Electronic System” (Ref. 2 and the appendices in Reference 2) which cover:

- Portals for Electronic Submissions;
- How to Obtain an FDA Industry Systems (FIS) Account through the FIS Electronic Portal;
- How to Enter the Electronic AF/LACF System Through the FIS Electronic Portal;
- General Information About Navigating the Process Filing Section of an Establishment’s Electronic AF/LACF System;
- How the Establishment Contact Person for an Establishment Manages Access to the Establishment’s Electronic AF/LACF System;
- General Information About the Organization of the Process Filing Folders;
- How to Manage Process Filings; and
- How to Search Process Filings.

II. How to Submit Electronic Process Filing Form FDA 2541f

A. General Information

The electronic Form FDA 2541f contains 10 Steps (Sections A through J).

- All mandatory fields on the electronic Form FDA 2541f must be completed. Only three sections include optional information:
 - In Step 1 (Section A), Question 1 (Food Product Group) is optional.
 - In Step 4 (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 Step 9 (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 Step 9 (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 Step 9 (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.

B. What You Need to Know About Saving Preliminary Drafts of Form FDA 2541f

In general, you can save information you enter into Form FDA 2541f after each step in the data entry process, exit the system, and return later to continue data entry into subsequent sections of the form. Importantly, the electronic system distinguishes required information from optional information. After you begin data entry for a section of the form, the “Save and Exit” function is not available until you complete data entry for all the required information in that section. Therefore, we recommend that you only begin data entry in a new section of the form if you expect to complete data entry in that section.

Likewise, when you will be submitting separate forms for related products (such as for a product that you manufacture, process, or pack in multiple container sizes), and much of the information about each of these products will be the same, the electronic system enables you to copy a previously submitted form to your Draft folder and then edit that form (e.g., to change the container size) for subsequent submission to FDA. (See Ref. 2

for instructions on how to copy a form.) As you edit a previously submitted form, you may save the edited information in your draft folder and continue editing the form later. However, you should be aware that deleting some required information from the form, without replacing that required information with new information before you try to save the form, may cause the system to prompt you to add that required information before you can save the form.

C. What You Need to Know About Adding Attachments to Form FDA 2541f

1. Types of Documents That You Can Attach

Some sections of Form FDA 2541f require that you provide documentation by attaching an electronic file to the form (see Figure 1). In addition, a “Review” screen allows you to add optional documentation (see Figure 2) that you consider would help FDA review the form. Examples of such documentation include pictures, schematics, or other supporting information. The electronic AF/LACF system supports attachments of the following document types: (1) PDF; (2) JPG; (3) GIF; (4) XLS; (5) XLSX; (6) DOC; (7) DOCX; (8) RTF; and (9) TXT. Within an FCE’s AF/LACF Online System, the file name for an attachment must be unique.

2. The Two Procedures That You Can Use to Attach a Document

There are two procedures that you can use to attach a document:

- Use the “Browse” function to attach a document from your personal computer or network. When you use the “Browse” function, you will be adding a new document to the “Document Library” already in the FCE’s AF/LACF Online System. The file name for this new document cannot be the same as the file name for any document already in that Document Library.
- Use the “Document Library” function to attach a document previously submitted to the FCE’s AF/LACF Online System. When you use the “Document Library” function, you will attach a document that already has a unique file name for the purpose of the FCE’s AF/LACF Online System, and you will not need to rename the file. In other words, attaching a document from within the FCE’s “Document Library” allows you to attach the same document to several SIDs without giving that document a different file name each time you attach it to a new SID.

Figure 1 is an example of a computer screen that provides buttons to select either the “Browse” or “Document Library” functions when the AF/LACF Online System prompts you to attach a required document during data entry. Later in this document (see section II.C.3), we describe how to add a required attachment during data entry.

Figure 1 - AF/LACF Online System Prompts You to Attach a Required Document During Data Entry

The screenshot shows the AF/LACF Online System interface. At the top, there is a navigation bar with the AF/LACF logo, the text "Acidified/Low Acid Canned Foods", and the FDA logo. A progress indicator shows steps from Step 01 to Step 09, with Step 03 highlighted. The main content area is titled "SECTION C CONTAINER TYPE" and includes a "Clear" button. Below this, there is a "Select one" instruction and a note: "Notes: If the product is not packaged in one of the container types identified below, select Other option." The form lists seven container types, with "Aluminum/Tinplate/Steel Can" selected. Under this selection, there are two questions: "a) What is the shape of the container?" with a dropdown menu set to "Other" and a text input field; and "b) How many pieces are used to construct the container?" with a "Select one" dropdown. Below these questions is a section for attaching documents, including a "Browse" button, an "Upload" button, and a "Document Library" section with an "Upload Selected Document Library" button. At the bottom of the form, there are navigation buttons: "Back", "Save & Edit", "Continue", and "Cancel & Start Again".

After you have entered required information into all sections of the form, the AF/LACF Online System will display a “Review” screen. The review screen displays the entire process filing form before submission and provides you an opportunity to attach optional documents that will help FDA review your form. See section II.P of this document for more information about the Review screen. Figure 2 shows an example of the “Additional Info” section that you will see on the “Review” screen. The “Additional Info” screen provides buttons to select either the “Browse” or “Document Library” functions. Later in this document (see section II.C.4), we describe how to add an attachment at the “Review” screen.

Figure 2 – Additional Information - Attach Document from the Review Screen

The screenshot shows a web interface for 'SECTION J ADDITIONAL INFORMATION'. At the top, there is a header bar with 'SECTION J' and 'ADDITIONAL INFORMATION'. Below this, a paragraph of instructions reads: 'Attach an electronic copy of any applicable product label(s). The maximum allowed file size is 50 MB. If the file size is more than 50 MB, please send the hardcopy via mail along with the application number. The accepted file types include the following: jpg, doc, docx, bxt, xls,xlsx, pdf, gif and rtf.' Below the instructions, there is a form with the following elements: 'Attachment Type:' with a dropdown menu set to 'Please Select'; 'Attach document:' with a text input field, a 'Browse...' button, and an '>> Upload' button; a 'Document Library' button; a 'Comments:' text area with a vertical scrollbar; a character count '(Maximum characters: 4000) You have 4000 characters left.'; a list of user information: 'Full Name: Tester Test', 'Establishment Name : Test Company', 'State or Province : Maryland', 'Country(other than U.S.) :', 'Date: 07/15/2014', and 'Telephone Number: 3011212121'; a 'Note:' stating 'If there are any attachments in addition to those that are required, they need to be added prior to submitting the filing.'; and three buttons at the bottom: '<< Cancel & Start Again', '>> Save & Exit', and '>> Submit'.

