An Examination of the Acidified Foods Rule with Regard to the Acid versus Acidified Foods Classification

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SUMMARY

This paper analyzes the Acidified Foods regulation (21 CFR Part 114). The origins of the rule and the types of products it was meant to cover are discussed, and clearer and more meaningful criteria are proposed for making the acid versus acidified food classification. Often the acid versus acidified determination is made by arbitrary decision based on compositional percentages, an approach that may lead products that are very similar to have different designations. Similarly, arbitrary pH shifts are sometimes used as a basis for the acid/acidified food determination without consideration for the food safety implications of the pH changes. The authors contend that the regulation was meant to cover products for which there may be some difficulty in reaching the equilibrium pH. Specifically, the regulation states that acidified foods "may be called, or may purport to be, 'pickles' or 'pickled.'" Pickled products are ones for which, generally, diffusion of the acid into a low-acid particulate is required in order to reach the equilibrium pH. The authors hereby contend that the delay in achieving the equilibrium pH, due to the diffusion process and/or other difficulties in achieving the equilibrium pH, should be the basis for the acid versus acidified foods classification.

OVERVIEW

Since its inception, the distinction between acid and acidified foods in the Acidified Foods Rule (21 CFR Part 114) has not been clearly delineated. This article presents a different perspective on how to make the acid versus acidified determination. An examination of the preambles to the rules and the rules themselves was used to develop an approach that conforms more closely, at least in the opinions of the authors, to the original intent of the rule. The approach used in this document is based on a reasonable, risk-based, scientific interpretation of the basis for the acidified foods regulation and the rule itself. Utilizing the concepts presented herein would likely lead to simpler and more consistent differentiation between acid and acidified products.

Foods determined to be acidified are subject to the Acidified Foods Rule and its process filing and related requirements. Foods determined to belong to "acid food" groups are excluded and are subject to the same food safety requirements as general foods. The recommendations made in this document are meant to comply with the rule. Some of the terms used in the rule that are used to distinguish between acid and acidified foods (e.g., "small amounts," "not significantly differ") are not defined in the rule. Arbitrary boundaries for these terms can lead to acidified designations that have no positive impact on enhancing the food safety of the product. Defining these terms within the context of the original intent of the rule provides a means to make the acid/acidified determination less arbitrary. A risk-based and scientific evaluation was used to develop potential guidance on these terms and other vague aspects of the rule to address the food safety concerns on which the rule is based.

Background

As a result of a petition from Pickle Packers International requesting that the U.S. Food and Drug Administration (FDA) "establish a current good manufacturing practice regulation for the pickle industry" *(1)*, an acidified foods rule was developed and published in 1976 as 21 CFR Part 128g—Pickled, Fermented and Acidified Foods *(2)*. This rule was modified in 1979 and was designated 21 CFR Part 114—Acidified Foods *(5)*.

The food safety concern that is addressed by the rule is the need for the equilibrium pH of the food to be such that *Clostridium botulinum* cannot grow. In adopting the rule, FDA determined that a food must have an equilibrium pH of 4.6 or less, with the exception of tomato products, which must have an equilibrium pH of 4.7 or less, in order to prevent the outgrowth of *C. botulinum*. The agency has acknowledged that *C. botulinum* spores will not grow out at a pH of 4.8 or less *(1, 4)*. Therefore, the boundary, by regulation, of a pH 4.6 or less has a safety margin of 0.2 pH units.

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The concept of pH is important for the classifications of these foods. Throughout the lifetime of this rule, the distinction between an acid food and an acidified food has been somewhat convoluted. If one looks at the types of product examples that are deemed acidified and the examples of product failures that are presented in the preambles and the final rules, it can be discerned the rule is intended to apply to those products that are susceptible to the potential of improper acidification. Similarly, by examining the types of products that are "excluded" from the rule and, thus, not considered acidified foods (e.g., carbonated beverages, jams, jellies, preserves, standardized and nonstandardized food dressings, condiment sauces), the shared trait of these products is that they do not contain large, low-acid particulates and they reach an equilibrium pH in a relatively short time. Products with particulates can require a significant pH equilibrium time and/or can result in a pH greater than 4.6, which are the kinds of products the rule addresses.

