Guidance for Industry

Acidified Foods

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-2411.

U.S. Department of Health and Human Services
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Acidified Foods

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I. Introduction

This guidance is intended for processors of acidified foods, fermented foods[2], and acid foods[3]. It pertains to the current good manufacturing practice (CGMP) requirements in 21 CFR part 114 for acidified foods and to the "Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit" for acidified foods in 21 CFR 108.25 and is intended to assist commercial food processors in determining whether their food products are subject to these regulations. It also provides FDA's (our) current thinking on several topics related to the processing of, and process filings for, acidified foods and describes a voluntary program for processors of foods that may not be subject to the regulations for acidified foods. Under the voluntary program, processors may submit process filings for these foods to facilitate our determinations regarding the regulatory status of their foods during inspection of a processor's facility and when their foods are offered for import. Taking part in this voluntary program does not automatically subject processors to the acidified food regulations.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Fermented dairy products, such as yogurt, are a separate category that is not relevant to the fermented foods that are the subject of this document.

[3] Low-acid foods are foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85, except that tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods (21 CFR 113.3(n)). Acidified foods are low-acid foods to which acid(s) or acid food(s) are added; they have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below (21 CFR 114.3(b)). Acid foods are foods that have a natural pH of 4.6 or below (21 CFR 114.3(a)). Fermented foods, as discussed in this guidance, are low-acid foods subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below.

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

A. CGMP Requirements for Low-Acid Foods and Acidified Foods

FDA (we) has established specific CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (i.e., "low-acid canned foods," hereafter referred to as LACF[4]) (21 CFR part 113) and acidified foods (21 CFR part 114). In the proposed and final rulemakings for LACF (proposed rule, 41 FR 30444, July 23, 1976; final rule, 44 FR 16209, March 16, 1979) and acidified foods (proposed rule, 41 FR 30457, July 23, 1976; final rule, 44 FR 16230, March 16, 1979), we discussed the need for CGMP requirements to control *Clostridium botulinum (C. botulinum)*. *C. botulinum* is a bacterium commonly found in soil. It can produce a nerve toxin (botulinum toxin) under anaerobic conditions such as those in canned foods. Botulinum toxin can cause botulism, a rare but serious paralytic illness that can be fatal and is considered a medical emergency (Ref. 1).

Under stress (such as thermal processing and physicochemical conditions that are not conducive to growth of vegetative cells), *C. botulinum* can form spores that are adapted for prolonged survival under adverse conditions (Ref. 2). Thermal processes using temperatures such as 212 °F (i.e., the temperature of boiling water) or even lower (e.g., 150 °F in some circumstances) can destroy the vegetative cells of *C. botulinum*, but do not destroy the spores of *C. botulinum* (see 41 FR 30442 at 30442, July 23, 1976).

An acidified food can pose a risk of botulism if pH and other critical factors are not carefully controlled during processing to prevent the germination and growth of viable spores of *C. botulinum* (44 FR 16204 at 16204, March 16, 1979). When critical factors are not carefully controlled, the vegetative cells of some microorganisms of nonhealth significance (such as some spoilage bacteria, yeasts, and molds) can grow in an acid environment and, in so doing, cause the pH of the food to increase (Refs. 3, 4, and 5). In addition, when critical factors are not properly controlled, some spoilage microorganisms (such as *Bacillus licheniformis* (*B. licheniformis*)) produce heat-resistant, acid-tolerant spores that can germinate, grow, and cause the pH to increase; thermal processing that is sufficient to destroy vegetative cells of such microorganisms may not be sufficient to destroy their spores (Refs. 3 and 6 through 9).[5] However, when the pH

[4] Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as "cans," the term "low-acid canned foods" has been used for decades as a shorthand description for "thermally processed low-acid foods packaged in hermetically sealed containers," and we continue to use that term (and its abbreviation, LACF) for the purposes of this document.

[5] Acid-tolerant pathogens such as *L. monocytogenes, E. coli O157:H7* and *Salmonella* species do not form spores. The spores of pathogens other than *C. botulinum* (e.g., *B. cereus* and *C. perfringens*) do not germinate and grow in an acid environment.

of a food is 4.6 or below, spores of *C. botulinum* will not germinate and grow (41 FR 30442 at 30442) [6].

The regulations in 21 CFR part 113 for LACF define a scheduled process as the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility (21 CFR 113.3(r)). "Commercial sterility" of thermally processed food means the condition achieved either by 1) the application of heat which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution and free of viable microorganisms (including spores) of public health significance, or by 2) the control of water activity and the application of heat which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution (21 CFR 113.3(e)).

The regulations in 21 CFR part 114 for acidified foods define a scheduled process as 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 114.3(e)). Because the pH of acidified foods is sufficiently low to prevent the germination of spores of *C. botulinum*, acidified foods may be held at ambient temperature without a heat treatment comparable to that applied to low-acid foods subject to the requirements of 21 CFR part 113 (41 FR 30442 at 30442).

Since the CGMP requirements in 21 CFR part 114 were established, acid-tolerant pathogenic microorganisms (such as *Escherichia coli O157:H7* (*E. coli O157:H7*) and *Salmonella* species) have caused outbreaks of foodborne illness in acid juices such as apple juice and orange juice (Refs. 10 - 12). Scientists have expressed concern that such acid-tolerant pathogens could survive in acidified foods and have investigated processing conditions to adequately reduce[7] the number of viable cells of pathogens such as *E. coli O157:H7*, *Salmonella* species, and *Listeria monocytogenes* (*L. monocytogenes*) in acidified foods (Refs. 13 and 14).

You should refer to 21 CFR part 114 for the complete CGMP requirements for acidified foods.

B. Emergency Permit Control Requirements for Acidified Foods

We have established emergency permit control requirements, under section 404 of the Federal Food, Drug, and Cosmetic Act, for acidified foods (21 CFR 108.25). We established these requirements, in part, because of the importance of controlling the pH of acidified foods. The

[6] Although it is well-known that spores of *C. botulinum* do not germinate and grow in a food that has a pH of 4.8 or below, FDA added a safety factor of 0.2 pH unit (and thus made the basic discriminating pH value 4.6 rather than 4.8 for acidified foods and low-acid foods packaged in hermetically sealed containers) (44 FR 16230 at 16231).

[7] In this document, we use the phrase "adequately reduce" to mean capable of reducing the presence of pathogenic microorganisms to an extent sufficient to prevent illness. The extent of reduction sufficient to prevent illness usually is determined by the estimated extent to which a pathogenic microorganism may be present in the food combined with a safety factor to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1000 (i.e., 3 logs) pathogenic microorganisms in the food, and a safety factor of 100 (i.e., 2 logs) is used, a process adequate to reduce the presence of the pathogenic microorganism would be a process capable of reducing the pathogenic microorganism by 5 logs.

emergency permit control requirements are intended to ensure safe manufacturing, processing, and packing processes and to permit us to verify that these processes are being followed. The emergency permit control regulations require commercial processors of acidified foods to register and file with us information, submitted on Form FDA 2541, that includes the name of the establishment, principal place of business, location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment (21 CFR 108.25(c)(1)). The emergency permit control regulations also require commercial processors of acidified foods to provide us with information, submitted on Form FDA 2541a, on the scheduled processes including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for each acidified food in each container size.

Forms associated with establishment registration and process filing under 21 CFR 108.25, and instructions for using the forms, are available on our Internet site (Refs. 15 and 16). You may submit the forms electronically or in paper format. As discussed in our guidance entitled "Instructions for Establishment Registration and Processing Filing for Acidified and Low-Acid Canned Foods" (Ref. 16), process filing forms are technically edited for completeness prior to computer entry, and we may return process filing forms to the firm for technical editing for clarification and additional information when necessary (e.g., if the data appear either incomplete or inaccurate). In addition, it is the responsibility of the processor to determine the adequacy of any process before it is used (Ref. 16).

You should refer to 21 CFR 108.25 for the complete emergency permit control requirements for acidified foods.

