



Black Bean and Corn Salsa

Thermal Processing & Process Filing Lab

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**U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition**

Low Acid & Acidified Canned Foods - LACF Online

FCE: 03703; SID: 2013-06-18/002

DRAFT PROCESS FILING

DEPARTMENT OF FOOD SCIENCE, NORTH CAROLINA STATE UNIVERSITY; RALEIGH, NC UNITED STATES

PRODUCT INFORMATION

Submitter: **Fletcher Arritt**

TOMATO SALSA WITH BLACK BEANS AND CORN (BLACK BEANS, CORN, DICED PEPPERS AND ONIONS, SPICES IN A TOMATO BASE)

(raw pH) 5.8

(processing method) ACIDIFIED

(process source)

Source	Attached Document
02/10/2012 -- LETTER NC State University	Process Source -- salsa_process_authority_letter.doc
04/01/2010 -- PUBLICATION Pflug	Process Source -- PflugReference.pdf

ACIDIFIED OR CONTROLLED FACTORS

(maximum equilibrium pH) 4.3

(method of acidification) BATCH

(acidifying agent) TOMATO PRODUCTS

(thermal processing method) STEAM JACKETED KETTLE

CRITICAL FACTORS

(other critical factor) particle size 1/2

SCHEDULED PROCESS

(container description) round

GLASS OR CERAMIC

1/ DIAMETER: 307 HEIGHT: 404 VOLUME: 016 FL OZ

PROCESS #	<u>1</u>
Cont Num	1
Start Temp (MIN IT) °F	200
Process Time (PROCESS TIME) min	5
Process Temp °F	200
Least Sterilizing Value Death Rate(z): 16.0°F; Ref.: 200.0°F	5

FILING COMMENTS

Product (with a maximum dimension of ½ inch for solids) is heated to achieve 200°F or above for a minimum of 5 minutes in a cooking vessel. Product is hot filled into all containers at a minimum temperature of 160°F. A new cap is immediately closed on each container and the containers are inverted.

Thermal Processing & Process Filing - Salsa 1

The initial heat process destroys microorganisms of public health significance and those of non-health significance capable of reproducing in the food at normal conditions of distribution and storage. The filling and inversion is designed to sanitize the jars, lid and headspace by eliminating microorganisms of non-health significance that can be carried in the air or may be on the container wall or lid. These parameters are monitored with a calibrated thermometer and records are kept for each production batch, assuring that thermal lethality has been achieved for each product and container.

February 10, 2012
 Yum Yum Salsa Co.
 123 Main St.
 Anytown, NC

To whom it may concern:

These results are for products which are composed of identical amounts of identical ingredients processed in exactly the same manner as the samples submitted. The critical control factor for these foods is a final pH of 4.3 or below.

Product:	Date submitted	pH final product	pH predominant acids	Classification / Processing Method
Tomato salsa with black beans & corn (black beans, corn, diced peppers and onions, spices in a tomato base)	1/2012	4.2	4.1	Acidified Food
Process Recommendation for Acidified Food				
Raw pH (before acidification)	5.8 onions, peppers, corn, black beans			
Maximum Equilibrium pH:	4.3			
Method of Acidification:	Batch			
Acidifying Agent:	Tomatoes (fresh and canned)			
Pasteurization Method:	Steam Jacketed Kettle Start Temp (Min IT) = 200°F, Process Time = 5 min., Process Temp = 200°F Other F Value: z-value= 16°F, Ref = 200°F, Least Sterilizing Value (LSV) = 5 min.			
<p>You must follow the process instructions below and cut and paste the next paragraph into the comments section of your scheduled process filing. You must also attach this letter and research paper to the on-line filing system with FDA as the Process Establishment Source. In order to limit the potential growth of gas forming organisms and mold once opened, we recommend the optional use of preservatives (sodium benzoate and potassium sorbate).</p> <p>Product (with a maximum dimension of ½ inch for solids) is heated to achieve 200°F or above for a minimum of 5 minutes in a cooking vessel. Product is hot filled into all containers at a minimum temperature of 160°F. A new cap is immediately closed on each container and the containers are inverted. The initial heat process destroys microorganisms of public health significance and those of non-health significance capable of reproducing in the food at normal conditions of distribution and storage. The filling and inversion is designed to sanitize the jars, lid and headspace by eliminating microorganisms of non-health significance that can be carried in the air or may be on the container wall or lid. These parameters are monitored with a calibrated thermometer and records are kept for each production batch, assuring that thermal lethality has been achieved for each product and container.</p>				

There are two classifications of foods that are preserved with added acid ingredients. The distinction between these two categories of foods is important.