3. How to Add Required Attachments During Data Entry

a) How to Attach a Document Using the “Browse” Function

Follow the steps below using the “Browse” function to add a document from your personal computer or network.

- Select “Browse” to display file folders from your personal computer system or network (See Figure 3)
- Select the folder containing the document to be attached and then select the document from within that folder.
- Click Open. The system will enter the folder path and file name on the screen (see Figure 4).
- Select “Upload.” The system will display the uploaded file’s name and size (see Figure 5). The system also will provide an opportunity to either (1) select a link to view the content of the file or (2) remove the file as an attachment.

Figure 3 – System Display After You Select the “Browse” Function

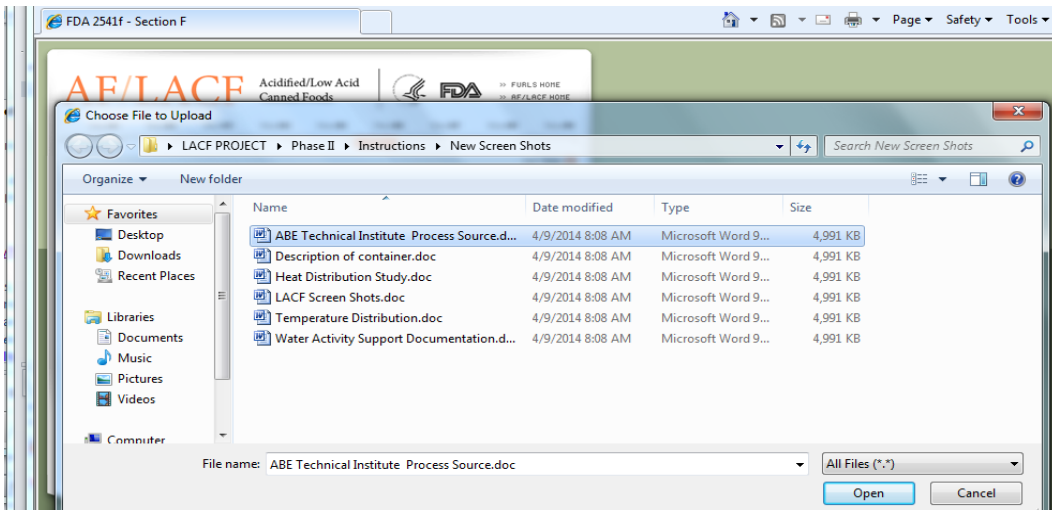


Figure 4 – System Display After You Select the Folder and File Using the “Browse” Function

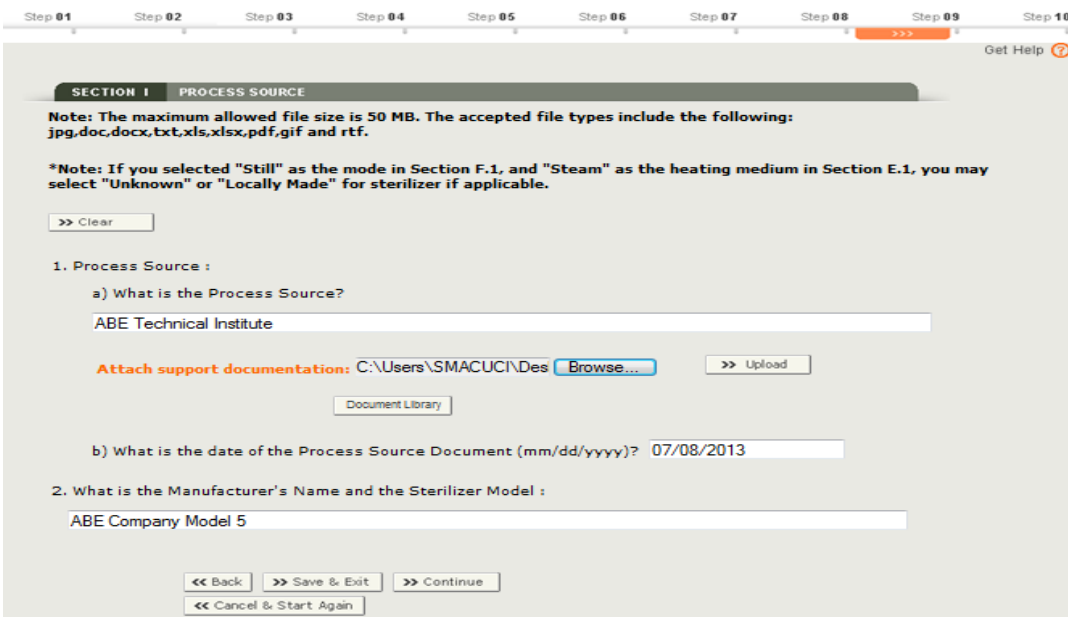


Figure 5 – System Display After You Upload a Document Using the “Browse” Function

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09

SECTION F PROCESS SOURCE

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf.

>> Clear

1. What is the Process Source? ABC Corporation

Attach support documentation:

	File Name	File Size (MB)	
1	ABE Technical Institute Process Source 2014 0716154550822.doc	4.874	>> Remove
Total Size:		4.874	

2. What is the date of the Process Source Document (mm/dd/yyyy)? 07/15/2013

<< Back >> Save & Exit >> Continue
<< Cancel & Start Again

b) How to Attach a Document Using the “Document Library” Function

Follow the steps below to attach a document from the Document Library in the FCE’s AF/LACF Online System.

- Select “Document Library” to display the document library for the FCE’s filed SIDs (see Figure 6).
- Select the check box next to the document name to be attached.
- Select “Upload Selected Document Library.” The system will display the uploaded file’s name and size (see Figure 7). The system also will provide an opportunity to either (1) select the link on the file name to view the content of the file or (2) remove the file as an attachment.

