

Guideline for Shelf Stable Acid and Acidified Foods

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Background

- BOD Initiative 2018
- Margo Pigeon (PepsiCo) BoD Sponsor
- Formed committee
 - Chris Balestrini** **CBG Consulting**
 - David Bresnahan** **Bresnahan TPC**
 - Wilfredo Ocasio** **Eurofins**
 - Raghu Ramaswamy** **Kraft Heinz**
 - Kurt Weise** **Eurofins**
 - Lou Yuqian** **PepsiCo**
- Split the guidance into sections
- First section *was* to be Acid/Acidified Determination
- Margo retired and Abdullatif Tay (PepsiCo) is now BoD Sponsor
- Put together a draft of Section 1

We did get one Like



The risk of improper acidification is mostly associated with products that have relatively large particulates and extended pH equilibrium times. However, consideration is also given to other products where buffering capacity or other compositional aspects cause the required amount of added acid to vary. Therefore, in this guidance the acid/acidified determination is mostly based on the equilibrium pH and the pH equilibrium time. Additionally, there are some products that are evaluated on the basis of the formulation impact on the variability of the required amount of acid to be added.

Justification for the Regulation

Incidents in low-acid foods led to the development of the regulation that is an acidified, Part 113 – Thermally Processed Low-Acid Foods Packaged in Beverages to Containers (1). Pickle Packers International filed a petition for an other products larger for *Clostridium botulinum* outgrowth if a product was not pickled.

In response to the petition, the FDA developed and published an acidified R Part 128g – Pickled, Fermented and Acidified Foods (2). This rule is the reason for devas designated 21 CFR Part 114 – Acidified Foods (3).

Addressed by the rule is that the equilibrium pH of the food be cannot grow. In adopting the rule, FDA determined that a food pH of 4.6 or less with the exception of tomato products that must have a pH of 4.5 or less in order to prevent the outgrowth of *Clostridium botulinum*. The rule states that *Clostridium botulinum* spores will not grow out at a pH of 4.8 or less if it is 4.9 or less (1, 4). Therefore, the boundary, by which a product is in tomato products where it is 4.7 or less, has a safety margin.

Under the current rule, several examples of incidents involving the need for the rule. The agency noted that, "From 1964 to 1976, 20 pickled, fermented, or acidified foods were involved in 4 recalls. ... Two of the recalls were due to botulism in commercially processed in the United States. As a result, 11 people became ill – seven from peppers and one from tomatoes and hearts of palm (5)."

From 1964, there were 29 reported outbreaks of botulism, 11 illnesses and 55 deaths from home canned products (5). Since botulinum toxin was present, these incidents were not due to botulism.

An incident in 1976 that resulted in seven illnesses and one death from the acidification of sweet cherry peppers (6).

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- Put together a draft of Section 1
- Draft not well received by Review Committee
- Now in the midst of extensive modifications

Sections

- Review of Acidified Foods Regulation (21 CFR Part 114)
- Microbiology of Acid/Acidified Foods
- Making Acid/Acidified Foods Safe
 - Formulation
 - Thermal Process
- Spoilage Considerations
- pH Measurement
 - How To
 - When To

Microbiology

- pH boundary between acid and low-acid foods
- Pathogens of Concern (e.g., *Listeria monocytogenes*, *Escherichia coli*, *Salmonella spp.*, *Cryptosporidium parvum*)
- Spoilage organisms (e.g., *Lactobacillus spp.*, Yeasts, Molds, Heat Resistant Molds, *Alicyclobacillus spp.*)

Making Acid/Acidified Foods Safe

- **Pathogen Growth/Survival**
- **Ingredients Bactericidal to Pathogens**
 - Acids (strong acids versus weak organic acids)
 - Other anti-microbial agents (e.g., ϵ -polylysine)
- **Interactions with other ingredients (e.g., salts)**
- **Thermal Processes**
 - $F_{16/200}$ Tables (Scientific Justification?)

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FOR INTERNAL USE

Acid Products

The following CT's should pre and lactobacilli (except B. fulva)

C.B.D. 9/25/75

pH During Process (Not after Process)	C.T.
3.0	150
3.1	153
3.2	156
3.3	160
3.4	164
3.5	167
3.6	171
3.7	175
3.8	178
3.9	182
4.0	185
4.15	190

Guidelines only
Specific recommendations should come from NFPA for a specific product.