The preambles and the rules focus on products that "may be called, or may purport to be, 'pickles' or 'pickled ____.'" *(5)* In other words, the rule is meant to be applied to products that consist of solid foods, such as cucumbers, peppers, hearts of palm, and the like, to which acid is added and for which a significant amount of time is required for the acid to diffuse into the food and ultimately reach a pH equilibrium throughout the product. These are the types of products that are cited in the preambles to the rules as the reason for the rules.

In the manufacturing of all of the products cited in the preambles and the final rules, there is a significant amount of time for the acid to diffuse into the low-acid particulate(s). As the acid diffuses from the liquid phase into the low-acid particulate(s), the pH of the liquid phase may go up as the pH of the particulate goes down. After a period of time, the liquid phase and the particulate(s) will reach equilibrium pH. If the finished product equilibrium pH is above 4.6, there could be a food safety concern due to improper acidification. Therefore, with these products it is important not only to add the correct amount of acid but also to ensure that the proper finished equilibrium pH has been achieved.

In the preamble to Part 128g, the FDA noted that between 1899 and 1964 there were 29 reported outbreaks of botulism in "home canned pickled beets, peppers, pimentos and pickles" *(2)*. The FDA further notes that from January 1972 through December 1975, there were two commercial botulism outbreaks from acidified foods: one from peppers and one from marinated mushrooms. In the same period, there were a total 36 recalls. Of these, 34 were due to improper acidification, which involved peppers, pimentos, and hearts of palm, whereas the other 2 recalls "involved filth" *(2)*. Incidents after December 1975 are noted in the 1979 preamble to Part 108 *(3)*. Two additional botulism outbreaks were mentioned. These outbreaks were due to improper acidification of canned, acidified sweet cherry peppers in 1976 and "improperly acidified and processed food" in 1977. All the acidified foods implicated in the recalls or botulism outbreaks that were cited in the preambles to the rules were those that contained low-acid particulates.

The important food safety criterion for an acidified food is 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" *(5)*. This criterion indicates that a significant pH equilibrium time is an important characteristic of an acidified food, along with the finished equilibrium pH value. If a food does not fit the type of food cited in the rules and preambles and does not have a significant pH equilibrium time, then the food could be considered an acid food. Because all of the improperly acidified foods cited in the preambles to the rules are particulate foods with extended pH equilibrium times, one can logically conclude that particulates and extended pH equilibrium times are important considerations in the determination of what constitutes an acidified food. Additional consideration should also be given to products for which the amount of acid needed to be added is variable due to some compositional aspects of the food.

Given the conditions that determine an acidified food, then one can also logically conclude that products with few or no solid components, such as teas, vegetable juices, sweetened or unsweetened flavored beverages, many barbeque sauces, condiments, and dressings, that come to pH equilibrium relatively quickly and consistently could be considered acid foods. Because these foods do not exist until all the ingredients are mixed, they do not fit the definition of acidified foods as "low-acid foods to which acid(s) or acid food(s) are added" *(5)*. These products are referred to as formulated acid foods.

Acidified foods definition

The definition of an acidified food is provided in 21 CFR Part 114.3(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 (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 non-standardized 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" *(5)*.

The following examples of acidified foods are provided in the rule: "beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, tropical fruits, and fish, singly or in any

combination." With the exception of pudding, all of these are low-acid particulate products that are pickled (acidified). Within the definition of an acidified food in the rule, it is stated that "These foods may be called, or may purport to be, 'pickles' or 'pickled _____.'" Given that all of the examples of improperly acidified foods in the preambles are similar types of pickled products, one can conclude that the major emphasis of the rule is proper acidification of these particulate products.

There are different types of puddings, some of which have low-acid particulates. The rule does not provide any further clarification of what type of pudding is being considered. The pudding category, like the exempted categories, may include acid and acidified products.

By its terms, the rule does not apply to "acid foods." The definition of "acidified foods" excludes several specific food types without explicitly categorizing them as "acid foods." Because these foods are not acidified foods, then one would normally regard them as acid foods.

Several food categories are exempted in 21CFR Part 114.3(b). However, to be exempted, a product must "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." The terms "small amounts" and "significantly differ" are not defined in the rule. Scientific and food safety-based potential guidance on these terms is presented below. Ultimately, the processing authority should determine whether a food meets the exemption criteria to be considered an acid food.