Figure 6 – System Display When You Select a Document from the Document Library

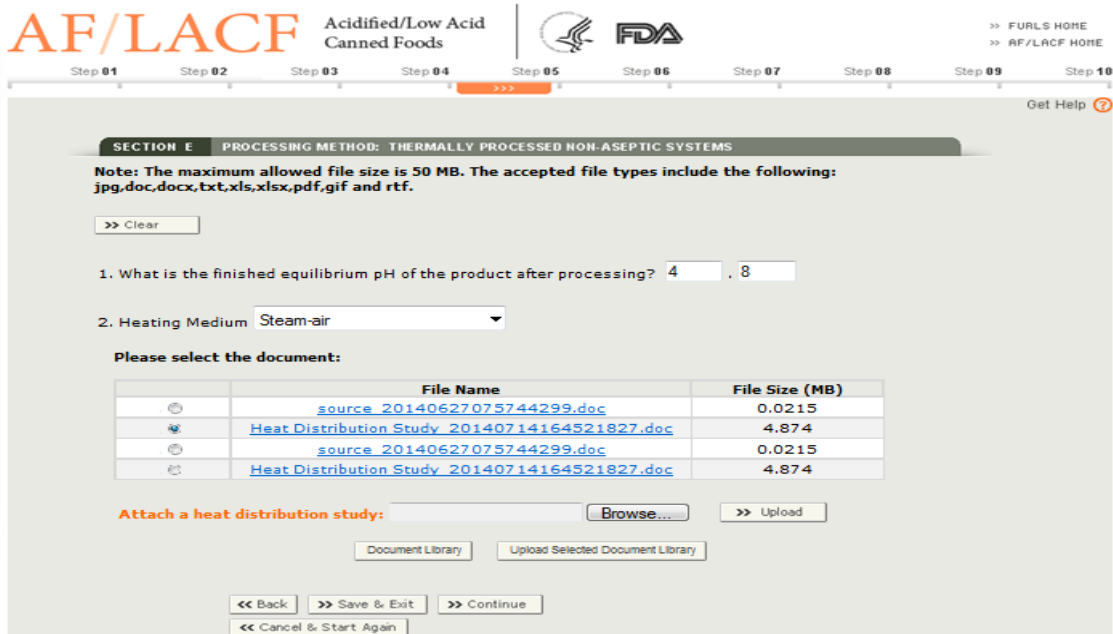
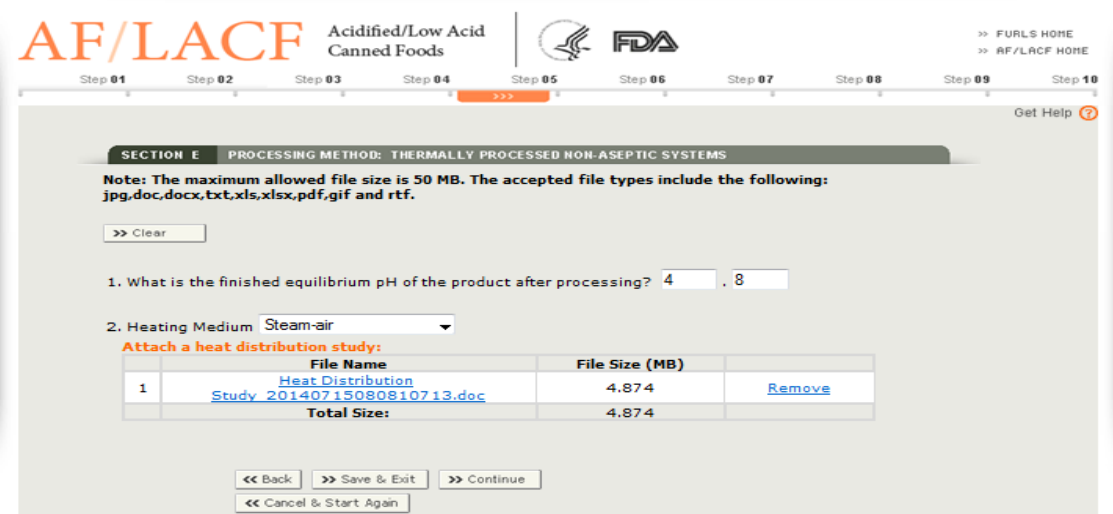


Figure 7 – System Display after Document Attached from Document Library and File Size



4. How to Add Optional Attachments from the Review Screen

You may add optional attachments during the final review of the process filing form under the “Additional Info” section of the “Review” screen.

Follow the steps below to attach a document from the “Additional Info.” section of “Review” screen using either the “Browse” or “Document Library” function.

- Select the down arrow next to “Type of Attachment” to display a List of Values. Figure 8 shows an example of the computer screen displaying Memo/Letter,

Study, Lab Report, Container Schematic, Retort Schematic, and Other Supporting Documentation within the List of Values.

- Select the “Browse” function and follow the steps in section II.c.3.a or “Document Library” function and follow the steps in section II.c.3.b.
- Repeat the above steps until all attachments are added.

Figure 8 - Attach Document –List of Values for the Type of Attachment

SECTION J ADDITIONAL INFORMATION

Attach an electronic copy of any applicable product label(s). The maximum allowed file size is 50 MB. If the file size is more than 50 MB, please send the hardcopy file via mail along with the application number. The accepted file types include the following: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf.

Attachment Type: Please Select
Attach document: Please Select
Heat Penetration Study
Temperature Distribution Study
Other

Browse... Upload

Comments:
(Maximum characters: 4000)
You have 4000 characters left.

Full Name:
Establishment Name :
State or Province :
Country (other than U.S.) :
Date: 07/17/2014
Telephone Number: 3011212121

Note: If there are any attachments in addition to those that are required, they need to be added prior to submitting the filing.

<< Cancel & Start Again Save & Exit Submit >>

D. How to Access the Process Filing Folders for a Specific Establishment

To access the Process Filing folders for a specific establishment, enter the FIS electronic portal using your FIS Account and then select the AF/LACF Main Menu. See Ref. 2 for instructions on how to enter the FIS electronic portal. From the AF/LACF Main Menu, select Access AF/LACF Process Filing.

The system will display a list of Food Canning Establishment (FCE) numbers you are authorized to access (Figure 9). If you are only authorized to access one FCE number, the system will display the FCE Process Filing Folder Main Menu for that FCE (Figure 10).

Figure 9 shows a picture of an example of a computer screen showing the FCE List Main Menu that you would see if you are the Establishment Contact Person (ECP) for an establishment. The “Manage User Role and Access” function, on this screen only, displays when the user is authorized as the ECP.

