

# SHELF-STABLE ACIDIFIED CANNED FOODS

Tung Phan, Mariana de Oliveira Cortes, Amanda J. Kinchla  
UMass Amherst, Food Science Department.

This work was supported by the MA Department of Agriculture, Specialty Crop Block Grant



# Relevance/why we want to increase value

- Opportunity to add value/earn money
- Conducting initial pro develop to decrease the burden
- Picture
- Producing shelf-stable acidified canned foods can help to add value to produce and help to increase markets, extend the agricultural season and reduce waste. However, in order to successfully sell and distribute shelf stable products, such as salsas, sauces and/or acidified pickled products, processors must comply with the Code of Federal Regulations (21CFR114). This project identified developed 12 shelf-stable acidified canned food recipes and converted them into scale-appropriate product formulations, established the appropriate food safety controls, and all had product formulas reviewed by a regulatory approved Process Authority to issue a validated scheduled process for commercial use.

# Agenda



Overview of project

*Project goals and outputs*  
*Information on CFR 114*



Understanding the process of the project

*Converting to gram weight*  
*Testing*  
*Obtaining a scheduled process*



Creation of dissemination material

*Manual*  
*Availability*



Challenges faced in the project

*Challenges in Production*  
*Challenges with the FDA form*

# Project Goal and Expected Outcomes

**Goal:** The overall goal of this project is to **increase the production** of specialty crops through value-added production.

**Objective 1:** Identify **12** minimally processed value-added **products** that optimize the usage of specialty crops. **Develop 12 shelf-stable products** that optimize the use of specialty crops to **increase utilization, reduce waste and extend the agricultural season** of specialty crops that grow well in the Massachusetts climate zone.

**Objective 2:** **Validate the product** formulations to ensure that the proper process controls and regulatory compliance are regulatory **compliant to meet the proper food safety parameters** utilizing scale appropriate process controls oriented to small scale production.

**Objective 3:** **Extension Education and Evaluation;** Research outcomes identified from this project will be translated for use by stakeholders through a variety of extension activities.

# Introduction to the CFR

[Code of Federal Regulations]  
 [Title 21, Volume 2]  
 [Revised as of April 1, 2018]  
 [CITE: 21CFR114]

TITLE 21--FOOD AND DRUGS  
 CHAPTER I--FOOD AND DRUG ADMINISTRATION  
 DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION  
 PART 114 ACIDIFIED FOODS

**Subpart A--General Provisions**

Sec. 114.3 Definitions.

For the purposes of this part, the following definitions apply.

(a) *Acid foods* means foods that have a natural pH of 4.6 or below.

(b) *Acidified foods* means low-acid foods to which acid(s) or acid food(s) are added; these foods include, but are not limited to, beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any combination. They have a water activity (aw) greater than 0.85 and have a finished equilibrium pH of 4.6 or below. These foods may be called, or may purport to be, "pickles" or "pickled \_\_\_\_." Carbonated beverages, jams, jellies, preserves, acid foods (including such foods as standardized and nonstandardized food dressings and condiment sauces) that contain small amounts of low-acid food(s) and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, and foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of this part.

(c) *Lot* means the product produced during a period indicated by a specific code.

(d) *Low-acid foods* means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(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.

(f) *Shall* is used to state mandatory requirements.

(g) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(h) *Water activity* (aw) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

[44 FR 16235, Mar. 16, 1979, as amended at 61 FR 14245, Apr. 1, 1996]

Follow FDA | En Español

**SEARCH**

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

**CFR - Code of Federal Regulations Title 21**

FDA Home | Medical Devices | Databases

**⚠ The information on this page is current as of April 1 2018.**  
 For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).

New Search Help | More About 21CFR

TITLE 21--FOOD AND DRUGS  
 CHAPTER I--FOOD AND DRUG ADMINISTRATION  
 DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION  
 PART 114 ACIDIFIED FOODS

**Subpart A--General Provisions**  
 § 114.3 - Definitions.  
 § 114.5 - Current good manufacturing practice.  
 § 114.10 - Personnel.

**Subparts B-D [Reserved]**

**Subpart E--Production and Process Controls**  
 § 114.80 - Processes and controls.  
 § 114.83 - Establishing scheduled processes.  
 § 114.89 - Deviations from scheduled processes.  
 § 114.90 - Methodology.

**Subpart F--Records and Reports**  
 § 114.100 - Records.

**Authority:** 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.  
**Source:** 44 FR 16235, Mar. 16, 1979, unless otherwise noted.

