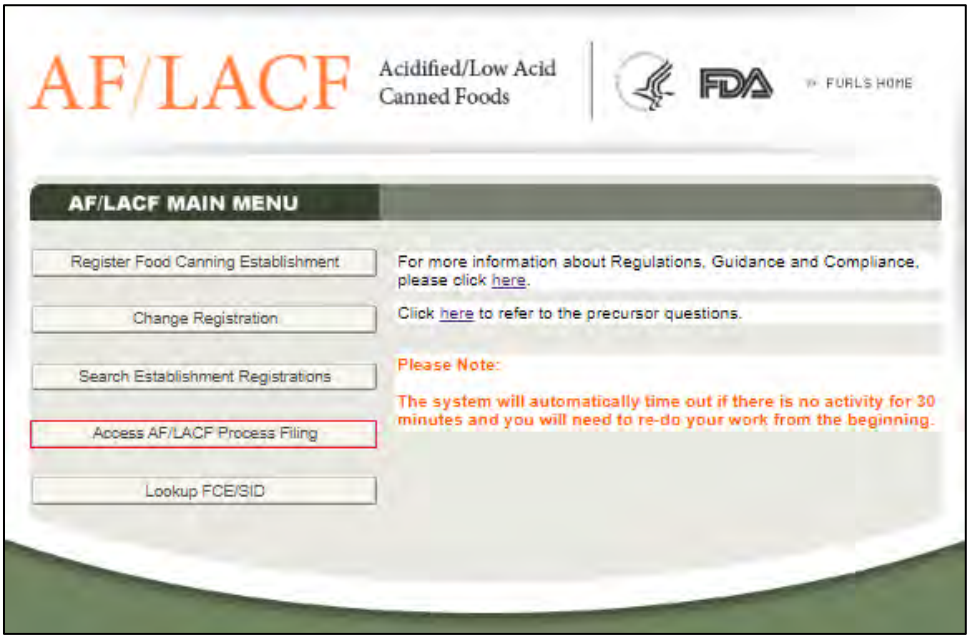
Task 5. ..... Setting up an Authorized Representative.

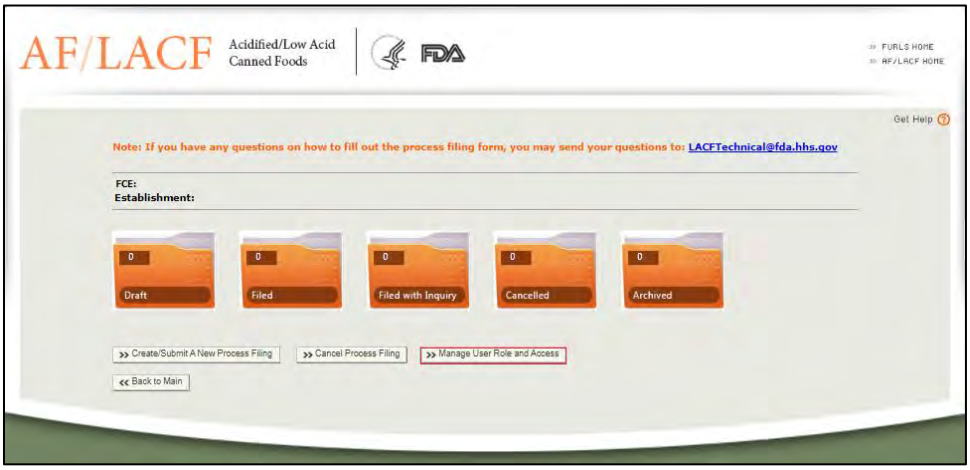
An Authorized Representative (AR) can conduct business for you in the FDA FURLS AF/LACF module. They have access only in the manner that you allow. Subject to these restrictions, they can view, create, & delete filed processes. An Authorized Representative can do this with filings that they create. A Super Authorized Representative (SAR) can do this on any filing. A Read-Only Authorized Representative (ROAR) can only view filings.

To add me as an authorized representative,

1. Login to your account. Don't forget to check the 18 USC §1001 ☑ **I understand.** box
2. Select Acidified/Low-Acid Canned Foods Registration and Process Filing
3. From the AF/LACF Main Menu, select Access AF/LACF Process Filing.

