FDA GUIDELINES ON ACIDIFIED FOODS

Impact on Small Food Processors

Arthur A. Teixeira and Samuel N. Aso
Agricultural and Biological Engineering Department
Institute of Food and Agricultural Sciences
University of Florida

What is Happening?

Food Safety Modernization Act

(FSMA)

Strengthening of FDA Regulations

(21 CFR Parts 108 and114)

“Acidified Foods Guidance Document”

Why is it Happening?

- Recent outbreaks involving fresh apple and orange juice, along with minimally processed and low-moisture foods have placed spotlight on the whole industry

- Discovery of acid-tolerant pathogens (E. coli 0157 H:7, Listeria monocytogenes, Salmonella enterica)

- Significant recalls in low-acid, shelf-stable products resulting from plant operations mistakes.

FDA Draft Guidance for Industry: Acidified Foods

What does it mean that your product is categorized as an “acidified food”, and is covered by 21 CFR part 114?

21 CFR Parts 108 and114
Eleven Compliance Activities

- *Plant registration.*
- *Process filing.*
- *Personnel training*
- *Equipment and procedures.*
- *Product preparation.*
- *Establishing scheduled processes.*
- *Processes and controls.*
- *Process deviations.*
- *Filling and sealing operations.*
- *Record keeping and storage.*
- *Recall planning.*

How is it happening?

- FDA has stepped up in-depth scrutiny of all new process filings
- FDA is assisted by state public health agencies, who are sending inspectors to visit food processing establishments within their state.
- Example: Florida Department of Agriculture & Consumer Services (FDACS)
  - Supermarkets
  - Retail Food Establishments
  - Food Manufacturing and Storage Facilities
  - Small Cottage Industries

What do they look for?

•Investigators identify and visit food processing establishments manufacturing shelf-stable foods and beverages, and ask to see copies of their process filings submitted to FDA.

•If the processor has submitted no filings the investigator will ask to see a letter from a process authority.

What is a “Process Authority”?

“An individual or group that has demonstrated expertise in the development, implementation, and evaluation of thermal and/or aseptic processes for shelf-stable foods”.*

*Institute for Thermal Processing Specialists (IFTPS)

What is an “Acidified Food”?

Presentation by

Dr. Samuel Aso (Sammy)

(New Ph.D. Graduate from University of Florida)

What is an “Acid Food” ?

- These are foods with natural pH equal to or less than 4.6 **[21 CFR 114.3(a)]**

Examples: Canned fruits and fruit juices, Ketchup, Vinegar.

What is a “Low Acid Food” ?

- This is a food with water activity greater than 0.85 and a finished equilibrium pH greater than 4.6
- **Examples: Canned meats and vegetables; Canned prepared foods ready to eat; Tomato products with pH greater than 4.7**
- **Note: Tomatoes/Tomato products with pH less than 4.7 are not classified as low acid foods [21 CFR 113.3(n)]**

What is an “Acidified Food”?

This is a Low-acid food to which acid ingredients (acids / foods) are added resulting with water activity greater than 0.85 and a finished equilibrium product pH equal to or less than 4.6.

[21 CFR 114.3(b)]

Examples: Pickled vegetables; BBQ sauces; Blended juice drinks; etc.

What might be an “Acidified Food”?

Food containing both acid food(s) and low-acid food(s) may or may not be considered an acidified food.

Acid Foods Containing "Small Amount" of Low-acid Foods.

Weight of low-acid ingredients must be less than 10% of weight of low-acid plus acid ingredients.

Low-acid < 0.10 (Low-acid + Acid)

AND

No significant shift in pH between predominant acid ingredients and finished product equilibrium.

Significant pH Shift ?

- What is the Equilibrium pH of the Predominant Acid Ingredients ?
- What is the Equilibrium pH of the Finished Product ?

Significant pH Shift ?

Determination of Equilibrium pH of the Predominant Acid Ingredients

A. Prepare the predominant acid ingredient by combining all acid ingredients into a batch

B. Add all water required for the formulation of the product to the batch (use your production water)

C. Determine the equilibrium pH of the mixture in the batch

Significant pH Shift ?