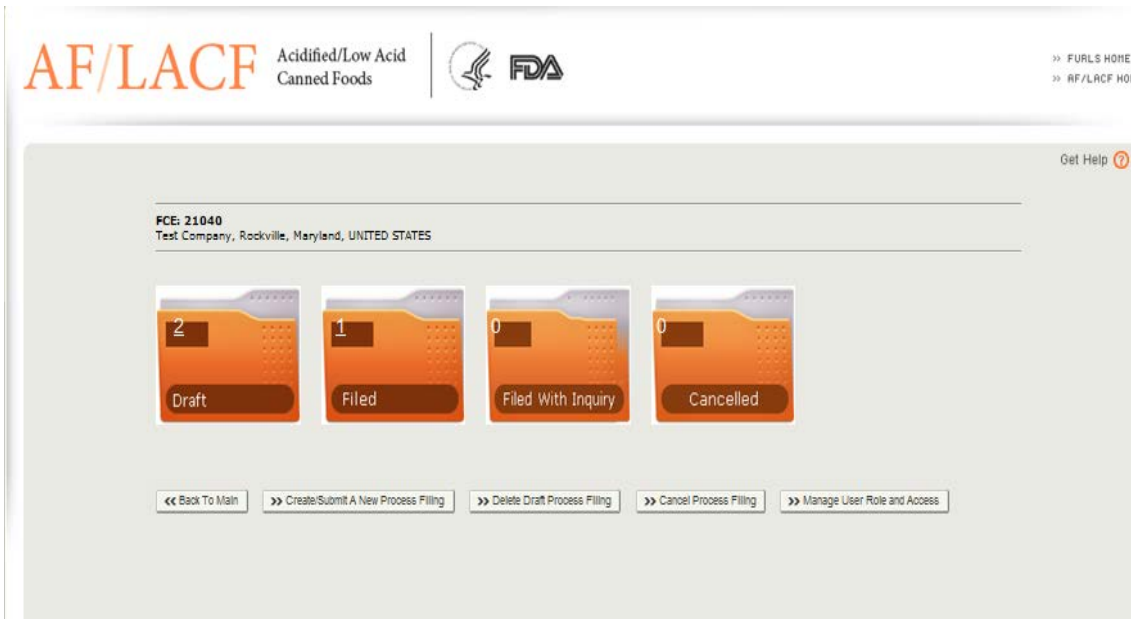
Figure 9 – Example of the FCE List Main Menu



Select the applicable FCE number to reach the FCE Process Filing Folder Main Menu for that establishment. The specific display of the AF/LACF Process Filing Folder Main Menu depends on the information already in the FCE’s AF/LACF Online System. For example, if there are no process filings in the Draft Folder (e.g., because all process filings prepared by the user have already been submitted) the AF/LACF Process Filing Folder Main Menu will display the Draft Folder with a zero (0) count to indicate that there are no process filing forms in the folder.

Figure 10 shows a picture of an example of the FCE Process Filing Folder Main Menu that you would see if you are the Establishment Contact Person (ECP) for an establishment. The system display would be the same for all other authorized users, except that users other than the ECP will not see the “Manage User Role and Access” function.

Figure 10 - FCE Process Filing Folder Main Menu

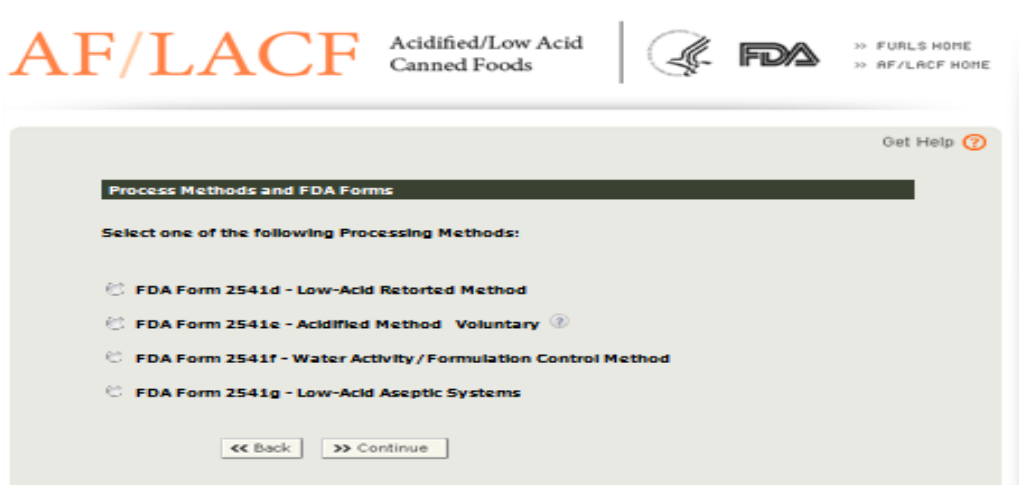


Select Create/Submit a New Process Filing. The system will display the Process Methods and Forms screen. See section II.E of this document for instructions on selecting the process method and form.

E. Process Methods and FDA Forms

Figure 11 shows a picture of the computer screen displaying the available process methods and forms. Select Form 2541f – Water Activity/Formulation Control Method and then select the “Continue” button to start the submission process.

Figure 11 - Process Methods and FDA Forms Screen



F. Top of Form – Food Canning Establishment Number and Submission Identifier

The system automatically enters the FCE number and a Submission Identifier (SID) at the top of Form FDA 2541f, before Section A, based on your selection of the FCE and process method/ FDA form (Figure 12). The “Date Received by FDA” will reflect the date you submit the form to FDA electronically and will appear on the completed submission. See Section II.F.2 of these instructions for detailed information about what a SID is and how it is assigned.

Figure 12 - Screen Display After You Select the Process Method and Form

AF/LACF Acidified/Low Acid Canned Foods | FDA | >> FURLS HOME >> AF/LACF HOME

Get Help ?

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 Electronic Submission of Form FDA 2541f \(Food Process Filing for Water Activity/Formulation Control Method\)](#)"

Food Canning Establishment (FCE) Number:

Submission Identifier (SID): (YYYYMMDD###)

<< Back >> Continue

1. Food Canning Establishment (FCE) Number:

The system automatically enters the FCE number.

2. Submission Identifier (SID):

The SID is a unique number associated with each new process filing. The system will 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 multiple *electronic* forms, the system will assign the SID and automatically enter the SID 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

G. Step 1 – Section A. Product Information

From the display screen for the Top of Form FDA 2541f as shown in Figure 12 above, select the “Continue” button. The system will display Step 1 (Section A).

Figure 13 shows a picture of the computer screen when a user is at Step 1 (Section A) in the procedure for creating a new process filing.