III. Discussion and Recommendations

A. Acid Foods

Acid foods are foods that have a natural pH of 4.6 or below (21 CFR 114.3(a)). Processors of acid foods are not required to register and file information about their establishment(s) and foods they process on Form FDA 2541 or to provide us with information on scheduled processes for their foods using Form FDA 2541a. Examples of acid foods include:

- Apples, oranges, and lemons (as well as the juices expressed from these fruits); and
- Standardized and nonstandardized food dressings (such as mayonnaise) and condiment sauces (such as ketchup) that have a natural pH of 4.6 or below.

The equilibrium pH of tomatoes varies from approximately 4.0 to 4.7, depending on factors such as the variety and ripeness (44 FR 16230 at 16231). Tomatoes and tomato products with a natural pH of 4.6 or below satisfy the definition of acid foods, but tomatoes and tomato products with a pH greater than 4.6, but less than 4.7, do not satisfy that definition. Data provided to FDA during the rulemaking to establish 21 CFR part 114 showed that *C. botulinum* will not grow in tomato products with a pH below 4.9 (44 FR 16230 at 16231). For this reason, FDA specifically exempted from the definition of low-acid foods tomatoes and tomato products that have a finished equilibrium pH below 4.7 (using a safety factor of 0.2); tomatoes and tomato products with a finished equilibrium pH that is 4.7 or above are low-acid foods subject to requirements for

low-acid foods when those foods are intended for use in hermetically sealed containers (44 FR 16230 at 16231). Therefore, tomatoes and tomato products with a finished equilibrium pH greater than 4.6, but below 4.7, do not meet the definitions of acid foods, acidified foods, or low-acid foods. However, for the purpose of this document, we recommend that you consider such tomatoes to be acid foods.

The natural pH range of a food (such as oranges) may be known to be 4.6 or below, but whether a packaged food is an acidified food or an acid food may not be readily apparent solely from the appearance of the food. Thus, we often must determine, during inspection of a processor's facility and when foods are offered for import, whether a particular packaged food is indeed an "acid food" that is not subject to the regulations in 21 CFR 108.25 and part 114, or is instead an "acidified food" that is subject to these regulations. To do so, we evaluate information provided to us by the processor to determine whether the information is consistent with a processor's conclusion that its product is an acid food.

Processors who are not certain as to whether specific food products are acidified foods subject to registration and process filing requirements sometimes provide us with information about their food products by voluntarily submitting Forms FDA 2541 and 2541a. If we have such information in our files, we can more readily determine whether it is consistent with a processor's conclusion that a product is an acid food and thus not subject to the requirements applicable to acidified foods.

If you choose to submit to FDA process filing information about a food that you conclude is an acid food using Form FDA 2541a, we recommend that you:

- Register your facility using Form FDA 2541 if you have not done so previously (e.g., because you do not also process any acidified foods or low-acid foods). Doing so will enable you to complete the process filing form (Form FDA 2541a), which requests the Food Canning Establishment (FCE) number we assign to your facility when you register using Form FDA 2541; and
- Submit one paper-based process filing form for each food that you conclude is an acid food, and include dimensions for all container sizes on that single form, rather than submitting one electronic form for each container size of that food. This will make any review by us more efficient. At this time, our electronic filing system does not process multiple container sizes for a single filing.

If you conclude that your product is an acid food, rather than an acidified food, and voluntarily submit process information about that food using Forms FDA 2541 and 2541a, we intend to continue to evaluate the process information to determine whether it is consistent with your conclusion that your product is an acid food that is not subject to the requirements of 21 CFR part 114 and 21 CFR 108.25. We plan to make available to our investigators the results of any FDA evaluation of such information, e.g., during an inspection of a food facility and during an evaluation of food offered for import. If we determine that the information provided to us on Form FDA 2541a is not consistent with your conclusion that your product is an acid food, we may request additional information to assist us in evaluating your product or take other action as appropriate.

If you voluntarily submit process information about a food using Forms FDA 2541 and 2541a, and later change the scheduled process for that food or change ingredients in a way that could affect the pH of the finished product, you should submit a Form FDA 2541a with updated information. As we do now, during inspection of your facility, or when your product is offered for import, we may ask to see information verifying that your scheduled process is consistent with your characterization of your product as an acid food.

B. Acidified Foods

"Acidified foods" are low-acid foods to which acid(s) or acid food(s) are added[8]; they have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below (21 CFR 114.3(b)). The definition of acidified foods provides that carbonated beverages and foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of 21 CFR part 114 (21 CFR 114.3(b)).

In the final rule establishing 21 CFR part 114 (44 FR 16230 at 16232), we specifically excluded jams, jellies and preserves from the general definition of acidified foods because experience and review of the evidence show that bacteria of public health significance cannot and do not grow in these foods. Thus, under 21 CFR 114.3(b), jams, jellies, and preserves are excluded from the coverage of 21 CFR part 114. We consider jams, jellies, and preserves that meet an applicable standard of identity under 21 CFR part 150 to be excluded from the coverage of 21 CFR part 114. We determine whether nonstandardized jellies (including non-fruit jellies), nonstandardized jams, and nonstandardized preserves are covered by 21 CFR part 114 based on the pH of the fruit, the pH of the final product, and the water activity level of the final product.

A food containing both acid food(s) and low-acid food(s) may or may not be covered by 21 CFR part 114 as an acidified food. Under 21 CFR 114.3(b), acid foods 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 are excluded from the coverage of part 114 (21 CFR 114.3(b)). The regulation in 21 CFR 114.3(b) establishes two criteria that must be satisfied to qualify for this exclusion: (1) the amount of low-acid food(s) in the product must be a "small amount," and (2) the finished equilibrium pH must not differ significantly from that of the predominant acid or acid food. See Section III.H of this guidance for recommendations on how to determine whether a food containing both acid food(s) and low-acid food(s) is covered under 21 CFR part 114.

We recommend that you consider any finished food product containing an acidified food as an ingredient to be an acidified food covered by 21 CFR part 114. As discussed above (see section II.A of this document), an acidified food (including an acidified food used as an ingredient) can pose a risk of botulism if pH and other critical factors are not carefully controlled during processing to prevent the germination and growth of viable spores of *C. botulinum.*

Examples of foods that may be acidified foods include:

[8] FDA also considers a low-acid food to which an acidified food is added to be an acidified food when the water activity of the finished food is greater than 0.85 and the finished equilibrium pH is 4.6 or below.

- Pickled beets, cocktail onions, and cherry peppers (normally pickled by the addition of acid);
- Red bell peppers treated in an acid brine;
- Some pears and tropical fruits that have a natural pH greater than 4.6 and are acidified to a pH of 4.6 or below;
- Fermented green olives subjected to processes (such as lye treatment or washing with low-acid foods) that raise the pH above 4.6, with subsequent addition of acid or acid foods to reduce the pH to 4.6 or below;
- Tomato salsa made from tomatoes with a pH of 4.6 or below and low-acid ingredients, when the amount of low-acid ingredients is not a small amount and/or the resultant finished equilibrium pH differs significantly from that of the predominant acid or acid food (see, e.g., Example 3 in Appendix 1); and
- Cold-pack pickles that are subjected to the action of acid-producing microorganisms but require the addition of acid or an acid food to achieve a pH of 4.6 or below.

C. Fermented Foods

The proposed rules to establish 21 CFR 108.25 (41 FR 30442) and part 114 (41 FR 30457) specifically addressed fermented foods and pickled foods (e.g., the title of the proposed regulations included fermented foods and pickled foods). Fermented foods (such as some kinds of sauerkraut, cucumber pickles, and green olives) are low-acid foods subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below. Pickled foods are low-acid foods that are reduced to a pH of 4.6 or below either by fermentation or by marinating in an acid solution (usually vinegar, i.e., acetic acid). Pickled foods may be maintained and stored in either the acid solution resulting from fermentation or in the marinating solution, or in a fresh acid solution applied after fermentation or marinating is complete.