Determination of Equilibrium pH of the Finished Product

D. Combine the mixture of predominant acid ingredients and water with all low acid ingredients and oils required for the formulation of the product into a batch

E. Determine the equilibrium pH of the resulting mixture in the batch

Significant pH Shift ?

Determination of Shift in pH
Shift in pH = Equilibrium pH of finished product minus Equilibrium pH of predominant acid ingredients

What might be an “Acidified Food”?

Having Determined:

- **Equilibrium pH of predominant acid ingredients**
- **Shift in pH**
- **Low-acid < 0.10 (Low-acid + Acid)**

UNIVERSITY OF FLORIDA

Classification of Acid Foods Containing "Small Amount" of Low-acid Foods.

Question	Answer	Shift in pH and its Significance	Product Classification
What is the equilibrium pH of predominant acid ingredients ?	> 4.2	Any shift in pH is significant	Acidified
	4.2	≤ 0.2 (Insignificant)	Acid
		> 0.2 (Significant)	Acidified
	≥ 3.8 and < 4.2	≤ 0.3 (Insignificant)	Acid
		> 0.3 (Significant)	Acidified
	< 3.8	≤ 0.4 (Insignificant)	Acid
		> 0.4 (Significant)	Acidified

Thank You

What about cold-fill?

Excerpt from Typical FDA Letter

"Therefore, we request that filers of cold fill processes provide scientific support (challenge study) for their cold fill process which establishes that if pathogens* are present, they are destroyed and if so, how long it takes for a five-log reduction of such microorganisms, and at what temperature the product must be held for this reduction to take place. "

*The pathogens customarily examined include the acid-tolerant E. Coli Ol57:H7, Salmonella, and Listeria Monocytogenes.

Journal of Food Protection. Vol. 70, No. I l, 2007, Pages 2638-2641

Research Note

Determination of 5-Log Reduction Times for Food Pathogens in Acidified Cucumbers during Storage at 10 and 25 C

FRED BREIDT, JR.,* JANET HAYES, and ROGER F, McFEETERS

USDA/ARS and North Carolina Agricultural Research Service.
North Carolina State University, Raleigh, NC 27695-7624, USA

- MS 07-100: Received 2l February 2007/Accepted 13 Junce2007

Determination of 5-Log Reduction Times for Food Pathogens inAcidified Cucumbers during Storage at 10 and 20C

FRED BREIDT, JR.,* JANET HAYES, and ROGER F, McFEETERS

- We have shown that manufacturers of acidified foods with pH at or below 3.3, with acetic acid as the primary acidulent, can therefore safely produce those products without heat treatment.”

