

# **Instructions for Electronic Submission of Form FDA 2541e (Food Process Filing for Acidified Method)**

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

**Food and Drug Administration**

**Center for Food Safety and Applied Nutrition**

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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 acidified foods (AF) packaged in hermetically sealed containers ; and
- Persons who are authorized to act on behalf of such commercial processors<sup>1</sup>.

Commercial processors who manufacture, process, or pack AF are subject to the registration requirements of 21 CFR 108.25(c)(1), as well as the process filing requirements of 21 CFR 108.25(c)(2). These provisions require two basic types of submissions:

- Food Canning Establishment Registration using Form FDA 2541; and
- Process filings using the following form:
  - Form FDA 2541e (Food Process Filing for Acidified Method)

This document provides detailed instructions on how to submit process filings by using an *electronic* Form FDA 2541e (Food Process Filing for Acidified Method). Form FDA 2541e is intended for acidified foods as defined in 21 CFR 114.3(b).

This document does not provide:

- Instructions for *paper* submission of Form FDA 2541e (Food Process Filing for Acidified Method);
- Instructions for submitting process filing Forms FDA 2541d, FDA 2541f, and FDA 2541g for Low-Acid 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).

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<sup>1</sup> 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.

## 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 2541e**

### **A. General Information**

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

- All mandatory fields on the electronic Form FDA 2541e 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 2541e 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 2541e, 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 2541e 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 2541e 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 2541e 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 2541e 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 2541e 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 2541e 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 2541e**

In general, you can save information you enter into Form FDA 2541e 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 2541e**

### **1. Types of Documents That You Can Attach**

Some sections of Form FDA 2541e 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, the logo for AF/LACF (Acidified/Low Acid Canned Foods) and the FDA logo are visible. A progress bar at the top indicates the current step is Step 03, with other steps (Step 01 to Step 09) shown as inactive. 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 sub-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, there are radio buttons for "Do you use perforated divider plates?" with "Yes" and "No" options. An "Attach a picture or schematic:" section includes 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 the header, a paragraph of text 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 this text, 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: 'Note: 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'.

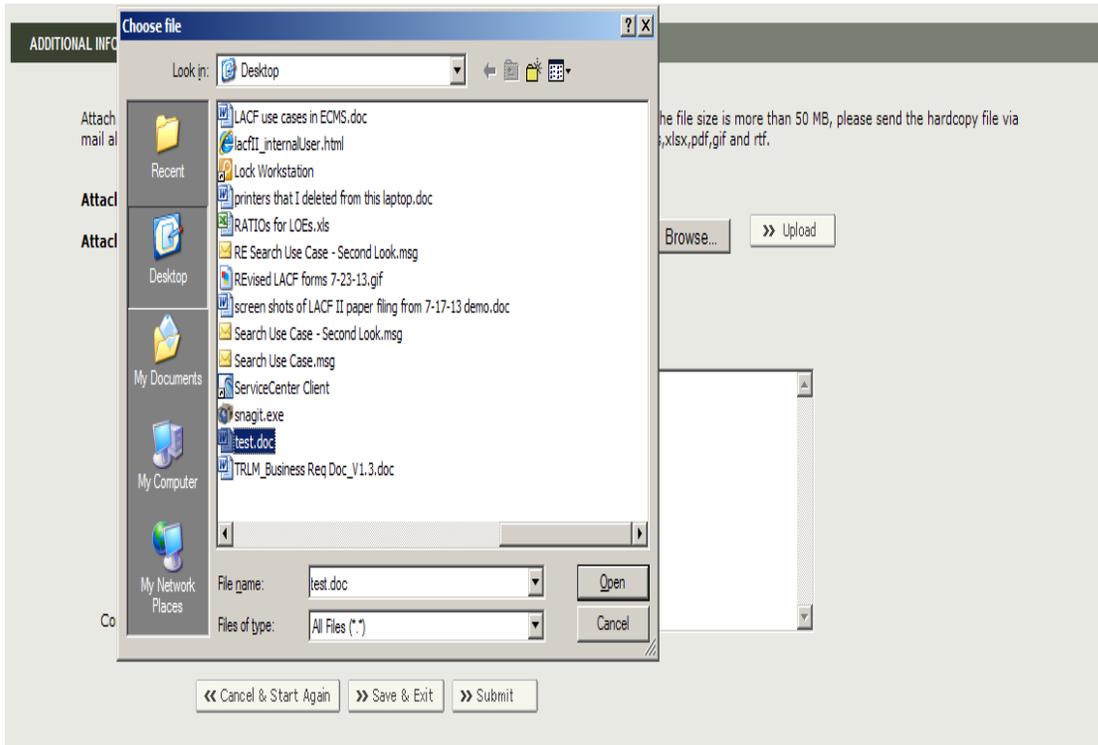
### 3. How to Add Required Attachments During Data Entry

