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Manufacture of Traditionally Fermented Vegetable Products: Best Practice for Small Businesses and Retail Food Establishments

ABSTRACT

Fermentation has a long tradition of improving the shelf life, acceptability, and safety of some food and beverages. Under the Food Safety Modernization Act, a business that manufactures fermented foods may be required to conduct a risk analysis and establish pertinent preventive controls. Retail food establishments operating under the FDA Food Code must often seek a variance for manufacture of fermented foods and beverages. Developing food safety programs can be a challenge for small-scale producers with little access to training and resources, especially as manufacture of fermented products involves microbiologically complex systems that may not be effectively or appropriately managed by standard time-temperature controls. We review the science behind traditional vegetable fermentation processes, e.g., cabbage, cucumbers and peppers, and discuss identification of relevant hazards based on intrinsic and extrinsic factors inherent in the fermentation systems that influence microbial survival. We advocate for one Critical Control Point (CCP) in the manufacture of traditionally fermented vegetable products, namely a steady and sustained pH decline to ≤ 4.6. We outline additional Control Points (CPs) at key steps, i.e., vegetable preparation and salt addition; fermentation time and temperature; refrigerated storage; and/or packaging for shelf stability. We illustrate these best practices with an example of kimchi manufacture.

INTRODUCTION

Fermented vegetables such as cabbage, cucumbers, and peppers are preserved through the production of organic acids, primarily acetic and lactic, by bacteria such as *Lactobacillus* and *Leuconostoc* spp. The U.S. Food and Drug Administration has defined fermented foods as "low-acid foods subjected to the action of acid-producing microorganisms to reduce the pH of the food to 4.6 or below" *(53)*. Fermentation to preserve foods has been used for centuries and provides unique flavors and textures to foods *(32)*. Retail food establishments and small-scale manufac-

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turers are capitalizing on a resurgence of interest in food fermentation. A 2018 survey of restaurant menus and sales data from nearly 9,000 restaurants found a 149% increase in fermented foods from the previous year *(14)*, with chefs and young consumers demanding fermented food and beverage options beyond traditional pickles, cheese, beer and wine *(47)*. Food manufacturers are addressing the increased consumer demand for fermented foods by experimenting with flavor and ingredient innovations. However, emerging interest in fermented vegetable production presents the industry and food safety regulators with the challenge of ensuring safe finished products through the application of process controls.

Under federal regulations implementing the Food Safety Modernization Act (FSMA), a business that manufactures fermented foods may be required to conduct a hazard analysis that identifies reasonably foreseeable hazards and determines whether identified hazards require preventive controls. If the need for a preventive control is identified, written documentation of monitoring and verification procedures, corrective actions, and a recall plan are required *(55)*. Similarly, a retail food establishment seeking a variance to engage in fermentation under the FDA Food Code is generally required to submit a HACCP plan to the pertinent regulatory agency for review *(54)*. For either food manufacturers or retail food establishments, the process of systematically identifying relevant hazards and developing targeted interventions would apply. Developing food safety programs can be a challenge for small-scale producers with little access to training and resources, especially as manufacture of fermented vegetable products involves microbiologically complex systems that may not be effectively or appropriately managed by standard time-temperature controls.

Food fermentation has a long tradition of improving not only the shelf life and acceptability but also the safety of foods. For most vegetable fermentations, the fermentation environment suppresses the growth of pathogenic or spoilage bacteria because of decreasing pH, low-oxygen conditions, and robust growth of lactic acid bacteria, with the associated production of organic acids and other inhibitory compounds *(5, 13)*. There have been, however, several instances of foodborne illness outbreaks linked to "lightly" fermented or under-acidified vegetable products, particularly kimchi *(9, 21, 27, 45, 49)*. The goal of this manuscript is to describe the microbiology behind traditional vegetable fermentation processes and to outline best practices for safe, small-scale manufacture of fermented vegetables, such as cabbage, peppers, and cucumbers.

Vegetable fermentation: The science

Food fermentation technology likely dates to the origin of pottery, a necessary antecedent, at the end of the Pleistocene era around 11,000 years ago. It was not until the early 1900s, however, that scientific research on the microbiology and chemistry of vegetable fermentations was first reported *(11, 29, 38)*. Since these early reports, extensive research has been conducted on vegetable fermentation microbiology and biochemistry, and comprehensive reviews are available *(5, 12, 15, 36, 45)*. Traditionally fermented vegetables include cabbage, cucumbers, peppers and olives. Important in the success and safety of vegetable fermentations are the establishment of fermentative organisms, principally lactic acid-producing bacteria; elevated NaCl concentration; proper ambient temperature, and a reduced dissolved oxygen concentration. In most vegetable fermentations, epiphytic aerobic microbiota are replaced by a succession of facultatively anaerobic, acid-tolerant lactic acid bacteria (LAB) *(Fig. 1)*. Temperature, NaCl concentration, organic acid concentration, and pH can influence the growth and survival of LAB microbiota. LAB have a fermentative (anaerobic) metabolism and predominate in NaCl brines as pH drops and organic acids accumulate *(5, 8)*.