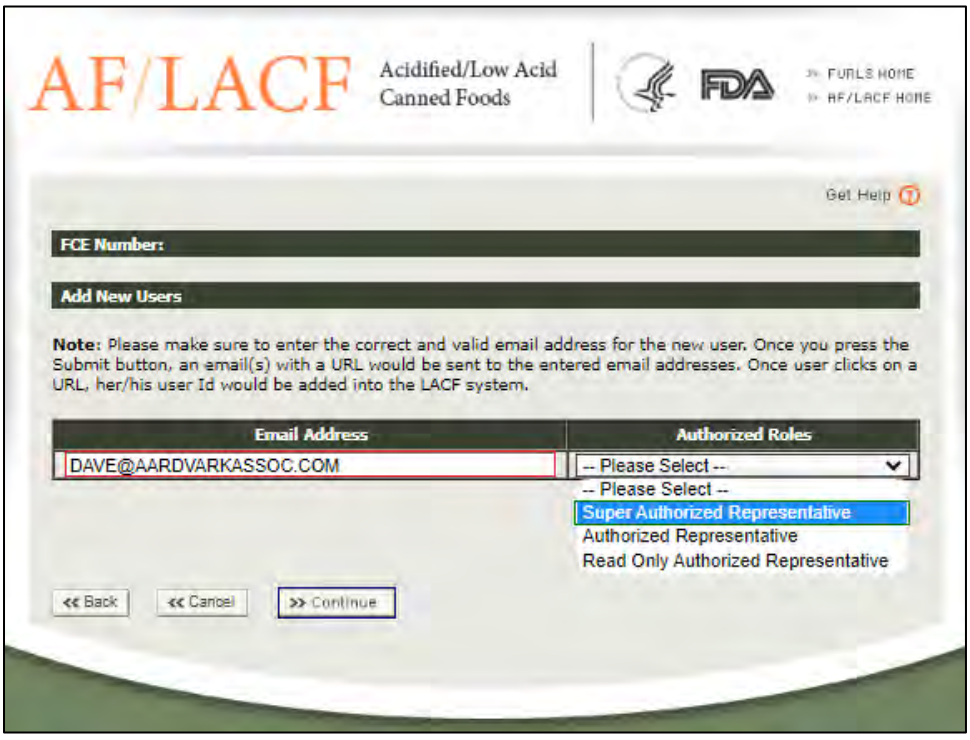


4. Select >> Manage User Role and Access



5. Select >> Add User.

6. Add my email as DAVE@AARDVARKASSOC.COM. Any other email for me will bounce. Select Super Authorized Representative (preferred) or Authorized Representative Then select >> Continue.



7. If the add was successful, you will see my email & role. Press [>> Edit User] or [<< Back to Main]

Task 6. ..... Qualified Facility Attestation

21 CFR §117 (Preventive Controls for Human Food) is the primary set of regulations for domestic food processors through the Food Safety Modernization Act (FSMA). It is a large regulation, spanning 41 pages in the April 2022 edition of 21 CFR. [21 CFR §114 (Acidified Foods) spans 7 pages, a manageable size for small-scale producers]. Acidified foods producers may be subject to some, if not all, of its provisions.

The Preventive Controls Rule consists of the following sections:

- ☐ Subpart A—General Provisions (12 pages)
- ☐ Subpart B—Current Good Manufacturing Practice (8 pages)
- ☐ Subpart C—Hazard Analysis & Risk-Based Preventive Controls (9 pages)
- ☐ Subpart D—Modified Requirements (3 pages)
- ☐ Subpart E—Withdrawal of a Qualified Facility Exemption (4 pages)
- ☐ Subpart F—Requirements Applying to Records That Must Be Established & Maintained (2 pages)
- ☐ Subpart G—Supply-Chain Program (7 pages)

Many small-scale producers (Qualified Facilities) are partially exempt from the Subparts C & G, the two largest subparts, **but only if they register for the exemption** in the form of a Qualified Facility Attestation (FDA Form 3942a). Only 10% of all Qualified Facilities file for the exemption. Attestation must also be renewed every 2 years. The form is due 31 July of the year of filing.

A Qualified Facility is a very small business with either

(a) a 3-year average of $1, 000,000 (2011 dollars) sales plus the market value of food processed and not for sale, or

(b) both of the following apply:
  (1) gross direct-to-consumer sales exceed all other sales, and
  (2) total gross sales are less than $500,000 (2011 dollars).

In place of Subpart C, Qualified Exempt Facilities need to follow pertinent state/local/tribal requirements, or in the absence of these, must prepare an abbreviated Food Safety Plan.