Page Last Updated: 09/04/2018  
 Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.  
 Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

# Code of Federal Regulations Title 21 Section 114

- Acidified foods shall be so manufactured, processed, and packaged that a finished equilibrium **pH value of 4.6 or lower** is achieved within the time designated in the scheduled process and maintained in all finished foods.
- Manufacturing shall be in **accordance with the scheduled process**.
- 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 nonhealth significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user.
- The **scheduled process** shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.
- A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods (AF) or low-acid canned Foods (LACF) **shall register and file with FDA** information including the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method, and a list of foods so processed in each establishment (21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1))



# Steps to Create an Acidified Food

1. Obtain a Scheduled Process from a qualified personnel
2. Register the facility where the product is being produced with the FDA
3. Register the product with the FDA
4. The producer must attend a Better Process Control Schools for acidified foods

# Project Update

Formulas Created	Sizes (oz)
Apple Butter	8 & 16
Bread and Butter Pickles	8 & 16
Bruschetta in a Jar	16
Cranberry Sauce	8 & 16
Diced Tomatoes	16, 32, & 64
Dill Relish	8 & 16
Jalapeno Tomato Salsa	16
Pickled Asparagus	8 & 16
Pickled Beets	8 & 16
Pickled Carrots	8 & 16
Pickled Dill Beans	8, 16, & 32
Pickled Radishes	8 & 16
Pickled Turnips	8 & 16
Red Hot Sauce	8
Zucchini Pickles	8 & 16







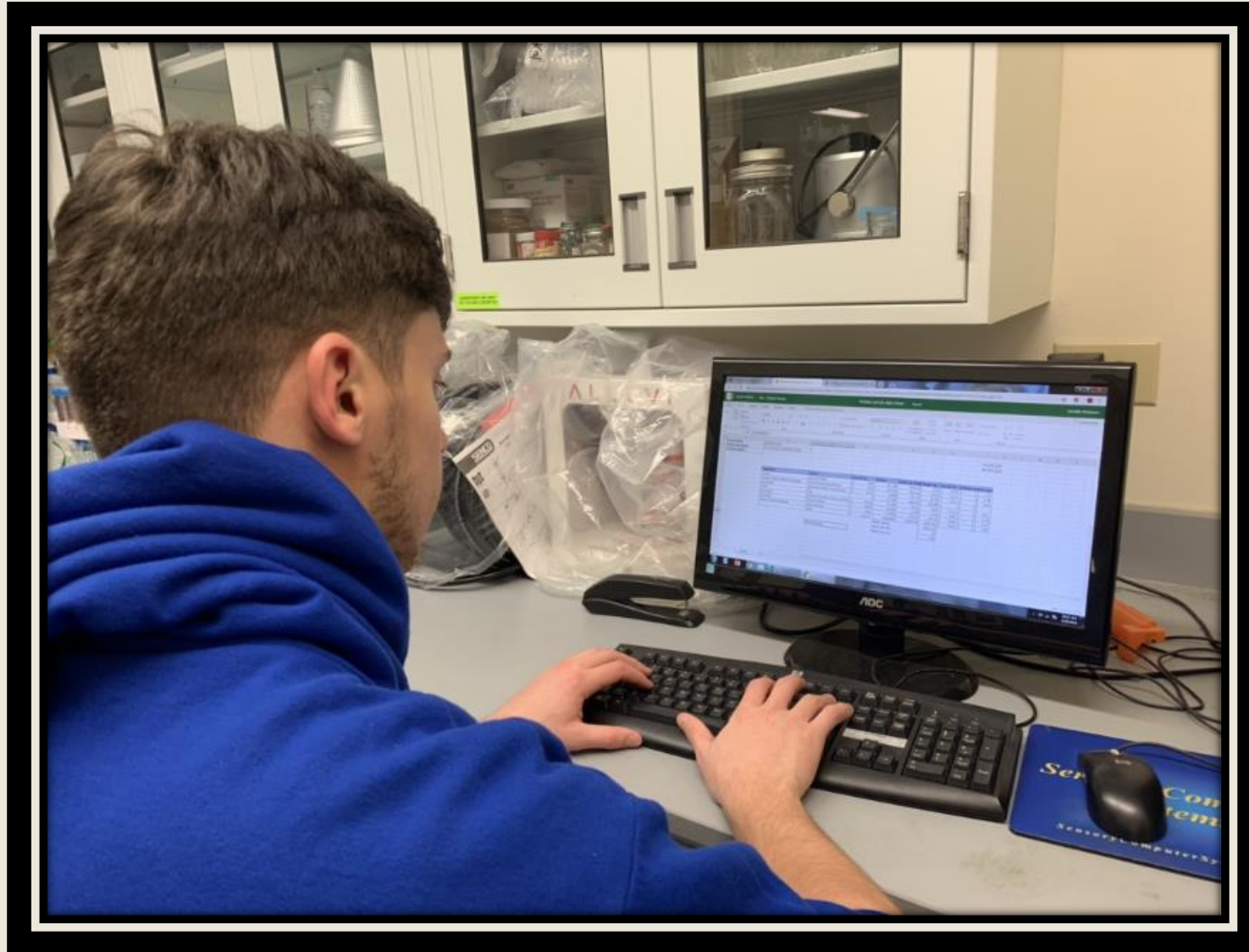
## Understanding the process of the project