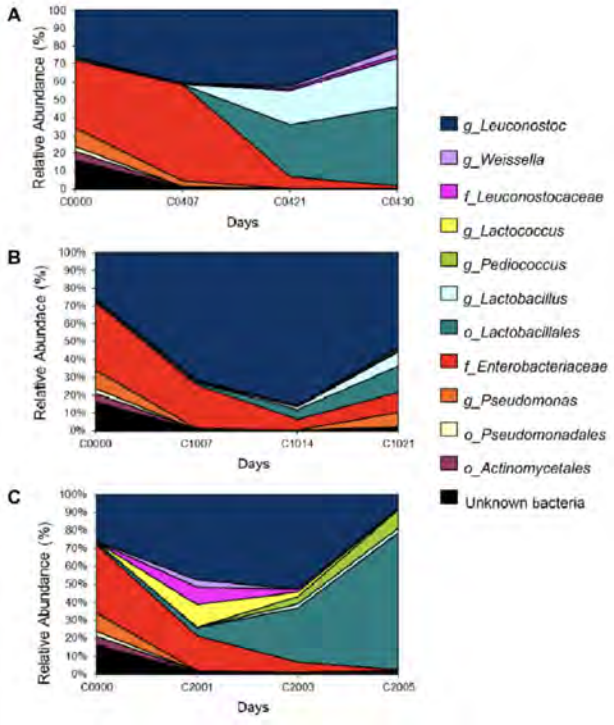

FIGURE 1. The effect of temperature on the relative abundance of microbiota for nabak (sliced) kimchi. Relative abundance is shown for nabak fermentations at (A) 4°C, (B) 10°C, and (C) 20°C. The color codes for each population are indicated in the legend *(28)*. X-axis labels refer to specific samples analyzed, e.g., C0407 is stored at 4°C with brine sampled on day 7, C0421 is stored at 4°C with brine sampled on day 21. For a full description of experimental design see reference *(28)*.

Cabbage-based products such as sauerkraut and kimchi are optimally fermented at 18°C and an NaCI concentration of around 2% *(45, 46)*. The initial pH of most vegetable fer-

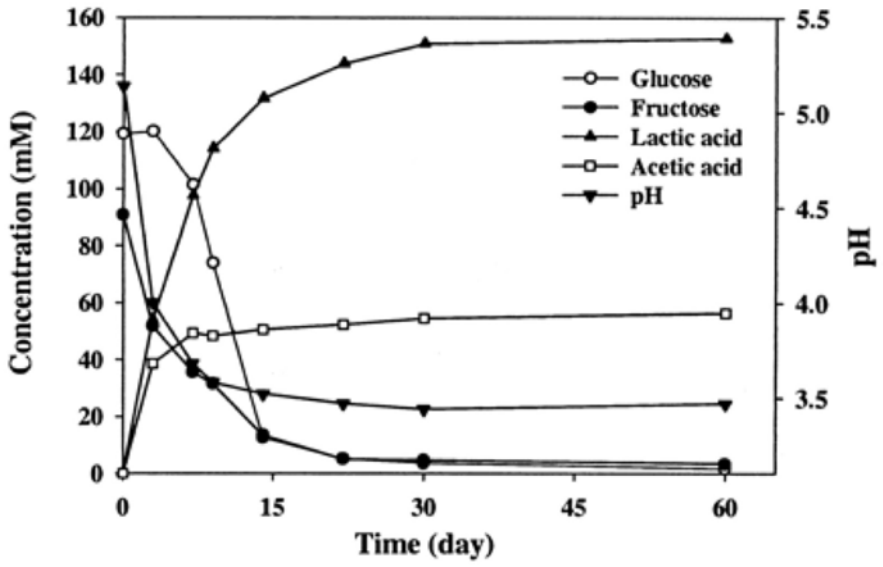

FIGURE 2. Changes in the concentrations of substrates and products and pH in a commercial sauerkraut fermentation *(31)*.

mentation brines is around 6. The NaCl concentration, pH, and temperature encourage a two-stage fermentation initiated by heterofermentative LAB, including *Leuconostoc* and *Weissella* spp., that produce both lactic and acetic acid *(Fig. 2)*. After about one week, the heterolactic fermentation is typically followed by a homolactic stage (*Lactobacillus* species) in which only lactic acid is produced. Other metabolic byproducts such as mannitol and sulfur compounds may contribute to the overall flavor profile *(23)*. Unlike cabbage fermentations, commercial cucumber fermentations are often carried out at ambient temperatures above 20°C with NaCl concentrations of 6% or higher. Under these conditions, the microbial population exhibits a homolactic fermentation dominated by *Lactobacillus plantarum* and related species; lactic acid production predominates, with little or no gas or acetic acid production *(5, 18)*. In either a hetero- or homofermentative system, growth of fermentative LAB is accompanied by a decrease in the diversity of potentially relevant spoilage microorganisms through competitive inhibition *(Fig. 1)*.

Acids produced during fermentation lend characteristic flavors to the final product, help control spoilage, and contribute to safety. The antimicrobial activity of fermentation acids (lactic, acetic and others) is primarily due to the protonated or uncharged form of the acid, which can passively diffuse through bacterial cell membranes *(4, 48)*. Antimicrobial activity of these acids depends on both the pH of the fermentation brine and the pK_a of the acids. The pK_a values at 25°C of typical fermentation acids are pH 3.03, 3.86, 4.76, and 4.87 for fumaric, lactic, acetic, and proprionic acids, respectively *(10)*. The lower the pH of the fermentation brine, the greater the percentage of the acid in the protonated (antimicrobial) form. For acetic acid, 50% of the acid is in the active antimicrobial form at the pK_a value (pH 4.7) and 50% is in the inactive (anion) form, whereas at pH 3.7, 1-pH unit below the pK_a value, 90% is in the active (protonated) form. While hydrophobic bacterial membranes are relatively impermeable to charged, polar acid anions *(4)*, protonated acids can be taken up readily by the cell. Once inside, the weak acid theory posits that the protonated acid will dissociate because of the near-neutral pH of the cellular cytoplasm. Intracellular dissociation results in two problems for the cell: the acidification of the cytoplasm due to the release of weak acid protons, and the accumulation of the acid anion in the cytoplasm. As internal pH drops, cellular metabolism becomes impaired, and the cumulative effect of acid anion accumulation and reduction of internal cell pH leads to cell death *(48)*. Internal pH measurements have shown that lactic acid bacteria may predominate in vegetable fermentations because of the ability of these organisms to metabolize and divide with lower internal cell pH than most other microorganisms *(33)*. An important key to the safety of fermented vegetables is, therefore, a steady and sustained drop in the pH of the fermentation brine.