To complete the attestation,

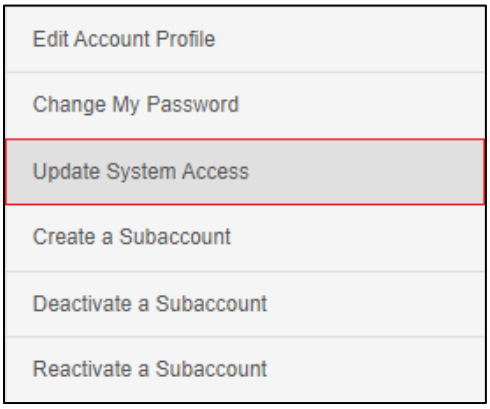
1. Login to your account. Don't forget to check the 18 USC §1001 ☑ **I understand.** box
2. Select ☑ **Qualified Facility Attestation**.
3. Select Initial Registation.
4. Select ◎ **Qualified Facility for Human Food**
5. Complete the facility registration information exactly as it appears in your Food Facility Registration. You will need your eleven digit FFR№.
6. Select one of the qualification statements [21 CFR §117.5(a)].
7. Select one of the food safety compliance statements [21 CFR §117.201(a)(2)].
8. Select ▸▸ **Submit**

Supplemental tasks

Appendix A..... Updating system access

If you need to update your system access,

1. Login to your account. Don't forget to check the 18 USC §1001 ☑ **I understand.** box
2. This brings you to the Account Management page (FURLS home). Select Update System Access.



3. Select the system that you need to access
4. Select Submit
5. Select the module that you next wish to visit.

Appendix B. ..... Biennial FFR renewal

Every two years, before 31 December of each even-numbered year, you will need to renew your FFR up to six months before the deadline.

To do so,

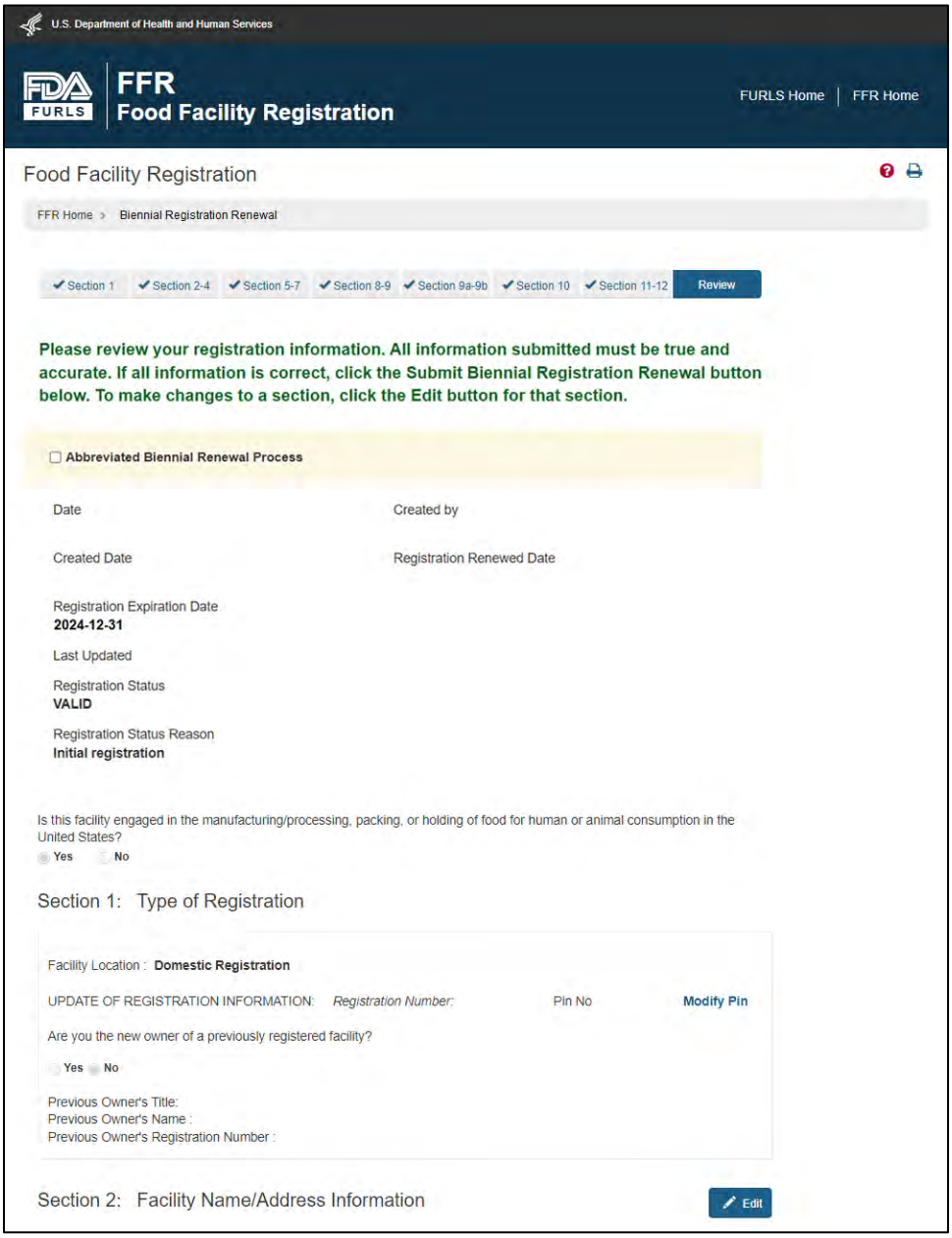
9. Login to your account. Don't forget to check the 18 USC §1001 ☑ **I understand.** box
10. Select ☑ Food Facility Registration
11. Select Biennial Registration Renewal.