#### 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**

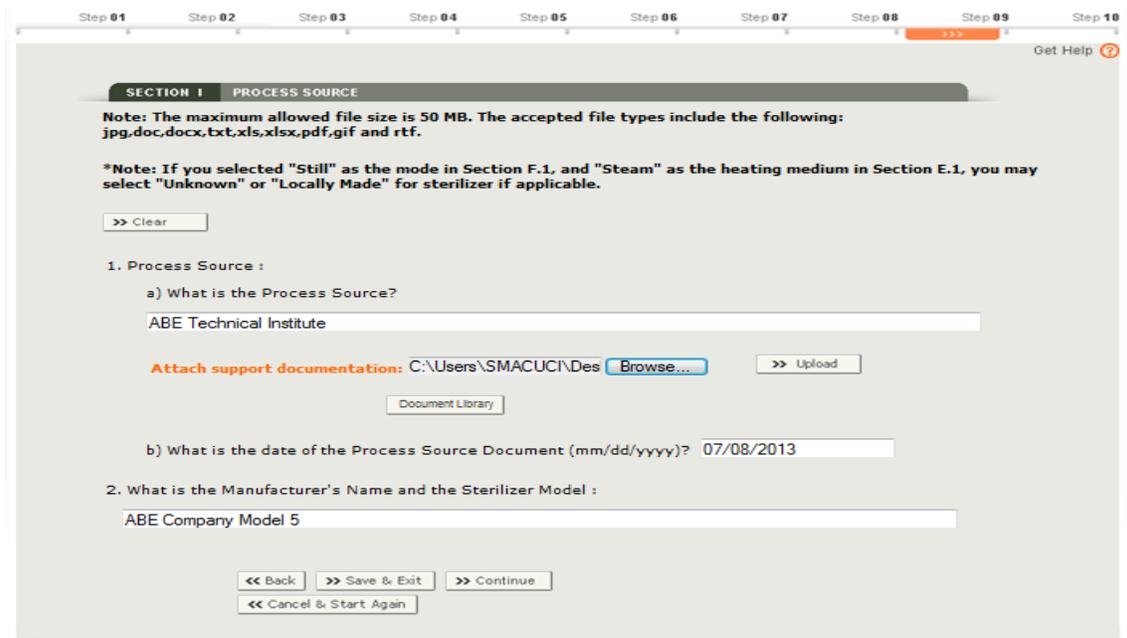


Figure 5 – System Display After You Upload a Document Using the “Browse” Function

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

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	<a href="#">ABE Technical Institute Process Source 2014 0716154550822.doc</a>	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

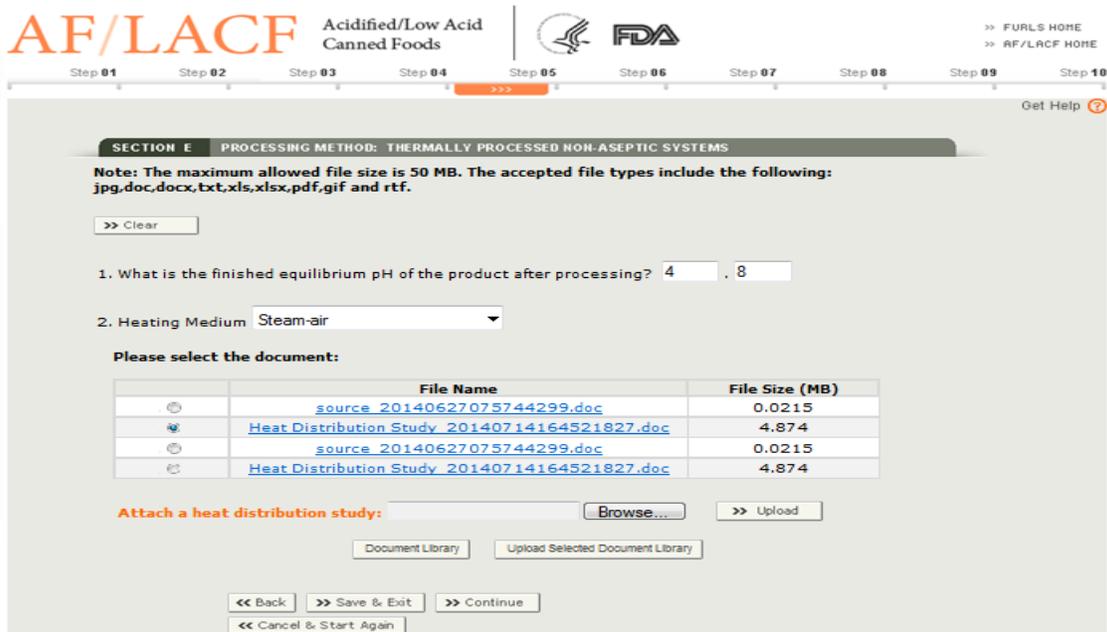


Figure 7 – System Display after Document Attached from Document Library and File Size



#### 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 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

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

Full Name: Tester Test  
Establishment Name : GNSI Foreign Company  
State or Province : Gujarat  
Country(other than U.S.) : INDIA  
Date: 09/26/2014  
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