Cold Fill at 10 C

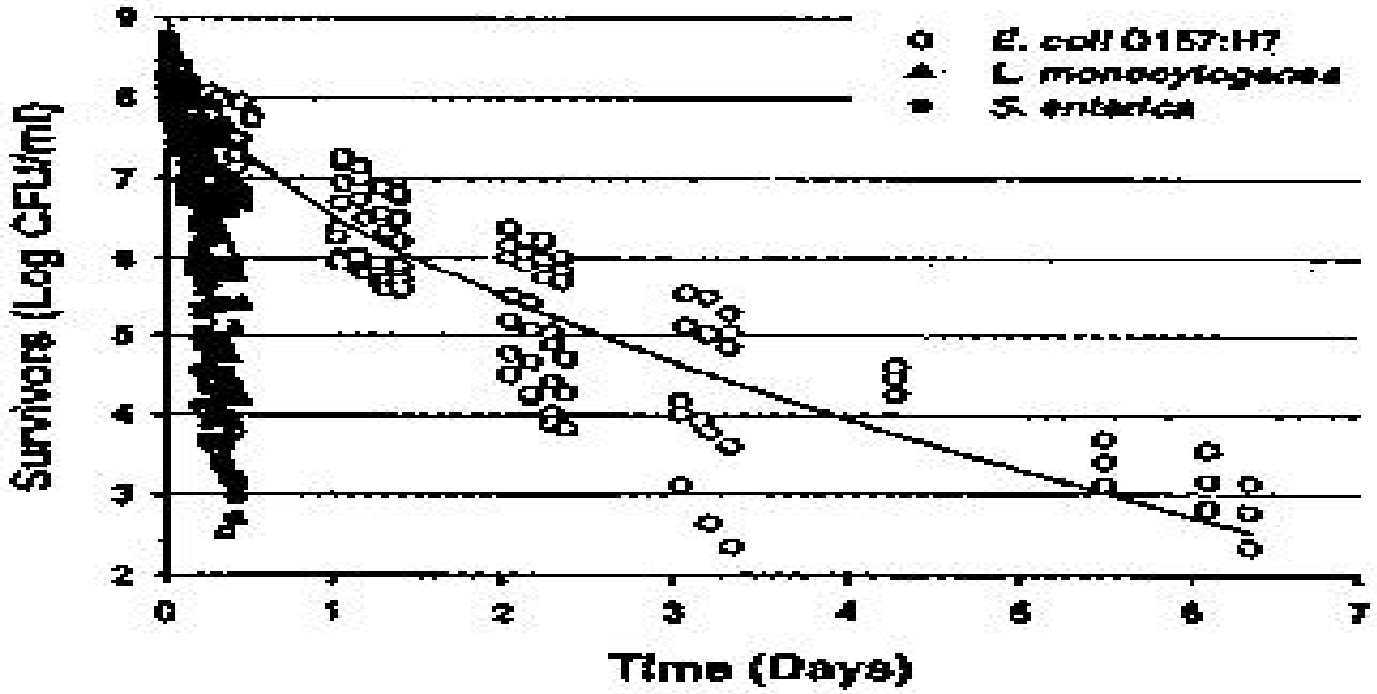

FIGURE 1. *The survival of E. coli O157:H7, S. enterica, and L. monocytogenes strains in acidified pickle jars at 10°C. The data for E. coli O157:H7 (circles), S. enterica (triangles), and L. monocytogenes (squares) show the log of the viable cell count from seven or more replicate experiments, each with a cocktail of five strains of a given species. The solid lines represent the predicted survival curves from the Weibull model.*