12. Select the Registration Number

Registration Number	Facility Name	Facility Address
12345678901	Facility name here	Facility address here

13. Review your registration on the review page (page 39). Only sections marked Edit may be changed.
14. When you are satisfied with your information, press Submit.
15. You shoud get a **Registration Renewal Successful✓** message. If you wish to view your registration, select View Complete Registration.

Biennial Registration Renewal



Appendix C..... Viewing & printing filings

Electronic filings are the electronic equivalents of FDA Forms 2541e-h. They contain all critical factors for your process, along with explanatory notes. As an acidified foods processor, your filings will be on FDA Form 2541e.

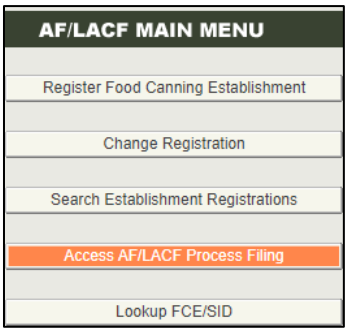
You can (& periodically should) view the filings that have been submitted on your behalf so that
a. You can verify their accuracy,
b. You can confirm your process parameters, including critical factors,
c. You can assure that you are keeping adequate records, &
d. You have a copy on-hand shoud the FDA or your state inspector come to visit.

You should print a copy of each filing, including any attachments such as process sources (scheduled process letters) (2541e Section F), & other documents that may be attached at the end (2541e Section J).

Filings are identified by the five-digit FCE & an eight-digit Submission Identifier (SID). Correspondence with the FDA Should include both. The SID is built as follows: yyyymmddnnn (year, month, day, sequence within the day). For ease of reading, I often write the SID as yyyy-mm-dd/nnn: 2023-03-04/001, for example. Each day, the sequence starts over at 001 & increments one process at a time. When I manage a group of processes for you, I assign each process a sequence, & file in a way that preserves the sequence, allowing easier process tracking. Each container size for a product must have a separate SID.

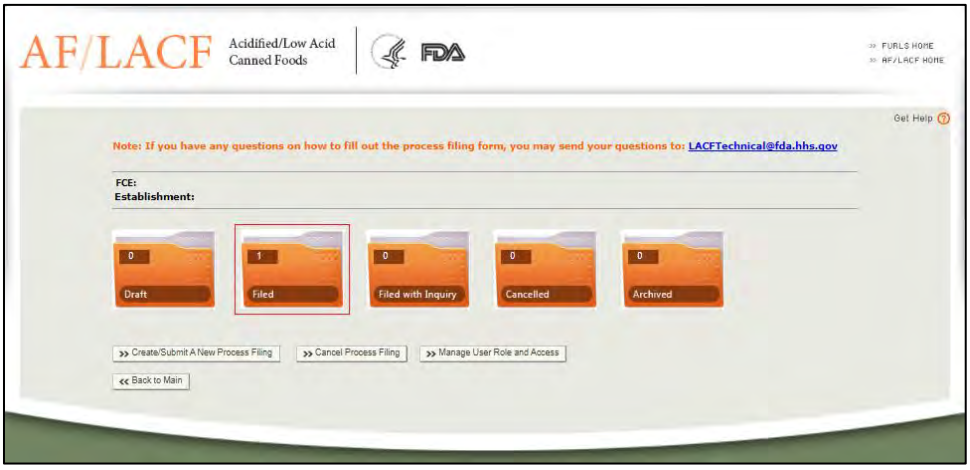
To access your filings:

1. Login to your account. Don't forget to check the 18 USC §1001 ☑ I understand. box.
2. Select Acidified/Low-Acid Canned Foods Registration and Process Filing
3. Select Access AF/LACF Process Filing