Acid production in a fermentation brine requires the presence of free sugars that are fermented to lactic and/or acetic acids *(Fig. 2)*. The carbon source for LAB fermentation of vegetables is fermentable sugars, primarily the glucose and fructose that are present as free sugars in many vegetables. Cucumbers have around 2% glucose and fructose, while cabbage varieties typically have these sugars at higher concentrations, 4% or greater *(5)*. Traditional fermented vegetables have sufficient sugar to lower pH to

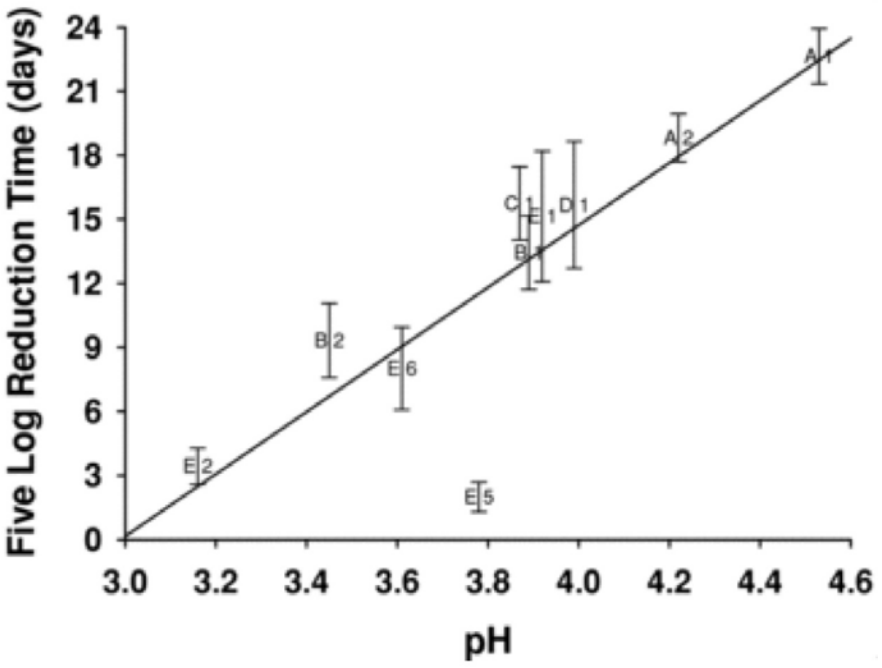

FIGURE 3. Five log reduction times and pH of commercial brines at 23°C under anaerobic conditions *(2)*.

well below 4.6, often as low as pH 3.1 or 3.2, and produce significant organic acid (>100 mM; 1%) to preserve the product *(5)*. Often little or no sugar remains upon completion of fermentation.

A relationship between pH drop and a 5-log reduction of *Escherichia coli* O157:H7 in commercial fermented vegetables has been documented *(2)* *(Fig. 3)*. The data showed a striking correlation between pH and 5-log reduction time. As acid accumulated and the pH of the brine subsequently dropped, the 5-log reduction time correspondingly dropped. A sterilized commercial brine having little or no lactic acid at the start of fermentation (brine sample A1) had a 5-log reduction time of approximately 3 weeks, compared with 3 days for a similarly prepared commercial brine with a pH of 3.1 and 150 mM lactic acid (brine sample E2). The reduction in brine pH may not persist, however, if spoilage occurs. In low NaCl cucumber fermentations, a secondary spoilage fermentation may develop wherein lactic acid is metabolized, with a resulting rise in pH *(25, 35)*. Consequently, monitoring brine pH throughout the vegetable fermentation process is critical for food safety.

Identification of relevant microbial hazards

In addition to the presence of LAB among the native biota on vegetable surfaces, the phyllosphere can also transiently contain numerous vegetative bacterial pathogens *(40, 60)*. These pathogens can include Shiga toxin-producing *E. coli* (STEC), nontyphoidal *Salmonella*, and *Listeria monocytogenes*, among others. Of these pathogens, STEC has been identified as the most acid-resistant pathogen of concern in acidified vegetables under anaerobic conditions *(Fig. 4)* *(3)*. Pathogens may be introduced onto vegetables from several vectors, including contaminated irrigation water and improperly handled soil amendments of biological origin as well as by people, themselves both reservoirs of enteric pathogens and vehicles for cross-contamination. During the post-harvest handling and processing of vegetables destined for fermentation, additional sources of biological hazards may emerge, including cross-contamination in the flume of wash tanks and environmental cross-contamination during comminution. Just as the release of plant exudate during cutting and crushing provides needed nutrients and moisture to support the proliferation of LAB, so too does it enhance growth potential and opportunity for cross-contamination with bacterial pathogens *(6, 7)*.

Fresh produce has been identified as the vector in outbreaks of >20 etiological agents, including vegetative and spore-forming bacteria, viruses, and parasites *(42)*, and prudent processors of fermented vegetables will incorporate specific risk mitigation measures, Critical Control Points (CCPs), sufficient to achieve a $\geq$ 5-log CFU/g reduction of pertinent pathogens *(37)*.