*Converting to gram weight*

*Testing*

*Obtaining a scheduled process*

# Creating the Formula



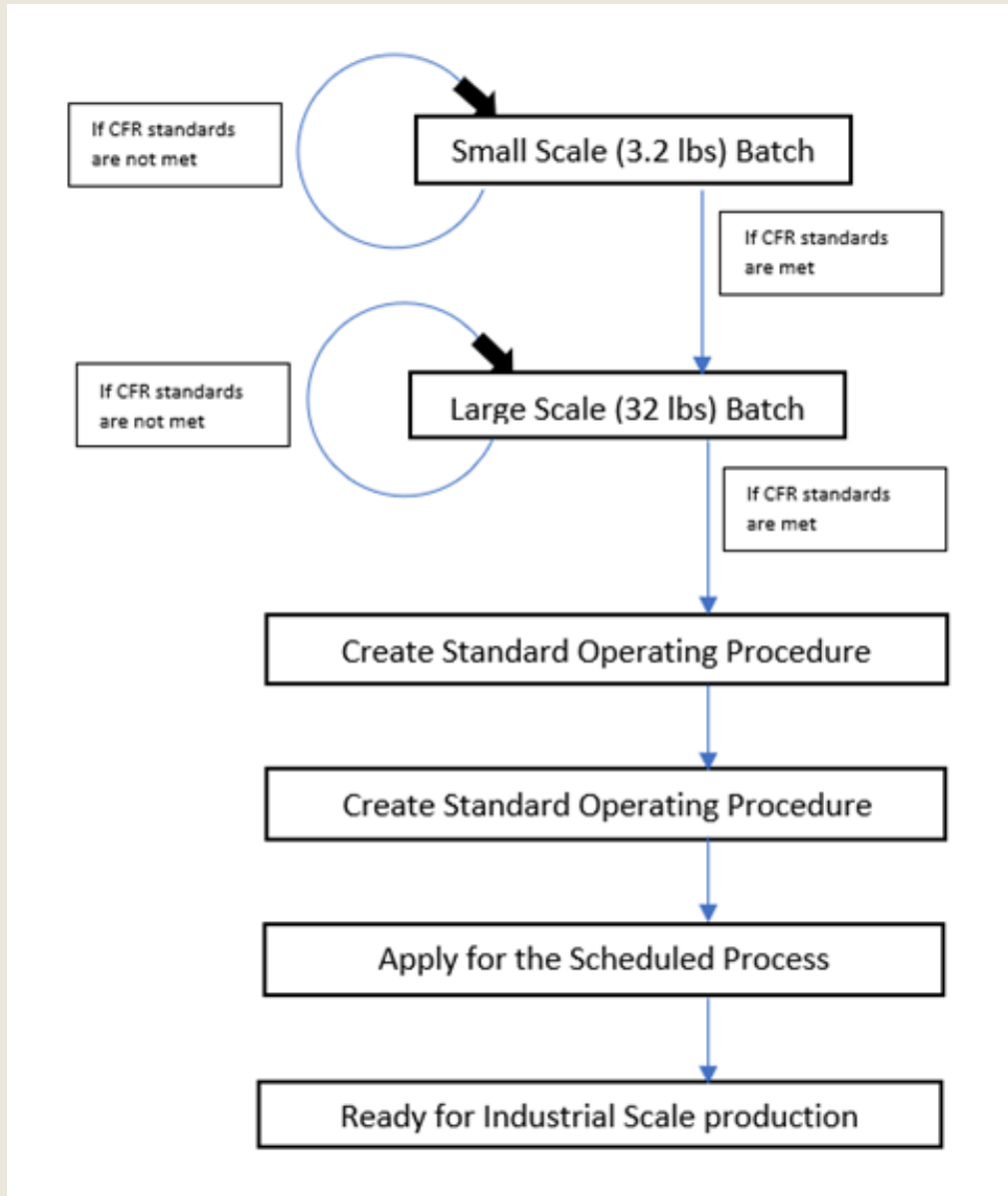
# Converting to Gram Weight



# Taking Measurements



# Procedure of Project



- After receiving scheduled process
  - Register with FDA

# Process of Project – Example Dilly Beans 08062016

Ingredients	Source	Ingredient Cost/lb	Percent	Weight (g)	Formula Cost/lb
Green Beans, fresh	Pilot Plant Market	\$ 1.99	37.91%	1065.00	\$ 0.75
Vinegar, white distilled 5% acidity	Pilot Plant Market	\$ 0.29	42.22%	1186.00	\$ 0.12
Water, tap water	Tap	\$ -	16.70%	469.00	\$ -
Salt, kosher	Pilot Plant Market	\$ 0.37	1.77%	49.70	\$ 0.01
Red Pepper, flakes dried	Pilot Plant Market	\$ 7.68	0.11%	3.03	\$ 0.01
Dill Sprigs, fresh	Pilot Plant Market	\$ 14.00	0.53%	14.86	\$ 0.07
Garlic, minced	Pilot Plant Market	\$ 29.72	0.76%	21.40	\$ 0.23
	<b>Total</b>		100.00%	2808.99	\$ 1.19

# Process of Project – Example Dilly Beans 08062016

8oz Jars	Triplicate 1	Triplicate 2	Triplicate 3
<b>pH brine:</b>	3.5	3.6	3.5
average:	3.5		
<b>pH solids:</b>	3.6	3.6	3.6
average:	3.6		
<b>pH equilibrated:</b>	3.5	3.6	3.6
average:	3.6		
<b>water activity:</b>	0.9712	0.9791	0.9729
average:	0.9744		


**Notes:** 13lb raw turnip pre slice  
refrigerated 3:30p

**Sensory:** nice sweet and sour flavor, more mild than beets  
nice crunch like pickles  
good mouth feel

- Replicate three times to show reproducibility
- Noting sensory aspects
- Ensuring that the CFR standards are met
  - pH below 4.6
  - Water Activity above 0.85