Figure 13 - Step 1 (Section A) Product Information

The screenshot shows the AF/LACF (Acidified/Low Acid Canned Foods) interface. At the top, there are logos for AF/LACF and FDA, along with navigation links for 'FURLS HOME' and 'AF/LACF HOME'. A progress bar at the top indicates steps from Step #1 to Step #9, with Step #1 being the current step. The main heading is 'SECTION A PRODUCT INFORMATION'. A note states: 'Note: Section A.1 (Food Product Group) requests optional information.' Below this, there is a 'Clear' button and a list of instructions. The first instruction is: '1. (Optional) Select one Food Product Group. If there is no single best Food Product Group that applies, select Other.' A dropdown menu is shown with 'Aquaculture Seafood (e.g., farming of aquatic organisms including fish, mollusks, crustaceans, etc.)' selected. The second instruction is: '2. Enter Product Name (e.g., soy sauce (low sodium), fish sauce, caramel sauce, cheddar sauce (with or without Jalapeno Peppers), etc.)'. A text input field contains 'caramel in water'. The third instruction is: '3. What is the form of the product?'. There are two columns of checkboxes. The first column includes: 'Chunks (e.g., chunks, nuggets, etc.)', 'Cut', 'Diced', 'Millet', 'French Cut', 'Liquid (i.e., all liquid no solids)', 'On the Cob', 'Paste/Purée'. The second column includes: 'Pieces', 'Round/Spheres', 'Shredded/Julienne', 'Sliced (e.g., slices, quarters, strips, etc.)', 'Spices/Stalks', 'Whole', 'Other'. The fourth instruction is: '4. What is the packing medium?'. There are checkboxes for: 'Brine', 'Cream/Sauce/Gravy', 'Oil', 'Solid (no packing medium)', 'Syrup', 'Water', and 'Other'. At the bottom, there are buttons for '<< Back', '>> Save & Exit', '>> Continue', and '<< Cancel & Start Again'.

Step 1 (Section A) of the electronic process filing system has required fields for the name of the product, the form of the product (e.g., whole, cut), and product packing medium (e.g., brine, all liquid). Step 1 (Section A) also includes optional information for the food product group (e.g., vegetables, baby food).

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.” If there is no packing medium, select “Solid (no packing medium).”

After you complete this section, select “Continue.”

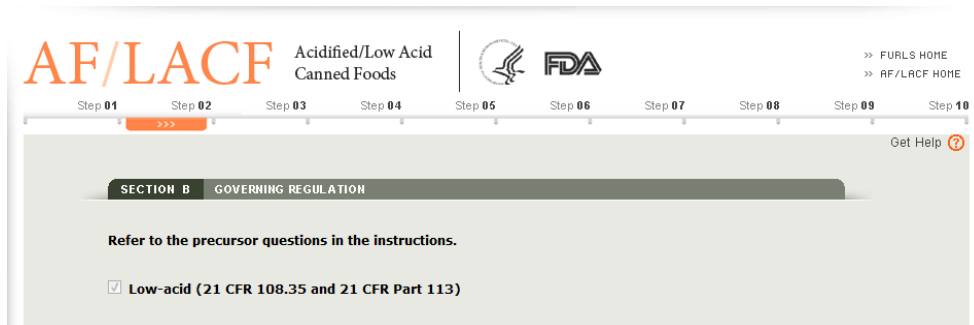
H. Step 2 – Section B. Governing Regulation

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. 2 of this document. The electronic system automatically enters this “Governing Regulation” in Section B of the form and, therefore, you do not have to enter this information yourself. Because the electronic system automatically enters the correct governing regulation in the form, the system will skip Step 2 (Section B) and display Step

3 (Section C). For your convenience, Figure 14 shows a picture of the computer screen showing Step 2 (Section B) with the governing regulation automatically entered.

At this stage in the data entry process, you can select “Save and Exit.” Doing so saves all the information you entered so far in the Draft Folder. Alternatively, you can select “Continue” to enter information for Step 3.

Figure 14 - Step 2 (Section B) Governing Regulation



I. Step 3 – 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. To submit additional container types and/or different container sizes for the same product, you may copy the form for the product in one container type and size and then edit the information on that form to reflect a different container type and/or size. (See Ref. 2 for instructions on how to copy a form.) For technical information about container types, refer to Appendix – A, Container Types and Shapes.

Figure 15 shows a picture of an example of a computer screen displaying container types available in Step 3 (Section C).

Figure 15 – Step 3 (Section C) Container Type

AF/LACF Acidified/Low Acid Canned Foods | FDA

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09

SECTION C CONTAINER TYPE

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf.

>> Clear

Select one:
Note: If the product is not packaged in one of the container types identified below, select "Other".

- Aluminum/Tinplate/Steel Can
- Ceramic/Glass
- Flexible Pouch
- Retortable Paperboard Carton
- Rigid Container (10 pounds or more of product)
- Semi-Rigid
- Other

<< Back >> Save & Exit >> Continue
<< Cancel & Start Again

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?

Select the shape that best applies to the container. If the container is asymmetrical in shape, select “Irregular” and attach a picture or schematic. If none of the shapes apply, select “Other” and attach a picture or schematic. See section II.C of this document for instructions on how to attach a document.

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.

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.

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” and attach a picture or schematic. If the shape choices listed on the form are not applicable, select “Other” and attach a picture or schematic. See section II.C of this document for instructions on how to attach a document.

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. After completing question c.i or questions c.ii through c.iv, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section 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.

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. See section II.C of this document for instructions on how to attach a document.

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” and attach a picture of the restraint used. See section II.C of this document for instructions on how to attach a document.

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 ¼ 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.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

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” and attach a picture or schematic. See section II.C of this document for instructions on how to attach a document.

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” and attach a picture of the restraint that is used. See section II.C of this document for instructions on how to attach a document.

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 ¼ 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 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.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

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” and attach a picture or schematic.

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” and enter the name of the container and attach a picture or schematic.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

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. See section II.C for instructions on how to attach a document.

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” and attach a picture of the restraint that is used.

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 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.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

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. See section II.C of this document for instructions on how to attach a document.

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.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 4 (Section D).

J. Step 4 – 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 intent 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.I 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. Figure 16 displays a picture of a computer screen for data entry of the container dimensions.

Refer to Appendix B - Container Dimension Measurements for examples.

Figure 16 – Step 4 (Section D) Container Size

Step 01 Step 02 Step 03 Step 04 Step 05 Step 06 Step 07 Step 08 Step 09

Get Help ?

SECTION 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.