TA > 0.55% ~~inhib. to~~ ^{inhib. to} flat sour, allowing pH > 4.2

Tomato based products
pH 4.2-4.5 F₀ = 0.5
For flat sour, i.e.
Bacillus Coagulans=Bacillus thermoacidurans

Cold fill

F₀ reductions for acid products

pH (This pH or less)	F ₀ for Non-Meat Items		F ₀ for Meat Items or Fish	
	AB	STILL	AB	STILL
4.6	0.37	0.25	1.125	0.75
4.7	0.75	0.5	1.5	1.0
4.8	1.5	1.0	2.25	1.5
4.9	2.25	1.5	3.0	2.0
5.0	3.0	2.0	3.75	2.5

(within 24 hours after processing)

F₁₆ values for Acid Products *of fresh Ag. products*

pH	F ₁₆
3.9 or less	0.1
3.9-4.1	1.0 185
4.1-4.2	2.5 190
4.2-4.3	5.0 195
4.3-4.4	10 205
4.4-4.5	20 210

Hot fill/hold

pH	Center Temperature	pH	Center Temperature
3.0	150	3.71-3.8	178
3.01-3.1	153	3.81-3.9	182
3.11-3.2	156	3.91-4.1	185
3.21-3.3	160	4.11-4.2	190
3.31-3.4	164	4.21-4.3	195
3.41-3.5	167	4.31-4.4	205
3.51-3.6	171	4.41-4.5	210
3.61-3.7	175		