# Scheduled Process

- Contains information about
  - Sizes allowed to produce
  - Processing method
  - Any relevant safety measures

**1865 THE UNIVERSITY OF MAINE**

School of Food and Agriculture

December 28, 2017

Ryan Claudino  
100 Holdsworth Way  
Amherst, MA 01003-9282  
INVOICE # 3233

Dear Ryan:

Following are the results of the analyses performed on the samples sent to us for testing:

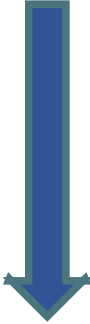
<u>SAMPLE</u>	<u>pH</u>	<u>WATER ACTIVITY @ 25 C</u>
1) Dill Relish	3.64	0.975
2) Dilly Beans	3.59	0.985

**Test Results:**  
Based on the pH results, you met our recommendations of an overall product pH level of 4.20 or below for water bath processed products. You must follow our processing method changes and critical factors below to ensure the microbiological safety of your products.

**Processing Methods:**  
You *must* follow Good Manufacturing Practices:  
<http://www.fda.gov/Food/GuidanceRegulation/CGMP/default.htm>.  
You must also become familiar with the new FDA Food Safety Modernization Act changes to foods safety regulations, which will impact most businesses:  
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/>. If you are processing food products, you must register your facility with the FDA:  
<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>.

Please make the following changes to your processing methods, which can ensure your product safety:

- Ensure proper sanitation methods. This website links to a sanitation fact sheet that may



## Test Results:

Based on the pH results, you met our recommendations of an overall product pH level of 4.20 or below for water bath processed products. You must follow our processing method changes and critical factors below to ensure the microbiological safety of your products.



# Scheduled Process

## Processing Methods & Critical Factors

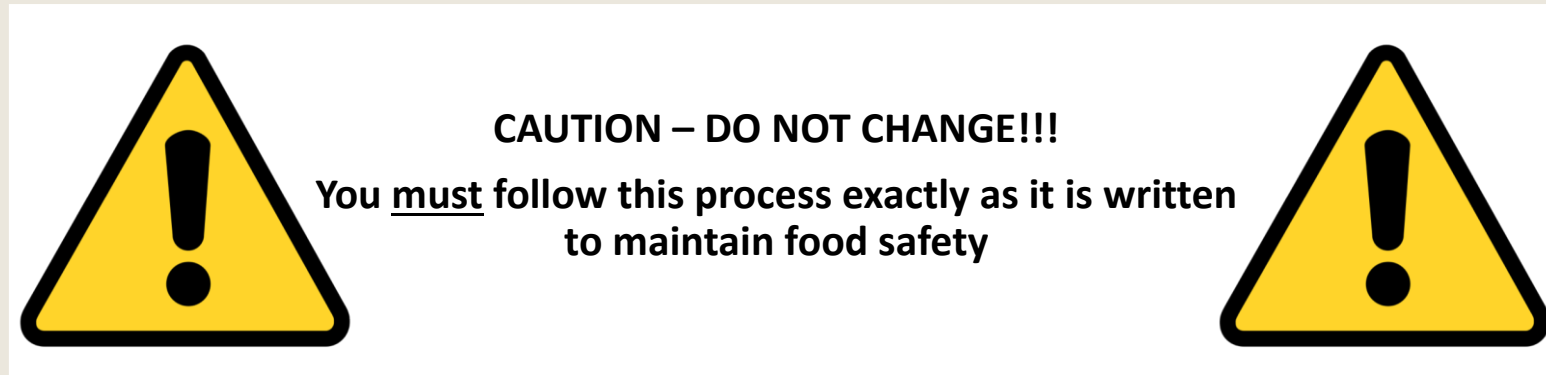
### **Dilly Beans:**

- We recommend a water bath process for this product.
- The green beans must be trimmed evenly to ensure no beans are protruding into the headspace.
- The product temperature must be monitored prior to water bath canning. The temperature must be at least 100 deg F or higher before water bath processing. You must check the center of the coldest container, which is usually the first container filled after all the containers from the entire batch have been filled.
- The products must be hot filled into sanitized jars and immediately water bath canned. A water bath canning time of **10-minutes** is adequate for **16-ounce** containers or less and also **32-ounce** containers.
- Be sure to have at least 1 inch of water covering your containers and you are timing your water bath processing time once the water reaches a rolling boil (212 deg F) with the

### **Dill Relish:**

- We recommend a water bath process for this product.
- Diced cucumbers and spices can be allowed to stand at room temperature for 2 hours or less or must be held under refrigerated temperatures.
- The product temperature must be monitored prior to water bath canning. The temperature must be at least 100 deg F or higher before water bath processing. You must check the center of the coldest container, which is usually the first container filled after all the containers from the entire batch have been filled.
- The products must be hot filled into sanitized jars and immediately water bath canned. A water bath canning time of **15-minutes** is adequate for **16-ounce** containers or less.
- Be sure to have at least 1 inch of water covering your containers and you are timing your water bath processing time once the water reaches a rolling boil (212 deg F) with the containers in the water bath.