>> Clear

1. Dimensions:

a) 600 Diameter 700 Height (Use for cylindrical shapes) (see accompanying instructions for proper coding)

2. Volume: . (Select one) Please Select

3. Net Weight (Optional) . (enter in ounces)

<< Back >> Save & Exit >> Continue

<< Cancel & Start Again

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 ¾ inches, first express the ¾ 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.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 5 (Section E).

K. Step 5 – 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. Figure 17 shows a picture of an example of a computer screen displaying Section E – 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.

c) What is controlling the water activity?

Select all applicable factors used to control the water activity and attach supporting documentation where referenced on the form. 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.”

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 6 (Section F).

2. Formulation Control

Select the critical variables that are necessary to control the formulation of the product and attach supporting documentation where referenced on the form. 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. 3 for detailed explanation of what is needed in a challenge study) to support the critical factors and filed process.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 6 (Section F).

Figure 17 - Step 5 (Section E) Processing Method

SECTION E PROCESSING METHOD

Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg,doc,docx,txt,xls,xlsx,pdf,gif and rtf.

>> Clear

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? 5 . 3

* b) What is the maximum water activity? 0. 83
Attach documentation to support this value.

	File Name	File Size (MB)	
1	Water Activity Doc_20140929084937790.doc	0.0215	>> Remove
Total Size:		0.0215	

c) What is controlling the water activity? (Select all applicable factors)

% Salt (e.g., sodium chloride, potassium chloride) 22 . minimum

Syrup Strength (degrees brix) . Please Select

% Solids . Please Select

% Moisture . Please Select

% Other(Enter Name) (Value) .

Please Select

d) Does the product contain microbial preservatives?

Yes No

<< Back >> Save & Exit >> Continue

<< Cancel & Start Again

L. Step 6 – 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) and attach the support documentation containing the process recommendations (e.g., letter, bulletin, scientific paper). 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.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 7 (Section G).

M. Step 7 – 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.

Figure 18 shows a picture of an example of a computer screen for Step 7 (Section G) (process mode). If none of the listed process modes fit the process mode for your product, select “Other” and attach the support documentation.

If you select either HTST, Steam Jacketed Kettle, or Hot Fill and Hold, you must complete Step 8 (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 Step 8 (Section H) of the form. Instead, continue to Section I of the form.

At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 8 (Section H).

Figure 18 - Step 7 (Section G) Process Mode

The screenshot displays the AF/LACF (Acidified/Low Acid Canned Foods) web application interface. At the top, the AF/LACF logo is on the left, and the FDA logo is on the right. A progress bar below the logos shows steps 01 through 09, with Step 07 highlighted in orange. The main content area is titled "SECTION G PROCESS MODE". A note states: "Note: The maximum allowed file size is 50 MB. The accepted file types include the following: jpg, doc, docx, txt, xls, xlsx, pdf, gif and rtf." Below the note is a "Clear" button. The section is labeled "G. Process Mode: (Select one)" and features a dropdown menu currently showing "Crateless Retort". At the bottom of the form are four buttons: "<< Back", ">> Save & Exit", ">> Continue", and "<< Cancel & Start Again". A "Get Help" link with a question mark icon is located in the top right corner of the form area.

N. Step 8 – 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 Step 7 (Section G) of the form, skip Step 8 (Section H) of the form and continue to Step 9 (Section I).

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

In completing Step 8 (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. At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 9 (Section I).

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. At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 9 (Section I).

3. Hot Fill and Hold:

In addition to being a process mode under Step 7 (Section G) of the form, Hot Fill and Hold can function as a method for container and container closure treatment in Step 8

(Section H) of the form---both for processors that select Hot Fill and Hold as a process mode under Step 7 (Section G), and for processors that select High Temperature Short Time (HTST) or Steam Jacketed Kettle under Step 7 (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.” At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 9 (Section I).

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. At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 9 (Section I).

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.” At this stage in the data entry process, you can either select “Save and Exit” or select “Continue” to go on to Step 9 (Section I).

O. Step 9 – 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.L.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.

The system will identify columns that do not apply to your processing system and “grey them out” (i.e., make them unavailable for data entry). In the instructions, we identify the processing systems that require data entry in the applicable columns.

To add additional rows for the columns available, select “Add Row” at the top of the screen. The screen will display a new row for the user to enter another process or continue for a multiple step process. After all entries have been added, you can either select “Save and Exit” or select “Continue” to navigate to the Confirmation screen. Figure 19 shows a picture of an example of computer screen for Step 9 (Section I).

Figure 19 - Step 9 (Section I) Scheduled Process

Col.1 Process No.	Col.2 Step	Col.3 Temperature	Col.4 Process Time	Col.5 Process Temperature	Col.6 F value (only one)	Col.7 Thruput (Containers per Minute)	Col.8 Headspace	Col.9 a. Reel Speed	b. Reel Diameter	c. Steps per Turn of the Reel	d. Chain / Conveyor Speed	e. Cooler Capacity	f. Frequency Strokes per Minute	Col.10 Maximum Fill Weight	Col.11 Other
1	1	70	50	267	7.2						66				

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 Step 7 (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 Step 7 (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 Step 7 (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 Step 7 (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 Step 7 (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 Step 7 (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 Step 7 (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 Step 7 (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 Step 7 (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 Step 7 (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

17. Add more entries:

To add additional rows to Step 9 (Section I), select the “Add Row” button located at the top left hand side of the screen and continue adding information under the appropriate columns. After you complete all the column entries, select “Continue” to navigate to the Review screen for comments and additional attachments.

18. Full Name, Signature, Establishment Name and Date

The system will automatically enter this information based on your FIS Account (i.e., person authorized to represent the facility, the date of the form submission, authorized person’s telephone number) and the FCE facility information (i.e., facility name, state (for US) or province (for foreign countries), country). Because the electronic system automatically enters this information in the form, the system will skip Step 18 and will display the Comment and additional attachment section on the Review screen. Figure 22 shows an example of a computer screen displaying Step 18 (i.e., name and date) above the comment box.

P. Review Step

The review step provides an opportunity for you to review all the information supplied for the process filing and to add additional attachments (such as schematics of irregular shaped containers) that were not attached in Steps 1 through 8 (Section A through H). See section II.C of this document for instructions on how to attach a document. Since all the information covers more than a single screen, use the Page Down, Page Up, or scroll bar to the right and bottom of the browser screen to view the information on multiple screens. The review step also provides an opportunity for you to provide any other information you consider pertinent to the product and/or the scheduled process critical factor(s) in a comment box.

Q. 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 and Additional Attachments:

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. The Comment text box allows up to 4,000 characters.

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 (see section II.C of this document for instructions on how to attach a document).