Comments to the proposed rules noted that the proposed rules gave no examples in which any proven improper fermentation caused a fermented food to be a health hazard (44 FR 16204 at 16204; 44 FR 16230 at 16231). These comments questioned the inclusion of fermented foods in the regulations. In the final rules we acknowledged that we could not find reports of cases of botulism caused by commercially processed fermented foods (44 FR 16204 at 16204; 44 FR 16230 at 16231). We stated that, in the absence of known illnesses or deaths from commercially prepared fermented foods, the regulation should apply only to acidified foods. We further advised that pickled foods (including foods pickled by fermentation) that are prepared by acidification are acidified foods (44 FR 16204 at 16204) and, thus, the definition of acidified foods states that some acidified foods may be called “pickles” or “pickled” (21 CFR 114.3(b)). Thus, low-acid foods to which acid(s) or acid food(s) are added and that have a pH of 4.6 or below and a water activity above 0.85 are acidified foods subject to the requirements in 21 CFR 108.25 and part 114, irrespective of whether the low-acid food is also subjected to the action of acid-producing microorganisms.

You should note that the pH of fermented foods that are processed with a lye treatment, washed with a low-acid food, or subjected to a similar process can rise above 4.6. Such foods may either be low-acid foods (if the pH remains above 4.6) or acidified foods (if acid is added and the finished equilibrium pH is 4.6 or below).

We do not require processors of fermented foods to register their establishment(s) and foods they process (using Form FDA 2541) if these foods do not also meet the definition of an acidified food (or if these processors do not process other foods subject to 21 CFR part 113 or part 114). We also do not require such processors to provide us with information on scheduled processes for their foods (using Form FDA 2541a). For processors who voluntarily submit to FDA registration and scheduled process on fermented foods that they conclude are not also acidified foods, we recommend and plan to follow the same approach described in Section III.A for voluntary submissions for acid foods.

D. Foods That Are Stored, Distributed and Retailed under Refrigeration

Under 21 CFR 114.3(b), foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of 21 CFR part 114. Refrigeration is a preservation process in which food is cooled and maintained at a cool temperature. We recommend that you consider foods cooled and stored at freezer temperatures, as well as foods cooled and stored at refrigerator temperatures, to be "under refrigeration" within the meaning of 21 CFR 114.3(b).

E. Repacking Acidified Foods

A previously acidified food that you receive for repacking is an acidified food subject to the requirements of 21 CFR 108.25 and part 114. These requirements apply to manufacturers, processors, and packers of acidified foods; therefore, packers of acidified foods, including repackers, must meet these requirements. Moreover, the definition of acidified foods in 21 CFR 114.3(b) does not exclude repacked foods. You are subject to the requirements of 21 CFR 108.25 and part 114 if you repack a previously acidified food.

F. Reprocessing Acidified Foods

A previously acidified food that you receive for reprocessing is an acidified food subject to the requirements of 21 CFR 108.25 and part 114. These requirements apply to manufacturers, processors, and packers of acidified foods; therefore, processors of acidified foods, including reprocessors, must meet these requirements. Moreover, the definition of acidified foods in 21 CFR 114.3(b) does not exclude reprocessed foods. You are subject to the requirements of 21 CFR 108.25 and part 114 if you reprocess a previously acidified food.

G. Equilibrium pH and Finished Equilibrium pH

"Equilibrium pH" and "finished equilibrium pH" are terms that are used in 21 CFR but not defined therein. For the purpose of this guidance, we use these terms as follows:

- "Equilibrium pH" – We use this term to mean the pH of a food at 25 °C when the acid is fully diffused throughout the food and successive pH readings using procedures such as those described in 21 CFR 114.90 produce the same results. We recommend that you use 25 °C as the reference temperature for measurements of equilibrium pH because this temperature is commonly used as the reference temperature in laboratory measurements of pH.

- "Finished equilibrium pH" – We use this term to mean the equilibrium pH of a finished product.

We recommend that you use the procedures in 21 CFR 114.90, as described below, to determine the equilibrium pH. We also recommend that you measure pH after adding the water specified by your formulation. Doing so will help to ensure that the acid is fully diffused throughout the product before you measure the pH.

We recommend that you consider and apply the sample preparation procedures described in 21 CFR 114.90(a)(6) when you develop manufacturing procedures to produce a product with a uniform pH level. Section 114.90(a)(6) notes that food products may consist of a mixture of liquid and solid components that differ in acidity, or they may be semisolid in character. Sections 114.90(a)(6)(i) through (iv) provide examples of sample preparation procedures for pH testing for liquid and solid components mixtures, marinated oil products, semisolid products, and special product mixtures, respectively. Although these procedures address sample preparation methods for obtaining an analytical measurement rather for manufacturing procedures, they may enable you to address the operational challenges associated with achieving a uniform pH level throughout a product during manufacture.

We recommend that the time it takes for your manufacturing process to consistently reduce the equilibrium pH of an in-process batch of an acidified food until it reaches 4.6 be no more than 24 consecutive hours. This is consistent with Federal regulations for the preparation of acidified meat products.[9] Spores of *C. botulinum* can germinate and grow as long as the pH remains above 4.6. Therefore, the likelihood that spores of *C. botulinum* will germinate and grow increases with the amount of time that it takes to reduce the equilibrium pH of a food to 4.6. After an equilibrium pH of 4.6 has been achieved, the risk that *C. botulinum* spores will germinate and grow is eliminated, regardless of the amount of time it then takes to achieve the finished equilibrium pH of your product, as long as the equilibrium pH does not rise above 4.6 during the time it takes to achieve the finished equilibrium pH.

H. Acid Food(s) Containing Small Amounts of Low-Acid Food(s)

1. Terms

The definition of "acidified foods" in 21 CFR 114.3(b) uses the terms "small amounts of low-acid food(s)," "predominant acid or acid food," and "pH that does not significantly differ" when describing certain criteria for determining whether an acid food containing a low-acid food is covered by the regulations for acidified foods. However, 21 CFR 114.3(b) does not define these three terms. Below, we describe the way we are using these three terms (or simplified variations of these terms) for the purpose of this guidance. We also describe additional associated terms

[9] Regulations established by the Food Safety and Inspection Service of the U.S. Department of Agriculture define an acidified low acid product as a canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe (9 CFR 318.300(b)).

(i.e., "acid food containing small amounts of low-acid food(s)," "acid ingredient," "low-acid ingredient," "shift in pH," "small amount provision," and "water-based liquid") we use for the purpose of this guidance.

- "Acid food containing small amounts of low-acid food(s)" - We use this term to refer to an acid food that is excluded from the coverage of 21 CFR part 114 because it contains small amounts of low-acid food(s) and has a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food.
- "Acid ingredient" - We use this term to mean an ingredient, having a pH of 4.6 or below, that is an acid (such as vinegar) or an acid food (such as strawberries and tomatoes that have a natural pH of 4.6 or below). As discussed above, for the purpose of this guidance, we recommend that you consider tomatoes that have a natural pH greater than 4.6, but less than 4.7, to be an acid ingredient.
- "Low-acid ingredient" - We use this term to mean an ingredient (including fresh and minimally processed foods (such as sliced onions) and processed foods (such as anchovies)) having a pH greater than 4.6.
- "Significant difference in pH" – We recommend that you evaluate whether the finished equilibrium pH significantly differs from that of the predominant acid or acid food according to the criteria in Table 1 below and using the steps described in Tables 4, 5 and 6 (see Section III.H.5)

Table 1
Recommendations for Significant Difference in pH

If the equilibrium pH of the predominant acid or acid food is:	Then you should consider a shift in pH to be significant when:
> 4.2	Any shift in pH is present
4.2	The shift in pH is > 0.2
≥ 3.8 and < 4.2	The shift in pH is > 0.3
< 3.8	The shift in pH is > 0.4

These recommendations depend on a number of factors, including:

  - The proximity of the resultant finished equilibrium pH to 4.6. pH measurements may not always be accurate. Therefore, the closer the finished equilibrium pH appears to be to 4.6, the greater than likelihood that the actual pH is above 4.6 but has not been accurately measured;
  - Limitations in the accuracy and precision of the methods for determining pH, including methods discussed in 21 CFR 114.90. For example, these limitations make it impractical to establish a procedure that relies on a very small (e.g., 0.1) shift in pH; and
  - The potential for variability in the finished equilibrium pH of a particular food product.

- "Predominant acid or acid food" - We recommend that you consider the "predominant acid or acid food" to be the mixture resulting from the combination of all acid ingredients used in the formulation of an acid food containing small amounts of low-acid food(s).