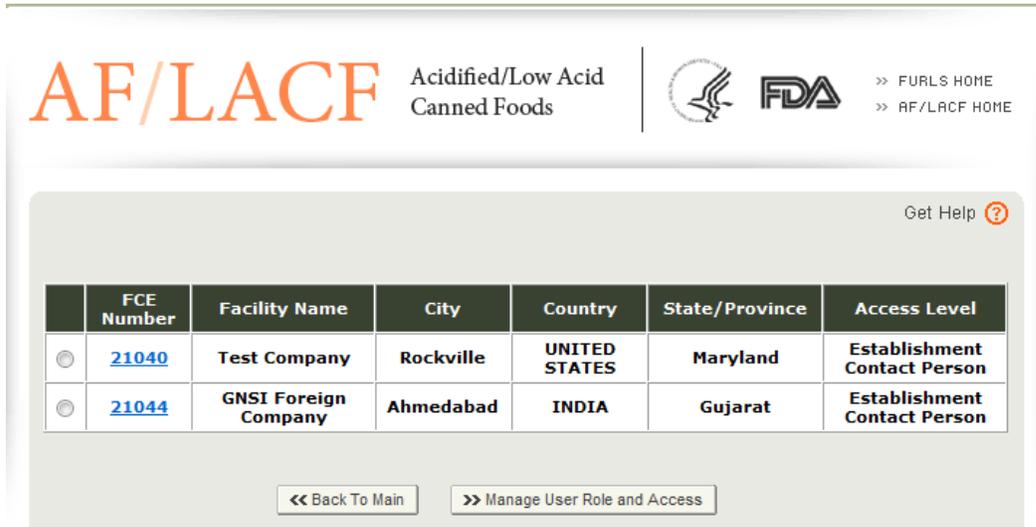
## **D. How to Access the Process Filing Folders for a Specific Establishment**

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.

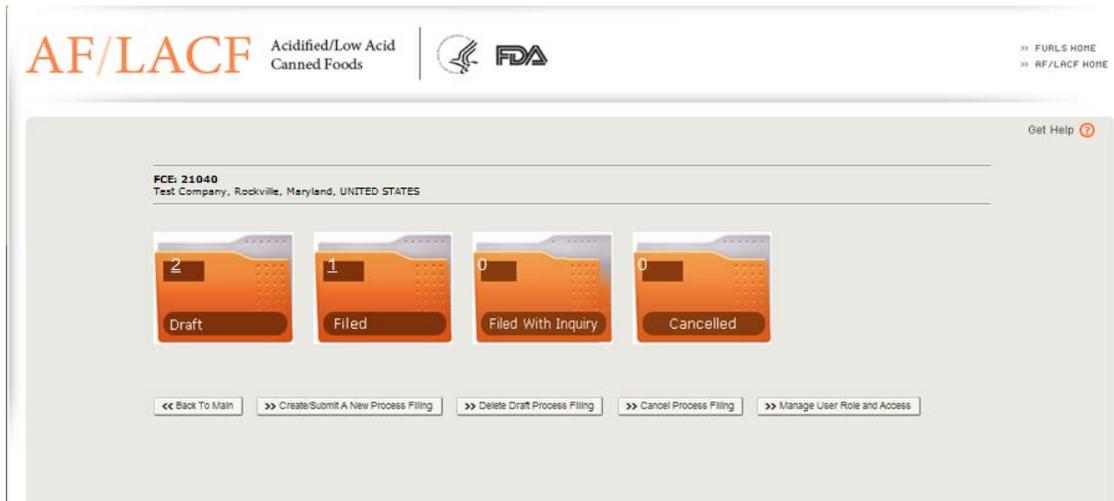
Figure 9 – Example of the FCE List Main Menu



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. Later in this document (see In Step 2 (Section H)), we provide more information about products that may be voluntarily submitted using this form. Select Form 2541e Acidified 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 2541e, 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 Acidified Method (Form FDA 2541e)

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 2541e (Food Process Filing for Acidified Method)"

Food Canning Establishment (FCE) Number: 21040

Submission Identifier (SID): 20140715002 (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 2541e 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 2541e created on February 22, 2013

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

2013-02-22/003: The third Form FDA 2541e 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 2541e 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**

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., salsa (mild), artichokes (marinated)).

- 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., green kidney beans (flageolets) in brine).

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 2541e 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 2541e for salsa that you make in mild, medium, and hot varieties, indicate those varieties as part of the product name. Some examples of product names:

- Enter “Salsa (mild, medium, or hot)” not “Salsa”
- Enter “Artichokes (marinated)” not “Artichokes”
- Enter “Jalapeno Peppers (red or green)” not “Jalapeno Peppers”
- Enter “Radishes, pickled (Szechuan)” not “Radishes”
- Enter “Mixed vegetables, pickled (matsutake meshi-no-moto)” not “Mixed vegetables”
- Enter “Beans (green or wax)” not “Beans”
- Enter “Mushrooms (button)” not “Mushrooms”

### **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 2541e 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 2541e 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 2541e applies to two categories of products: (1) Acidified Foods; and (2) foods that the processor has determined are not subject to the regulations for acidified foods, but for which the processor has decided to voluntarily submit process information to facilitate FDA determinations regarding the regulatory status of the foods.

With respect to the first category of products (i.e., acidified foods), these foods are regulated pursuant to 21 CFR 108.25 and 21 CFR Part 114. Refer to Part 114 and Ref. 3 of this document for information on whether a product is an acidified food. If your product is an acidified food within the meaning of Part 114, select “Acidified.”