Besides refrigerated products, the types of products listed in the exemption clause of the acidified foods definition are often referred to as formulated acid foods. Formulated acid foods are products with a pH ≤4.6 that only become the food with its desired taste and/or functional properties after all the ingredients are mixed together. 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 originated from the FDA Center for Food Safety And Nutrition to help distinguish products that are merely a mixture of acid and low-acid ingredients with no significant pH equilibrium time. Therefore, formulated acid foods are acid products versus those in which the low-acid components take a significant amount of time to reach pH equilibrium in processes commonly referred to as pickling or acidification.

Fermented foods are low-acid foods in which an equilibrium pH of 4.6 or less is achieved by acids produced by microorganisms growing within the food matrix. These products were included as acidified foods in the original Acidified Foods rule (21 CFR Part 128g). They were excluded from the revised rule (21 CFR Part 114) because there were "no known illnesses or deaths from commercially processed fermented foods" *(5)*. Because fermentation is a form of pickling, the word "pickled" was removed from the title of the revised rule. Note that fermented foods were removed from the jurisdiction of the acidified foods rule because there had been no public health incidents with fermented foods. Conversely, it makes sense that products and product types that were not previously considered to be acidified foods should not be newly considered as such unless they fit the definition of an acidified food and there is a public health incident linked to this product or product type.

Water as a food, not as a low-acid food

The Food, Drug, and Cosmetic Act of 1938 [21 CFR Chapter 9, Subchapter II, Section 321(f)] states "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 Processed *Low-Acid Foods* Packaged in Hermetically Sealed Containers" [21 CFR Part 113.3(n)] states "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, is not considered a low-acid food. Rather, bottled water, although legally defined as a food, is treated separately from low-acid foods and has its own regulations (e.g., 21 CFR Part 129, 21 CFR Part 165.110).

Because water by regulatory treatment is not considered a low-acid food, then it is suggested that water not be considered one of the "low-acid foods to which acid(s) or acid food(s) are added" *(5)*. Because 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 determination of acid versus acidified should focus on low-acid ingredients and their impact on pH equilibrium time as per the intent of the Acidified Foods regulation.

Finished pH equilibrium time

In describing the pH equilibrium time above, the terms "relatively short" and "relatively long" are used in the suggested way to determine an acid versus an acidified food. This section is meant to provide some guidance on how to determine the two terms. This determination may not be straightforward for all products and it will be up to the processing authority to make the final assessment. The pH equilibrium time is a part of the scheduled process and should be a time that is scientifically verified as being safe.

Foods with no low-acid particulates

Foods that have no low-acid particulates will generally reach equilibrium after all the ingredients are combined.

If the pH of the batched product and the product after processing are both at a pH of 4.6 or below, then these products could be considered acid products with short pH equilibrium times.

Foods with acid or acidified particulates

Products that have an acidic liquid component and no low-acid particulates, but that contain acid or acidified particulates, are considered to be acid foods. Although there may be a shift in pH and there may be a significant pH equilibrium time, because the particulate starts out in the acid range and remains in the acid range, per the regulation, this would be an acid food because no low-acid food is being brought into the acid realm.

If there is a product that has acid or acidified particulates and a low-acid liquid component, then this food might be construed to be an acidified product. Even though it would not match the types of products being addressed by the regulation, it would meet the intent of the regulation, that is, there would be a significant amount of time for the acid to diffuse out of the particulate to acidify the liquid component. Therefore, with this type of product, the pH equilibrium time could be the determining factor in the acid versus acidified characterization.

Foods with low-acid particulates

Products in which acid is added to low-acid particulates are the main reason for the development of the Acidified Foods regulation. The concern was that not enough acid would be added to the product and the finished equilibrium pH would not be at or below the pH 4.6 threshold, resulting in an improperly acidified product.

If the low-acid particulates are large enough in all dimensions to require a long (e.g., several hours) time to reach equilibrium pH, then these products would be considered acidified. If the particulates, regardless of quantity, have one dimension that is small enough (e.g., 3/8 in. [9.5 mm] or smaller) such that they reach equilibrium pH in a relatively short period of time (e.g., < 2 hours), then the product could be considered an acid product.

The Process Authority should evaluate the amount of low-acid particulates, the particulate dimensions, the pH equilibrium time, and the equilibrium pH relative to the pH 4.6 limit in order to classify the product as acid or acidified.

Establishing the finished pH equilibrium value and time

Final equilibrium pH

Final equilibrium pH is determined by taking the final product and blending all container components. The resulting puree is then tested with a calibrated pH meter. The value observed represents the pH value that will result once the pH equilibration is achieved by all product components.