- "Shift in pH" - We use this term to describe the difference between the finished equilibrium pH of an acid food containing small amounts of low-acid food(s) and the equilibrium pH of a mixture of water and the predominant acid or acid food. We recommend that you calculate the shift in pH using the steps described in Table 6 (see Section III.H.5).
- "Small amount of low-acid food(s)" - We recommend that you consider a "small amount of low-acid food(s)" to be no more than 10 percent by weight of low-acid food(s) in the finished product (as determined by the calculation in Table 3 in Section III.H.5 of this guidance). Our recommendation is based on our experience with determining, on a case-by-case basis for processes filed on Form 2541a, the amount of low-acid food that should be considered a "small amount." We have found 10 percent by weight to be a reasonable starting point for evaluating whether a food is excluded from the coverage of 21 CFR part 114.
- "Small amount provision" – We use this term to refer to the provision in 21 CFR 114.3(b) that acid foods 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 are excluded from the coverage of 21 CFR part 114.
- "Water-based liquid" – We use this term to mean a food, such as a conventional beverage or dietary supplement, that:
    - Contains, in its finished form, a greater quantity of water than the quantity of all other ingredients combined; and
    - Lists water as the predominant ingredient in the ingredient statement on the food label (21 CFR 101.4).

  Examples of water-based liquids as that term is used in this guidance are beverages or dietary supplements that consist primarily of water with added fruit flavors, extracts, or herbs, or added vitamins, minerals, or other nutrients. Examples of liquids that are not "water-based liquids" as that term is used in this guidance are beverages, such as fruit juice- or milk-based beverages, that principally contain water as an inherent component of the predominant ingredient of the food in its finished form (in this example, fruit juice or milk). For the purpose of this guidance, we are not considering fruit juice for which a standard of identity is established in 21 CFR part 146, other fruit juices such as apple juice, blended juices, and reconstituted juices; and vegetable juices to be "water-based liquids."

*2. Examples of foods that **may be** acid foods containing small amounts of low-acid food(s)*

The following are examples of foods that may be acid foods containing small amounts of low-acid food(s) depending on the percent by weight of low-acid food(s) in the finished product and the significance of the shift in pH between the finished food and the predominant acid or acid food(s). The steps we recommend that you follow in calculating the percent by weight of low-acid food(s), and in evaluating the significance of the shift in pH, are described in Tables 3 through 6 in Section III.H.5 of this document. For examples of calculations and analyses using Tables 3 through 6, see Appendix 1.

Tomato puree with added spices:

- Predominant acid food: Tomato puree.
- Low-acid ingredients: Spices.

Thousand Island Salad Dressing:

- Predominant acid food: Mixture of all acid ingredients, such as mayonnaise, lemon juice, and tomato paste.
- Low-acid ingredients: Green peppers, celery, and onions.

Ketchup with added color:

- Predominant acid food: Mixture of all acid ingredients, such as tomato concentrate and vinegar.
- Low-acid ingredients: Color additive to make the ketchup green and other ingredients such as spices and corn syrup.

*3. Examples of foods that **are not** an acid food containing small amounts of low-acid food(s)*

The following are examples of foods to which the calculations in the Decision Tables (Tables 2 through 6) in Section III.H.5 do not apply because the foods are not acid foods containing small amounts of low-acid food(s). Foods such as those described below are covered by 21 CFR part 114.

Tomato salsa made from low-acid tomatoes processed by acidification to pH 4.0, fresh onions, garlic, peppers, salt and spices:

- The food is not an acid food containing small amounts of low-acid food(s) because the finished food does not contain any acid foods. The tomatoes are an acidified food, and the remaining ingredients are low-acid foods. The small amount provision does not apply when low-acid foods are added to an acidified food.

Green olives (previously prepared by fermentation) that are reprocessed by stuffing with a low-acid food:

- The stuffed green olives are not an acid food containing small amounts of low-acid food(s) because the green olives are a fermented food rather than an acid food. Fermented foods are low-acid foods subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below and, therefore, are not acid foods as defined by 21 CFR 114.3(a).

4. Water-based liquids (other than carbonated beverages) with a pH of 4.6 or below

Water is a low-acid food. A water-based liquid may contain acid ingredients such as citric acid or lemon juice, usually to reduce and stabilize the pH to 4.6 or below. The quantitative amount of water in a water-based liquid is greater than the quantitative amounts of all other ingredients combined, regardless of whether the other ingredients are acid foods or low-acid foods. Therefore, based on the definitions of “water-based liquids” and “small amount of low-acid food(s)” used in this guidance, the total amount of low-acid food in a water-based liquid should

not be considered a "small amount" because the percent by weight of low-acid food(s) in the liquid is greater than 10 percent (see Table 3). When the finished equilibrium pH of a water-based liquid that contains acid(s) or acid food(s) is 4.6 or below, you should consider the water-based liquid to be an acidified food subject to the requirements of 21 CFR part 114 unless the liquid is a carbonated beverage (see 21 CFR 114.3(b)).

5. Decision tables and calculations for acid foods containing added low-acid foods

When a food product contains both acid and low-acid foods, we recommend that you apply the Decision Tables below (Tables 2 through 6) to evaluate whether the product is covered by 21 CFR part 114 or is excluded from coverage as an acid food containing small amounts of low-acid food(s). The Decision Tables employ a stepwise approach to this evaluation as follows:

- Table 2: Recommendations for determining whether to evaluate your product as an acid food containing small amounts of low-acid food(s).
- Table 3: Recommended calculations for determining whether to consider the amount of low-acid food as a "small amount."
- Table 4: Recommendations for determining the equilibrium pH of the predominant acid or acid food.
- Table 5: Recommendations for determining the finished equilibrium pH of your product.
- Table 6: Recommendations for evaluating whether the resultant finished equilibrium pH of your product differs significantly from that of the predominant acid or acid food.

The "small amount provision" of 21 CFR 114.3(b) applies to "acid food(s)" that contain(s) added low-acid food(s) and have a finished equilibrium pH of 4.6 or below and a water activity greater than 0.85. The "small amount provision" does NOT APPLY if:

- Your product does not contain any low-acid food;
- The food to which you add low-acid ingredients is an acidified food rather than an acid food;
- The food to which you add low-acid ingredients is a fermented food rather than an acid food; or
- Your product is excluded from the coverage of 21 CFR part 114, e.g., because it has a finished equilibrium pH greater than 4.6, has a water activity less than or equal to 0.85, is a carbonated beverage, or is stored, distributed, and retailed under refrigeration.

As discussed above (see section III.B of this document), we recommend that you consider any finished food product containing an acidified food as ingredient to be an acidified food covered by 21 CFR part 114. Consistent with that recommendation, we recommend that you not evaluate a food product that is an acid food containing both low-acid food(s) and acidified food(s) under the "small amount provision."

When applying the Decision Tables to your product, we recommend that you use a pilot batch (which may be either a full-scale batch or a small-scale batch prepared according to the formulation of your product) when following the steps in Tables 3, 4, and 5. The calculations in Table 3 for determining the percent by weight of low-acid food(s) in a finished product (see Step E) exclude the weight of any water and oil used to formulate the product. Water and oil are low-acid foods that do not appreciably affect the finished equilibrium pH for the purpose of

evaluating whether the amount of low-acid food(s) in the finished product is a "small amount." (As discussed in Section III.H.4 of this guidance, the recommendations for applying the "small amount provision" do not apply to water-based liquids, in which the amount of water is greater than the amount of all other ingredients combined).

The Decision Tables and other recommendations in this guidance do not preclude consideration of other factors relating to your product or your manufacturing process in determining whether your product is an acid food containing small amounts of low-acid food(s) in a specific situation. If you determine that use of the Decision Tables results in an inappropriate characterization of your acid food containing added low-acid food, you should provide FDA with formulation and process information to support your determination.