# Disclaimer



Please note, you are accepting these recipes under the known expectation that you will not change any of the formulations as making any changes to these products can introduce a food safety hazard.

# Agenda



Overview of project

*Project goals and outputs*

*Information on CFR 114*



Understanding the process of the project

*Converting to gram weight*

*Testing*

*Obtaining a scheduled process*



Creation of dissemination material

*Manual*

*Availability*



Challenges faced in the project

*Challenges in Production*

*Challenges with the FDA form*

# Manual

- General set up
  - *Introduction to the project*
  - *The acidification method*
  - *Understanding the material*
  - *Section for each recipe*
- Each Recipe
  - *Cover Sheet*
  - *Standard Operating Procedure*
  - *Scheduled Process*
  - *FDA Registration Template*
  - *Any Notes about the Formula*

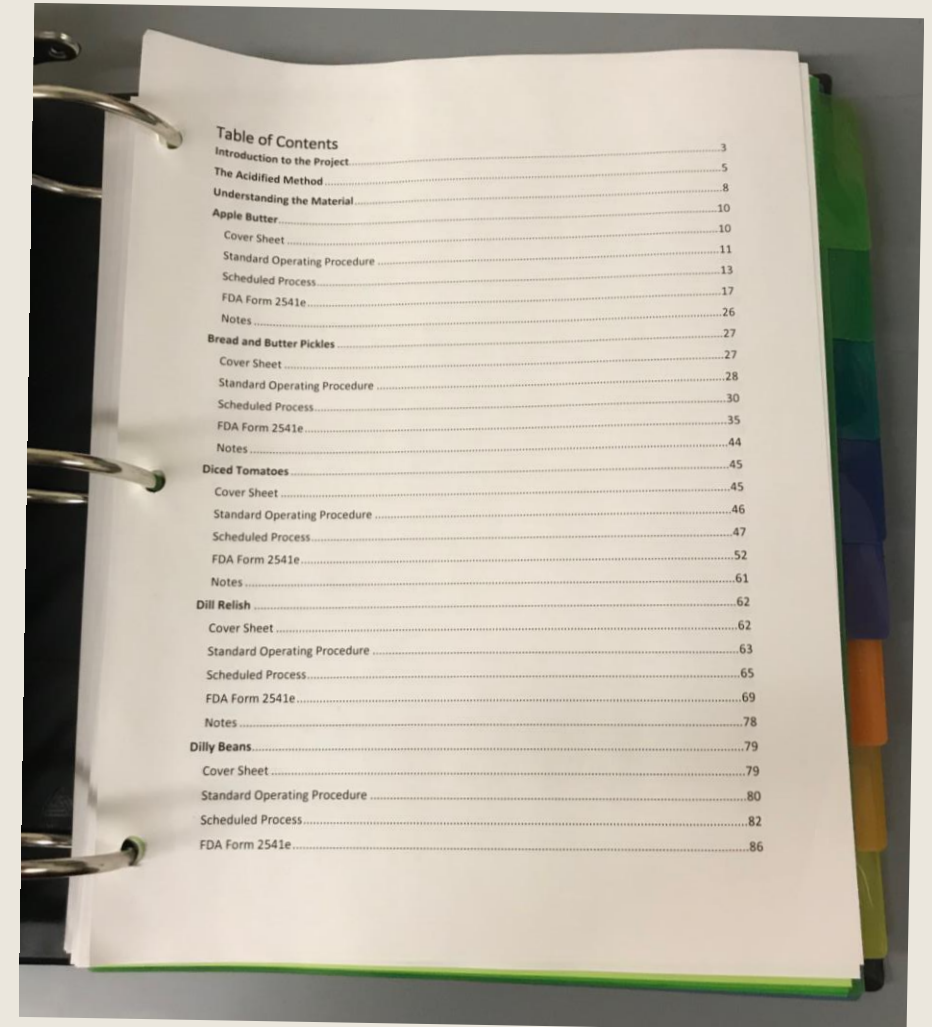


Table of Contents	3
Introduction to the Project	5
The Acidified Method	8
Understanding the Material	10
Apple Butter	10
Cover Sheet	11
Standard Operating Procedure	13
Scheduled Process	17
FDA Form 2541e	26
Notes	27
Bread and Butter Pickles	27
Cover Sheet	28
Standard Operating Procedure	30
Scheduled Process	35
FDA Form 2541e	44
Notes	45
Diced Tomatoes	45
Cover Sheet	46
Standard Operating Procedure	47
Scheduled Process	52
FDA Form 2541e	61
Notes	62
Dill Relish	62
Cover Sheet	63
Standard Operating Procedure	65
Scheduled Process	69
FDA Form 2541e	78
Notes	79
Dilly Beans	79
Cover Sheet	80
Standard Operating Procedure	82
Scheduled Process	86
FDA Form 2541e	