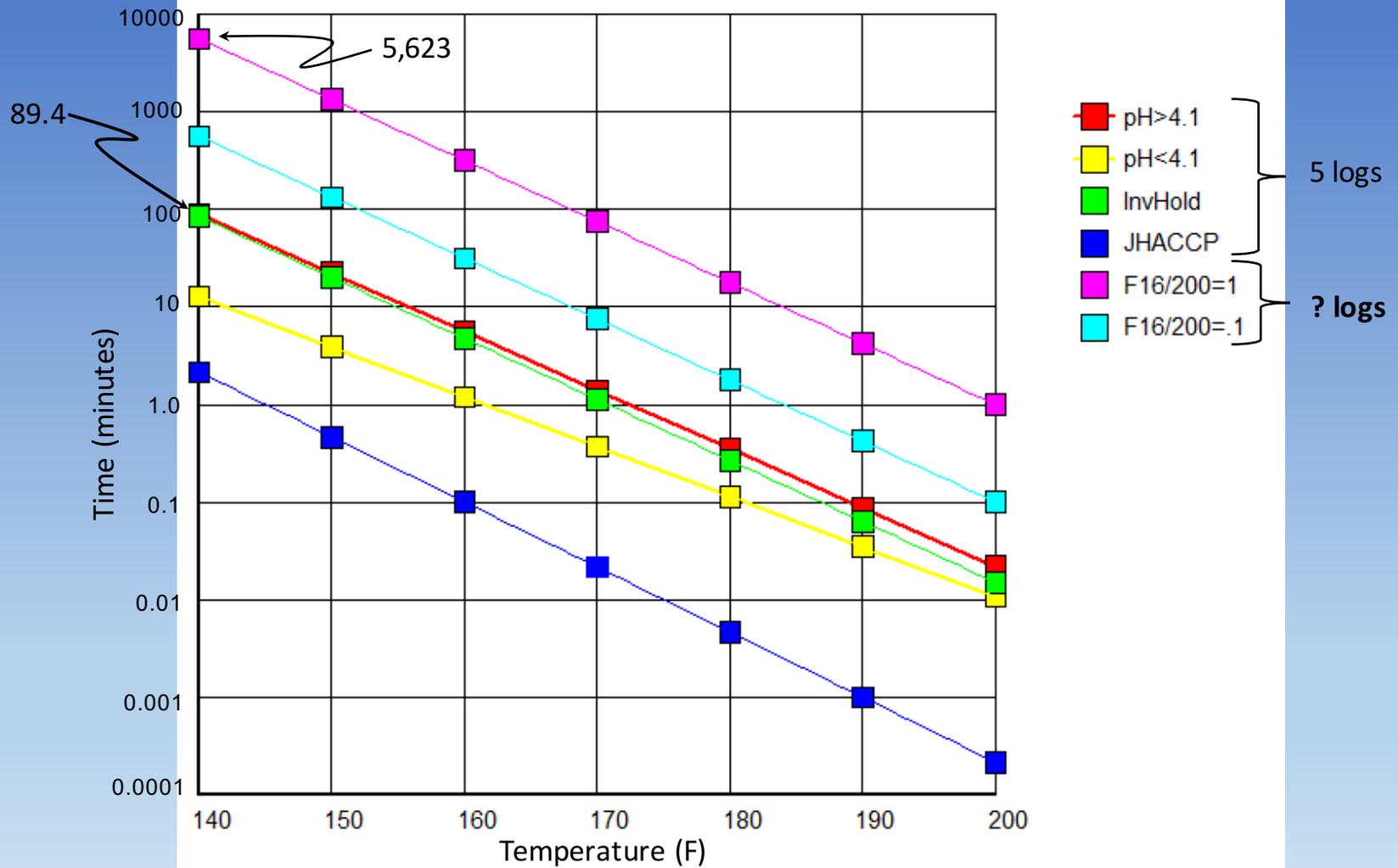
Use 2-10 min to attain pH

recommended 1-2 min hold
inversion recommended

Making Acid/Acidified Foods Safe

- **Pathogen Growth/Survival**
 - **Ingredients Bactericidal to Pathogens**
 - Acids (strong acids versus weak organic acids)
 - Other anti-microbial agents (e.g., ϵ -polylysine)
 - **Interactions with other ingredients (e.g., salts)**
 - **Thermal Processes**
 - F_{16/200} Tables (Scientific Justification?)**
 - Breidt pH 4.1 or less**
(Breidt et al, Food Protection Trends, Vol 30, No 5)
 - Breidt pH >4.1, <4.6**
(Breidt et al, Food Protection Trends, Vol 34, No 3)
 - Hot-Fill-Hold**
(Collier and Townsend, Proceedings NCA Conference, Jan. 1954)
- Juice HACCP Guidance**