With respect to the second category of products (i.e., foods that the processor has determined are not subject to the regulations for acidified foods), these foods can be the subject of voluntary submissions. If FDA has information about such foods in our files, we can evaluate that information and determine whether it is consistent with the processor’s conclusion that a product is not subject to the requirements applicable to acidified foods. For more information about the voluntary submission process, and to identify whether your product falls into this second category, refer to “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).

If your product falls into this second category and you choose to inform us about your product using Form FDA 2541e, select “Voluntary.”

If you select “Voluntary,” attach documentation to support the determination that the product is not an acidified food. If the product appears to be a fermented food, include a detailed process flow diagram of fermentation processes, including the pH at each step. For your convenience, Figure 14 shows a picture of the computer screen showing Step 2 (Section B) with the governing regulation and select “Voluntary”.

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

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

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

Get Help ?

**SECTION B GOVERNING REGULATION**

>> Clear

**Select one:**

- Acidified (Product is an acidified food and is governed by 21 CFR 108.25 and 21 CFR Part 114)**
- Voluntary (The processor has concluded that the product is not an acidified food. The processor is voluntarily submitting process information about the product to facilitate FDA determinations regarding the regulatory status of the product.)** If you select this choice, attach documentation to support the determination that the product is not an acidified food. If the product appears to be a fermented food, include a detailed process flow diagram of fermentation processes, including the pH at each step.

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

## 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 2541e. Therefore, for any Form FDA 2541e 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**

## 1. Aluminum/Tinplate/Steel Can

The first container type listed on Form FDA 2541e is for a container of all non-flexible metal (i.e., aluminum,<sup>2</sup> tinfoil, 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.<sup>3</sup>

### *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.

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<sup>2</sup> Note that we consider an aluminum can to be a non-flexible metal container rather than a semi-rigid container.

<sup>3</sup> Note that we consider a combination of metal and other material containers to be a retortable paperboard or semi-rigid container.

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

You may select “2-piece container”, “3-piece container” or both, as applicable.

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

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).

## **2. Ceramic/Glass**

The second container type listed on Form FDA 2541e 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.

Select “Yes” or “No.” 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 2541e 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?*

Pouches can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. 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 2541e 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?*

Retortable paperboard carton can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. 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 2541e 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 of the container.

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 2541e 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., corn and green beans where corn and green beans 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 additional external pressure required to conform the semi-rigid 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 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?*

Semi-rigid containers can be processed without any physical restraints. Maximum thickness during processing is critical for either overpressure or physical restraints. 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 2541e 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 if you intend to select the thermal process mode in Section G (Process Mode) of Form 2541e 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 2541e, 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 these instructions 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**

**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: Acidification**

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

**1. What is the natural pH of the product before acidification?**

Enter the pH value of the low-acid ingredient (i.e. pH above 4.60) with the highest pH in its natural state before processing or acidification, using a maximum of two digits before the decimal point and two digits after the decimal point. In instances where there is no decimal value, the decimal portion will be two zeros.

**2. What is the finished equilibrium pH of the product after acidification?**

Enter the representative pH value of the product after processing using a maximum of two digits before the decimal point and two digits after the decimal point. In instances where there is no decimal value, the decimal portion will be two zeros.

**3. What is the maximum time it takes for the product to achieve the finished equilibrium pH of 4.60 or lower?**

Enter the amount of time it takes for all locations of the product in the container to achieve the same pH value. This includes the geometric center of any solid pieces/particulates of the product.

**4. Method of Acidification**

Select the method of acidification. In accordance with CFR 114.80(a)(3), procedures for acidification to attain acceptable equilibrium pH levels in the final food include the following:

- Addition of Acid Foods: Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations.
- Blanch: Blanching of the food ingredients in acidified aqueous solutions.
- Direct Batch: Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification.
- Direct In Container: Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than solid or pelleted acids. Care must be taken to ensure that the proper amount of acid is added to each container.
- Immersion: Immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care must be taken to ensure that the acid concentration is properly maintained.
- Other: Use this choice when none of the other choices apply. Identify what acidification method is used in the area next to "Other."

**5. Acidifying agent(s)**

Select one or more acidifying agents as listed on the form. A microbial preservative added to the product is not considered an acidifying agent and should be identified under microbial preservatives in Question e.6. If none of the choices apply, select "Other" and enter the acidifying agent in the space provided.

## 6. Microbial Preservative(s) critical to the scheduled process

Select all microbial preservatives incorporated into the finished product that are critical to the scheduled process and indicate the concentration of the preservative as a percent of the finished product using a maximum of two digits before the decimal point and two digits after the decimal point. If a microbial preservative in the product is not listed, select “Other” and enter the microbial preservative in the space provided. If there are no microbial preservatives, select “None.”