Table 2
Recommended Steps for Determining Whether to Evaluate Your Product Under the "Small Amount Provision"

Step	Question	Answer to the Question	Outcome
A	Does your product contain any acid foods?	NO	STOP. You should consider that your product: • IS NOT an acid food containing small amounts of low-acid food(s); and • MAY BE covered by 21 CFR part 114. You should evaluate the product based on the characteristics of its ingredients.
		YES	PROCEED to Step B
B	Does your product contain any low-acid ingredients?	NO	STOP. You should consider that your product: • IS NOT an acid food containing small amounts of low-acid food(s); and • MAY BE covered by 21 CFR part 114. You should evaluate the product based on the characteristics of its ingredients.
		YES	PROCEED to Step C.
C	Is the finished equilibrium pH of your product 4.6 or below?	NO	STOP. Your product: • IS NOT covered by 21 CFR part 114; • MAY BE covered by 21 CFR part 113.
		YES	PROCEED to Step D.
D	Is your product a water-based liquid?	NO	PROCEED to Step E.

Step	Question	Answer to the Question	Outcome
		YES	STOP. You should consider that your product is: • NOT an acid food containing small amounts of low-acid food(s); and • COVERED by 21 CFR part 114.
E	Do any of the following descriptions apply to your product containing both acid food(s) and low acid food(s)? • E1. Water activity < 0.85 • E2. Carbonated beverage • E3. Stored, distributed, and retailed under refrigeration	NO	PROCEED to Step F.
		YES	• STOP. Your product is EXCLUDED from the coverage of 21 CFR part 114.
F	Does your product contain any acidified foods?	NO	PROCEED to Table 3.
		YES	STOP. You should consider that your product is: • NOT an acid food containing small amounts of low-acid food(s); and • COVERED by 21 CFR part 114.

Table 3
Recommended Calculations for Determining Whether to Consider the Amount of Low-Acid Food as a "Small Amount" When the Outcome of Table 2 is to Proceed to Table 3

Step	Question	How To Address the Question	Answer to the Question	Outcome
G	Is the amount of low-acid food in the finished product ≤ 10 percent by weight?	Perform the following calculation: • G1. Determine the weight of all acid ingredients used in formulating your product. • G2. Determine the weight of all low-acid ingredients (excluding water and oil you will add based on formulation) used in formulating your product. • G3. Add the weight of all acid ingredients and the weight of low-acid ingredients. • G4. Divide the weight in G2 by the weight in G3. Multiply by 100 and express as percent.	NO	STOP. You should consider that: • The amount of low-acid food is NOT a small amount; and • Your product is COVERED by 21 CFR part 114.
			YES	PROCEED to Table 4. You should consider that the amount of low-acid food IS a small amount.

Table 4
Recommendations for Evaluating the Equilibrium pH of the Predominant Acid or Acid Food When the Outcome of Table 3 is to Proceed to Table 4

Step	Question	How To Address the Question	Answer to the Question	Outcome
H	Is the equilibrium pH of the predominant acid or acid food $\leq$ 4.2?	Determine the equilibrium pH of the predominant acid or acid food as follows. • H1. Prepare the "predominant acid or acid food" by combining all acid ingredients in a pilot batch. • H2. Add all water used in the formulation of the food to the predominant acid food. Use your production water. • H3. Determine the equilibrium pH of the resulting mixture.	NO	STOP. You should consider that your product is: • NOT an acid food containing small amounts of low-acid food(s) with a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food; and • COVERED by 21 CFR part 114.
			YES	PROCEED to Table 5.

Table 5
Recommendations for Evaluating the Finished Equilibrium pH of Your Product When the Outcome of Table 4 is to Proceed to Table 5

Step	Question	How To Address the Question	Answer to the Question	Outcome
I	Is the finished equilibrium pH of your product $\leq$ 4.4?	Determine the finished equilibrium pH of your product as follows. • I1. Combine the mixture from Step H with all low-acid ingredients and oil used in the formulation of the food (or, process with lye treatment or similar treatment). • I2. Determine the equilibrium pH of the resulting mixture.	NO	STOP. You should consider that your product is: • NOT an acid food containing small amounts of low-acid food(s) with a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food; and • COVERED by 21 CFR part 114.
			YES	PROCEED to Table 6.

Table 6
Recommendations for Evaluating Whether the Resultant Finished Equilibrium pH of Your Product Significantly Differs From That of the Predominant Acid or Acid Food When the Outcome of Table 5 is to Proceed to Table 6

Step	Question	How To Address the Question	Answer to the Question	Outcome
J	What is the equilibrium pH of the predominant acid or acid food?	Refer to your determination in Step H in Table 4.	4.2	The shift in pH is $\leq$ 0.2. You should consider that: • The resultant finished equilibrium pH of your product does not significantly differ from that of the predominant acid or acid food; and • Your product is EXCLUDED from the coverage of 21 CFR part 114.
			$\geq$ 3.8 and < 4.2	PROCEED to Step K.
			< 3.8	PROCEED to Step L.

Step	Question	How To Address the Question	Answer to the Question	Outcome
K	If the finished equilibrium pH of the predominant acid or acid food is ≥ 3.8 and < 4.2, is the shift in pH ≤ 0.3?	Calculate the shift in pH. Shift in pH = Finished equilibrium pH (Step I in Table 5) minus equilibrium pH of the predominant acid or acid food (Step H in Table 4).	NO	You should consider that: • The resultant finished equilibrium pH of your product significantly differs from that of the predominant acid or acid food; and • Your product is COVERED by 21 CFR part 114.
			YES	You should consider that: • The resultant finished equilibrium pH of your product does not significantly differ from that of the predominant acid or acid food; and • Your product is EXCLUDED from the coverage of 21 CFR part 114.

Step	Question	How To Address the Question	Answer to the Question	Outcome
L	If the finished equilibrium pH of the predominant acid or acid food is < 3.8, is the shift in pH ≤ 0.4?	Calculate the shift in pH. Shift in pH = Finished equilibrium pH (Step I in Table 5) minus equilibrium pH of the predominant acid or acid food (Step H in Table 4).	NO	You should consider that: • The resultant finished equilibrium pH of your product significantly differs from that of the predominant acid or acid food; and • Your product is COVERED by 21 CFR part 114.
			YES	You should consider that: • The resultant finished equilibrium pH of your product does not significantly differ from that of the predominant acid or acid food; and • Your product is EXCLUDED from the coverage of 21 CFR part 114.

I. Fermented Food(s) Containing Small Amounts of Low-Acid Food(s)

As discussed above (see section III.C of this document), in 1979 we acknowledged that we had not found reports of cases of botulism caused by commercially processed fermented foods (44 FR 16204; 44 FR 16230 at 16231) and, thus, stated that the regulation should apply only to acidified foods. We further advised that pickled foods (including foods pickled by fermentation) that are prepared by acidification are acidified foods (44 FR 16204).

Since 1979, we have not received information implicating commercially processed fermented foods in cases of botulism. However, the food industry evolves over time, and some of the products available today (such as fermented olives stuffed with a low-acid food) may not have been on the market in 1979. We see no meaningful scientific difference between potential safety

concerns presented by fermented foods containing added low-acid foods and potential safety concerns presented by acid foods containing added low-acid foods. Therefore, if you add a low-acid food to a fermented food, we recommend that you evaluate the product using the stepwise process described in Decision Tables 2 through 6 in section III.H.5 of this document. To do so, you would evaluate a fermented food as if it were an acid food, using the steps in these tables. If the amount of low-acid food(s) in your fermented food is not a "small amount," or if the resultant finished equilibrium pH of your product containing a small amount of low-acid food significantly differs from that of the fermented food, we recommend that you consider the fermented food to be an acidified food subject to the requirements of 21 CFR 108.25 and part 114.

J. Processing Acidified Foods

1. Background on thermal processing

The ability of vegetative cells of microorganisms to grow in an acidified food, and of microbial spores to germinate and grow in an acidified food, depends on a number of factors associated with the food, such as its water activity, its pH, its redox potential[10], the nature of any added acid, and the presence of antimicrobial substances (Ref. 5). Microorganisms that grow in an acidified food may have significance for public health, spoilage, or both.

Microorganisms such as *E. coli O157:H7, L. monocytogenes* and *Salmonella* species have public health significance. Microorganisms such as *B. coagulans* have significance for spoilage (Ref. 17). However, some microorganisms that are generally associated with spoilage, such as *B. subtilis* and *B. licheniformis*, (Ref. 17) can also affect the safety of an acidified food if spores that are not destroyed during thermal processing germinate, grow, and cause the pH to increase above 4.6 (Ref. 9). Therefore, destroying the spores of such spoilage microorganisms is especially important in maintaining the food under conditions that will not permit the growth of microorganisms having public health significance when permitted preservatives are not used to prevent the growth of any germinated spores.