Figure 20, Figure 21, Figure 22, Figure 23, and Figure 24 show a complete example of the confirmation screen.

You can return to any previous step to edit information in that step by selecting the applicable “Edit” button adjacent to the Step (Section) on the review screen.

After reviewing the information and adding any applicable attachments and/or comments, you can select (1) Cancel the process filing; (2) Save and Exit to Draft Folder; or (3) Submit the process filing to FDA.

Figure 20 - Review Screen (Section A)

PROCESS FILING FORM FOR LOW-ACID FOODS CONTROLLED BY WATER ACTIVITY OR FORMULATION (FDA 2541F)

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 2541a); 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 Electronic Submission of Form FDA 2541f (Food Process Filing for Water Activity/Formulation Control Method)"

Food Canning Establishment (FCE) Number:

Submission Identifier (SID): (YYYYMMDD###)

SECTION A **PRODUCT INFORMATION** **EDIT**

Note: Section A.1 (Food Product Group) requires optional information.

1. (Optional) Select one Food Product Group. If there is no single best Food Product Group that applies, select Other.

Select one

2. Enter Product Name (e.g., soy sauce (low sodium), fish sauce, caramel sauce, chileac sauce (with or without Jalapeno Peppers), etc.)

3. What is the form of the product?

<input type="checkbox"/> Chunks (e.g., chunks, nuggets, etc.)	<input type="checkbox"/> Pieces
<input type="checkbox"/> Cut	<input type="checkbox"/> Round/Spherical
<input type="checkbox"/> Diced	<input type="checkbox"/> Shredded/Julienne
<input type="checkbox"/> Milled	<input type="checkbox"/> Sliced (e.g., slices, quarters, strips, etc.)
<input type="checkbox"/> French Cut	<input type="checkbox"/> Spears/Stalks
<input type="checkbox"/> Liquid (i.e., all liquid no solids)	<input type="checkbox"/> Whole
<input type="checkbox"/> On the Cob	<input type="checkbox"/> Other
<input checked="" type="checkbox"/> Paste/Purée	

4. What is the packing medium?

Brine
 Cream/Sauce/Gravy
 Oil
 Solid (no packing medium)
 Syrup
 Water
 Other

Figure 21 - Review Screen (Sections B - D)

SECTION B GOVERNIN G REGULATION EDIT

Low-acid (21 CFR 108.32 and 21 CFR Part 112)

SECTION C CONTAINER TYPE EDIT

Select one:
 Note: If the product is not packaged in one of the container types identified below, select "Other".

- Aluminum/Tinplate/Steel Can
- Ceramic/Glass
- Flexible Pouch
- Retortable Paperboard Carton
- Rigid Container (10 pounds or more of product)

a) What is the shape of the container?

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.)

- Semi-Rigid
- Other

SECTION D CONTAINER SIZE EDIT

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.4, 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.2 (net weight) is optional information.

1. Dimensions:

a) Diameter Height (Use for cylindrical shapes) (see accompanying instructions for proper coding)

2. Volume: (Select one)

3. Net Weight (Optional): (enter in ounces)

Figure 22 - Review Screen (Sections E – F)

SECTION E PROCESSING METHOD EDIT

What method is used for processing this product?(Select One)

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

b) What is the maximum water activity?
 Attach documentation to support this value.

	File Name	File Size (MB)
1	Water Activity Support Documentation_20140716161550827.doc	4.874
Total Size:		4.874

c) What is controlling the water activity? (Select all applicable factors)

% Salt (e.g., sodium chloride, potassium chloride)

Syrup strength (degrees brix)

% Solids

% Moisture

% Other (Enter Name) (value)

d) Does the product contain microbial preservatives?
 Yes No

SECTION F PROCESS SOURCE EDIT

1. What is the Process Source?

Attach support documentation:

	File Name	File Size (MB)
1	COOC Technical Institute Process Source_20140716161729743.doc	4.874
Total Size:		4.874

2. What is the date of the Process Source Document (mm/dd/yyyy)?

Figure 23 - Review Screen (Sections G - I)

SECTION G PFD 02:52 02:00 EDIT

G. Process Mode: (Select one)
 Crustless Retort

SECTION H CONTAINER AND CONTAINER CLOSURE TREATMENT
 Not Applicable.

SECTION I SCHEDULE D PFD 02:53 EDIT

Col.1 Process No.	Col.2 Step	Col.3 Temperature	Col.4 Process Time	Col.5 Process Temperature	Col.6 F value (only one)	Col.7 Thruput (Containers per Minute)	Col.8 Headspace	Col.9 a. Reel Speed	b. Reel Diameter	c. Steps per Turn of the Reel	d. Chain / Conveyer Speed	e. Cooker Capacity	f. Frequency Strokes per Minute	Col.10 Maximum Fill Weight	Col.11 Other
		<input checked="" type="checkbox"/> Min. Initial <input type="checkbox"/> Fill	<input checked="" type="checkbox"/> Seconds <input type="checkbox"/> Minutes		<input checked="" type="checkbox"/> Fo (18-250) <input type="checkbox"/> Other F Ref: [] [] - [] (S - F only)		<input type="checkbox"/> Net <input type="checkbox"/> Gross <input type="checkbox"/> NA			<input type="checkbox"/> Sterilmatic ONLY		<input type="checkbox"/> Sterilmatic ONLY	<input type="checkbox"/> Feet <input type="checkbox"/> Carriers <input checked="" type="checkbox"/> Flights (per minute)	<input type="checkbox"/> Fill <input checked="" type="checkbox"/> NA	
Number	Number	°-1 Fahrenheit	See above	°-1 Fahrenheit	Minutes	Number	Inches	RPM	Inches	Number	Number	Number	Number	Ounces	
1	1	70	30	257	7.2						55				

Figure 24 - Review Screen (Section J)

FDA 2541f - Review

SECTION J ADDITIONAL INFORMATION

Attach an electronic copy of any applicable product label(s). The maximum allowed file size is 50 MB. If the file size is more than 50 MB, please send the hardcopy file via mail along with the application number. The accepted file types include the following: .jpg, .doc, .docx, .txt, .xls, .xlsx, .pdf, .gif and .rtf.

Attachment Type: Other

Attach document: Browse... >> Upload

Comments :

(Maximum characters: 4000)
 You have 4000 characters left.

Full Name: Tester Test
 Establishment Name :
 State or Province :
 Country (other than U.S.) :
 Date: 09/29/2014
 Telephone Number: 3011212121

Note: If there are any attachments in addition to those that are required, they need to be added prior to submitting the filing.