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: Acidification

**SECTION E PROCESSING METHOD: ACIDIFICATION**

39 Clear

1. What is natural pH of the product before acidification? 4 . 7

2. What is the finished equilibrium pH of the product after acidification? 4 . 3

3. What is the maximum time it takes for the product to achieve the finished equilibrium pH of 4.60 or lower? 30 Minutes

4. Method of Acidification: Blanch

5. Acidifying Agent(s): (Select all that apply)

<input type="checkbox"/> Acetic Acid	<input type="checkbox"/> Malic Acid
<input type="checkbox"/> Acid Food(s)	<input type="checkbox"/> Phosphoric Acid
<input type="checkbox"/> Apple Product(s) (other than vinegar)	<input type="checkbox"/> Sodium Acid Sulfate
<input type="checkbox"/> Citric Acid	<input type="checkbox"/> Tamarind Product(s)
<input type="checkbox"/> Fruit Juice(s)	<input type="checkbox"/> Tartaric Acid
<input type="checkbox"/> Fumaric Acid	<input checked="" type="checkbox"/> Tomato Product(s)
<input type="checkbox"/> Gluconic Acid	<input checked="" type="checkbox"/> Vinegars (All Types)
<input type="checkbox"/> Hydrochloric Acid	<input checked="" type="checkbox"/> Wine
<input type="checkbox"/> Lactic Acid	<input type="checkbox"/> Other

6. Microbial Preservative(s) critical to the scheduled process: (Select all that apply and enter percent concentration(s))

Microbial Preservative	Concentration (%)	Microbial Preservative	Concentration (%)	Microbial Preservative	Concentration (%)
<input type="checkbox"/> Alcohol	-	<input type="checkbox"/> Potassium Benzoate	-	<input type="checkbox"/> Sodium Metabisulfite	-
<input type="checkbox"/> Ascorbic Acid	-	<input type="checkbox"/> Potassium Bisulfate	-	<input type="checkbox"/> Sodium Polyphosphate	-
<input type="checkbox"/> Benzoic Acid	-	<input type="checkbox"/> Potassium Metabisulfite	-	<input type="checkbox"/> Sodium Propionate	-
<input type="checkbox"/> Butylated Hydroxyanisole	-	<input type="checkbox"/> Potassium Propionate	-	<input type="checkbox"/> Sodium Sorbate	-
<input type="checkbox"/> Butylated Hydroxytoluene	-	<input type="checkbox"/> Potassium Sorbate	-	<input type="checkbox"/> Sodium Sulfite	-
<input type="checkbox"/> Calcium Chloride	-	<input type="checkbox"/> Potassium Sulfite	-	<input type="checkbox"/> Sorbic Acid	-
<input type="checkbox"/> Calcium Propionate	-	<input type="checkbox"/> Propylparaben	-	<input type="checkbox"/> Triiodium Citrate	-
<input type="checkbox"/> Calcium Sorbate	-	<input type="checkbox"/> Salt	-	Other	
<input type="checkbox"/> Erythorbic Acid	-	<input type="checkbox"/> Sodium Benzoate	-		
<input checked="" type="checkbox"/> Ethanol	2 . 4	<input type="checkbox"/> Sodium Bisulfate	-		
<input type="checkbox"/> Guano Delta Lactone	-	<input type="checkbox"/> Sodium Chloride	-	<input type="checkbox"/> None	
<input type="checkbox"/> Polyorbate	-	<input type="checkbox"/> Sodium Erythorbate	-		

Navigation: << 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 acidified foods must be established by qualified persons having expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods (21 CFR 114.83). Figure 18 shows a picture of a computer screen for Step 6 (Section F).

Figure 18 - Step 6 (Section F) Process Source

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

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

Get Help ?

**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? AAA Corp

**Attach support documentation:**

	File Name	File Size (MB)	
1	<a href="#">ABE Technical Institute Process Source 2014 0715120456584.doc</a>	4.874	>> Remove
<b>Total Size:</b>		4.874	

2. What is the date of the Process Source Document (mm/dd/yyyy)? 07/14/2013

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

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). 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

In an acidified processing method, acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food

under the conditions in which the food is stored, distributed, retailed and held by the user. Permitted preservatives may be used to inhibit reproduction of microorganisms of non-health significance (in lieu of thermal processing) (21 CFR 114.80(a)(1)).

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 and G.6-G11 of the form, the food is placed in the container and the container is heated with the food inside, treating both the food and the container simultaneously.
- The Cold Fill and Hold process mode (G.5) is sometimes used for products that have inherent qualities (such as pH) that destroy vegetative cells of microorganisms of public health significance and those of nonhealth significance at ambient temperatures. In the Cold Fill and Hold process mode, the containers do not require a heat treatment. If this process mode is selected, attach a challenge study (refer to Ref. 4 for detailed explanation of what is needed in a challenge study) demonstrating that the product, as formulated, will result in the destruction of vegetative cells of microorganisms of public health significance and those of nonhealth significance. Permitted preservatives may be used to inhibit reproduction of microorganisms of nonhealth significance.

Figure 19 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.

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 19 - Step 7 (Section G) Process Mode

The screenshot shows the AF/LACF web application interface for Step 7 (Section G) Process Mode. The header includes the AF/LACF logo and 'Acidified/Low Acid Canned Foods', along with the FDA logo and navigation links for 'FURLS HOME' and 'AF/LACF HOME'. A progress bar at the top indicates steps 01 through 09, with Step 07 highlighted. The main content area is titled 'SECTION G PROCESS MODE' and contains a note about file size and types, a 'Clear' button, a dropdown menu for 'G. Process Mode: (Select one)' with 'Steam Jacketed Kettle' selected, and navigation buttons: '<< Back', '>> Save & Exit', '>> Continue', and '<< Cancel & Start Again'. A 'Get Help' link is also visible.

