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Acidified Foods: Food Safety Considerations for Food Processors

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<http://dx.doi.org/10.5772/55161>

1. Introduction

The food processing industry is one of the United States' largest manufacturing sectors, accounting for more than 10 percent of all manufacturing shipments. Concerns over food safety have increased as the industry has been hit by several high profile and large-scale food recalls. Thus, commercial food processors must be vigilant about ensuring the safety of their products. If inadequate or improper manufacturing, processing or packaging procedures are used in the production of low-acid or acidified canned foods serious health hazards, especially *Clostridium botulinum*, could result. To prevent this, processors must be in compliance with regulations established by the U.S. Food and Drug Administration (F.D.A., U.S. Department of Agriculture) and state agriculture and health departments across the United States (Barron, 2000).

2. Acidified foods

The term "acidified foods" means low-acid foods to which acid(s) or acid food(s) are added. These products include, but are not limited to:

- 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; 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.

All acidified foods must have a water activity (a_w) greater than 0.85 and a finished equilibrium pH of 4.6 or below within the time designated in the scheduled process. These parameters must be maintained in all finished foods as outlined in 21 CFR 114.80(a). These foods may be called, or may purport to be, "pickles" or "pickled." However, some barriers exist in the preparation of acidified foods, including inadequate acid in the cover brine to overcome buffering capacity of the food, the presence of alkaline compounds from peeling or other processing aids, and the peels, waxing, piece size or oil in the product which can cause a barrier to penetration of the acid. These barriers may cause the failure to achieve the final equilibrium of a pH value of 4.6 and raise concerns about the growth of pathogens and production of toxins in the finished product.

After proper acidification, all acidified foods must then be heat processed to destroy the vegetative cells of pathogenic microorganisms or other microorganisms that cause spoilage and to inactivate enzymes that might affect color, flavor, or texture of the product. Acidified foods can be heat processed in a boiling water canner or by low-temperature pasteurization. The processing time, temperature, and procedure necessary to safely preserve acidified foods are determined by factors such as level of acidity (pH), size of food pieces (density) and percentage salt. An FDA recognized process authority must review the product and process and make the appropriate recommendations about time and temperature requirements. Processing temperatures higher than 185°F (85°C) could break down pectin and cause unnecessary softening of acidified foods (FDA 2010a).

All commercial establishments engaged in the manufacture of Acidified Foods and Low-Acid Canned Foods (LACF) offered for interstate commerce in the United States are required by 21CFR Parts 108, 113 and 114 to register their facility with form FDA 2541, "Food Canning Establishment Registration," and file scheduled processes for their products with forms FDA 2541a, "Food Process Filing for all Methods Except Low-Acid Aseptic," and FDA 2541c, "Process Filing for Low-Acid Aseptic Systems." The following items are not considered to be acidified foods or low-acid foods.

- Acid foods (naturally acid foods have a pH of 4.6 or less)
- 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
- Alcoholic beverages
- Carbonated beverages
- Standardized jams, jellies and preserves (21 CFR 150)

- Tomatoes and tomato products having a finished equilibrium pH less than 4.7
- Foods that are NOT packaged in hermetically sealed containers
- Any food prepared under the continuous inspection of the meat and poultry inspection program of the Animal and Plant Health Inspection Service of the Department of Agriculture under the Federal Meat Inspection Act and the Poultry Products Inspection Act
- Foods that are stored distributed and retailed under refrigeration
- Foods with water activity of 0.85 or below
- Food that are not thermally processed

Because these foods are not recognized as acidified foods, commercial processors do NOT have to file and register their processing information for these products with the Food and Drug Administration (FDA 2010b).

3. Pathogens of concern

In 1979, the Code of Federal Regulations (CFR) published the acidified regulations identified today as 21 CFR Part 114. Since then, new food processing technologies and methodologies have been developed and are frequently used in the industry. Furthermore, pathogens, such as *E. coli* 0157:H7 and *Salmonella* spp. have been shown to survive and grow in acidic environments. As a result of changing technologies and emerging pathogens, actions by federal agencies have motivated researchers to investigate new ways to eliminate pathogens, such as *E. coli* and *Salmonella* spp. The following are several research citations that provide a brief history of developments related to pathogens in acidified foods.

In 1996, an outbreak of *E. coli* 0157:H7 was identified when an individual contracted hemolytic uremic syndrome after drinking apple juice packaged in sealed containers. The outbreak affected 45 individuals across the USA and Canada. The product was voluntarily recalled by the manufacturing company (*Centers for Disease Control and Prevention*, 1996)

In 1999, an outbreak of *Salmonella* Muenchen serotype in the United States and Canada caused 298 cases of illness, which were attributed to unpasteurized orange juice. The outbreak affected 17 states, primarily in the Midwest, as well as regions of Canada. The product was voluntarily recalled after unopened product tested positive for the causative serotype (*Centers for Disease Control and Prevention*, 1999).