# Cover Sheet

<b>Category of Product</b>	<b>Dilly Beans</b> Acidified Food 08162018	<b>Name of Product</b>	
		<b>Identification Number</b>	
<b>Date and Place Developed</b>	<b>Date Developed:</b> 12/28/2017 100 Holdsworth Way Amherst, MA 01003-9282	<b>Critical Factors</b>	
<b>Possible Sizes</b>	<b>Sizes:</b> 32 oz, 16 oz, 8 oz	<b>Max pH &lt; 4.20</b> <b>Fill Temperature &gt; 100°F</b> <b>Water Bath Can Time: 10 min</b>	
		<b>Product pH: 3.59</b>	<b>Actual Product pH &amp; AW</b>
		<b>Product Water Activity: 0.985</b>	
<b>Formula by Weight</b>	<b>Ingredients</b> Green Beans White Vinegar Water Salt Dried Red Pepper Dill Sprigs Garlic Cloves <b>Total</b>	<b>By Weight (%)</b> 37.91% 42.22% 16.70% 01.77% 00.11% 00.53% 00.76% <b>100%</b>	<b>Skeleton Procedure</b>
		<b>Procedure</b> 1. Cut ends off green beans 2. Chop dill and garlic 3. Pack green beans into jars 4. Bring all ingredients except green beans to a boil (212°F) 5. Fill jars with brine at 180°F 6. Thermally process in water bath for 10 minutes at 212°F	
		<b>CAUTION – DO NOT CHANGE!!!</b> You <u>must</u> follow this process exactly as it is written to maintain food safety	<b>Warning Statement</b>



# Standard Operating Procedure

## Dilly Beans Standard Operating Procedure

Name of Product

CFR 21 Guidelines for Dilly Beans:  
- pH under 4.6  
- Water Activity above 0.8500

CFR Requirements

SOP

### Procedure

1. Gather all equipment and ingredients. Scale, knife, cutting board, large pot, ladle, jars, lids, closures, green beans, white vinegar, water, salt, dried red pepper, dill sprigs, and garlic cloves
2. Clean jars, lids, and closures in warm soapy water and lay them facedown on a paper towel to dry near the canning area
3. Measure all ingredients following the percentages

Green Beans, fresh	37.91%
White Vinegar, white 5% acidity	42.22%
Water, tap	16.70%
Salt, kosher	01.77%
Garlic, diced	00.76%
Dill Sprigs, fresh diced	00.53%
Dried Red Pepper, flakes dried	00.11%

Ingredients by Percentage

4. Cut the ends off the beans and make sure that there are none longer than the height of the jars
5. Fill jars with beans by placing them straight up in down in the jars, pack jars tightly
6. Chop the dill sprigs into small size
7. Chop the garlic cloves into small size
8. Place vinegar, water, red pepper, dill sprigs, and garlic into the steam kettle
9. Bring the mixture to a boil (should boil at 214°F)
10. Ladle hot mixture into the jars with the beans leaving 1.2 inch headspace, make sure the mixture maintains a constant temperature of at least 190°F
11. Tighten lid and closure on jar
12. Follow instructions below for thermal processing

Instructions for Processing Method

### Steam Kettle Thermal Processing

1. Fill the steam kettle with water to the halfway line, or to the point above where all the jars in the basket will eventually be placed.
2. Turn the pressure gauge up to bring the water to a rolling boil.
3. Once the jars have been filled with the product and have been wiped down and capped, they should all be placed in the metal basket and put in the hot water.
4. Place the metal basket into the hot water and cap the steam kettle and start a timer for 10 minutes
5. After 10 minutes, turn the pressure gauge off to lower the heat and remove the lid of the steam kettle, but allow the jars to sit in the hot water for another 5 minutes.
6. At the end of the 5 minutes, remove the metal basket and the hot jars from the steam kettle
7. Drain the steam kettle of the hot water, and wipe the steam kettle and the lid down to

# Scheduled Process

- Contains information about
  - Sizes allowed to produce
  - Processing method
  - Any relevant safety measures



December 28, 2017

Ryan Claudino  
100 Holdsworth Way  
Amherst, MA 01003-9282  
INVOICE # 3233

Dear Ryan:

Following are the results of the analyses performed on the samples sent to us for testing:

<u>SAMPLE</u>	<u>pH</u>	<u>WATER ACTIVITY @ 25 C</u>
1) Dill Relish	3.64	0.975
2) Dilly Beans	3.59	0.985

**Test Results:**

Based on the pH results, you met our recommendations of an overall product pH level of 4.20 or below for water bath processed products. You must follow our processing method changes and critical factors below to ensure the microbiological safety of your products.

**Processing Methods:**

You **must** follow Good Manufacturing Practices:

<http://www.fda.gov/Food/GuidanceRegulation/CGMP/default.htm>.

You must also become familiar with the new FDA Food Safety Modernization Act changes to foods safety regulations, which will impact most businesses:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/>. If you are processing food products, you must register your facility with the FDA:

<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>.

Please make the following changes to your processing methods, which can ensure your product safety:

- Ensure proper sanitation methods. This website links to a sanitation fact sheet that may be helpful to follow proper sanitation practices: <http://edis.ifas.ufl.edu/fs077>.
- Use food grade detergents, sanitizers and use the concentration recommended by the manufacturer for sanitizing food contact surfaces. If you decide to use bleach as a sanitizer, be sure to purchase “Germicidal Bleach” and do not exceed 200 ppm for food contact surfaces. The concentration needs to be checked with test strips.
- Any containers that come in contact with your ingredients/food product must be made of food-grade materials.
- The hot fill temperatures must be monitored with a calibrated thermometer and documented in your batch records.