4. If you have more than one FCE, select the FCE for which you want to view submissions.
5. >> Continue .

6. Select the folder that you wish to visit.



7. Select >> View or >> Print.

8. >> View allows you to view the filing before (optionally) printing it. >> Print goes straight to a print dialog. A sample printout is shown on pages

Filing view (1st part)

AF/LACF Acidified/Low Acid Canned Foods | FDA

» FURLS HOME
» AF/LACF HOME

Get Help

FOOD PROCESS FILING FOR ACIDIFIED METHOD (FORM FDA 2541e)

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:
Submission Identifier (SID): 20220607001 (YYYYMMDD###)

SECTION A PRODUCT INFORMATION

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

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

Gravies/Sauces (spaghetti sauce, mushroom gravy)

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

Tomato-based sauce (acidified)

3. What is the form of the product?

Paste/Puree

4. What is the packing medium?

None

SECTION B GOVERNING REGULATION

Select one:

1. Acidified (Product is an acidified food and is governed by 21 CFR 108.25 and 21 CFR Part 114)
2. 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 such as a list of ingredients with the pH and weight % of each ingredient and the finished equilibrium pH. If the product appears to be a fermented food, include a detailed process flow diagram of fermentation processes, including the pH at each step.

SECTION C CONTAINER TYPE

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

Select one:

1. Aluminum/Tinplate/Steel Can
2. Ceramic/Glass
   a) What is the shape of the container? (Select one) Cylindrical
   b) Do you use perforated divider plates? Yes No
   c) Is overpressure used during the processing of the product to maintain container integrity?
   Yes No (If using a Process Mode of: Batch Agitating, Hydrostatic Retort, or Still Retort; continue to c.ii-c.iv; otherwise, continue to Section D.)
   ii. What is the percent (%) headspace?
   iii. What is the minimum initial temperature? (enter in Fahrenheit)
   iv. What is the vacuum? (enter in inches of mercury (Hg))
3. Flexible Pouch
4. Retortable Paperboard Carton
5. Rigid Container (industrial size)
6. Semi-Rigid
7. Other

SECTION D CONTAINER SIZE

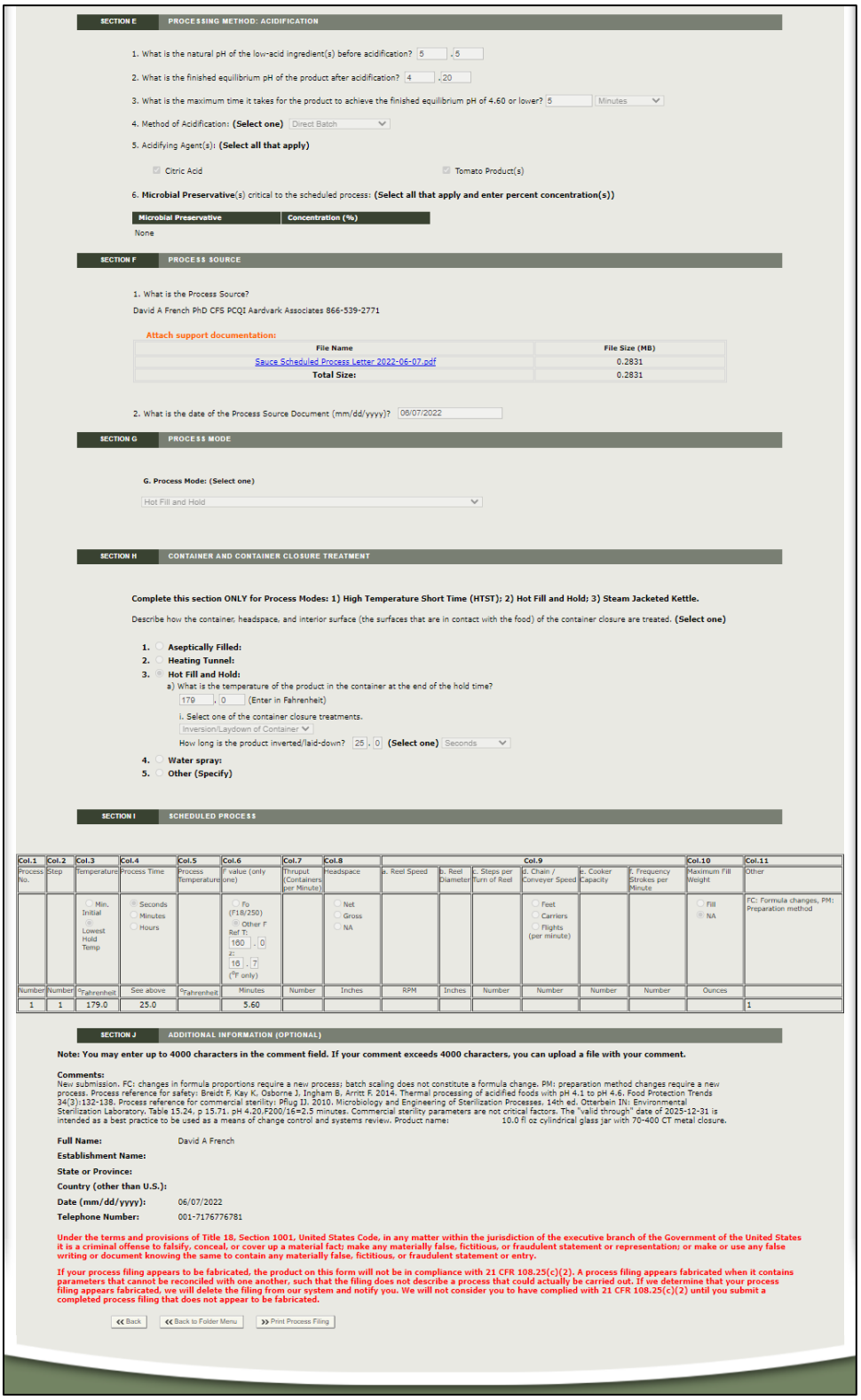
Note: You are required to complete either D.1 (Dimensions) or D.2 (Volume). You may complete D.2 if you intend to select the thermal process mode in Section G as: 1) High Temperature Short Time (HTST); 2) Hot Fill and Hold; or 3) Steam Jacketed Kettle.