Process Model Comparisons



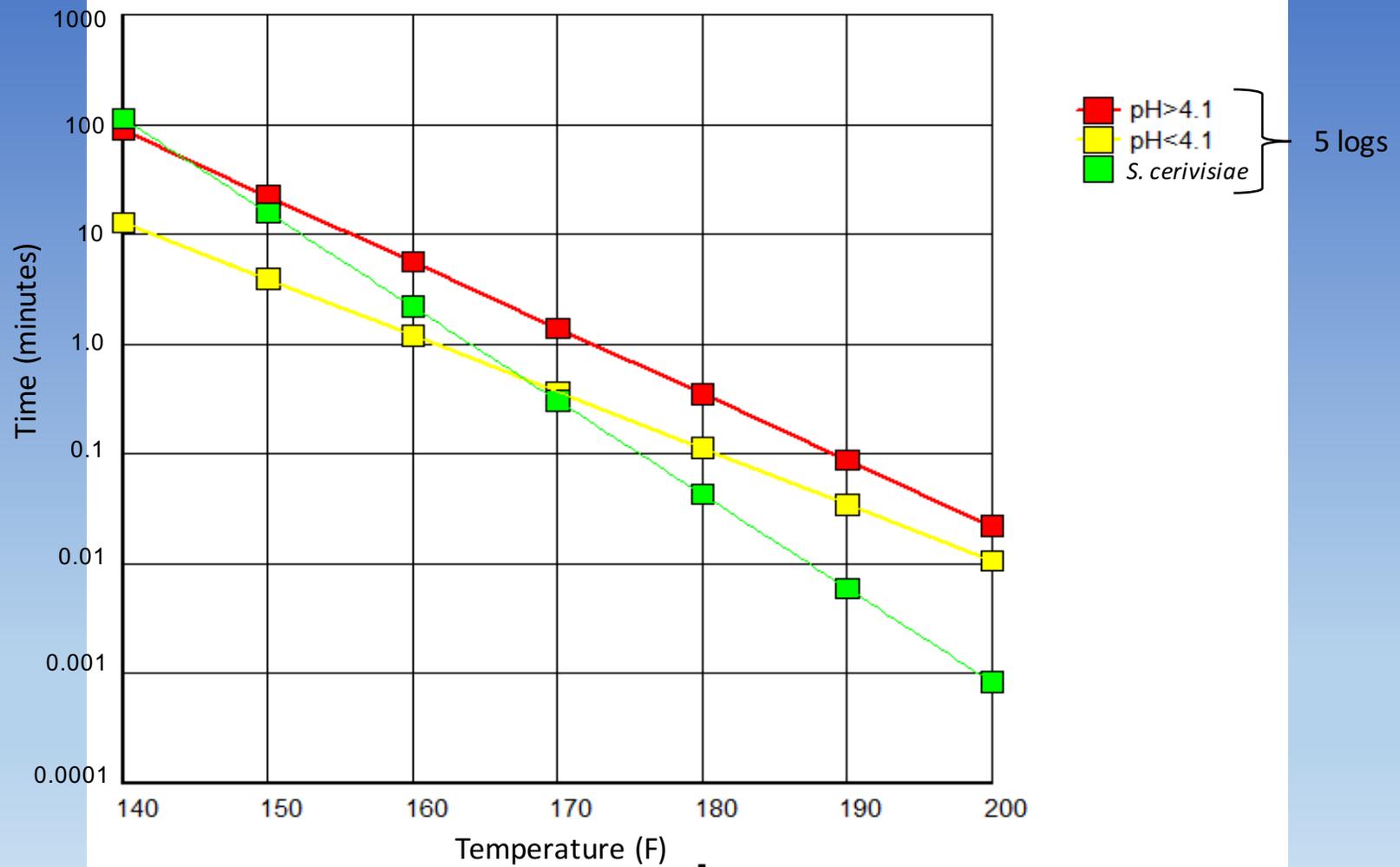
Making Acid/Acidified Foods Safe

- **Pathogen Growth/Survival**
- **Ingredients Bactericidal to Pathogens**
- **Interactions with other ingredients (e.g., salts)**
- **Thermal Processes**
- **Fermentation**

Spoilage Considerations

- Spoilage Organisms (e.g., Yeast, Molds, *Lactobacillus spp.*, ACB)
- Types of Control
 - Ingredient selection
 - Thermal Process
 - Sanitation
 - Product versus Package Risk Difference

Process Model Comparisons



pH Measurement

- **pH Measurement Fundamentals**

 - Theory of Operation

 - Calibration

 - Temperature Compensation

- **pH Measurement in Products**

 - Establishing the equilibrium pH and equilibrium pH time

 - How to measure

 - Liquid products

 - Semi-solid products

 - Products with particulates

 - When to measure

Part 114 Comments

- Part 114 was not exempted from FSMA
- Duplicity in regulations
- Difficulty in distinguishing between acid and acidified food
- FDA Investigators have been applying the regulation to products not previously covered by the rule and for which no food safety incidents have occurred
- Many in industry would not be sad to see 114 go away and perhaps replaced with a comprehensive guidance document.

Review of the Acidified Foods Regulation

21 CFR Part 114

- Status of Section 1
- History – How the rule came about
- Definitions
- Included products
- Excluded products
- Formulated Acid Foods
- Water as a Low-Acid Food
- pH measurement

Status of Section 1 of the Guidance

- First draft meant to show a means to determine acid versus acidified based on the product types mentioned in the preambles and in the rule.
- Not well received by the document review committee – seen as setting policy
- Major rewrite in progress – will contain observations but not conclusions.



History of Part 114

- Low-Acid-Canned Foods regulation developed due to outbreaks of *Clostridium botulinum*
- Pickle Packers International feared *C. bot* could be a risk due to not achieving the proper equilibrium pH (≤ 4.6 except for tomato products, ≤ 4.7)
- In 1976 the FDA published the rule 21 CFR Part 128g – Pickled, Fermented and Acidified Foods
- In 1979 a modified rule was published as 21 CFR Part 114 – Acidified Foods

Differences Between 128g and 114

- Fermented foods not included in Part 114

Comments noted that no incidents with *C. bot.* had ever been reported for fermented foods

- The word ‘Pickled’ removed from the title “Because pickled foods include those pickled by fermentation or by acidification” (44-Fed. Reg. 16204, 1979)

Incidents Cited in the Preambles

- 1899-1964 – 29 botulism outbreaks of home-canned foods, 101 illnesses, 55 deaths; pickled beets, peppers, pimentos, and pickles (41 Fed. Reg. 30442)
- 1972-1975 – 2 recalls of domestic commercially processed acidified foods, botulinum poisoning of 8 people; 7 from peppers and 1 from marinated mushrooms. (41 Fed. Reg. 30442)
- 1972-1975 – 34 other recalls with pH not less than or equal to 4.6; peppers, pimentos, hearts of palm (41 Fed. Reg. 30442)
- 1976 - 7 people with clinical symptoms of botulism due to canned acidified sweet cherry peppers (44 Fed. Reg. 16205)