A study performed on the relative safety of pickled cucumbers from *Clostridium botulinum* infection, as a response to a 1976 study in which the organism was found in sealed containers previously believed to be safe. The study involved introducing *C. botulinum* spores into experimentally packed pickles artificially adjusted to a target pH and checking for growth of the organism. It was reported that any pH less acidic than 4.8 was insufficient to effectively kill *C. botulinum* spores, thus establishing a minimum safe pH for pickled cucumbers. (Ito et al, 1996).

A study investigating the effects of acetic acid on *E. coli* O157:H7 in apple juice and pickle brine found that increasing the pH of the food product yielded an increased inhibitory effect on pathogen growth. The study also demonstrated that acetic acid, a key component in vinegar, had a significant effect on the aforementioned inhibition over other methods of manipulating pH. (Breidt et al, 2004).

A study investigating the thermal resistance of *E. coli* O157:H7 found evidence for the phenomenon known as cross-protection, or the ability of a bacterium to apply resistance to one negative condition against another. These authors reported that microorganisms grown in an acidic environment display increased resistance to killing via thermal methods, indicating an increased threat by these types of organisms against current food safety methods involving both heat and acid (Buchanan and Edelson, 1999).

Recently, a study found that the Breidt model could be used to measure five-log reduction times in a less conservative manner, allowing for a more encompassing approach to determining safe preparation times for various foods. Acidified vegetable products with a pH above 3.3 must be pasteurized to assure the destruction of acid resistant pathogenic bacteria. The times and temperatures needed to assure a five log reduction by pasteurization have previously been determined using a non-linear (Weibull) model. Recently, the Food and Drug Administration has required that linear models be used with online electronic process filing forms for acidified foods. A linear model was developed that is based on the existing safe processing data. The processing times and temperatures meet or exceed the established heat processing conditions needed to assure safety (Breidt et al, 2010).

4. Control measures for ensuring food safety of acidified foods

Control measures for ensuring the safety of acidified foods are well documented in the scientific literature. A simple overview of appropriate measures includes:

- Acidified foods must be properly acidified to a pH below 4.6, but most foods are acidified to a pH of 4.2 or below.
- To assure quick and proper acidification, the food is normally cooked or heated with the acid before being filled into the final container.
- A thermal process or heating step is required to kill all pathogens and any other non-pathogenic microorganisms that could grow during storage of the product. Thermal processing must be completed by hot-filling the product or by the boiling water bath process. The heating temperature and time must be validated by an FDA recognized process control authority and be monitored, controlled and documented.
- The final equilibrium pH must be checked, controlled and documented after the product has completed the thermal processing step. A pH meter with two decimal places accuracy must be used to measure the pH if the final pH is 4.0 or above; other methods can be used such as pH paper or a pH meter with one decimal place, if the final pH is below 4.0.

- Containers for acidified foods should be such that a hermetic seal is obtained. Vacuum is a good indicator of a hermetic seal and helps to keep the quality of the product.

5. Acidified food guidance

Probably the most comprehensive guide to assist food processors in determining what constitutes an acidified food is a document prepared by the FDA in 2010 titled "Guidance for the Food Industry: Acidified Foods." This guidance document provides nonbinding recommendations but nevertheless presents step by step guidelines to determine if a food can be classified as an acidified food. In this document standardized and non-standardized food dressings, such as mayonnaise, and condiment sauces, such as ketchup, are considered acid foods, which have a natural pH of 4.6 or below.

Processors who are not sure if a particular food is classified as an acidified or not, can voluntarily submit the respective FDA forms for a preliminary evaluation. The draft guidance reminds processors that jams, jellies and preserves are excluded from the 21CFR114 as long as these products meet the applicable standard of identity under 21CFR150; otherwise, the non-standardized products are covered by 21CFR114 based on the pH of the fruit, the pH of the final product and the water activity level of the finished product.

Another important aspect to be considered by a food processor is the use of acid foods and small amounts of low amounts of low acid foods as ingredients to produce an acidified food.

There are two basic criteria needed to exclude any food from being subject to 21 CFR Part 114. The first is that acid foods contain small amounts of low acid foods and the second is that acid foods have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food.

Fermented foods with a water activity level above 0.85, such as cucumber pickles and green olives, are considered low acid foods subject to the action of acid producing microorganisms to reduce the pH of the food to 4.6 or below. As such, these products are subject to the requirements of 21CFR114. Processors repacking and reprocessing previously acidified foods are also subject to 21CFR114.

Common questions of food processors new to the food processing industry are precisely related to this matter of reprocessing or repacking a previously acidified food and to procedures to determine a finished equilibrium pH. The draft guidance reminds processors about the meaning of equilibrium pH. It is recommended to use a reference temperature of 25°C, commonly used in laboratory measurements. Equilibrium means the acid is fully diffused throughout the food (especially solid particles) and any successive measurements produce the same results. Further recommendations about food preparation for pH measurements and indicated to follow 21CFR114.90 and to ensure the pH of an in process batch to be reduced and reach the 4.6 within 24 consecutive hours. The likelihood that spores of *C. botulinum* will germinate and grow increases with the length of time it takes to reduce the equilibrium pH of a food to 4.6

There are three very important terms embedded in the definition of acidified foods (21 CFR par 114): (1) small amount of low acid food(s), (2) predominant acid or acid food, and (3) pH that does not significantly differ. Regarding the small amount of low acid food(s), it has been recommended to be no more than 10% by weight in the finished product. This recommendation is based on FDA experience when evaluating filed processed. This recommendation has been identified by FDA as the ‘small amount provision’ which means 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 complying with 21CFR114. Some examples under this provision may be products such as tomato puree with added spices, or a salad dressing where the predominant acid is the mixture of all acid ingredients, such as mayonnaise, lemon juice, vinegar and tomato paste, and the small amount of low acid foods are red peppers, onion and garlic.