Cold Fill at 25 C

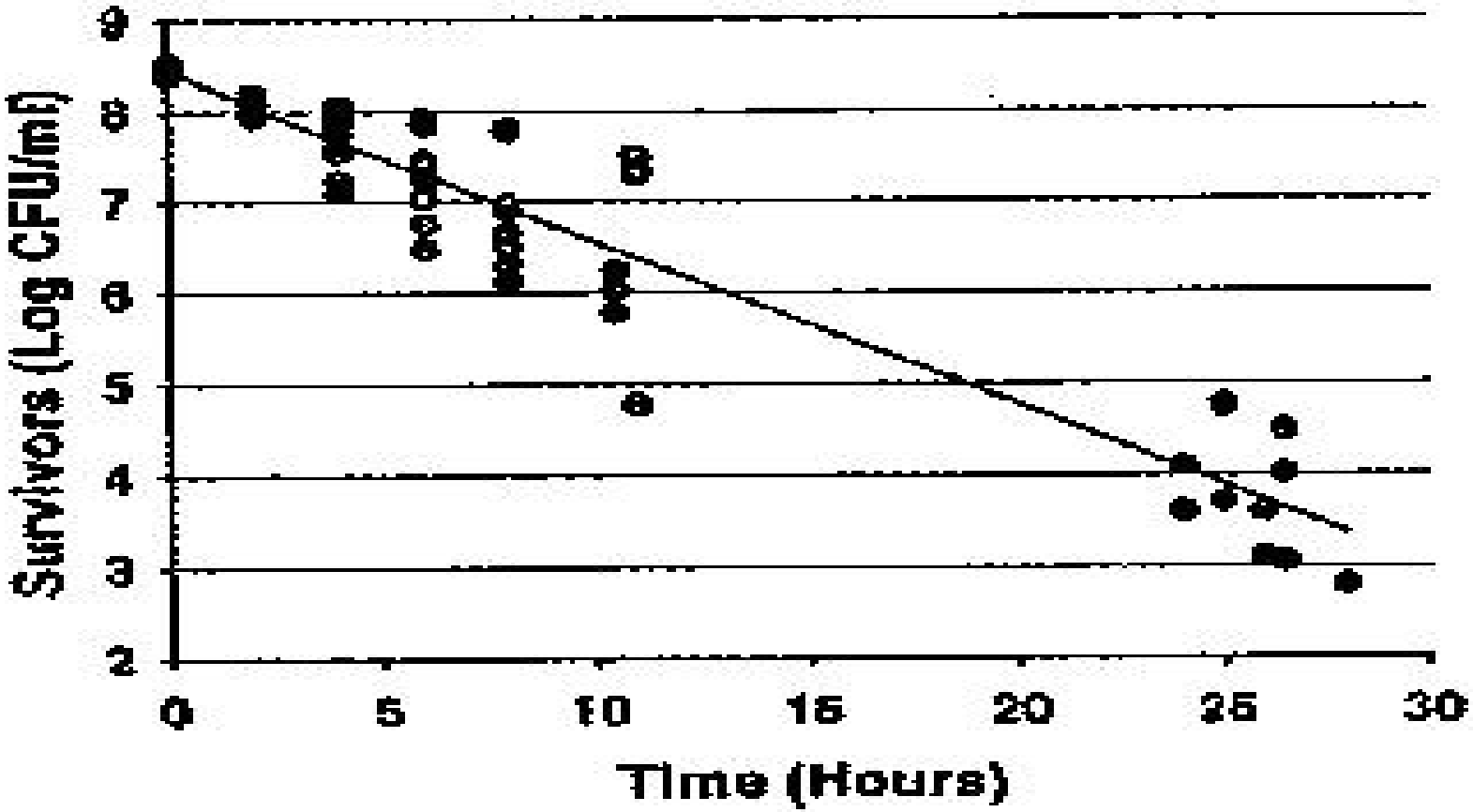

FIGURE 2. *The survival of E. coli O157:H7 in acidified pickle jars at 25°C. The data for E. coli O157:H7 (circles) show the log of the viable cell count for nine independent replications with a five strain cocktail. The solid line represents the predicted survival curve from the Weibull model.*

Challenge Study Protocols

You can also refer to:

"NACMCF Challenge Study Protocols" published in Journal of Food Protection,Vol. 73, No. 1, 2010.

Please bear in mind that these guidelines and protocols have not been developed by FDA and that the FDA requirements are not solely based on and/or not limited to these protocols.

What does this mean to Dressings and Sauces Industry

- Assume more foods will be classified acidified
- Assure safety and stability of acidified products
- Rely on published or publishable scientific data
- Obtain results from challenge studies on cold-filled products with pH > 3.3
- Rely on proper implementation, execution and documentation of food processing activities

Experience with Small Processors in State of Florida

(2011 – 2013)

1. Requests for assistance normally arrive by telephone as a result of referrals from FDACS and other sources.

2. These inquiries are followed up by e-mail confirmation of the request along with instructions for submitting product samples and ingredient/processing information.

3. When all data are analyzed, a one-page “product certification” is prepared for each product and accompanied by a “process authority” cover letter on official UF letterhead signed by the process authority.

UF | UNIVERSITY of FLORIDA
Institute of Food and Agricultural Sciences
Agricultural and Biological Engineering Dept.

Arthur A. Teixeira, Ph.D., P.E.
Process Authority
207 Rogers Hall,
Gainesville, FL. 32611-0570
Tel: 352-392-1864, x-207
E-mail: atex@ufl.edu

PROCESS CERTIFICATION

Issued October 8, 2013

PRODUCT NAME:
Rectal Rocket Fuel
5 oz. Bottle, pH = 3.11, $a_w > 0.85$

Hot-fill shelf-stable acidified food
Covered by FDA regulations in
21 CFR Part 114 for acidified foods.
If entered into interstate commerce.