Additional generalized postharvest biological risk mitigation strategies include various prerequisite programs such as Good Manufacturing Practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs) in food manufacturing facilities, employee health and hygiene and environmental sanitation programs in retail food establishments,

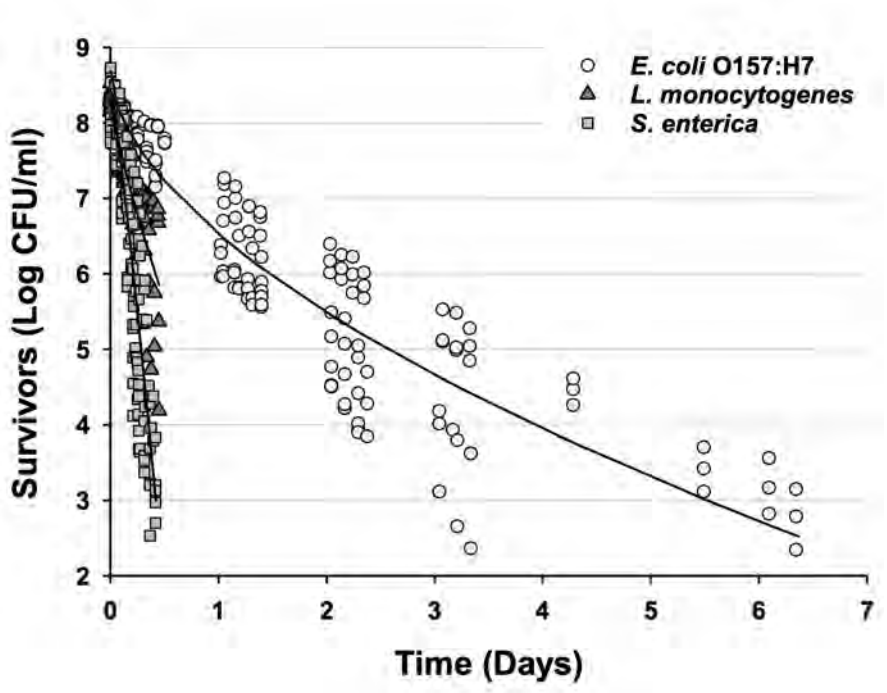

FIGURE 4. The survival of *E. coli* O157:H7, *S. enterica*, and *L. monocytogenes* strains in acidified pickle jars at 10°C. The data for *E. coli* O157:H7 (circles), *S. enterica* (triangles), and *L. monocytogenes* (squares) show the log of the viable cell count from seven or more replicate experiments, each with a cocktail of five strains of a given species. The solid lines represent the predicted survival curves from the Weibull model *(3)*.

and approved supplier programs in both manufacturing facilities and retail food establishments. Additionally, prudent processors should consider potential chemical and physical hazards. This review focuses on microbiological pathogens and their control, i.e., mitigation of biological risks.

While a diverse array of microbial pathogens may potentially contaminate vegetables, identification of only the most treatment-tolerant pathogen(s) reasonably likely to be present is necessary in the hazard analysis. In vegetable fermentation, the 5-log pathogen reduction target is generally achieved through acidification during fermentation. Pathogenic *E. coli*, *Salmonella* spp. and *L. monocytogenes* are reasonably likely to be found on raw produce and must be controlled, especially early in the fermentation process *(2, 5)*. Breidt and colleagues investigated the holding time needed to achieve a 5-log reduction in *E. coli* O157:H7, *Salmonella*, and *L. monocytogenes* in vegetable products acidified with acetic acid (pH 3.3) at 10 and 25°C *(3)*. Results indicated that *E. coli* O157:H7 was generally the most acid-tolerant pathogen, especially in acidified-vegetable systems *(Fig. 4)*. In other work, Inatsu et al. noted that *Salmonella* survival was similar to *E. coli* O157:H7 survival in kimchi fermentations *(20)*. Fermentation management, therefore, requires identification of controls validated for the inactivation of pathogenic *E. coli*; these controls may include time, temperature, final pH, and/or NaCl concentration.

In addition to control of vegetative bacterial pathogens potentially present on the raw material, risk enhancement due to processing and packaging conditions must also be considered in the hazard analysis. Specifically, the creation of low oxygen environments that allow for spore germination, growth, and toxin production by *Clostridium botulinum* should be considered. Competitive growth of LAB and the accompanying decrease in pH can mitigate spore germination of *C. botulinum* during fermentation. Ito and colleagues originally showed that the outgrowth of *C. botulinum* was inhibited at pH as high as 4.8 in fresh-pack pickles acidified with acetic acid. Inoculation experiments with whole cucumbers showed that as little as 0.9% acetic acid in the brine was sufficient to prevent outgrowth from spore inocula as high as 10^6 per cucumber *(22)*. The pH in fermented vegetable products eventually decreases below the minimum necessary for germination and growth of C. botulinum, considered to be pH 4.6 for high-water-activity shelf-stable food products *(54)*.

Processing steps such as transfer or filling operations can also introduce pathogens into the product and must be considered in risk management. Depending on the extent to which fermentation is allowed to progress, *E. coli* O157:H7 and related serotypes may survive in commercial fermentation brines for extended periods, e.g., up to 2 weeks at 20°C *(2)* and up to 1 month or longer in acidified brines at 4°C *(30)*. An illness outbreak in 2012 that sickened 1,642

Korean school children was linked to enterotoxigenic *E. coli* O169-contaminated kimchi that was only lightly fermented *(9)*. Investigation into the illnesses did not identify contamination on the raw vegetables (radish and cabbage) but did identify contamination on the prepared kimchi that the school children consumed, suggesting that contamination had occurred during preparation.

In the production of a shelf-stable finished product, a validated pasteurization treatment may be applied to ensure destruction of surviving vegetative microbiota that could alter the product during room-temperature storage, potentially raising product pH and creating a risk of *C. botulinum* outgrowth *(22)*. For example, *Bacillus licheniformis* has been shown to survive and grow in acidic tomato products, increasing product pH over time *(61)*. Generally, however, properly fermented vegetable products are very stable. In fact, large commercial processors of fermented cucumbers rely on the 5-log pathogen reduction achieved during fermentation to ensure safety and effectively manage re-contamination risks during desalting and packing of the final product (Fred Breidt, personal communication). Processors wishing to avoid pasteurization would need to verify the shelf stability of their product, generally based on chemical inhibitors.