If you are completing D.2 because you intend to select HTST, Hot Fill and Hold, or Steam Jacketed Kettle, and if 1) your product is a cheese product under Section A.1, and 2) you have identified "Other" under Section C, you may indicate "Not Applicable" in your response to D.2. In all other circumstances, if you are completing D.2 in accordance with the directions in paragraph 1, you may not select "Not Applicable."

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

1. Dimensions: Container Dimension Assistance
   a) 214 Diameter 308 Height (Use for cylindrical shapes) (see accompanying instructions for proper coding)
2. Volume: (Select one) Please Select
3. Net Weight (Optional): (enter in ounces)

Filing view (next part)



SECTION E PROCESSING METHOD: ACIDIFICATION

1. What is the natural pH of the low-acid ingredient(s) before acidification? 5 .5
2. What is the finished equilibrium pH of the product after acidification? 4 .20
3. What is the maximum time it takes for the product to achieve the finished equilibrium pH of 4.60 or lower? 5 Minutes
4. Method of Acidification: **(Select one)** Direct Batch
5. Acidifying Agent(s): **(Select all that apply)**

Citric Acid Tomato Product(s)

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

Microbial Preservative	Concentration (%)
None	

SECTION F PROCESS SOURCE

1. What is the Process Source?

David A French PhD CFS PCQI Aardvark Associates 866-539-2771

Attach support documentation:

File Name	File Size (MB)
Sauce Scheduled Process Letter 2022-06-07.pdf	0.2831
Total Size:	0.2831

2. What is the date of the Process Source Document (mm/dd/yyyy)? 06/07/2022

SECTION G PROCESS MODE

G. Process Mode: (Select one)

Hot Fill and Hold

SECTION H CONTAINER AND CONTAINER CLOSURE TREATMENT

Complete this section ONLY for Process Modes: 1) High Temperature Short Time (HTST); 2) Hot Fill and Hold; 3) Steam Jacketed Kettle.

Describe how the container, headspace, and interior surface (the surfaces that are in contact with the food) of the container closure are treated. **(Select one)**

1. **Aseptically Filled:**
2. **Heating Tunnel:**
3. **Hot Fill and Hold:**
   a) What is the temperature of the product in the container at the end of the hold time?
   179 . 0 (Enter in Fahrenheit)
   i. Select one of the container closure treatments.
   Inversion/Laydown of Container
   How long is the product inverted/laid-down? 25 . 0 **(Select one)** Seconds
4. **Water spray:**
5. **Other (Specify)**