INGREDIENTS	Composition (% weight)
Habanero Mash	88
Balsamic Vinegar	4
White Vinegar	1
Water	2
Lime Juice	1
Garlic	1
Salt	2
Sage	<1
Allspice	<1
Fennel Seed	<1
Paprika	<1
Cumin	<1
Coriander	<1
Xanthan Gum	<1
Total	100

CRITICAL FACTORS:
1. Maintain Batch records.
2. Maintain pH less than 4.1.
3. Assure internal temperature in last bottle is above 185°F at time of filling.

PROCESS PROCEDURE:

1. Fresh Garlic is inspected, washed, and ground up
2. All liquid ingredients are added to the kettle
3. The rest of the ingredients are blended into the sauce with a high speed mixer
4. Product is cooked to 185 degrees
5. The kettle is turned down to hold product at the targeted temperature of 185 degrees during bottling
6. Finished product is pH tested. The temperature of the finished product is taken at the beginning, the middle, and the end of bottling
7. Bottled into 5 oz. glass bottle by hot-fill and hold.
8. A plastic cap with a foam liner and a heat shrink tamper seal is applied to each bottle
9. Inkjet batch code is applied to each bottle
10. Batch code sticker is applied to each box

Arthur A. Teixeira, Ph.D., P.E.
Professor and Process Authority

NOTE: Any changes to formulation or procedure should be approved in writing by a process authority.

UF UNIVERSITY of FLORIDA
Institute of Food and Agricultural Sciences
Agricultural and Biological Engineering Department

Frazier Rogers Hall
PO Box110570
Gainesville, FL 32611-0570
352-392-1864, x-207
352-392-4092Fax
Website: www.abe.ufl.edu
E-mail: atex@ufl.edu

October 22, 2013

Food Processor
Food Company
Company Location

RE: Process Certification of Hot-pack Hot Sauces

Dear Mr. Food Processor:

Enclosed with this letter are my process certifications on samples of two hot-pack hot sauces you submitted for evaluation (Orange Crush and Rectal Rocket Fuel). These are representative of the twenty-five (25) hot sauce products identified on the attached list of approved hot-pack sauces. These products fall into the category of "Acidified Foods", and are covered by FDA regulations 21 CFR Part 114 for acidified foods, but only if you enter them into interstate commerce. In that case, I recommend that you become familiar with these regulations, and proceed to submit the "Establishment Registration" and "Process Filing" forms to the FDA (after my review and input), and arrange to attend a "Better Process Control School" for acidified foods. If you do not enter interstate commerce, you must still comply with Florida State regulations regarding food preparation for human consumption. These are outlined in Florida Statutes, Chapter 500, more commonly referred to as the Florida Food Safety Act. For more information, you may contact the Florida Department of Agriculture and Consumer Services (FDACS) Division of Food Safety: (http://www.freshfromflorida.com/fs/).

Be sure to measure pH in finished product samples from every batch, as well as internal product temperature during the hot-fill process, and maintain batch records. Meanwhile, you should keep this letter with attached sample process certifications on file as documentation that your products have been evaluated by a process authority, and judged to be safe so long as they are processed in accordance with the attached certifications.

Sincerely

Art Teixeira

Arthur A. Teixeira, Ph.D., P.E.
Professor and Process Authority

Program Impact:

1. In 2013, a total of 45 inquiries were handled.

2. Of these, 18 chose to go no further than obtain the information requested.

3.Twenty-seven processors submitted samples, and have received the process authority letter with product certifications.

4. Five processors required follow-on assistance that carried over from 2012.

Program Impact:

1. In 2012, a total of 40 requests for assistance were handled. Of these, 20 chose to go no further than obtain the information requested. Twenty (20) processors submitted samples and fifteen (15) received their process authority letter with product certifications. The remaining five were carried over to 2013 for completion.

2. In 2011, a total of 29 inquiries were handled. Of these, ten chose to go no further than obtain the information requested. Five processors submitted samples and received the process authority letter with product certifications.