The scientific and technical details supporting commercial thermal processing of acidified foods are available in a number of scientific journals (e.g., Refs. 4, 18, and 19) and in books that are available for purchase (see, e.g., the books we list in Section IV of this guidance). Such scientific and technical details are beyond the scope of this guidance. However, in this guidance we summarize some of the basic principles of thermal processing, as discussed in Refs. 2 and 20 through 22, and explain technical terms associated with thermal processing.

A thermal process for a particular food product is developed based on the most heat-resistant microorganism that must be controlled in the food. The pH of the food product is a principal factor in determining the microorganism(s) that must be controlled in the food. For example, the thermal process for a low-acid food is developed to ensure that the spores of *C. botulinum* are destroyed. The thermal process for an acidified food with a pH in the range of 4.0 – 4.6 is

[10] The redox potential of a substance is a measurement of the ease by which a substance gains or loses electrons. For additional information about redox potential of foods, see Ref. 3.

developed to ensure that the spores of acid-tolerant spoilage microorganisms (e.g., *B. licheniformis*) are destroyed. The thermal process for an acidified food with a pH < 4.0 is developed to ensure that the vegetative cells of yeasts, molds, and non-spore-forming bacteria such as *Lactobacillus* species are destroyed (Refs. 2 and 22).

After determining the most heat-resistant microorganism to control in a particular food product, one or more strains of the microorganism can be isolated and cultured to obtain vegetative cells or spores in a sufficient number to enable an experimental determination of the thermal resistance of the strain(s). In this determination, a known number of vegetative cells or spores is subjected to a series of processes (with specified durations and temperatures), and the number of cells or spores surviving each process is determined. The relationship between the duration of a thermal treatment and the percentage of microorganisms surviving the treatment is logarithmic, and the results of such studies are usually presented in a plot that represents the log of the percent of surviving vegetative cells or spores versus time at a given temperature. The time required to destroy 90 percent of the vegetative cells or spores at a given temperature is called the decimal reduction time, usually referred to as the "D-value" (Ref. 2). The D-value usually varies inversely with temperature.

In general, the slope of a plot of the log of the D-value versus temperature is approximately linear. A "z-value" is derived from the reciprocal of the slope of the best straight line and is equal to the increase in the number of degrees (from a given starting temperature) that results in a 90 percent reduction in the D-value (Ref. 2). The D-value and z-value for the vegetative cells or spores of a microbial strain at a specified temperature characterize its thermal resistance at that temperature. Therefore, D-values and z-values provide a means to compare the thermal resistance of different microorganisms, or different strains of the same microorganism, at one or more temperatures. Table 7, adapted from Refs. 2 and 22, with additional information from Ref. 18, shows a typical comparison of the heat resistance of several microorganisms relevant to the safety or spoilage of thermally processed foods.

Table 7
Comparative Heat Resistance of Bacteria Important to Thermally Processed Foods (Adapted from Refs. 2 and 22)

Class of Food	Type of Microorganism	Microorganism(s)	Reference Temperature (°F)	D-Value (minutes)	Z-Value (°F)
Low-acid food (pH > 4.6)	Thermophiles[a] (spores)	Flat-sour group (*B. stearothermophilus*)	250	4.0 – 5.0	14-22
	Mesophiles[b] (spores)	Putrefactive anaerobes (*C. botulinum* types A and B)	250	0.10 – 0.20	14-18
		C. sporogenes group (including P.A. 3679)	250	0.10 - 1.5	14-18
Acid food and acidified food (pH 4.0 – 4.6)	Thermophiles (spores)	*B. coagulans* (facultatively mesophilic[c])	250	0.01 – 0.07	14-18
	Mesophiles (spores)	*B. polymyxa* and *B. macerans*	212	0.10 – 0.50	12-16
		Butyric anaerobes (*C. pasteurianum*)	212	0.10 – 0.50	12-16
		B. licheniformis[d]	200	4.5	27
Acid food and acidified food (pH < 4.0)	Yeasts, molds, and mesophilic non-spore-bearing bacteria	*Lactobacillus* species, *Leuconostoc* species	150	0.50 – 1.00	8-10

[a] A thermophilic microorganism is one that thrives at a relatively high temperature, such as 50 °C or above.
[b] A mesophilic microorganism is one that thrives at a moderate temperature, such as 37 °C.
[c] A facultative microorganism is one that can live under more than one set of environmental conditions.
[d] Ref. 18.

Food processors typically compare thermal treatments at various temperatures using a reference thermal treatment, referred to as an "equivalent treatment." The equivalent treatment is developed for a reference temperature that is selected for the purpose of conducting experiments to determine appropriate thermal processing conditions. The reference temperature is selected based on the heat resistance of microorganisms under particular conditions of pH; in general, the reference temperature is higher when the microorganisms of interest are more heat-resistant. For example, the reference temperatures listed in Table 7 for both thermophilic spores and mesophilic spores in low-acid foods (with a pH greater than 4.6) is 250 °F. In contrast, the reference temperatures listed for mesophilic spores in acid foods in the pH range 4.0 – 4.6 are

212 °F and 200 °F, and the reference temperature for yeasts, molds, and non-spore-forming mesophilic bacteria listed in Table 7 is 150 °F. The destruction time at the reference temperature for a given number of specific microorganisms is designated "F." Additional information about how to do such comparisons is available in Ref. 22.

The extent of thermal processing (i.e., time and temperature) adequate to prepare a commercial food product that is both safe and resistant to spoilage is called the thermal process lethality. The relationship between the finished equilibrium pH of a product and the thermal process lethality is well established (e.g., Refs. 4, 17, 18 and the books we list in Section IV of this guidance). The thermal process lethalities listed in Table 8 demonstrate this relationship. Information about the specific microorganisms and D-values used to determine the thermal process lethality is available in the cited references.

Table 8
Thermal Process Lethalities for Acidified Foods

Finished Equilibrium pH	Thermal Process Lethality[a]
3.1 – 3.2	F10/195 = 0.1 minutes[b]
3.3 – 3.5	F10/195 = 1.0 minutes[c]
3.5 – 4.0	F10/195 = 16-23 minutes[d]
4.0 – 4.2	F15/200 = 5.0 minutes[e]
4.3 – 4.4	F15/200 = 23 minutes[f]
4.3 – 4.4	F15/200 = 10 minutes[e]
4.3 – 4.4	F15/212 = 10 minutes[f]
4.5 – 4.6	F15/212 =10 minutes[g]
4.5 – 4.6	F18/230 = 1.6 minutes[g]

[a] Expressed as Fz/Ref, where F is the destruction time, z is the increase in temperature that results in a 90 percent reduction in the D-value, and Ref is the reference temperature (see the discussion in Section III.I.1 of this guidance for further information about the designations F, z-value, and D-value).
[b] See, e.g., Ref. 4.
[c] See, e.g., Nelson P, and Tressler D. 1980. *Fruit and Vegetable Juice Processing Technology*. Westport, CT: AVI Pub. Co.
[d] See, e.g., Barrett DM, Somogyi L, and Ramaswamy HS. 2004. *Processing Fruits: Science and Technology*. Boca Raton, FL: CRC Press.
[e] See, e.g., National Canners Association Research Laboratories. 1968. *Laboratory Manual for Food Canners and Processors*. Westport, CT: AVI Pub. Co.
[f] See, e.g., Ref. 17.
[g] See, e.g., Ref. 18.

The scheduled process for an acidified food is 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 (21 CFR 114.3(e)). To be adequate, the scheduled process for an acidified food generally is designed to destroy all microorganisms that could be present in or on the food product, the package (including

containers and closures), or both. Below, we describe the two most common methodologies (Ref. 21) for processing an acidified food.

- The product may be heated in a bulk container to a pre-determined temperature, held at that temperature for a pre-determined period of time to achieve thermal process lethality, filled into containers, and closed (e.g., under steam vacuum). Thermal processing of the containers and closures is accomplished by rotating, tilting, or inverting the filled, sealed containers to bring all sections of the containers and closures (caps or lids) in contact with hot product. This type of process is often referred to as "hot fill and hold."
- The product may be filled into containers and sealed. The thermal processing to achieve thermal process lethality at a pre-determined temperature for a pre-determined time takes place in the filled and sealed containers. This procedure usually takes place in commercially available processing equipment. Thermal processing of the containers and closures occurs simultaneously with the thermal processing of the product.