Acid Foods: Foods, such as tomatoes, which have a natural pH of 4.6 or below are considered to be acid foods. Some foods which contain small amounts of low-acid foods in a predominantly acid food, such as herbal vinegars, are also in this category. If the finished equilibrium pH does not vary significantly from the pH of the predominant acid foods, the food is considered to be an acid food.

Acidified foods are low-acid foods to which acids or acid foods have been added to produce a final equilibrium pH of 4.6 or below. In the absence of information to the contrary, foods preserved with acid are considered by FDA to be acidified foods. Acidified foods have additional requirements. The manufacturer **must register and file a scheduled process** established by a competent process authority and the operation must be under the **supervision of an individual who has successfully completed an FDA approved course on processing acidified foods. See instructions on page 3.**

Where do I go from here? Attached you will find further information on processing, regulatory agencies, required records, labeling and additional on-line resources. If we can be of assistance, please contact us.

Sincerely,



Fletcher Arritt, Ph.D.
 Professor

Processing:

Foods preserved with acid must have a pH of 4.6 or below to be considered safe. The pH value is a measure of the acidity. Lower pH values indicate higher levels of acidity. Most foods which have a pH above 4.6 must be commercially canned, refrigerated or frozen. Because all products and processes exhibit normal variation, the pH must be monitored using a pH meter. For products with a pH below 4.0, pH test strips may be used for monitoring purposes. The proper acidity will prevent the growth of spores of deadly botulism bacteria. However, other vegetative bacteria, yeasts and molds must be destroyed by heating the product to 200°F and holding for 5 minutes and filling and capping at 160°F or higher. Inverting the hot jars will destroy microorganisms on the lid.

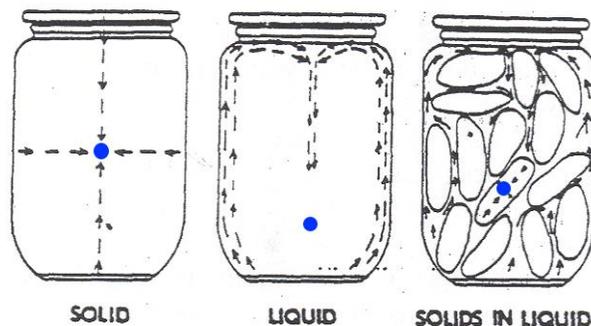
When **oil** is used in the formulation, low-acid foods must be properly acidified to a pH of 4.6 or below **prior** to the addition of oil. This will prevent the oil from coating the food and producing a barrier to acidification.

Usually, **preservatives** such as potassium sorbate and sodium benzoate are added to inhibit the growth of yeasts and molds once the product is opened. **Preservatives will not take the place of proper acidification.** Products which do not receive a final heat treatment, such as salad dressings, require preservatives to prevent mold growth, or gas production from yeast growth.

In addition, there is the requirement to conduct the operation with appropriate sanitary practices. Specifically, there should be a planned and systematic procedure for quality control. Responsibility for assuring compliance must be clearly assigned to competent supervisory personnel. This means the supervisor should have a background of education or experience necessary to produce clean and safe food.

Determination of the cold spot in a container with calibrated thermometer:

With solid or semi-solid foods, the slowest heating point in the container, or cold spot, is the geometric center. In more liquid food, there are convection currents that distribute the heat. The cold spot in containers with convection heating is about ¾ inch from the bottom in the center of the container. For foods with large pieces suspended in liquids, such as whole pickles, the coldest point is typically the center of a large piece located below the center of the container. See figures below. Cold spot for measurement is indicated by the dot.



Instructions for Facility Registration and Processing Filing for Acidified Foods

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/EstablishmentRegistrationThermalProcessFiling/Instructions/ucm125590.htm>

Form 2541 - Facility Registration - <http://vm.cfsan.fda.gov/~acrobat/frm2541.pdf>

Form 2541a - Process Filing for Acidified Foods -

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM076784.pdf>

Regulatory Considerations:

These products are regulated by the FDA and the North Carolina Department of Agriculture and Consumer Services, Food and Drug Protection Division, 919-733-7366. Contact them for the appropriate regulatory guidance concerning registration, GMP's (Good Manufacturing Practices) and labeling. Show them a copy of this letter. They can provide copies of:

1. 21 CFR 114 Acidified Foods (the rules for manufacturing acidified foods)
2. 21 CFR 110 Good Manufacturing Practices (the rules you must follow to manufacture any food)

If you are producing your product in a different state, you will need to contact the equivalent agencies in your state.