After reviewing the information on the review screen, editing information if appropriate, and adding any applicable attachments or comments, you can either:

- Select “Cancel and Start Again” to start over without saving any information;
- Select “Save and Exit” to save the process filing form to the Draft Folder without sending it to FDA. Process filings in the Draft Folder remain available to the user who creates them and to users authorized as the ECP or a Super AR (see the Appendix section of Ref. 2 for information about user roles). Process filings in

the Draft Folder cannot be viewed by FDA or by users other than the ECP and Super AR for an FCE; or

- Submit the completed process filing form to FDA.

Q. Filing Message

After you select Submit, the system will provide a message that your form has been successfully filed. Figure 25 shows a picture of an example of the message screen informing a user that a process filing has been submitted for a particular FCE. This message screen specifies the SID assigned to the submitted process filing form.

Figure 25 - System Display of Successful Message of a Filed Process Filing Form



You can select either:

- Return to Folder Menu to return to the FCE Process Filing Folder Main Menu;
- Return to Main Menu to return to the AF/LACF Main Menu; or
- View Process Filing to view the submitted process filing. When you view the submitted process filing, you can print it.

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. Accessible at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm309376.htm>
2. How to Use AF/LACF Electronic System. Accessible at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM417291.pdf>
3. 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. Accessible at http://www.fsis.usda.gov/wps/wcm/connect/a7f8aa06-d2ac-40bf-bd7f-11c5a59b6c6a/NACMCF_JFP_Inoculated_Pack.pdf?MOD=AJPERES

V. Appendix

A. Container Types and Shapes



Figure 26 – Cylindrical Shape 2-Piece Aluminum Containers Depicting Double Seams



Figure 27 – Low-Profile Rectangular Shape 2-Piece Aluminum Containers

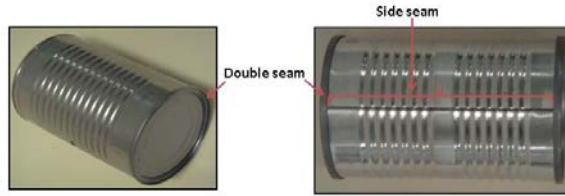


Figure 28 – Cylindrical Shape 3-Piece Steel Containers with a Double Seam and Side Seam



Figure 29 – Cylindrical Shape 2-Piece Steel Containers with a Double Seam



Figure 30 – Flexible Pouch



Figure 31 – Glass Containers



Figure 32 – Semi Rigid Body, Oval Shape Containers with Heat Seal



Figure 33 – Semi Rigid Body, Rectangle Shape Containers

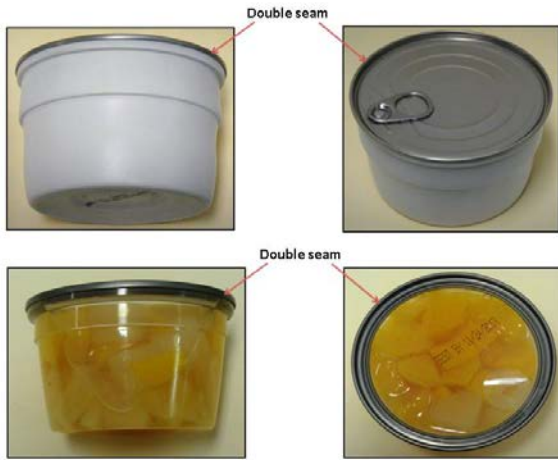


Figure 34 – Semi Rigid Body with an Aluminum Double Seam



Figure 35 – Semi Rigid Body, Cylinder Shape Containers with Induction Weld Seal



Figure 36 – 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).

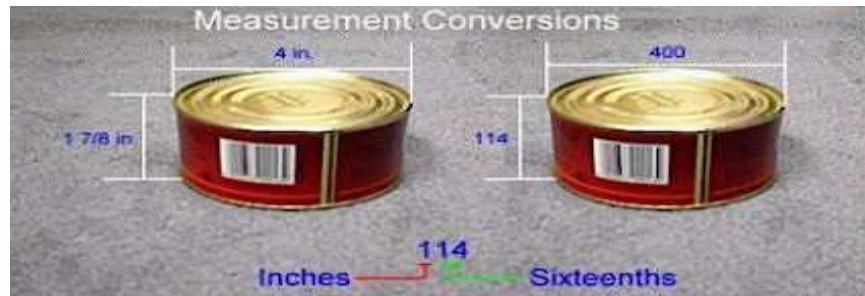


Figure 37 – Measurement of a Cylindrical Shape Container.

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



Figure 38 – 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 39 – Measurement of an Oval Shape Container



Figure 40 – 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

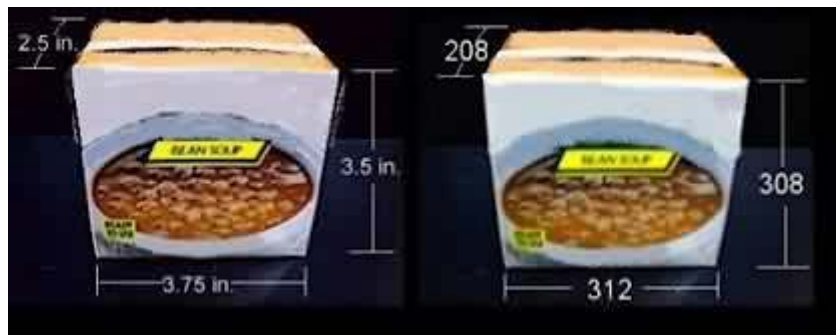


Figure 41 – Measurement of a Rectangular Shape Container

5. Rectangular Tray Measurement

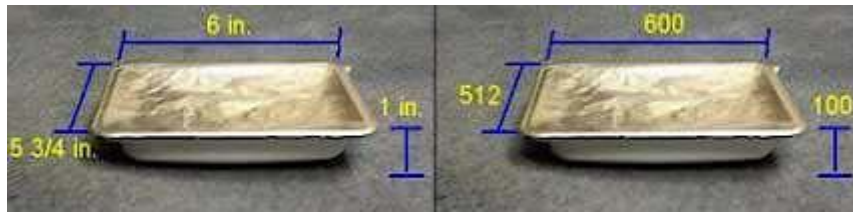


Figure 42 – Measurement of a Rectangular Tray Shape Container

6. Low-Profile Measurement



Figure 43 – Measurement of a Low-Profile Container