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 Paper Submission of Form FDA 2541e (Food Process Filing for Acidified Method)"**

**FDA USE ONLY** Date Received by FDA: \_\_/\_\_/\_\_\_\_ (MM/DD/YYYY)

Food Canning Establishment (FCE) Number (Enter number assigned by FDA)

Submission Identifier (SID) (YYYY-MM-DD/SSS)

20\_\_-\_\_-\_\_/\_\_

**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.**

- Aquaculture Seafood (e.g., farming of aquatic organisms including fish, mollusks, crustaceans, etc.)
- Baby Food (infant/junior foods including infant formula)
- Bakery Products (canned brown bread, bakery glazes)

**Beans, Corn, or Peas**

- Beans or Peas - Dry or Mature Soaked
- Beans, Corn, Peas - Fresh Succulent

**Berry/Citrus/Core Fruit**

- Berry/Citrus/Core Fruit
- Berry/Citrus/Core Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

- Beverage Base
- Breakfast Foods (liquid form – ready-to-eat, such as porridge, gruel)
- Cheese (does not include soy cheese or imitation dairy)
- Cocoa
- Coffee/Teas (excluding herbal and botanical teas)
- Crustacean (e.g., crab, shrimp, lobster, etc.)
- Dairy (milk-based)
- Dietary Supplement and/or herbal and botanical teas
- Dressings/Condiments (e.g., salad dressing, chutney, salsa, pepper sauce, etc.)
- Engineered Seafood (e.g., shelf-stable imitation crab, surimi, etc.)
- Fishery (finfish)
- Fishery (other aquatic (e.g., alligator, cuttlefish, frog legs, squid, etc.))

**Fruit as a Vegetable**

- Fruit as a Vegetable (e.g., eggplant, pumpkin, etc.)
- Fruit as a Vegetable Juice or Drink (e.g., eggplant juice, pumpkin juice, etc.)

**A.1 (Food Product Group) (Continued)**

- Fungi (e.g., mushrooms, pleurotus, truffles, etc.)
- Gelatin, Pudding Filling for Pies, Pie Filling (liquid form ready-to-eat such as apple pie filling, etc.)
- Gravies/Sauces (spaghetti sauce, mushroom gravy)
- Imitation Dairy (includes soy-based products)

**Imitation/Pit/Mixed/Subtropical Fruit**

- Imitation/Pit/Mixed/Subtropical Fruit
- Imitation/Pit/Mixed/Subtropical Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

**Leafy/Stem Vegetables**

- Leafy/Stem Vegetable
- Leafy/Stem Vegetable as a Juice or Drink (e.g., spinach juice, etc.)

**Meal Replacement/Medical Foods (e.g., supplemental liquid nutrition, etc.)**

- Meat Products (Exotic Meat (emu, elk, etc.))
- Mixed Fishery (e.g., seafood salad, etc.)

**Mixed Vegetables**

- Mixed Vegetables (e.g., carrots and peas, etc.)
- Mixed Vegetables as a Juice or Drink (e.g., carrot and green bean juice, etc.)

**Multiple Food (one container with a separate compartment for each product item (e.g., lasagna dinner, chop suey dinner, etc.))**

- Noodle/Pasta
- Nut Spread and Nut Topping
- Other Vegetables
- Pet Food (e.g., dog/cat food, etc.)
- Rice, Wheat, Oat or Grain (liquid form – ready-to-eat such as grits)

**Root and Tuber Vegetables**

- Root/Tuber Vegetables (e.g., carrots, leeks, potatoes, etc.)
- Root/Tuber Vegetables as a Juice or Drink (e.g., carrot juice, etc.)

# FDA Form 2541e

- Extensive Government form
- Uses information from scheduled process
- Filed after receiving approval from FDA for facility registration





# FDA Form 2541e - Example Dilly Beans 08062016

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

**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:

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

2. Volume: 8.0 (Select one)

Fluid Ounces     Gallons     Liters     Milliliters     Not Applicable

**E. Processing Method: Acidification:**

1. What is the natural pH of the low-acid ingredient(s) before acidification? 6.20

2. What is the finished equilibrium pH of the product after acidification? 3.61

3. What is the maximum time it takes for the product to achieve the finished equilibrium pH of 4.60 or lower? 27

Minutes     Hours

4. Method of Acidification (Select One)

Addition of Acid Foods     Blanch     Direct Batch     Direct In Container

Immersion

## E. Processing Method: Acidification: (Continued)

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

- Acetic Acid     Acid Food(s)     Apple Product(s) (other than vinegar)
- Citric Acid     Fruit Juice(s)     Fumaric Acid     Gluconic Acid
- Hydrochloric Acid     Lactic Acid     Malic Acid     Phosphoric Acid