2. Competent processing authority

Section 21 CFR 114.3(e) requires that the control of pH and other critical factors for a scheduled process for an acidified food be equivalent to the process established by a competent processing authority. The full range of critical factors that a competent processing authority would consider in establishing a scheduled process is outside the scope of this guidance. Following the recommendations in this guidance does not necessarily satisfy the requirement of 21 CFR 114.3(e) that your scheduled process be equivalent to that established by a competent processing authority.

3. Challenge studies

The scientific and technical data supporting scheduled processes established over time by competent processing authorities are available in a number of scientific journals (e.g., Refs. 4, 18 and 19) and in books that are available for purchase (see, e.g., the books we list in Section IV of this guidance). If a new scheduled process is being established and adequate scientific support for the scheduled process is not available, we recommend that data and information from appropriate challenge studies be developed for consideration by the competent processing authority who will establish the new scheduled process. The challenge studies should demonstrate that one or more critical factors (or combinations of critical factors) such as pH, temperature, or storage time satisfy the requirements of 21 CFR 114.80(a) (e.g., Refs. 14, and 23 through 25).

Processes using ambient temperature as one of a combination of critical factors have been reported in the scientific literature (Ref. 14). The ambient temperatures studied include those likely to be associated with a food processing facility (such as 25 °C) and those likely to be associated with a warehouse in a cool climate (such as 10 °C). If one of the critical factors reported in a scheduled process filed under 21 CFR 108.25 is an ambient temperature, we will consider whether using the ambient temperature as a critical factor satisfies the requirements of 21 CFR 114.3(e) and 114.80(a) based on the available data and information provided with the process filing.

4. Potential for microbial contamination from packaging

Packaging such as containers and lids can be a source of microbiological contamination. The competent processing authority should consider the potential for such contamination when developing a scheduled process.

5. Adequacy of the Scheduled Process

The scheduled process for acidified foods:

- Is 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 (see 21 CFR 114.3(e)), and
- Must be sufficient to destroy the vegetative cells of microorganisms of public health significance (see 21 CFR 114.80(a)(1)); and
- Must be sufficient to destroy the vegetative cells of microorganisms 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 (see 21 CFR 114.80(a)(1)).

To be adequate in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance, the scheduled process should be sufficient to destroy spores of those microorganisms of nonhealth significance capable of germinating and reproducing and increasing the pH of acidified foods above 4.6, unless permitted preservatives are used to prevent the growth of the microorganisms of non-health significance in lieu of thermal processing.

To be adequate in destroying the vegetative cells of microorganisms of public health significance, the scheduled process for acidified foods should be sufficient to destroy or prevent the presence of vegetative cells of pathogenic microorganisms, including pathogenic microorganisms (such as *E.* O157:H7, *L. monocytogenes* and *Salmonella* species) that are acid-tolerant but do not produce spores.

Under 21 CFR 108.25(c)(3)(ii), we may request that a processor provide information we deem necessary to determine the adequacy of the process. Consistent with 21 CFR 114.3(b) and 114.80(a)(1), the requested information may include information related to:

- Adequacy of the process to destroy vegetative cells of microorganisms, including microorganisms of public health significance and microorganisms of nonhealth significance; and
- Adequacy of the process to destroy spores of microorganisms capable of germinating and reproducing and increasing the pH of acidified foods above 4.6.

K. Quality Control Procedures to Address Spoilage

Under 21 CFR 114.80(a), you must employ appropriate quality control procedures to ensure that finished foods do not present a health hazard. We recommend that such quality control procedures include:

- Developing and implementing a written plan to systematically investigate manufactured lots for signs of spoilage;
- Promptly and thoroughly investigating the cause of any spoilage;
- Promptly taking corrective actions if spoilage occurs; and
- Documenting any investigation and corrective actions relevant to spoilage.

IV. Examples of Books Available for Purchase

1. Stumbo CR. 1973. *Thermobacteriology In Food Processing*. New York: Academic Press.

2. Larousse J, and Brown B. 1997. *Food Canning Technology*. New York: Wiley-VCH.

3. Barrett DM, Somogyi L, and Ramaswamy HS. 2004. *Processing Fruits: Science and Technology*. Boca Raton, FL: CRC Press.

4. Lund BM, Baird-Parker TC, and Gould GW. 2000. *Microbiological Safety and Quality of Food*. Gaithersburg, MD: Aspen Publishers.

5. National Canners Association Research Laboratories. 1968. *Laboratory Manual for Food Canners and Processors*. Westport, CT: AVI Pub. Co.

6. Nelson P, and Tressler D. 1980. *Fruit and Vegetable Juice Processing Technology*. Westport, CT: AVI Pub. Co.

7. Pflug IJ. 2003. Microbiology and Engineering of Sterilization Processes. 11th edition. Minneapolis: Environmental Sterilization Laboratory.

V. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of September 24, 2010, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after September 24, 2010.

1. Shapiro RL, Hatheway C, and Swerdlow DL. 1998. Botulism in the United States: A Clinical and Epidemiologic Review. *Annals of Internal Medicine* 129 (3): 221-228.

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Appendix 1. Examples of the Application of Tables 2 Through 6 For Evaluating An Acid Food Containing Small Amounts of Low-Acid Food(s)

Example 1: Tomato Salsa Manufactured by Company A

- Description of product:
  - Processed tomatoes (acidified to pH 4.0);
  - Previously acidified onions, garlic, and green peppers;
  - Salt, spices;
  - Finished equilibrium pH: 4.1.
- Table 2: Step A: None of the ingredients are acid foods; the ingredients with a pH of 4.6 or below are all acidified foods.
- STOP evaluating whether the product is an acid food containing small amounts of low-acid food(s). You should consider that your product:
  - Is NOT an acid food containing small amounts of low-acid food(s); and
  - May be COVERED by 21 CFR part 114.

- Evaluate the product based on the characteristics of its ingredients.
    - The ingredients with a pH of 4.6 or below are all acidified foods;
    - The product has a finished equilibrium pH of 4.6 or below;
    - The water activity of tomatoes is greater than 0.85;
- You should consider that your product is COVERED by 21 CFR part 114.

Example 2: Tomato Salsa Manufactured by Company B

- Description of product:
    - Processed tomatoes (acidified to pH 4.0);
    - Fresh onions, garlic, and green peppers;
    - Salt, spices;
    - Finished equilibrium pH: 4.1.
- Table 2, Step A: None of the ingredients are acid foods; the ingredients with a pH of 4.6 or below are all acidified foods.
- STOP evaluating whether the product is an acid food containing small amounts of low-acid food(s). You should consider that your product:
    - Is NOT an acid food containing small amounts of low-acid food(s); and
    - May be COVERED by 21 CFR part 114.
- Evaluate the product based on the characteristics of its ingredients.
    - The ingredients with a pH of 4.6 or below are all acidified foods;
    - The product has a finished equilibrium pH of 4.6 or below;
    - The water activity of tomatoes is greater than 0.85;
- You should consider that your product is COVERED by 21 CFR part 114.

Example 3: Tomato Salsa Manufactured by Company C

- Description of product:
    - A variety of vine-ripened fresh tomatoes that naturally has a pH of 4.4;
    - Fresh onions, garlic, and green peppers;
    - Salt, spices;
    - Finished equilibrium pH: 4.5.
- Table 2, Step A: The product contains an acid food (tomatoes with a natural pH of 4.4). PROCEED to Step B.
- Table 2, Step B: The product contains low-acid ingredients (fresh onions, garlic, green peppers, salt, and spices). PROCEED to Step C.
- Table 2, Step C: The finished equilibrium pH of the product is below 4.6. PROCEED to Step D.
- Table 2, Step D: The product is not a water-based liquid. PROCEED to Step E.
- Table 2, Step E: None of the listed exclusions (for water activity, carbonated beverage, or refrigeration) apply. PROCEED to Step F.
- Table 2, Step F: The product does not contain any acidified foods. PROCEED to Table 3.
- Table 3, Step G:
    - The weight of all acid ingredients (fresh tomatoes) is 480 pounds;
    - The weight of all low-acid ingredients (fresh onions, garlic, peppers, salt, and spices) is 20 pounds;

  - The total weight of all ingredients is 500 pounds;
  - The percent of low-acid ingredients is 4 percent (20 pounds/500 pounds) – i.e., less than 10 percent.
  - PROCEED to Table 4.
- Table 4, Step H: The predominant acid food is fresh tomatoes; the pH of this variety of fresh tomatoes is 4.4, i.e., greater than 4.2.
- STOP: You should consider the product to be COVERED by 21 CFR part 114.