## 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 choices listed. If none of the choices listed 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 choices 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 114.3(e), scheduled process means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority. For more information about establishing the scheduled process, see section II.L.1 of this document.

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 20 shows a picture of an example of computer screen for Step 9 (Section I).

**Figure 20 - Step 9 (Section I) Scheduled Process**

Col.1	Col.2	Col.3	Col.4	Col.5	Col.6	Col.7	Col.8	Col.9	Col.10	Col.11	Col.12	Col.13	Col.14	Col.15
Process No.	Step	Temperature	Process Time	Process Temperature	F value (only one)	Headpiece	Reel Speed	Reel Diameter	Steps per Turn of the Reel	Chain / Conveyor Speed	Cooker Capacity	Frequency	Maximum Fill Weight	Other
1	1	70	55	240	5					30				

**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 three choices available under the column heading, and you should only select one of these choices: 1) Seconds; 2) Minutes; 3) Hours. If you selected Cold Fill and Hold as your process mode in Step 7 (Section G) of the form, enter the process time in units of hours. For all other process modes, select the “Seconds” or “Minutes” and do not select “Hours.”

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 your process mode is Cold Fill and Hold and the process time is 2 days, enter 48.00 and select “Hours.”
- 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; 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 displays the Comment and additional attachment section on the Review screen. Figure 23 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 21, Figure 22, Figure 23, Figure 24, and Figure 25 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 21 - Review Screen (Section A)

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Food Process Filing for Acidified Method (Form FDA 2541a)

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 2541a (Food Process Filing for Acidified Method)"

Food Canning Establishment (FCE) Number:

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

---

SECTION A PRODUCT INFORMATION EDIT

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

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

2. Enter Product Name (e.g., salsa (mild, medium, hot), artichokes (marinated), peppers (red or green), etc.).

3. What is the form of the product?

<input checked="" type="checkbox"/> Chunks (e.g., chunks, nuggets, etc.)	<input type="checkbox"/> Pieces
<input type="checkbox"/> Cut	<input type="checkbox"/> Round/Spheres
<input type="checkbox"/> Diced	<input type="checkbox"/> Shredded/Julienne
<input type="checkbox"/> Fillet	<input type="checkbox"/> Sliced (e.g., slices, quarters, strips, etc.)
<input type="checkbox"/> French Cut	<input type="checkbox"/> Spears/Sticks
<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 type="checkbox"/> Pasta/Purée	

4. What is the packing medium?

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

Figure 22 - Review Screen (Sections B - D)

**SECTION A**    **DO YOU HAVE INFORMATION**    **EXIT**

**Return area:**

1.  **Added/Not** (Product has added/Not added and is governed by 21 CFR 102.22 and 21 CFR Part 114)

2.  **Volume** (The processor has established that the product is an added/Not added food. The processor is voluntarily submitting process information about the product to facilitate FDA determinations regarding the regulatory status of the product.) If you select this status, fill in the information requested in the information that is provided in an added/Not added food. If the product is an added/Not added food, include a detailed process flow diagram of the information process, including the HACCP plan.

---

**SECTION C**    **CONTAINER TYPE**    **EXIT**

**Return area:**

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

1.  Aluminum/Tinplate/Steel Can

2.  **Canvex/Block**

3. What is the shape of the container?

4. Do you use perforated end caps?  Yes  No

5. Is any pressure used during the processing of the product in a can or canister (e.g., Yes  No )?

6. What is the total pressure used during processing?  (Enter in pounds per square inch gauge (psig))

7.  Flexible Pouch

8.  Retortable Paper-based Carton

9.  Rigid Container (10 pound or more of product)

10.  Stand-Rigid

11.  Other

---

**SECTION D**    **CONTAINER SIZE**    **EXIT**

Notes: You are required to complete either D1 (Dimensions) or D2 (Volume). You may complete D2 if you intend to select the thermal process in Section E and D3 High Temperature Short Time (HTST), D4 Hot Fill and Hold, or D5 Steam Jacketed Kettle, and if D1 your product is a viscous product under Section D1, and D2 you have identified "Other" under Section C, you may indicate "Not Applicable" in your response to D2. In all other circumstances, if you are completing D2 in accordance with the directions in paragraph 1, you may not select "Not Applicable".

For all other circumstances, complete D2, Section D2 (net weight) is optional information.