Intrinsic and extrinsic factors influence microbial survival

The proliferation or destruction of microbiota present in the fermentation vessel at the start of the fermentation period are influenced by intrinsic factors such as composition and physiochemical properties of the growth substrate as well as by extrinsic factors such as addition of NaCl and temperature control. Vegetable fermentation systems generally contain 2–4% simple sugar at the outset and near-neutral pH, providing a favorable environment for all types of microbial growth. Some raw ingredients commonly utilized in vegetable fermentation contain compounds with varying degrees of natural antimicrobial capacity. For example, red pepper, such as the Korean red chili pepper used in kimchi production, as well as the addition of dried red pepper flakes to the fermentation brines of some fermented cucumber pickles, introduces capsaicin, a bioactive plant metabolite with known antimicrobial activity *(58)*. Minced, dried, or whole garlic cloves are sometimes included during the fermentation of cucumber and cabbage. The thiosulphinate allicin, found in garlic and other alliums, is antimicrobial, especially against yeast, although the concentration of allicin can vary throughout the bulk of the fermentation vessel *(59)*. Capsaicin has also been shown to suppress spoilage *(19)*. In general, however, natural antimicrobial capacity in raw materials such as red peppers or garlic should not be relied upon to contribute to final product safety because of the considerable variability in these raw materials based on cultivar and growing and processing conditions.

Extrinsic factors also play a major role in microbial survival in traditional vegetable fermentations. The level of NaCl addition is critical for mediating the relative growth potential among the various microbial species in the ferment as well as for imparting important sensory characteristics to the final product. While traditional vegetable fermentations rely on levels of added NaCl that are not directly antimicrobial (<2 to 4% w/w), Dupree and colleagues demonstrated that these typical NaCl levels do preferentially select for the outgrowth of the LAB that biosynthesize the organic acids responsible for pathogen lethality *(13)*. Decreasing or eliminating NaCl may still result in a fermented product with sufficient acid content to achieve a 5-log reduction in pathogenic *E. coli*, but these ferments are more likely to be unstable fermentations, systems that support secondary fermentation reactions wherein lactate is metabolized to acetate, then to propionate and eventually to butyrate, with an accompanying rise in pH *(5)*. In contrast, including more than 2.5% NaCl in fermentation brines tends to limit the initial growth of heterofermentative LAB, thereby limiting production of important organoleptic compounds that support the complex aroma profile associated with fermented vegetables *(41)*. Because yeasts and filamentous fungi tend to be more halotolerant than most foodborne bacterial species, including LAB, NaCl levels typical in fermentation brines will select for fungal spoilage if oxygen is present *(50)*. A desire to decrease NaCl content should therefore be evaluated with both food safety and quality in mind.

Other added ingredients, e.g., sugars or acetic acid, may impact the fate of a microbial fermentation. While a small portion of sugar, e.g., 0.1 g/liter, may be added at the start of fermentation to enhance LAB proliferation, the addition of sugar is not typically used in the fermentation of cucumbers or cabbage, because these vegetable tissues naturally contain >2% sugar. Calcium acetate may be added to brine to buffer the fermentation system and allow for greater sugar utilization *(17)*. On occasion, processors add acetic acid or use diluted recycled fermentation brines to reduce the typical starting brine pH of ~6 to ~5. Recent research showed that the addition of acetic acid to a fermentation brine reduced *Enterobacteriaceae* at the start of fermentation *(34)*. While added ingredients influence microbial growth and death, most are not managed as CCPs, since they do not represent necessary or sufficient intervention strategies.

Oxygen content in the fermentation vessel is an important controlling factor. Film yeast are often found growing at the brine-air interface of vegetable ferments if the fermentation vessel is not well sealed. While outgrowth of spoilage biota does not typically constitute a food safety hazard, it may create undesirable and unmarketable finished products. The best way to mitigate this problem is to maintain anaerobic conditions.

Another extrinsic factor relevant to the success of vegetable fermentations is the temperature at which the fermen-

tation proceeds. Many vegetable ferments are optimally stored between 18.3 and 22.2°C (65 and 72°F), allowing for efficient metabolic activity from the LAB, with subsequent rapid lactic acid biosynthesis and enhancement of complex flavor development throughout the stages of microbial succession. For example, optimum conditions for cabbage fermentation are 2% NaCl and 18°C *(46)*. However, temperatures ranging from 10 to 24°C (50 to 75°F) have been used to successfully produce fermented vegetable products *(46, 51)*. Fermentation at > 30°C can negatively impact product quality, resulting in undesirable changes in texture and the development of off-odors *(44)*. Changes in quality attributes are the consequence of both biotic and abiotic changes in the ferment; temperature influences the selective growth of spoilage biota relative to fermentative LAB, as well as the enzymatic activity occurring within the vegetable substrates. In general, vegetable fermentation below 10°C will proceed normally, but at a slower pace, increasing the time required to reach the final pH. Partly for this reason, there is no universally specified time for a fermentation to achieve a pH below 4.6. However, because acid accumulation and the accompanying pH decrease are essential to the control of biological hazards, e.g., pathogenic *E. coli* and *C. botulinum*, active managerial control over endpoint pH monitoring is usually necessary. As a result, while pH rather than temperature is the critical factor addressed in many fermented-vegetable HACCP plans, when deviations in monitoring pH occur, addressing fluctuations in storage temperature may be a part of the root-cause analysis and corrective action. The food safety risks must also be carefully considered in the manufacture of incompletely acidified 'half-sour' products, as refrigerated storage significantly slows fermentation and accompanying pH drop. At room temperature these 'half-sour' products will rapidly ferment to 'full-sour' pickles, typical of a normal cucumber fermentation, with concomitant reduction in bacterial pathogens as described *(2)*. Overall, vegetable ferments are dynamic systems, and an interplay of factors influences microbial metabolism with the resultant target pH achieved over time.

