

Completing Form FDA 2541a for Acidified Foods

Adapted from: <http://www.cfsan.fda.gov/~comm/lacf-s1.html>

Complete a **separate** process filing form FDA 2541a for:

- Each **processing method** (acidified, pressure canned, etc).
- **Each product form or style** (whole, diced, etc.) which receives a **different scheduled process** or when the characteristics of the food affect the **heat transfer rate**. Products having minor formulation differences or several forms or styles **may** be filed on the **same** 2541a if other factors do not require separate filing, and if the same scheduled process applies to each product variation.

For example:

"Beans in tomato sauce (with or without pork)"

- In any case, mushrooms* **must always be separated by product form or style** (i.e., a separate form submitted for each form or style: whole, buttons, pieces and stems).
*applies only to mushrooms (*Agaricus bisporus* or *A. Bitorguis*) which meet the standard of identify (21 CFR 155.201).
- **Each type of container** (glass, etc.) in which the product is packed, even though all other information is exactly the same. However, multiple container sizes of the same container type **may** (and should) be included on a single form for a given product, as long as the container type, packing medium, and other such information not related to container size is identical.
- **Each different packing medium** (e.g., water, oil, sauces, etc.).

PART A. PRODUCT:

- **FCE** - Enter the 5-digit Food Canning Establishment (FCE) Number assigned to your business by the FDA when you registered (from Form FDA 2541). If registering concurrently with initial process filing, leave blank (FDA will complete).
- **Submission Identifier (SID)** - Enter a different SID on each process filing form, based on the date the form is being submitted. The same SID can be entered on forms submitted the same day.
YY is the last two digits of the year (e.g., 06, 07, 08, etc.)
MM is the numerical designation of the month (e.g., 05 for May, 10 for October)
DD is the day of the month (e.g., 03, 28, etc.)
SSS is a unique sequence number within the date (e.g., 001, 002, etc.)
- **Name, Form or Style, and Packing Medium** - Enter the food product name, form or style, and packing medium in that order, e.g., Baby carrots (whole), pickled. Product forms or styles receiving the same scheduled process should be included in parentheses after the product name. For example, "Carrots (whole, cut, quartered, sliced, diced, or shoestring), pickled".
- **Raw pH** - Enter the normal or natural pH of the product before processing, to the nearest tenth (e.g., 6.5). For **acidified products**, enter the **highest natural pH of the low-acid component(s)**(the component(s) or ingredient(s) having a pH value(s) greater than 4.6). See the **Table of Approximate pH of Selected Foods at tab-7 in your binder** for information which can help you complete this section.
- **Governing Regulation** - Place a mark by the governing regulation under which the process is being filed – Acidified.
- **Type of Submission** - Mark "new" if no previous processes have been filed for this product in the container sizes being listed or if these are additional processes for the container sizes listed (i.e., this form does not replace a previously submitted form).
- **Process Use** - Check "scheduled" if this is the process used regularly for this product under normal conditions.

PART B. PROCESSING METHOD:

Acidified Products - If 21 CFR 108.25 and 114 was marked as the governing regulation, mark "**acidified**" and complete all applicable information as follows:

- **Maximum Equilibrium pH** - Enter the maximum equilibrium pH (upper limit) of the finished product **after acidification, measured** within 24 hours after processing, to the nearest tenth (e.g., 4.2). Recheck **Section A**. Product to assure that the raw pH (Item (4)) was also completed properly.
- **Method of Acidification** - Enter the method of acidification (e.g., direct batch acidification, direct addition, etc.).
- **Acidifying Agent** - Enter acidifying agent(s), e.g., citric acid, acetic acid (5% vinegar), lemon juice, tomato sauce, etc.
- **Pasteurization Method** - If a heat treatment (e.g., pasteurization) is recommended by the process source as part of the scheduled process, enter the type of treatment, such as boiling water canning, hot fill hold, etc.
- **Preservative Used** - If a preservative is used along with pH control, specify the preservative (e.g., sodium benzoate, potassium sorbate, etc.) and the concentration (%) of the finished product. If no preservative is used, enter N/A.
- **Process Establishment Source** - NOTE: If more than one process source is listed, the process(es) must have been established jointly by the listed sources. Otherwise, use a separate form for each process source.
 - Enter the name of the process source (organization, company, or individual, etc.) which scientifically established the scheduled process(es) and the type of document containing the process recommendations (i.e., letter, bulletin, etc.). Use the following guidelines in making entries:
 - Limit entries to 30 characters,
 - If the process was established by your firm, enter your firm's name.
 - For universities, enter name of university followed by the name of an individual (if appropriate).
 - Date Last Established
 - Process Recommendations Attached? If you are attaching a copy of the process recommendation from the process establishment source, check "YES". Otherwise check "NO".

C. CRITICAL FACTORS. Mark (x) for **ALL** critical factors. If none were specified, Mark (x) "**None** "

D. SCHEDULED PROCESS.

Container Dimensions - Enter the dimensions of each container size which is used for the product listed IN ENGLISH UNITS (inches and sixteenths). Forms submitted without conversion to English units will be returned. Use a separate line for each different container size and its process parameters or characteristics, numbering each line sequentially (1, 2, etc.) in the "Cont. No." column. Do not leave blank lines between container sizes.

Proper Measuring Techniques for Cylindrical Containers

When measuring unusually shaped cylindrical containers, always measure the widest part of the container. The measurements must be from the outside edge of the container.



IMPORTANT: Report measurements in inches and sixteenths using the standard format: 0405 x 0311 for a container which is 4 5/16 inches tall, and 3 11/16 inches wide.

SCHEDULED PROCESS

- **Step No.** - Enter "1" unless: This is a multiple step process.
- **Temp (°F)** - For Acidified food processes, check "Fill" and enter that temperature (in °F) if any of the above have been specified by the process establishment source. If none are applicable, enter "N/A".
- **Process Time (Minutes)** - For Acidified food processes, check "Process Time", or "Hold Time" and enter the time in minutes to the nearest hundredth if any of the above have been specified by the process establishment source.
- **Sterilization Temp (°F)** - For Acidified food processes check "Process Temp" and enter the minimum process temperature in F to the nearest whole degree if a sterilizer processing temperature has been specified by the process establishment source. Otherwise, check "N/A".
- **Least Sterilizing Value of the Scheduled Process**

1. Enter the following information.

Check - other F-value

Death Rate (z): 19.5°F

Ref. Temp (T): xxx°F (Enter the processing temperature identified in your scheduled process)

The target F value (minutes) is the time needed to achieve a 5-log reduction in *E. coli* O157:H7 at the reference temperature. Use the following table to complete form 2541a.*

Temp (°F)	Target F-value (min)	Temp (°F)	Target F-value (min)	Temp (°F)	Target F-value (min)
140	12.7	154	2.4	168	0.5
142	10.1	156	1.9	170	0.4
144	7.9	158	1.6	172	0.3
146	6.3	160	1.2	174	0.2
148	4.9	162	0.9	176	0.2
150	3.9	164	0.7	178	0.1
152	3.1	166	0.6	180	0.1

*What this means: For a hot-fill product like salsa with a fill temperature of 160°F, hold the product at 160°F for 1.2 minutes to achieve the target lethality (5-log reduction); at a fill temperature of 180°F, hold the product for 0.1 min (6 seconds) to reach the target lethality.

2. Enter the reference temperature ,target F value, and publication reference in the Comments section:

T_{ref}= xxx°F

Target F=xx min

[In the above example, T_{ref}=160°F, Target F = 1.2 min]

Reference: Breidt, F., K.P. Sandeep, and F.M. Arritt. May 2010. Use of linear models for thermal processing of acidified foods. Food Protection Trends. 30:268-272.

Be sure to sign and date the form!