Facility Registration:

The [Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#) (the Bioterrorism Act) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA. There is no fee and registration can be completed on-line at: <http://www.cfsan.fda.gov/~furls/ovffreg.html>

Records:

Records are extremely important and must be maintained to reflect the following:

1. Packaging material, ingredients, and other materials such as cleaning compounds must be examined for suitability and a record of origin and lot numbers maintained.
2. **Records of pH testing and the thermal process for each batch** must reflect that critical control factors have been achieved.
3. Lot numbers and number of units manufactured in each batch,
4. Records that container closures have been inspected to ensure seal integrity, and
5. Records of initial distribution of the product.

In addition, the processor must have a written recall procedure in place. All records must be clearly traceable to lot numbers of ingredients and finished products. We recommend you attend a course on HACCP and have a proper HACCP plan in place.

Labeling:

If you are in North Carolina, show a copy of your label to NCDA &CS (919-733-7366) to be sure it conforms to their extensive labeling rules. Generally, you must include the following on your label:

1. Name of the product in **BOLD** print
2. Name, address and zip code of manufacturer
3. Quantity of fill or net content's statement (in lower 1/3 of the label)
4. Listing of ingredients in descending order of predominance by weight`
5. Nutrition facts (often not required if manufacturing less than 10,000 units per year)
6. Allergens must be clearly stated on containers.

You can copy the format and type size of a national brand of your product sold in the grocery store. Examine several labels and choose one from a similar size container. Nutrition facts will require analysis of your specific product. The FDA has an excellent Food Labeling Guide available at:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm>

Goodness Grows in North Carolina:

If you are interested in marketing information and services available through the North Carolina Department of Agriculture and Consumer Services, contact the Goodness Grows in North Carolina program at 919-733-7912. The Goodness Grows in North Carolina program is specifically designed to identify top-quality products that are either grown or processed in North Carolina. The major emphasis of the program is to heighten awareness and availability of North Carolina products to the consumer, retail and food service industries.

Additional Information:

The following site has a list of publications for developing a food business:

http://ncsu.edu/foodscience/extension_program/publications.html

MICROBIOLOGY and ENGINEERING

of

STERILIZATION PROCESSES

Fourteenth Edition

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University of Minnesota

Published by
Environmental Sterilization Laboratory
Otterbein, IN 47970

State University Department of Food Science

Presents this certificate of completion of the
Acidified Foods Course held October 10-12, 2011 to

**Acidified Foods Course
Better Process Control School
Certificate of Completion**

Joe Yum



Jane Croissant

Jane Croissant, Ph.D
Extension Specialist

10/22/2011

Date

Jack Chutney

Jack Chutney, Ph.D
Extension Specialist

10/23/11

Date

Yum Yum Salsa Co. Heat Temperature Log

Product: Black Bean & Corn Salsa

Container Size: 16 oz

<u>Date</u>	<u>Batch Number</u>	<u>Temp. (F)</u>	<u>Start Time</u>	<u>End Time</u>	<u>End Temp. (F)</u>	<u>Initials</u>
5/4/2013	LB3351322	201.7	1:22:10	1:27:32	200.1	NLA
5/4/2013	LB3351323	200.4	1:23:05	1:29:14	200.3	NLA
5/4/2013	LB3351324	200.3	1:24:15	1:30:35	200.1	NLA
5/10/2013	LB3351335	200.6	1:35:35	1:41:05	200.4	NLA
5/10/2013	LB3351336	201.1	1:39:19	1:42:10	200.1	RKC
5/14/2013	LB3351355	200.4	1:55:13	2:01:41	200.2	RKC
5/14/2013	LB3351356	200.6	1:56:40	2:02:52	200.1	RKC
5/14/2013	LB3351400	201.1	2:00:34	2:06:36	200.6	NLA
5/19/2013	LB3351410	201.3	2:10:06	2:16:01	200.7	NLA
5/19/2013	LB3351411	200.5	2:11:52	2:17:33	200.1	NLA
5/19/2013	LB3351412	200.3	2:12:58	2:18:40	198.2	NLA
5/21/2013	LB3351426	200.9	2:26:02	2:32:19	200.7	ABZ
5/21/2013	LB3351427	200.4	2:27:20	2:33:15	200.1	ABZ
5/21/2013	LB3351428	201.3	2:28:36	2:34:28	200.8	ABZ
5/23/2014	LB3351441	200.7	2:41:12	2:47:52	200.3	SAS
5/23/2014	LB3351442	200.4	2:42:19	2:48:20	200.1	SAS