1. Dimensions:

a)  Diameter  Height (Use for non-cylindrical) (See accompanying instructions for proper filling)

2. Volume:   **Other area:**

3. Net Weight (Optional)  (Enter in grams)

Figure 23 - Review Screen (Sections E – F)

**SECTION E**    **PROCESSING METHOD AND INFORMATION**    **EXIT**

1. What is the natural pH of the product before acidification?

2. What is the final acid level in pH of the product after acidification?

3. What is the maximum time (in minutes) for the product to be heated to the final acid level at 100°C or lower?

4. Method of acidification:

5. Heating Regime (s): (Select all that apply)

Direct Heat     Hot Water     Microwave

Indirect Heat     Steam Jacketed     Pressure Cook

Spare/Preheated (after other heating)     Steam Cook in Water

Direct Heat     Thermal Preheated

Hot Water     Retort Cook

Microwave     Steam Jacketed

Spare/Preheated     Vacuum Cook

Indirect Heat     Other

6. Method of Pressure (s) in the product during process: (Select all that apply) and/or vacuum cook (s) (s)

Pressure/Preheating (s)	Contribution (s)	Retortable/Preheating (s)	Contribution (s)	Retortable/Preheating (s)	Contribution (s)
<input type="checkbox"/> Direct	<input type="checkbox"/>	<input type="checkbox"/> Sodium Benzoate	<input type="checkbox"/>	<input type="checkbox"/> Sodium Metabisulfite	<input type="checkbox"/>
<input type="checkbox"/> Indirect	<input type="checkbox"/>	<input type="checkbox"/> Sodium Bisulfite	<input type="checkbox"/>	<input type="checkbox"/> Sodium Phosphate	<input type="checkbox"/>
<input type="checkbox"/> Sparingly	<input type="checkbox"/>	<input type="checkbox"/> Sodium Hydroxide	<input type="checkbox"/>	<input type="checkbox"/> Sodium Propionate	<input type="checkbox"/>
<input type="checkbox"/> Retort	<input type="checkbox"/>	<input type="checkbox"/> Sodium Phosphate	<input type="checkbox"/>	<input type="checkbox"/> Sodium Sorbate	<input type="checkbox"/>
<input type="checkbox"/> Blended/Preheating	<input type="checkbox"/>	<input type="checkbox"/> Sodium Propionate	<input type="checkbox"/>	<input type="checkbox"/> Sodium Sulfite	<input type="checkbox"/>
<input type="checkbox"/> Blended/Preheating	<input type="checkbox"/>	<input type="checkbox"/> Sodium Benzoate	<input type="checkbox"/>	<input type="checkbox"/> Sorbic Acid	<input type="checkbox"/>
<input type="checkbox"/> Calcium Chloride	<input type="checkbox"/>	<input type="checkbox"/> Sodium Bisulfite	<input type="checkbox"/>	<input type="checkbox"/> Sodium Citrate	<input type="checkbox"/>
<input type="checkbox"/> Calcium Phosphate	<input type="checkbox"/>	<input type="checkbox"/> Sodium Sulfite	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Calcium Sorbate	<input type="checkbox"/>	<input type="checkbox"/> Sorbic Acid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Erythorbic Acid	<input type="checkbox"/>	<input type="checkbox"/> Sodium Chloride	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Ethanol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Guaiac Resin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Papain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. What is the Process Source?

**Search support documentation:**

File Name	File Size (KB)
2007 Technical Guidance Process Source, 20140718130108000.doc	0.274
Technical	0.274

8. What is the Date of the Process Source Document (YYYYMMDD)?

Figure 24 - Review Screen (Sections G - I)

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 Throughput (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. Cooker Capacity	f. Frequency	Col.10 Maximum Weight
		<input type="checkbox"/> Min. Initial <input type="checkbox"/> Fill	<input type="checkbox"/> Seconds <input type="checkbox"/> Minutes <input type="checkbox"/> Hours	See above	<input type="checkbox"/> Fo (16-250) <input type="checkbox"/> Other F Reel T: <input type="text"/> Z: <input type="text"/> (F only)	Number	<input type="checkbox"/> Net <input type="checkbox"/> Gross <input type="checkbox"/> NA	Reel Speed	Reel Diameter	Steps per Turn of the Reel	Chain / Conveyor Speed	Cooker Capacity	Frequency	<input type="checkbox"/> Fill <input type="checkbox"/> NA
Number	Number	° Fahrenheit	See above	° Fahrenheit	Minutes	Number	Inches	SPM	Inches	Number	Number	Number	Number	Ounces

Figure 25 - Review Screen (Section J)

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, txt, xls,xlsx, pdf, gif and rtf.

Attachment Type: Please Select

Attach document:  Browse... >> Upload

Document Library

Comments:

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

Full Name: Tester Test  
Establishment Name : Test Company  
State or Province : Maryland  
Country(other than U.S.) :  
Date: 07/15/2014  
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

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.