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
Process No.	Step	Temperature	Process Time	Process Temperature	F value (only one)	Thruput (Containers per Minute)	Headspace	a. Reel Speed	b. Reel Diameter	c. Steps per Turn of Reel	d. Chain / Conveyer Speed	e. Cooker Capacity	f. Frequency Strokes per Minute		Maximum Fill Weight	Other
		Min. Initial Lowest Hold Temp	Seconds Minutes Hours		Fo (F18/250) Other F Ref T: 160 . 0 z: 16 . 7 (°F only)		Net Gross NA				Feet Carriers Flights (per minute)				Fill NA	FC: Formula changes, PM: Preparation method
Number	Number	°Fahrenheit	See above	°Fahrenheit	Minutes	Number	Inches	RPM	Inches	Number	Number	Number	Number		Ounces	
1	1	179.0	25.0		5.60											1

SECTION J ADDITIONAL INFORMATION (OPTIONAL)

Note: You may enter up to 4000 characters in the comment field. If your comment exceeds 4000 characters, you can upload a file with your comment.

Comments:
New submission. FC: changes in formula proportions require a new process; batch scaling does not constitute a formula change. PM: preparation method changes require a new process. Process reference for safety: Breidt F, Kay K, Osborne J, Ingham B, Arritt F. 2014. Thermal processing of acidified foods with pH 4.1 to pH 4.6. Food Protection Trends 34(3):132-138. Process reference for commercial sterility: Pflug IJ. 2010. Microbiology and Engineering of Sterilization Processes, 14th ed. Otterbein IN: Environmental Sterilization Laboratory. Table 13.24, p 15.71. pH 4.20,F200/16=2.5 minutes. Commercial sterility parameters are not critical factors. The "valid through" date of 2025-12-31 is intended as a best practice to be used as a means of change control and systems review. Product name: 10.0 fl oz cylindrical glass jar with 70-400 CT metal closure.

Full Name: David A French
Establishment Name:
State or Province:
Country (other than U.S.):
Date (mm/dd/yyyy): 06/07/2022
Telephone Number: 001-7176776781

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

If your process filing appears to be fabricated, the product on this form will not be in compliance with 21 CFR 108.25(c)(2). A process filing appears fabricated when it contains parameters that cannot be reconciled with one another, such that the filing does not describe a process that could actually be carried out. If we determine that your process filing appears fabricated, we will delete the filing from our system and notify you. We will not consider you to have complied with 21 CFR 108.25(c)(2) until you submit a completed process filing that does not appear to be fabricated.

<< Back << Back to Folder Menu >> Print Process Filing

Appendix D..... Sample scheduled process letter

Scheduled process

Tomato-based sauce with diced peppers, seasoned (acidified)

Product name: Pattys Perky Pasta Sauce. Formula date: 01-Mar-2023
FDA food category (FDA Form 2541e Section B2): gravies/sauces (spaghetti sauce, mushroom gravy)
Pursuant to 21 CFR §108 (Emergency Permit Control), 21 CFR §114 (Acidified Foods), and 21 CFR §117 (Preventive Controls for Human Food).

Prepared for

<firm>
Attn: <name>
<street>
<CSZ>
<telephone>
<email>
<website>

Processing at

<firm>
Attn: <name>
<street>
<CSZ>
<telephone>
<email>
FCE Number: <here>

Date.....30-Apr-2023
valid through.....31-Dec-2026
The "valid through" date is intended as a best practice to be used as a means of change control and systems review.
Include this document with your Food Safety Plan.

Batch formula (100 gal batch) (changes in formula proportions require new scheduled process letter)

Ingredient	Weight (lb)	Weight %	Weight % of acid or low-acid groupings
Tomatoes, crushed, concentrated, canned, RedGold (0-72940-11013-3)[tomatoes, salt, citric acid]	506.2	59.0%	
Tomato paste, canned, RedGold (0-72940-11016-4)[tomatoes, citric acid] or equivalent	47.2	5.5%	
Lemon juice concentrate, 500 gpL, frozen, thawed	4.3	0.5%	65.00%
Pepper fruit, sweet red, fresh, trimmed, without seeds or stems, diced	167.3	19.5%	
Oil, olive, extra virgin	85.8	10.0%	
Onion bulbs, fresh, peeled, trimmed, diced	25.7	3.0%	
Garlic cloves, fresh, peeled, trimmed, minced	12.9	1.5%	
Basil leaves, fresh, chopped	8.6	1.0%	
Total	858.0	**100.0%**	100.00%

Critical Factors (in red)

Finished pH.....4.10 maximum
Measured at 70±10°F

Hot fill & hold
Fill temperature.....165 °F minimum
(Temperature at end of hold.....159 °F minimum)
Inversion hold.....1:22 minutes minimum
82 seconds minimum

FC: **Changes in formula proportions require a new process.**
Batch scaling does not constitute a formula change.
PM: **Preparation method changes require a new process.**

Thermal process calculation factors

For safety
LSV for *Escherichia coli* O157:H7
F.....1.20 minutes
T_{ref}.....160.0 °F
z.....19.5 °F
Process reference:
Breidt F, Sandeep KP, Arritt FM. 2010. Use of Linear Models for Thermal Processing of Acidified Foods. Food Protection Trends 30 (5): 268-272.