Determination of pH equilibration time

Equilibration time refers to the time it takes for all components of a product to reach the final product equilibrium pH. The time is typically determined for the pH equilibration of low-acid particulates contained within the finished product. The amount of time needed to reach pH equilibration for particulates varies, depending on particle composition, particle dimensions, the particulate to liquid ratio, and the rate of acid infusion throughout the particulates.

The determination is conducted by separating the particulates from the remainder of the product using a screen mesh of adequate size to capture the particulates. The liquid portion of the product is retained for pH measurement. If the formulation contains several different types of particulates, they are separated and grouped for pH testing. Once the particulates for testing are separated, each particulate type is rinsed with a small amount of distilled water and comminuted (blended) to form a slurry or paste, and the pH is measured. (It is acceptable to add a small quantity of distilled water [e.g., not more than 20 ml per 100 gm of product] if the paste is too thick to measure the pH value.) The values from each of the particulate types and the liquid portion are compared to the final equilibrium pH of the total product. Once all components are within 0.1 pH of the equilibrium pH, the lapsed time is determined. This approach represents the pH equilibration time. This test is typically performed at predetermined times, which can be hourly, every two hours, or at some other time increment.

Time zero for testing purposes depends on how the product is manufactured. For products that are packaged and do not receive a subsequent heat treatment (including hot-fill-hold), time zero begins when the package is closed. For products that receive an in-container heat treatment, time zero begins when the package exits the processing vessel. If all components are at the equilibrium pH value at time zero, the product could be considered an acid food. Products that take 2 or more hours to equilibrate would tend to be acidified foods. Equilibration time could be one of the key data points considered when making the determination of whether the food is acid or acidified.

Suggested method for the determination of acid versus acidified foods

To be classified as an acid or acidified product, the finished equilibrium pH of the product must be 4.6 or less. There is an exception in that tomato and tomato products must have a pH of 4.7 or less.

Acid foods

Certain products are easily identified as acid foods. If a product does not have any low-acid ingredients, it is, by the definition given in the rule, an acid food. Acidified ingredients are not considered to be low-acid foods in the determination of whether a product is an acidified food, because the pH of the ingredient is below 4.6 at the time the ingredient is received for further manufacturing.

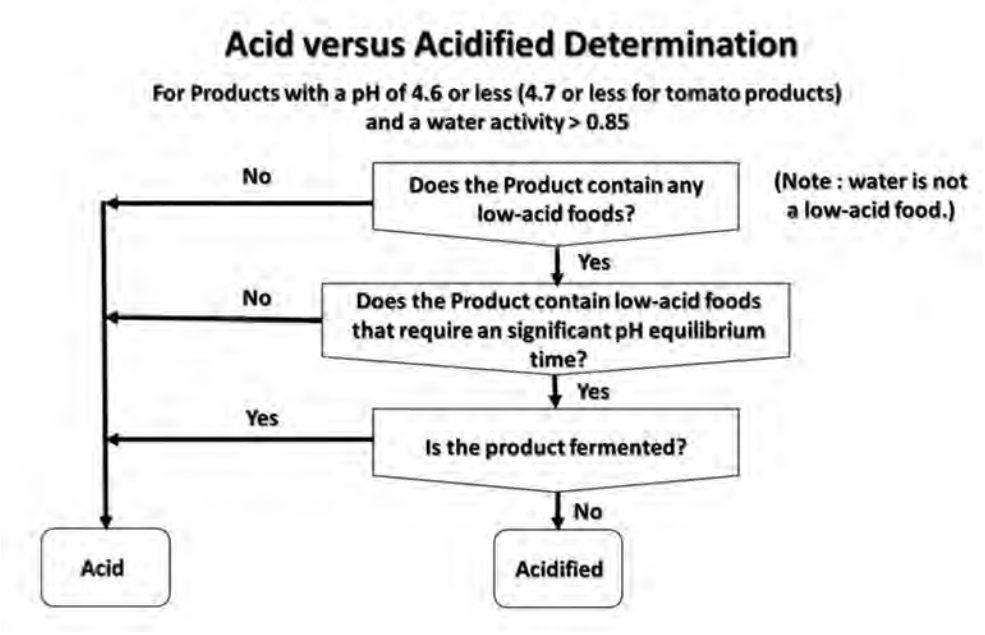

Figure 1. Acid/Acidified Flowchart.