Example 4: Applesauce Made from Fresh McIntosh Apples and Fresh Dates, Manufactured by Company D

- Description of product:
  - Fresh McIntosh apples (natural pH of 3.4);
  - Fresh dates (natural pH of 4.7);
  - Finished equilibrium pH: 3.5.
- Table 2, Step A: The product contains an acid food (fresh apples). PROCEED to Step B.
- Table 2, Step B: The product contains a low-acid ingredient (fresh dates). PROCEED to Step C.
- Table 2, Step C: The finished equilibrium pH of the product is below 4.6. PROCEED to Step D.
- Table 2, Step D: The product is not a water-based liquid. PROCEED to Step E.
- Table 2, Step E: None of the listed exclusions (for water activity, carbonated beverage, or refrigeration) apply. PROCEED to Step F.
- Table 2, Step F: The product does not contain any acidified foods. PROCEED to Table 3.
- Table 3, Step G:
  - The weight of all acid ingredients (fresh apples) is 490 pounds;
  - The weight of all low-acid ingredients (fresh dates) is 10 pounds;
  - The total weight of all ingredients is 500 pounds;
  - The percent of low-acid ingredients is 2 percent (10 pounds/500 pounds) – i.e., less than 10 percent.
  - Proceed to Table 4.
- Table 4, Step H: The predominant acid food is apples; the pH of the fresh apples is 3.4, i.e., less than 4.2. PROCEED to Table 5.
- Table 5, Step I: The finished equilibrium pH of the applesauce with added fresh dates is 3.5, i.e., less than 4.4. PROCEED to Table 6.
- Table 6, Step J: The equilibrium pH of the predominant acid food (fresh apples) is < 3.8. PROCEED to Step L.
- Table 6, Step L: The shift in pH is 0.1 (3.5 – 3.4), which is < 0.4. You should consider that:
  - The resultant finished equilibrium pH of your product does not differ significantly from that of the predominant acid food; and
  - Your product is EXCLUDED from the coverage of 21 CFR part 114.

Example 5: Applesauce Made from Fresh McIntosh Apples and Fresh Dates, Manufactured by Company E

- Description of product:
    - Fresh McIntosh apples (natural pH of 3.4);
    - Fresh dates (natural pH of 4.7);
    - Finished equilibrium pH: 3.7.
- Table 2, Step A: The product contains an acid food (fresh apples). PROCEED to Step B.
- Table 2, Step B: The product contains a low-acid ingredient (fresh dates). PROCEED to Step C.
- Table 2, Step C: The finished equilibrium pH of the product is less than 4.6. PROCEED to Step D.
- Table 2, Step D: The product is not a water-based liquid. PROCEED to Step E.
- Table 2, Step E: None of the listed exclusions (for water activity, carbonated beverage, or refrigeration) apply. PROCEED to Step F.
- Table 2, Step F: The product does not contain any acidified foods. PROCEED to Table 3.
- Table 3, Step G:
    - The weight of all acid ingredients (fresh apples) is 440 pounds;
    - The weight of all low-acid ingredients (fresh dates) is 60 pounds;
    - The total weight of all ingredients is 500 pounds;
    - The percent of low-acid ingredients is 12 percent (60 pounds/500 pounds) – i.e., greater than 10 percent.
- STOP. You should consider that:
    - The amount of low-acid food is not a small amount; and
    - Your product is COVERED by 21 CFR part 114.

Example 6: Applesauce Made from Fresh Delicious Apples and Fresh Figs, Manufactured by Company F

- Description of product:
    - Fresh Delicious apples (natural pH of 3.9);
    - Fresh figs (natural pH of 5.7);
    - Finished equilibrium pH: 4.3.
- Table 2, Step A: The product contains an acid food (fresh apples). PROCEED to Step B.
- Table 2, Step B: The product contains a low-acid ingredient (fresh figs). PROCEED to Step C.
- Table 2, Step C: The finished equilibrium pH of the product is less than 4.6. PROCEED to Step D.
- Table 2, Step D: The product is not a water-based liquid. PROCEED to Step E.
- Table 2, Step E: None of the listed exclusions (for water activity, carbonated beverage, or refrigeration) apply. PROCEED to Step F.
- Table 2, Step F: The product does not contain any acidified foods. PROCEED to Table 3.
- Table 3, Step G:
    - The weight of all acid ingredients (fresh apples) is 450 pounds;
    - The weight of all low-acid ingredients (figs) is 50 pounds;
    - The total weight of all ingredients is 500 pounds;
    - The percent of low-acid ingredients is 10 percent (50 pounds/500 pounds).

  - Proceed to Table 4.
- Table 4, Step H: The predominant acid food is apples; the pH of the fresh apples is 3.9, i.e., less than 4.2. PROCEED to Table 5.
- Table 5, Step I: The finished equilibrium pH of the applesauce with added figs is 4.3, i.e., less than 4.4. PROCEED to Table 6.
- Table 6, Step J: The equilibrium pH of the predominant acid food (fresh apples) is 3.9, i.e., 3.8 or more and less than 4.2. PROCEED to Step K.
- Table 6, Step K: The shift in pH is 0.4 (4.3 – 3.9), which is > 0.3. You should consider that:
  - The resultant finished equilibrium pH of your product differs significantly from that of the predominant acid food; and
  - Your product is COVERED by 21 CFR part 114.

Example 7: Barbecue Sauce Manufactured by Company G

- Description of product:
  - Vinegar (pH of 2.5);
  - Tomato paste (pH of 4.0);
  - High fructose corn syrup, modified food starch, molasses, spices, and flavors;
  - Equilibrium pH of the mixture of vinegar and tomato paste: 3.0;
  - Finished equilibrium pH: 3.7.
- Table 2, Step A: The product contains an acid (vinegar) and an acid food (tomato paste). PROCEED to Step B.
- Table 2, Step B: The product contains low-acid ingredients (high fructose corn syrup, modified food starch, molasses, spices, and flavors). PROCEED to Step C.
- Table 2, Step C: The finished equilibrium pH of the product is less than 4.6. PROCEED to Step D.
- Table 2, Step D: The product is not a water-based liquid. PROCEED to Step E.
- Table 2, Step E: None of the listed exclusions (for water activity, carbonated beverage, or refrigeration) apply. PROCEED to Step F.
- Table 2, Step F: The product does not contain any acidified foods. PROCEED to Table 3.
- Table 3, Step G:
  - The weight of all acid ingredients (fresh apples) is 450 pounds;
  - The weight of all low-acid ingredients (high fructose corn syrup, modified food starch, molasses, spices, and flavors) is 50 pounds;
  - The total weight of all ingredients is 500 pounds;
  - The percent of low-acid ingredients is 10 percent (50 pounds/500 pounds).
  - Proceed to Table 4.
- Table 4, Step H: The predominant acid or acid food is the mixture of vinegar and tomato paste. The pH of the mixture is 3.0, i.e., less than 4.2. PROCEED to Table 5.
- Table 5, Step I: The finished equilibrium pH of the barbecue sauce is 3.7, i.e., less than 4.4. PROCEED to Table 6.
- Table 6, Step J: The equilibrium pH of the predominant acid or acid food (mixture of vinegar and tomato paste) is 3.0, i.e., less than 3.8. PROCEED to Step L.
- Table 6, Step L: The shift in pH is 0.7 (3.7 – 3.0), i.e., > 0.4. You should consider that:

- The resultant finished equilibrium pH of your product differs significantly from that of the predominant acid food; and
- Your product is COVERED by 21 CFR part 114.