Observation

- All the products cited involve low acid particulates that are put into an acid environment in one of the processes commonly known as pickling

Conclusion

- The regulation is addressing products that have a significant pH equilibrium time or otherwise present some difficulty in achieving a pH equilibrium

Definitions From the Regulation

- “*Acid foods* means foods that have a natural pH of 4.6 or below.” [21 CFR Part 114.3(a)]
- “*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 (a_w) 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.” [21 CFR Part 114.3(b)]
- *Low-acid foods* means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods. [21 CFR Part 114.3(d)]
- *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. [21 CFR Part 114.3(e)]

Observation

- All the products mentioned in the acidified foods definition, with the exception of pudding, involve low-acid particulates.
- Pudding is not defined. Puddings may have low-acid particulates or may present some challenges in achieving a consistent equilibrium pH due to varying buffer capacity.
- The definition states that “These foods may be called, or may purport to be, ‘pickles’ or ‘pickled _____.’”

Conclusion

- The regulation is addressing products that have a significant pH equilibrium time or otherwise present some difficulty in achieving a pH equilibrium

Definitions of Terms Used in the Regulation but not Defined

- *Equilibrium pH or Finished equilibrium pH* is the uniform pH that a product achieves after mixing components of different pH values.
- *Food* “means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” [FD&C Act of 1938, 21 CFR Chapter 9, Subchapter II, Section 321]
- *Particulates* are the solid portion of a food product that roughly maintains its physical integrity in the finished product. If the particulate starts out as a low-acid food and after a significant delay achieves a pH of 4.6 or less, the particulate is said to be pickled or acidified.
- *pH shift* is the difference between the pH of the predominant acid or acid food and the finished equilibrium pH.
- *Pickled* is the process by which a low-acid particulate food is brought to a pH of 4.6 or less. This can be accomplished through a fermentation process or by the direct addition of an acid or acid brine solution to the low-acid particulate food.

Definitions of Terms Used in the Regulation but not Defined (cont'd)

- *Predominant acid or acid food* is the major component of a food product that is responsible for making the equilibrium pH be 4.6 or less.
- *Process/“Processing Authority* means the person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this part”. [USDA 9 CFR 431.1]
- *Refrigerated foods* are foods that are stored in a cold environment to help preserve quality and/or to inhibit or prevent the growth of microorganisms. Refrigerated temperatures should be 5°C (41°F) or less. [FDA 2017 Food Code]
- *Shelf-stable acid/acidified foods* are foods with a pH of 4.6 or less in a hermetically sealed container that can be stored at ambient, non-refrigerated conditions.
- *Time to achieve equilibrium pH* is the elapsed time from time zero of the production of the product, when the low-acid and acid ingredients are combined, until the equilibrium pH is reached.

Definitions of Foods Mentioned in the Exclusionary Portion of the Acidified Foods Definition

- *Carbonated beverages* are a type of soft drink to which 2 to 4 volumes of carbon dioxide are generally added and typically has a pH between 2.5 and 4.0. This is a class of products that usually contains no low-acid particulates
- *Condiment sauces* are a class of products that are considered to be formulated acid foods. Examples of these foods include mustard, ketchup, flavored/spicy sauces, and barbeque sauces. If a condiment sauce were to have large low-acid particulates that cause a significant delay in the pH equilibrium time, then this product could be determined to be acidified by the Process Authority.
- *Fermented foods* are low-acid foods where an equilibrium pH of 4.6 or less is achieved by acids produced by microorganisms growing within the food matrix. Acid is often added at the start of the fermentation process to help inhibit the growth of competing undesirable microorganisms. Fermentation is a form of pickling. Fermented foods were exempted from the rule because there were “no known illnesses or deaths from commercially processed fermented foods”. [44 FR Vol 53, March 16, 1979, pg. 16204].