Acidified foods

Certain foods are characteristically acidified foods, per the acidified foods rule. The products mentioned in the preambles to the rule and in the rule itself almost always have a low-acid particulate food to which acid is added. These products are often referred to as pickles or pickled. These products also tend to require a significant time to reach the finished pH equilibrium (e.g., several hours).

Conceivably, there could be products that present some other challenge to reliably achieving the proper pH equilibrium. There could be a product that has variable buffering capacity, which requires variable amounts of the acidulant to achieve an equilibrium pH within the product's specified range. These products could be determined by the Process Authority to be acidified.

Acid or acidified?

The regulation excludes (and, thus, implicitly designates as acid food) products that may have "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." Given the history of the rule and the food safety concerns it is designed to address, this language could be informed by examining the pH equilibrium time.

If a food has low-acid particulates in low enough quantity or that are small enough dimensionally, such that a relatively short-finished pH equilibrium time is achieved, then these products could be considered acid foods. The percentage, by itself, of the low-acid food has no food safety implications. Rather, it is the impact of the low-acid food on the pH equilibrium time that could impact the food safety of the product. Therefore, the proposal is that the evaluation of the criterion of "small amounts of low-acid food(s)" as stated in the rule should not be made based on the percentage of the low-acid ingredient(s) in the formulation, but, rather, should be interpreted by examining the effect on the pH equilibrium time.

Similarly, guidance on the words "significantly differ" is not provided in the rule. Given that the food safety focus of the regulation is on the growth of *C. botulinum*, if the finished equilibrium pH is 4.6 or less, then one could conclude that there is not a significant difference.

Precise changes in pH (i.e., pH shifts) and comparisons of the acid ingredients to the finished product equilibrium pH, although important to know, have no bearing on whether a product should be considered acid or acidified. The pH shift in isolation has no food safety implications. The relevant measure is the equilibrium pH. For an acid or acidified food, the equilibrium pH must be at 4.6 or below. The proposal is that if the finished equilibrium pH is 4.6 or less, then the resultant finished equilibrium pH would not be considered significantly different from that of the predominant acid or acid food.

Note that the equilibrium pH is also sometimes used in determining the appropriate process to apply to the product to make it safe and shelf stable.

Figure 1 is a flowchart that can be used for the acid versus acidified food determination. This chart deals with the products that are the main concern of the regulation: those that consist of low-acid particulates and are pickled by the addition of acid ingredients. As stated in the rule,

the example products "may be called, or may purport to be, 'pickles' or 'pickled _____.'"

Consideration also needs to be given to products that may present difficulties in achieving consistent acidification. Some products may have ingredients that have natural variability in their buffering capacity (e.g., some high-protein products) and, therefore, may require differing amounts of the acidulant to achieve the same equilibrium pH value. The Process Authority should evaluate the difficulties in achieving consistent equilibrium pH values in the determination of whether a product is acid or acidified.

In all cases, the determination of whether a product is acid or acidified should be made by the Process Authority. Careful consideration needs to be given to the food safety characteristics of the product and how the equilibrium pH is achieved.

CONCLUSION

The acidified foods rule was developed to help reduce the chances of improper acidification. A critical examination of the original and current rules and their preambles provides insight into the types of products that were intended to be governed by the rule and, therefore, to be classified as acidified. Acidified foods are those low-acid foods (almost exclusively foods with low-acid particulates) that are exposed to an acid environment and that have an extended pH equilibrium time. This simple delineation could make the determination of whether a food is acid or acidified relatively easy; at the same time, it focuses on the food safety concern for which the rule was developed. Although the classification techniques contained herein can be easily applied to the vast majority of products, there will likely be products that are not so easily classified and that will require extra scrutiny by a processing authority.

REFERENCES

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In Memory

Douglas O. Abbott

We extend our deepest sympathy to the family of Douglas O. Abbott who recently passed away. Mr. Abbott became a member of the Association in 2014. IAFP will always have sincere gratitude for his contribution to the Association and the profession.

In Memory

Donald L. Barrett

We extend our deepest sympathy to the family of Donald L. Barrett who recently passed away. Mr. Barrett became a member of the Association in 2009. IAFP will always have sincere gratitude for his contribution to the Association and the profession.