Yum Yum Salsa Co. Fill Temperature Log

Product: Black Bean & Corn Salsa

Container Size: 16 oz

<u>Date</u>	<u>Batch Number</u>	<u>Start Temp. (F)</u>	<u>Start Time</u>	<u>End Time</u>	<u>End Temp. (F)</u>	<u>Initials</u>
5/4/2013	LB3351322	182.7	1:43:40	1:48:11	172.4	NLA
5/4/2013	LB3351323	185.3	1:35:53	1:52:17	170.3	NLA
5/4/2013	LB3351324	180.4	1:37:19	1:54:12	169.2	NLA
5/10/2013	LB3351335	184.3	1:46:37	2:03:54	169.7	NLA
5/10/2013	LB3351336	175.7	1:49:14	2:07:11	151.3	RKC
5/14/2013	LB3351355	185.3	2:06:57	2:21:34	172.4	RKC
5/14/2013	LB3351356	175.4	2:08:42	2:24:19	171.3	RKC
5/14/2013	LB3351400	182.3	2:11:33	2:30:53	169.2	NLA
5/19/2013	LB3351410	180.5	2:22:40	2:39:19	168.7	NLA
5/19/2013	LB3351411	180.9	2:24:19	2:42:27	171.3	NLA
5/19/2013	LB3351412	176	2:35:52	2:50:24	168.7	NLA
5/21/2013	LB3351426	174.9	2:39:47	2:54:16	172.3	ABZ
5/21/2013	LB3351427	180.7	2:50:24	2:56:13	170.2	ABZ
5/21/2013	LB3351428	179.3	2:42:11	2:58:37	168.2	ABZ
5/23/2014	LB3351441	182.1	2:53:36	3:12:41	171.2	SAS
5/23/2014	LB3351442	180.7	2:56:11	3:15:09	169.3	SAS

Yum Yum Salsa Co.

Product: Black Bean & Corn Salsa

Container Size: 16 oz

Product pH spec: 4.0 - 4.3

<u>Date</u>	<u>Batch Number</u>	<u>pH</u>	<u>Initials</u>	<u>Comments</u>
5/4/2013	LB3351322	4.15	ABT	
5/4/2013	LB3351323	4.22	ABT	
5/4/2013	LB3351324	4.18	ABT	
5/10/2013	LB3351335	4.24	TKR	
5/10/2013	LB3351336	4.28	TKR	
5/14/2013	LB3351355	4.29	SAS	
5/14/2013	LB3351356	4.28	SAS	
5/14/2013	LB3351400	4.28	SAS	
5/19/2013	LB3351410	4.2	JKL	
5/19/2013	LB3351411	4.15	JKL	
5/19/2013	LB3351412	4.22	JKL	
5/21/2013	LB3351426	4.27	ABT	
5/21/2013	LB3351427	4.37	ABT	
5/21/2013	LB3351428	4.39	ABT	
5/23/2014	LB3351441	4.18	JKL	
5/23/2014	LB3351442	4.2	JKL	

Records reviewed by: _____

Date: _____

Yum Yum Salsa Co.
thermometer calibration log

<u>Date</u>	<u>Time</u>	<u>Thermometer ID</u>	<u>Temp</u>	<u>Initials</u>
5/4/2013	7:45	B	212	TFK
5/4/2013	7:45	A	212	TFK
5/10/2013	8:30	A	212	BAS
5/10/2013	9:00	B	212	BAS
5/14/2013	7:50	B	212	TFK
5/14/2013	8:15	A	212	TFK
5/19/2013	7:53	A	212	BAS
5/21/2013	8:37	A	212	BAS
5/23/2013	8:15	A	212	TFK

Records reviewed by: _____

Date: _____