The acid ingredient, such as vinegar has a pH of 4.6 or below; the acid food such as tomatoes has a natural pH of 4.6 or below. These acid ingredients need to be at least 90% of the total weight of the finished product to be considered predominant.

Regarding the term pH that does not significantly differ from that of the predominantly acid or acid foods, FDA recommends the following criteria:

If the equilibrium pH of the predominant acid or acid food is:	Then one 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

It is important to consider variability factors, such as the accuracy of the pH meter and variations in the finished equilibrium pH of the food itself. Also, as a reminder to processors, water, being an important ingredient in many acidified foods, it is a low acid food and if it is a predominant ingredient in the finished product, this product is considered a water-based acidified food. Apple juice, bended juices, reconstituted juices and vegetable juices are all considered to be water-based liquids. When the finished equilibrium pH of a water-based liquid that contains acid(s) or acid food(s) is 4.6 or below, the product is subject to 21CFR114, unless the liquid is a carbonated beverage.

The draft guidelines recommend the use of decision tables to determine if a given food, including fermented foods to which low acid foods are added fall under the coverage of 21CFR114. These tables are a step-by-step series of questions that lead to the most probable correct answer about a food being an acidified or not product; however, it is recommended to consider other factors related to the product and the manufacturing process to make the final decision. The guidelines indicate that most acidified foods would require a heat treatment step. This thermal process is to be developed based on the most resistant microorganism that must be controlled under the given pH conditions. For example for a pH range of 4.0 to 4.6 the spores

of acid tolerant spoilage microorganisms such as *B. licheniformis* need to be destroyed, while at a pH range below 4.0, the vegetative cells of yeasts, molds and non spore forming bacteria such as lactobacillus need to be destroyed.

The thermal destruction of spores and microorganisms can be expressed in terms of heat resistance parameters. The adequate combination of time and temperature (extent of thermal processing) to safely manufacture a commercial food product and is also resistant to spoilage is called thermal process lethality. The draft guidance document provides a table demonstrating relationships between finished equilibrium pH of products and the thermal process lethality of acidified foods. For example, for a pH range between 3.3 and 3.5 the F value of 1 minute is recommended. F being the destruction time desired at reference temperature of 195 F and a Z value of 10 F. This is typically written as $F_{10/195} = 1.0$ minutes. The thermal process lethality is part of a scheduled process required by FDA to prevent the growth of microorganisms of public health significance in the thermally processed food. This process need to be established by a competent process authority as defined in 21CFR114.3(e).

The draft guidance also includes final recommendations to address spoilage problems through quality control procedures such as systematically implementing written plans to investigate signs of spoilage and their causes, as well as corrective actions to solve the problem.

6. Recalls

A commercial processor engaged in the processing of acidified foods is also required by 21CFR108.25 to prepare and maintain a written recall plan. Guidelines for product recalls are contained in 21CFR7. This plan will provide a current procedure for implementation, including:

- notifying FDA of any recalls
- a procedure for distributors to follow to recall products which may be injurious to health
- a procedure for identifying, collecting, warehousing and controlling products and a method for determining the effectiveness of any recalls.

Recall is a voluntary action taken by manufacturers and distributors to remove food that is in violation of laws administered by the FDA and USDA. These agencies may request a recall, but cannot order one without a court order. Product recovery is only classified as a recall when the product is violative.

Product Identification. Each batch or production lot must be properly coded. This code will allow the product lot to be identified as to date, batch product personnel production records, and ingredient records.

Records. Records are key to the recall plan and must be maintained for three years. They include:

- Records of examination of raw materials, packaging materials, and finished product along with any supplier guarantees or certifications.
- Processing and production records showing adherence to scheduled processes, including records of pH measurement and other critical factors.
- A log of all departures from scheduled processes, actions taken to rectify them, and disposition records of the portion of product involved.
- Records of initial distribution of the finished product adequate to facilitate separation of food lots which may have become contaminated or otherwise unfit for use.

Notification. Persons to be notified in the event of a recall include FDA and USDA, key company personnel, and distributors. The notification should include the product, container size, and code of affected lots. The extent of the hazard and the level of the recall will be as determined by FDA and USDA. Based on this determination, FDA will approve the recall strategy. The notification will include instructions for consumers and distributors for product recovery and information feedback. The contact person should be listed on all notification forms.

Product Recovery. Plans for recovery include procedures for segregation of affected lots, storage, warehousing, and control. Procedures in place shall allow determination of the effectiveness of the recall. The recall is concluded when FDA and USDA determine that recovery is adequate and there is no longer any threat to the public.

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