Control principles

Regardless of which food safety system governs manufacturing activities — Preventive Controls or HACCP — the identification of key hazard reduction steps is critical. Critical control points (CCPs) are key processing steps under active management, in contrast to various other prerequisite programs and activities that, while also supporting food safety, do not provide an equal degree of control over the relevant microbial hazards. The U.S. FDA has issued guidance on differentiation of CCPs from prerequisite activities *(37)*. While numerous intrinsic and extrinsic production factors contribute to microbial proliferation or lethality, process control requires differentiation between those factors for which active management and record keeping as CCPs are crucial for ensuring safety and those factors that play supporting roles, here termed Control Points, or CPs. Given the importance of this distinction in the development of food safety programs by small food processors, a sample process flow diagram and hazard analysis for the manufacture of kimchi has been provided to illustrate these points *(Table 1)*.

We advocate for one CCP in the manufacture of traditionally fermented vegetable products, and that is pH reduction accompanying fermentation. Based on published research and extensive experience in the field, we further advocate for additional Control Points (CPs) that are necessary to support the manufacture of a safe product but that are not managed in the same way as a CCP. Post-fermentation, we note that there are additional CPs for refrigerated storage and/or packaging and labeling as a shelf-stable product.

CCP1: Fermentation

The fermentation step is a key food safety control because of acid production and corresponding 5-log inactivation of the target pathogen, enterohemorrhagic *E. coli*. Control is verified via pH monitoring during fermentation. Decreasing pH to below 4.6 makes the outgrowth of *C. botulinum* spores a hazard not reasonably likely to occur in traditionally fermented vegetable products. A steady decrease in pH over time is necessary for the fermentation process to be under control. Because the vegetables used for fermentation typically exhibit little buffering capacity, pH may be monitored in the brine. The brine pH should be monitored in each fermentation vessel with sufficient frequency during active fermentation so that a continued decline in pH to $\leq$ 4.6 is recorded. The brine pH should also be monitored after evident microbial activity has ceased to demonstrate that pH is not increasing. Incompletely fermented vegetables, referred to as lightly fermented or half-sours, may represent an increased risk to food safety *(9)* *(Fig. 3)*. Additionally, vegetable ferments that fail to reach a pH of $\leq$ 4.6, or products in which a continued pH decline is not recorded, should be discarded. Effectively managed vegetable fermentation systems typically expect to reach a pH of $\leq$ 4.6 within a week after the start of fermentation, although it may take longer depending on the vegetable matrix and temperature at which fermentation occurs *(Fig. 1)*. While many factors such as NaCl concentration and storage temperature contribute to the rate and extent of acidification, these are most effectively applied as CPs.

Processors should consider the development of an SOP that specifies appropriate methods for brine sampling in each fermentation vessel, and the method and frequency of brine pH determination. pH can be measured directly on brine samples taken from each fermentation vessel; samples must be representative of the whole, and generally two or three distinct measurements are taken at each time point

TABLE 1. Food safety control in manufacture of Kimchi. Adapted from Kang and Bauer *(26)*. Refer to *Figure 5* for process steps

Step	Hazards Created, Eliminated or Reduced	Preventive Measures/Management[a]	Control[a]
Ingredient receipt & storage		Supplier specifications. –SOP for Ingredient Specifications Clean and sanitary storage limits the possibility of contamination. –SOP for Ingredient Storage	
Prepare & salt cabbage	Biological: Cross-contamination Pathogen growth	Clean and sanitary production environment limits the possibility of cross-contamination. Damaged or spoiled cabbage discarded. Accurate weighing of ingredients. –SOP for Ingredient Preparation (cabbage, brine, seasonings) The presence of high salt content (>5%) will select for LAB and reduce the likelihood of pathogen growth. Holding at room temperature (3–6 hrs) will encourage salt penetration without promoting spoilage. –SOP for Salting	CP1
Rinse/Drain	Biological: Cross-contamination	Sanitation and employee hygiene program limit the possibility of contamination while handling salted cabbage. –Sanitation SOP (SSOP) –Employee Hygiene Plan	
Mixing	Biological: Cross-contamination	Clean and sanitary storage and production environment limits the possibility of cross-contamination. Employee hygiene policy in place. Complete mixing ensures proper fermentation. Pack kimchi tightly into food-grade fermentation vessel(s) to reduce air exposure and encourage brine formation, drawing out sugars. –SSOP –Employee Hygiene Plan –SOP for Mixing/Combining Ingredients	
Fermentation	Biological: Pathogen growth	Brine pH is measured in each fermentation vessel every 12 h for 2 days until pH ≤ 4.6 (for room temperature fermentation); every day for 4 days until pH ≤ 4.6 for fermentation under refrigeration. –SOP for pH Monitoring	**CCP1** (Ferment to pH ≤ 4.6)
		Option 1: ferment at ~68 – 72°F (~20°C) for up to 2 days. Option 2: ferment at ≤ 41°F (≤ 5°C) for 3–4 days. Fermentation encourages growth of LAB and reduces the opportunity for pathogen growth or spoilage.	CP2
Refrigerated storage	Biological: Cross-contamination	Store fermented kimchi covered tightly in the refrigerator at ≤ 41°F. Fermented kimchi is a ready-to-eat food; package in clean food-grade containers; avoid bare hand contact. Discard if mold or other signs of spoilage develop. [May be kept refrigerated; package and label for distribution.] –SOP for Refrigerated Storage –SOP for Packaging and Labeling as a Refrigerated Product	CP3
Packaging	Biological: Cross-contamination	Package and label for distribution as a shelf-stable product. A hermetic seal will maintain product integrity. A thermal process may be applied (optional). –SOP for Packaging and Labeling –SOP for Thermal Processing (optional)	CP3

[a]CP = control point; SOP = standard operating procedure; CCP = critical control point.