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

Microbial Preservative	Concentration (%)
<input type="checkbox"/> Alcohol	---
<input type="checkbox"/> Ascorbic Acid	---
<input type="checkbox"/> Benzoic Acid	---
<input type="checkbox"/> Butylated Hydroxyanisole	---
<input type="checkbox"/> Butylated Hydroxytoluene	---
<input type="checkbox"/> Calcium Chloride	---
<input type="checkbox"/> Calcium Propionate	---
<input type="checkbox"/> Calcium Sorbate	---
<input type="checkbox"/> Erythorbic Acid	---
<input type="checkbox"/> Ethanol	---
<input type="checkbox"/> Gucono Delta Lactone	---
<input type="checkbox"/> Polysorbate	---
<input type="checkbox"/> Potassium Benzoate	---
<input type="checkbox"/> Potassium Bisulphate	---
<input type="checkbox"/> Potassium Metabisulphite	---
<input type="checkbox"/> Potassium Propionate	---
<input type="checkbox"/> Potassium Sorbate	---
<input type="checkbox"/> Potassium Sulphite	---
<input type="checkbox"/> Propylparaben	---
<input checked="" type="checkbox"/> Salt	<u>0.21</u>
<input type="checkbox"/> Sodium Benzoate	---
<input type="checkbox"/> Sodium Bisulphate	---
<input type="checkbox"/> Sodium Chloride	---
<input type="checkbox"/> Sodium Erythorbate	---
<input type="checkbox"/> Sodium Metabisulphite	---
<input type="checkbox"/> Sodium Polyphosphate	---
<input type="checkbox"/> Sodium Propionate	---



# Dissemination

## Form to Receive Approval from Amanda Kinchla for Acidified Shelf Stable Foods

By filling out this form it is understood that you recognize the seriousness of producing these products as they are written. Not doing so will jeopardize the safety of the food and its consumers. Deviation from the formulas makes you (the participant) liable for any external cause. Sharing this information with any third party is prohibited.

Name (first and last)\*

Email\*

Phone Number\*

### Approval Information

To gain approval you will need to provide FCE number for the kitchen you are planning to produce at, and the approved processors name, date and location that they completed the better process control schools for acidified food.

FCE (food canning establishment number)\*

Location of Processing Facility

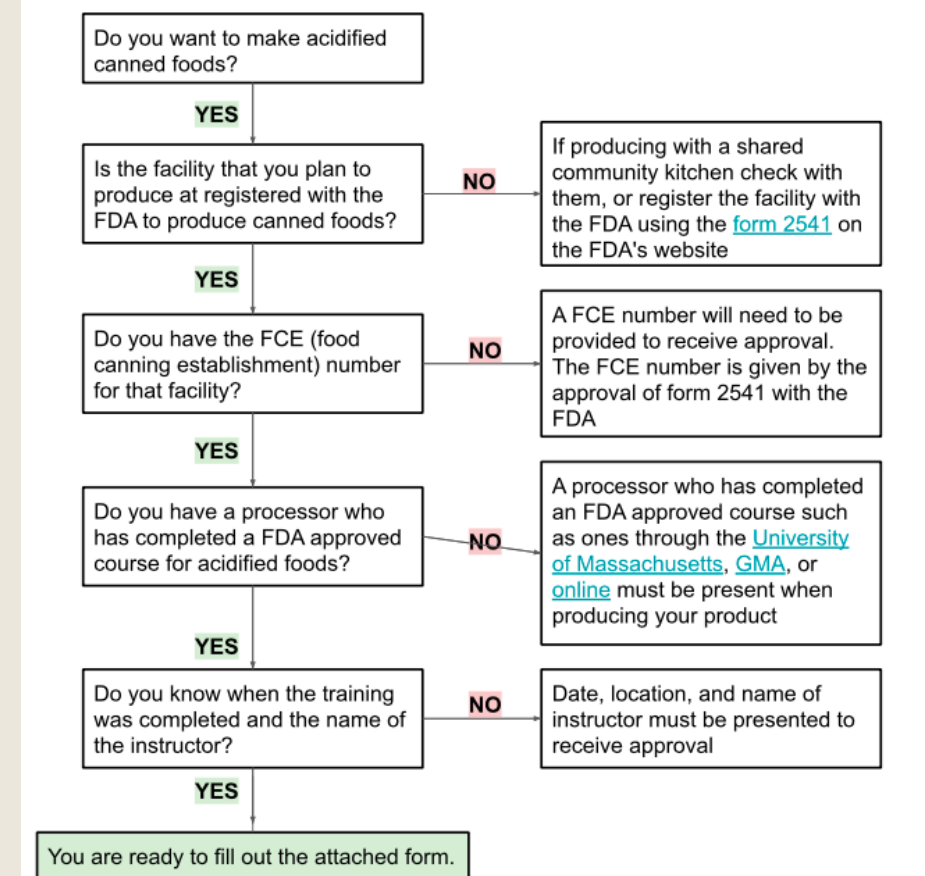
Name of processor who attended better process control schools\*

Date of process control school\*  
MM/DD/2019

Location of process control school\*

Your response has been recorded  
Submit another response

\*Require answers



\*Upon receiving approval you **must** register each product you plan to make with the FDA, unless the products have already been approved for production at that facility. Instructions and templates to follow for FDA form 2541e will be given upon approval.

# Thank you

- MA Department of Agriculture, Specialty Crop Block Grant
- UMASS Food Science Department
- UMASS Experimentation Station
- UMASS Honors College Program
- Franklin County Community Development Center, Food Processing Center
- Commonwealth Kitchen



Questions and Comments Please!