For commercial sterility
maximum pH.....4.10
F.....1.00 minutes
T_{ref}.....200.0 °F
z.....16.0 °F
Process reference:
Pflug IJ. 2010. Microbiology and Engineering of Sterilization Processes, 14th ed. Otterbein IN: Environmental Sterilization Laboratory. Table 15.24, p 15.71.

Preparation method (changes require new scheduled process letter)..... Critical and operating limits

Abbreviation key
CL Critical limit
LCL Lower critical limit
UCL Upper critical limit
LL Lower operating limit
UL Upper operating limit

1. Regarding temperature measuring devices (TMDs):
   a. Use TMDs accurate to ±2°F or closer. Identify each TMD by a unique code.
   b. Calibrate each TMD against a NIST-traceable standard at temperatures of use.
   c. Calibrate bimetal (dial-type) TMDs daily.
   d. Calibrate other TMDs regularly to assure reproducible results.
   e. Maintain a calibration log for each TMD.
2. Regarding pH meters:
   a. Use pH meter accurate to 0.01 pH unit.
   b. Use 2-point calibration with buffers at pH 4.01 and 7.00.
   c. Calibrate pH meter daily and as needed to assure reproducible results.
   d. Maintain pH calibration log that includes date, time, buffer lots, and measured pH values in buffer before correction.
3. Document results of measurement of each critical factor.
4. Wash containers and closures. Drain and keep inverted until use.
5. Record types, sources, and quantities of all ingredients.
6. Sauté onions in oil over low heat until caramelized.
7. Add garlic. Cook until garlic is browned, but not burnt.
8. Add tomatoes, tomato paste, & lemon juice concentrate. Blend until smooth.
9. Add remaining ingredients.
10. Cook 30 minutes over medium heat.
11. Check product pH on a cooled homogenized sample. Record pH & temperature..... UL: pH 4.00 maximum at ambient temperature
    As necessary, adjust pH with lemon juice concentrate.
12. Heat mixture to at least 199°F..... LL: Cook temperature: 199°F minimum
    or use an equivalent temperature-time combination (table on right).
13. Fill containers at 170°F minimum. Cap.
14. Promptly invert containers. LL: Fill temperature: 170°F minimum
15. Measure temperature of last container filled..... LCL: Fill temperature: 165°F minimum
16. Hold inverted for 90 seconds (1:30 minutes) minimum..... LL: Hold time: 90 seconds minimum
    LL: Hold time: 82 seconds minimum
17. Cool containers in ambient air.
18. Measure product pH at ambient temperature. Record pH & temperature..... UL: pH 4.00 maximum at ambient temperature
    Blend entire contents of container to a uniform paste before pH measurement. UCL: pH 4.10 maximum at ambient temperature

Other process factors

Equivalent cook time-temperature combinations for pH ≤ 4.10

Temp (°F)	Time (h:mm:ss)	Temp (°F)	Time (h:mm:ss)	Temp (°F)	Time (h:mm:ss)
188	30:10	192	8:33	196	1:42
189	22:15	193	6:02	197	0:55
190	16:19	194	4:10	198	0:19
191	11:53	195	2:46	199	0:00

Test results

pH of low-acid ingredients (estimated).....5.5
Finished equilibrium pH.....3.96

Template revised 9 Feb 2023

Product identifiers & container characteristics

(inches-16ths)

Description	GTIN-12 (UPC)	SID	Diameter	Height
16 fl oz cylindrical glass jar with 70-450 CT metal closure (Ball 61000 or smaller)	0-12345-67890-5	2023-04-30/001	3-07	5-03
32 fl oz cylindrical glass jar with 70-450 CT metal closure (Ball 62000 or smaller)	0-12345-67891-2	2023-04-30/002	4-03	6-13

Scheduled process prepared by

David A French PhD CFS PCQI
Food process authority with over 20 years of experience
Member: Institute for Thermal Processing Specialists, https://www.ifps.org/
Member: International Association for Food Protection, https://www.foodprotection.org/
Aardvark Associates
591 Pine Grove Furnace Rd
Aspers PA 17304-9652
dave@processauthority.com
http://www.processauthority.com/
717-677-6781, 866-539-2771 toll free
Let us vark aard for you!