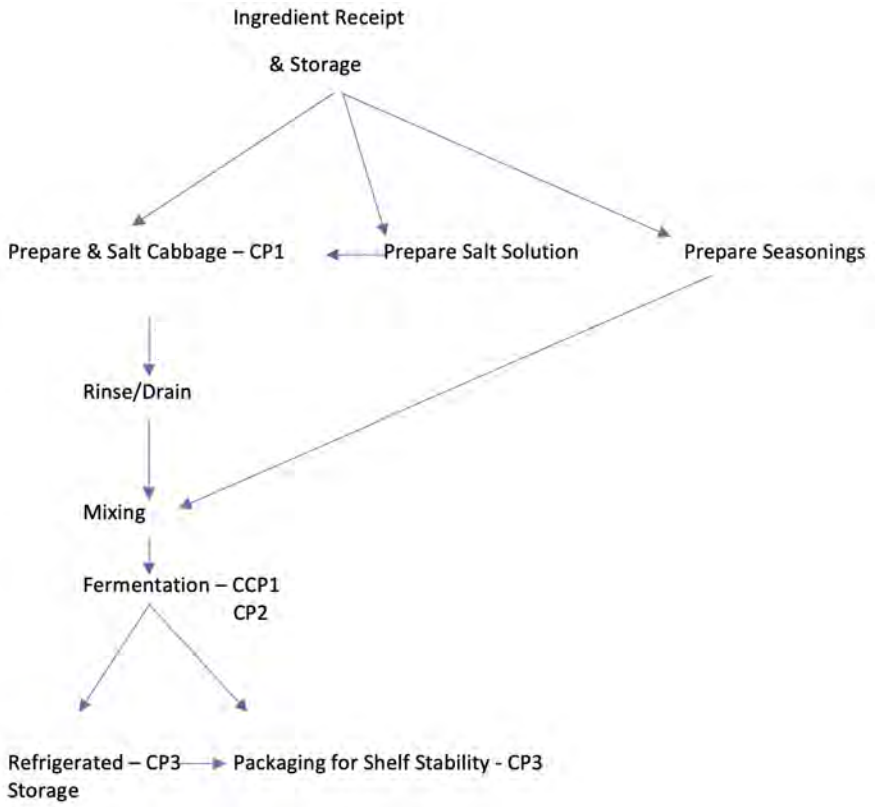

FIGURE 5. Flow chart of typical kimchi-making process, adapted from Kang and Bauer *(26)*.

from each vessel. pH is most accurately measured with a properly calibrated pH meter. Once sufficient replicate batches are monitored using a meter, a processor may be able to justify switching to litmus paper that has the proper pH measurement range, e.g., 3.0 – 5.5. In any case, litmus paper may be used to monitor pH whenever the brine pH falls below 4.0. The SOP must allow for sufficient pH sampling times to ensure that a continued pH decrease is recorded during active fermentation, with monitoring even after the pH decrease is complete. Generally, pH measurements are taken daily for the first several days and less frequently thereafter. Effective control requires that appropriate records are kept, including the date, time and pH measurement for sample(s) taken.

CP1: Vegetable preparation and NaCl addition

The addition of NaCl is often described as an essential food safety factor in the production of fermented vegetables. NaCl preferentially selects for the growth of LAB in comparison with pathogenic bacterial targets. Vegetable fermentations typically contain between 2% and 3% NaCl. The exception is large-scale commercial cucumber pickling operations that use ferment brines equilibrated to 6% NaCl but pack vegetables in a fresh solution with a lower NaCl content (2–3%) to meet consumer preferences. Despite the emphasis that is often placed on NaCl addition, it is worth emphasizing that it is organic acids, rather than NaCl content, that serve as the primary control agents during fermentation and finished product storage. Recent evidence has demonstrated that even in cases where NaCl content is < 2.0%, LAB fermentation progresses and eventually achieves a final pH sufficient to ensure a 5-log reduction in enterohemorrhagic *E. coli (13)*. In reduced/no-salt fermentations, however, the quality of the fermented vegetables may be significantly reduced, and brine pH may be unstable. In some low-salt fermentations, secondary fermentations have been observed in which lactic acid is metabolized, resulting in a potentially dangerous rise in pH above 4.6 along with malodorous propionic acid and butyric acid production *(24, 35)*. The addition of NaCl in vegetable fermentation is most appropriately managed as a control point (CP) rather than a CCP.

The addition of ≥ 2% NaCl is an important food safety consideration due to the selective advantage it provides to LAB; NaCl concentration below 2% decreases this selective pressure. Fermentation brine NaCl content above 2% begins to favor homolactic fermentations. The level of added NaCl impacts the final pH of the product; the rate at which the vegetables acidify, and flavor; it potentially influences the ratio of lactic to acetic acid produced by the LAB. Establishing a set NaCl concentration between 2.0 and

2.5% will help processors produce a consistent product and increase their ability to determine the necessary fermentation duration for every batch. The level of added NaCl also impacts the flavor of the final product.

Development of an SOP for vegetable preparation and NaCl addition promotes consistency, quality and safety in the finished product. Since acid penetration is slower in larger vegetable pieces than in smaller ones, a separate SOP should address vegetable preparation so that there is consistency from batch to batch. NaCl may be added through a dry brining method (e.g., for cabbage) or by submerging vegetables in a liquid brine (for cucumbers, hot peppers). Dry brining involves the direct addition of NaCl to shredded or chopped vegetables, with the subsequent release of exudate containing plant sugars from the vegetables, creating a brine. Alternatively, NaCl can be dissolved in water and used to cover vegetable pieces. Since the preparation method and form of the vegetable tissue has been shown to affect fermentation, this should also be addressed in the SOP *(28)*.

SOPs for vegetable preparation and preparation and addition of NaCl therefore address: preparation of vegetable tissue, including form, e.g., whole, shredded, chopped, etc.; the mass of each type of prepared vegetable tissue in the fermentation vessel; the weight of NaCl added per total mass; the method of NaCl addition, and, in aqueous applications, the amount of added water. Appropriate records should be kept. Iodized salt, some specialty and flavored salts, and other forms of NaCl have traditionally not been recommended in vegetable ferments because they contain heavy metals that may inhibit fermentation and decrease overall quality.