## R. Filing Message

After you select Submit, the system will provide a message that your form has been successfully filed. Figure 26 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 26 - 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](mailto: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. LACF/AF Precursor Questions. Accessible at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/UCM417292.pdf>
4. 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](http://www.fsis.usda.gov/wps/wcm/connect/a7f8aa06-d2ac-40bf-bd7f-11c5a59b6c6a/NACMCF_JFP_Inoculated_Pack.pdf?MOD=AJPERES)

## V. Appendix

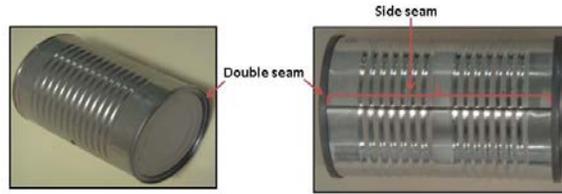
### A. Container Types and Shapes



Figure 27 – Cylindrical Shape 2-Piece Aluminum Containers Depicting Double Seams



**Figure 28 – Low-Profile Rectangular Shape 2-Piece Aluminum Containers**



**Figure 29 – Cylindrical Shape 3-Piece Steel Containers with a Double Seam and Side Seam**



**Figure 30 – Cylindrical Shape 2-Piece Steel Containers with a Double Seam**



**Figure 31 – Flexible Pouch**



**Figure 32 – Glass Containers**



**Figure 33 – Semi Rigid Body, Oval Shape Containers with Heat Seal**



**Figure 34 – Semi Rigid Body, Rectangle Shape Containers**



**Figure 35 – Semi Rigid Body with an Aluminum Double Seam**



**Figure 36 – Semi Rigid Body, Cylinder Shape Containers with Induction Weld Seal**



**Figure 37 – Semi Rigid Body with Heat Seal**

## **B. Container Dimension Measurements**

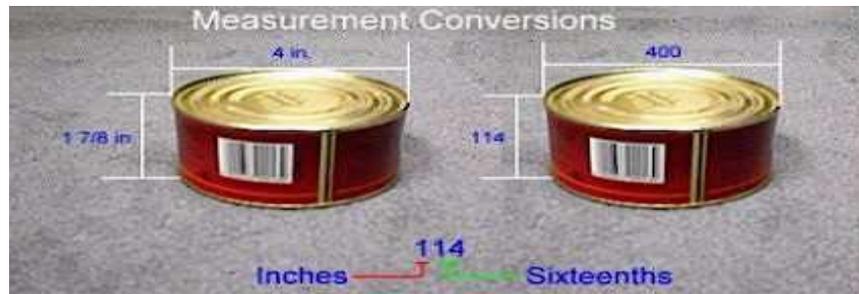
Container dimension measurements should always be measured from the outside edge of the container. Below, we list different types of materials and descriptions of how to properly measure the dimensions of the container.

### **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 38 – Measurement of a Cylindrical Shape Container.**

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



**Figure 39 – 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 40 – Measurement of an Oval Shape Container**



**Figure 41 – 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**

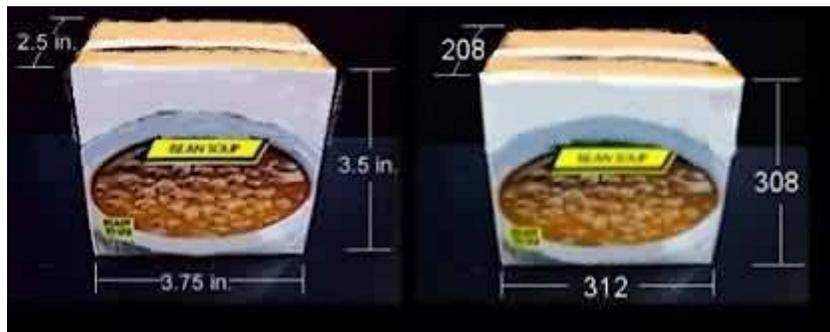


Figure 42 – Measurement of a Rectangular Shape Container

5. Rectangular Tray Measurement

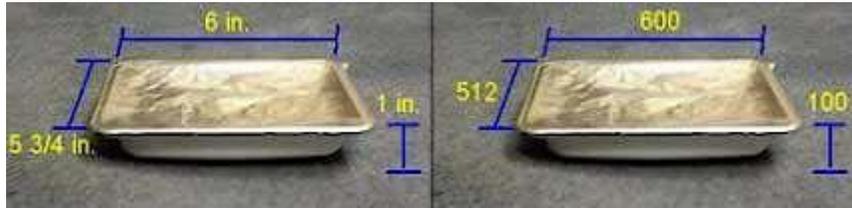


Figure 43 – Measurement of a Rectangular Tray Shape Container

6. Low-Profile Measurement

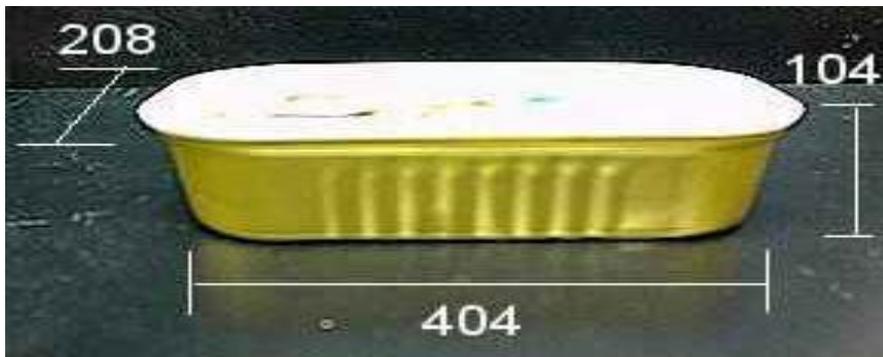


Figure 44 – Measurement of a Low-Profile Container