Definitions of Foods Mentioned in the Exclusionary Portion of the Acidified Foods Definition

- *Jams, jellies, and preserves* are a class of products that is comprised mainly of acid fruit ingredients along with other ingredients such as sweeteners, thickeners, additional acidifying agents and flavorings. These products are defined in 21 CFR Part 150 – Fruit Butters, Jellies, Preserves, and Related Products.
- *Standardized and nonstandardized dressings* are a class of products that are considered to be formulated acid foods. Some standardized dressings are defined in 21 CFR Part 169 – Food Dressings and Flavorings. Examples of these foods include mayonnaise and salad dressings. Often these products use vinegar (acetic acid) as the main acidulant although other acids such as citric acid can also be used.

The Exclusionary Clause

- 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.” [21 CFR Part 114.3(b)]

The Exclusionary Clause

- The products mentioned in the exclusionary clause of the regulation are not considered as acidified foods provided they meet the conditions that they;

“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”

Food Safety Implications of the Exclusion Terms

- “small amounts of low-acid food(s)”

More than a small amount of low acid foods could impact pH equilibrium time and therefore lead to improper acidification

Conclusion: “Small amount” should be evaluated based on the impact to pH equilibrium time and not on an arbitrary percentage.

Food Safety Implications of the Exclusion Terms

- “resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food”

The change in pH itself has no food safety implications unless the change is to a pH above 4.6 (4.7 for tomato products)
The equilibrium pH may impact the thermal process that is required

- **Conclusion:** Unless the resultant pH is above the food safety limit, then the equilibrium pH is not significantly different from the predominant acid or acid food.

Additional Definition

- *Formulated acid foods* are products with a $\text{pH} \leq 4.6$ that only becomes the food with its desired taste and/or functional properties after all the ingredients are mixed together.

Formulated acid food is a term that originated from the FDA Center for Food Safety And Nutrition (CFSAN).

Formulated acid food is a term that appropriately applies to the product categories listed in the exclusionary portion of the acidified foods definition.

Formulated Acid Foods

- If the product comes to the finished equilibrium pH quickly, it is an acid food and therefore falls under the acid food designation.
- If there are significant amounts of low-acid particulates that significantly delay the attainment of the finished equilibrium pH, then the product could be an acidified food as determined by the Process Authority.
- Formulated acid food is a term that helps to distinguish between products that are merely a mixture of acid and low-acid ingredients with no significant pH equilibrium time, and therefore acid products, versus those where the low-acid components take a significant amount of time to reach pH equilibrium in a process commonly referred to as pickling or acidification.



Water as a Food – Not a Low-Acid Food

- The FD&C Act of 1938 [21 CFR Chapter 9, Subchapter II, Section 321(f)] states that “The term ‘food’ means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” This definition states that legally, water as an ingredient is a food.
- Regulations subsequent to the Act treat water as a food other than a low-acid food. The regulation “Thermally Processes Low-Acid Foods Packaged in Hermetically Sealed Containers” [21 CFR Part 113.3(n)] states that “*Low-acid foods* means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85.” Water meets the criteria for this definition but is not subject to this regulation and therefore not considered a low-acid food. Rather, bottled water, while legally defined as a food, is treated separately from being a low-acid food and has its own regulations (e.g., 21 CFR Part 129, 21 CFR Part 165.110).
- **Conclusion:** Since water by regulatory treatment is not considered a low-acid food, then water is not considered as one of the “low-acid foods to which acid(s) or acid food(s) are added” [21 CFR Part 114.3(b)]. Since it does not qualify as a low-acid food, the amount of water as an ingredient in a food should not be used in determining whether a product is acid or acidified. Rather the focus on the determination of acid versus acidified should be on low-acid ingredients and their impact on pH equilibrium time as per the intent of the Acidified Foods regulation.

pH Measurement

- A significant portion of the regulation deals with pH measurement
- Description of types of samples - “Some food products may consist of a mixture of liquid and solid components that differ in acidity. Other food products may be semisolid in character.” [21 CFR Part 114 (a)(6)]
- **Conclusion:** Further evidence that the types of products intended to be covered by the regulation are those with significant pH equilibrium times or otherwise present challenges to consistent acidification. Beverages and other similar types of products are not the “food products” considered as acidified foods.

Summary/Conclusions



- All incidents noted for the reason for the rule involved particulate products
- The rule refers to acidified products as “pickles or pickled”
- A scheme could be devised to distinguish between acid and acidified based on pH equilibrium time and/or other obstacles to achieving pH equilibrium



Thank you for your attention.

Questions?