CP2: Temperature and time

The temperature at which traditional vegetable fermentations proceed will impact the growth rate and rate of acid biosynthesis. However, strictly limiting those conditions to ensure acidification in a prescribed amount of time is not necessary to ensure food safety. This is particularly true at cooler temperatures, which extend fermentation periods but do not necessarily enhance food safety risk. Typical vegetable fermentations are held at 18–23°C (65–72°F) for three to six weeks *(52)*. Decreasing the temperature to below this range slows LAB metabolic activity and extends fermentation time but does not necessarily impact quality. Quality impacts are, however, noted if temperature increases significantly above the desired range (>27°C/80°F) as the result of selective growth of spoilage bacteria and enhanced enzymatic activity that contributes to vegetable softening, off-flavor development, and discoloration *(16)*. It is worth noting that excessively sluggish fermentations can lead to quality problems and, in some cases, may increase risk because of the development of secondary fermentations and subsequent outgrowth of clostridial species. Effective pH monitoring, as noted previously, will help detect problems that may lead to spoilage.

Park and colleagues investigated the effect of fermentation at 4 or 25°C (39 or 77°F) on the final pH of kimchi *(43)*. The purpose of the study was to understand the rate at which kimchi ferments at different temperatures. Results showed that at a fermentation temperature of 25°C it took 46 h before a pH below 4.6 was recorded, i.e., 4.21, whereas no significant change in pH was noted for samples held at 4°C for the same period of time. The pH of cabbage fermentation brine was monitored for up to 15 days as Niksic et al. investigated the survival of *Listeria monocytogenes* and *E. coli* O157:H7 in sauerkraut fermented at 18 and 22°C (64.4 and 71.6°F) with NaCl concentrations of 1.8, 2.25 or 3% *(39)*. Regardless of fermentation condition, brine pH decreased steadily over the first 4 days, from ~6.2 to 4.2, eventually reaching a pH of 3.5 when shredded cabbage was fermented at 22°C, or a pH of < 4.0 for fermentation at 18°C. A 5-log pathogen reduction was seen over the first 4 days, with continued log reductions until day 10, when the detection limit was reached.

An SOP should be developed for the fermentation process that identifies expected temperature and time for completion of the process and options for storage post-fermentation. The SOP also identifies factors such as sealing of the fermentation vessel. Record keeping will support effective decision-making in the event of a fermentation that is progressing more slowly than expected, or when spoilage becomes an issue. Once fermentation is complete, the processor may choose to hold the sealed fermentation vessel at ambient or refrigeration temperatures without compromising safety. Extended room-temperature storage may lead to softening of texture (depending on the type and concentration of salts present) but does not present a food safety risk because of the low pH, high levels of organic acids present, and lack of fermentable sugars. It is best to limit ambient temperature storage in favor of refrigerated storage for finished products.

CP3: Packaging for shelf stability

Vegetable ferments may be packaged as a shelf-stable product or packaged and stored under refrigeration. Effectively performed, the fermentation process achieves a 5-log pathogen reduction and uses up simple sugars, so that thermal processing is not required for product safety. Pasteurization will, however, inactivate the fermentative cultures that may continue to produce carbon dioxide and acid during storage, thus helping to stabilize the product. Processors packaging fermented product in hermetically sealed containers without a thermal process would need to verify shelf stability *(1)*.

Packaging involves placing fermented vegetable tissue, either hot or at room temperature, into containers with added fermentation brine or acidic cover-brine and applying

the closure. A pasteurization step may be employed *(52)*; regardless, a hermetic seal must be maintained throughout storage and distribution. Records related to container size and thermal process time and temperature (if employed) should be kept and must link back to records related to ingredients and the fermentation process itself, e.g., batch logs. Since federal regulations do not consider shelf-stable fermented foods to be 'acidified', businesses do not have to file forms 2541 or 2541e with the FDA for shelf-stable fermented vegetable products *(56, 57)*.

CP3 [alternate]: refrigerated storage

If the fermented product is not heat processed, metabolic activity of the LAB may continue in the fermentation vessel, albeit at a reduced rate under refrigeration. Fully fermented vegetable products contain intrinsic factors which help ensure safety, and therefore these products should not be subject to time-limiting standards for holding product, such as date marking *(54)*. Fermented vegetable products are considered ready-to-eat foods, and an SOP for packaging and labeling would outline safe handling practices, especially related to hand hygiene, to prevent contamination and help ensure public health. Labeling standards and lot coding information must be addressed when packaging the final product for sale.

Miscellaneous CPs

Other food safety measures would be outlined in additional SOPs, e.g., an SOP that sets supplier specifications for raw agricultural products used in production of fermented vegetables. Vegetables should be grown in alignment with Good Agricultural Practices (GAPs) and harvested, transported, and stored to maintain safety and quality. Receiving, production, and distribution records should be maintained that allow for traceback and to support recall procedures. Additionally, sanitation activities and employee health and hygiene practices that prevent the introduction of pathogens into product should be developed.

CONCLUSIONS

This paper is intended to serve as a guide for small processors in the application of food safety control principles to traditional vegetable fermentations. The inherent safety of traditionally fermented cabbage, pepper, and cucumber products is due to accumulated acid content achieved over time. Certain processing parameters, notably NaCl content and fermentation time and temperature, support the necessary pH reduction. Other, nontraditional fermentation processes are less well understood, e.g., those used for producing lightly fermented products and the fermentation of carrots, beets and other vegetable tissues, where intrinsic factors such as buffering capacity may impact safety to a different degree. Manufacture of a wide array of fermented foods is generally being driven by consumers' desire for culturally relevant foods and foods with purported health properties. There is a need, therefore, to develop relevant science that would speak to emerging trends in food fermentation.

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