



## Memorandum

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From: Division of Biotechnology and GRAS Notice Review (HFS-255) Sodium Team

Subject: Survey of Microbiological Issues in FDA-Regulated Products

To: Administrative Record - Sodium Reduction Voluntary Guidance

### Introduction

#### *Sodium Reduction Overview*

The Strategies to Reduce Sodium Intake in the United States Institutes of Medicine (IOM) Report (2010) notes that achieving lower intakes of excessive sodium should be a critical public health focus for all Americans and that excess sodium content in processed foods and restaurant menu items should be gradually reduced to a safer level. The Healthy People 2020 objective, Nutrition and Weight Status-19, is to “Reduce consumption of sodium in the population aged 2 years and older” to a population target of 2,300 mg per day or less, consistent with the 2015-2020 Dietary Guidelines for American’s dietary intake recommendations and Healthy People 2020.<sup>1</sup>” The 2015-2020 Dietary Guidelines estimated average intake of sodium for all Americans ages two years and over adult intake as approximately 3,400 milligrams per day<sup>2</sup>. The Sodium Intake in Populations: Assessment of Evidence IOM Report (2013) reaffirmed that even the subset of the evidence from studies on sodium intake and involving direct health outcomes continues to support population-based efforts to reduce excessive sodium intake in the U.S. population. Consistent with these goals and findings, the U.S. Food and Drug Administration (FDA or we) supports efforts to create a broad, effective, and sustainable reduction of excessive sodium in the food supply, which will support recommendations for reducing the population intake of dietary sodium.

FDA’s sodium reduction voluntary guidance is exploring sodium reduction in the food supply, expressed as measurable voluntary goals for sodium content (from sodium chloride, commonly called “salt,” as well as other sodium-containing ingredients) in commercially processed, packaged, and prepared foods . The goals are designed to support reductions in excess sodium

<sup>1</sup> <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=29>

<sup>2</sup> The 2015-2020 Dietary Guideline recommendation to limit intake of sodium to less than 2,300 mg per day is the upper intake level (UL) for individuals ages 14 years and older set by the IOM. The recommendations for children younger than 14 years of age are the IOM age- and sex-appropriate ULs. The DGA estimate of population dietary sodium intake is from 20075-200106 NHANES data.

added to the food supply, keeping in mind the importance of sodium in food for microbial safety, stability, and other technical effects.

Our goals should be applicable to all foods with respect to technical challenges and opportunities. However, we particularly encourage attention by food manufacturers whose products make up a significant proportion of national sales in one or more of our food categories, as well as restaurant chains that are national or regional in scope. This focus on market leaders reflects our desire to ensure that reformulations that may be undertaken by industry, and the burden they represent, will mainly occur where they will have the most impact on population sodium intake and public health. By creating a shared understanding of what meaningful sodium reduction would look like, and by establishing a common vocabulary for describing it, the goals are intended to promote a level playing field and to complement and coordinate existing efforts by food manufacturers and restaurant/food service operations.

The process for developing these goals involves three steps. First, the food supply is organized into categories (discussed in the section 2 of FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance). A subset of categories ("target categories") is selected for goal assignment. The target categories are the subject of the subsequent steps in the process and are often referred to more generally as categories. Second, baseline sodium concentrations are calculated for each category (discussed in section 3 of FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance). Third, quantitative goals are assigned to each food category (discussed in sections 4 and 5 of FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance).

#### *Survey of Microbiological Issues in FDA-Regulated Products*

To further support this effort, we have reviewed available information on the technical functions of salt<sup>2</sup> (sodium chloride) and other sodium containing ingredients. This memorandum summarizes information related to sodium (primarily as salt) and microbiological safety and stability (preservation functions) in foods regulated exclusively by FDA. Meat and poultry products, which are regulated by the United States Department of Agriculture (USDA), are described in a separate memorandum, **Survey of Microbiological Issues in Meat and Poultry Products**. Flavor functions are discussed in the memorandum "**Salt Taste Preference and Sodium Alternatives**." The main goals of this memorandum are to discuss:

- the role of salt and sodium in the microbiological safety and stability of foods,
- food categories for which salt plays a particularly prominent preservative role,
- available literature on salt's preservative role and sodium reduction strategies, and
- techniques for assessing the microbiological impact of sodium reduction.

Discussion in each memorandum illustrates the existence of some available food technologies that may be useful in sodium reduction, and to provide some context for our draft sodium reduction goals in terms of what is feasible. Not all findings in the studies described in this

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<sup>2</sup> The focus of this document is "sodium." "Salt" refers specifically to the compound sodium chloride, which is the most common source of sodium in the diet.

memorandum translate well to large scale production environments. Additional validation may be necessary to ensure that scaled-up processes based on literature findings can continue to produce a safe product. These review memoranda are not prescriptive or comprehensive, particularly given the proprietary nature of many relevant food technologies, but represent a survey of the literature. These data are not the dominant factor in our selection of target concentrations for food categories as our primary basis was an exhaustive analysis of concentration data from commercially available foods. Safety must remain a paramount consideration in the development of all new foods and reformulation of existing products. Additional technologies and strategies may be identified through public discussion of our sodium reduction voluntary guidance and incorporated into future review documents.

Salt is one of the most frequently used ingredients in the food supply. It affects flavor, texture, and microbial activity. Through this last function, salt plays a key role in food safety and maintenance of product shelf life. Because intake of sodium in the U.S. continues to surpass recommendations, there is increasing interest in reformulating sodium-contributing foods to reduce salt and other sodium-containing ingredients. The food industry has responded with efforts to reduce sodium in foods. The range of sodium content in comparable commercial food products currently available suggests both that some sodium reduction has already occurred in certain foods, and that potential may remain for reduction in others. More research is needed to better understand the impact of sodium reduction on food safety and stability. Further research on food technologies that can address potential sodium reduction impacts would also be valuable.

## **Background**

### ***The role of salt in food preservation***

Refrigeration and improvements in processing, packaging, transport, and storage have reduced the need to use high salt levels to prevent the growth of pathogens and spoilage microorganisms (Bidlas and Lambert, 2008). However, in many foods, salt still contributes to safety or longer shelf life for the end product in combination with other factors, such as pH, temperature, and use of other preservatives. Reducing added salt in these foods has the potential to negatively impact safety or reduce shelf life unless appropriate measures are taken (Bidlas and Lambert, 2008).

### **Basis of microbiological safety and stability**

The unintended growth of microorganisms in food can, depending on the organisms, cause foodborne illness if the microorganisms are pathogens or produce toxins (Zeuthen and Bøgh-Sørensen, 2003) or lead to undesirable changes organoleptic properties of the food. Microbial spoilage lowers food product quality, which may result in economic loss, but does not in itself render food unsafe.

The microbiological safety and stability of most foods are influenced by a combination of factors. These “critical factors” involve temperature control, water activity, pH, redox potential,<sup>3</sup>

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<sup>3</sup> “Redox” or “oxidation/reduction” potential is the measure of the tendency of a chemical to acquire electrons and be reduced. A liquid or food matrix has a particular redox potential. Biological systems are affected by the specific

use of chemical preservatives, among others (Leistner, 1994). When a critical factor is manipulated to reduce the risk of foodborne illness or spoilage, the factor becomes a “hurdle” that negatively impacts the ability for the undesirable microorganism(s) to persist, survive, and grow in the food. Common factors and their effect on microorganisms are summarized in Table I of the Appendix. As an alternative to employing particular factors at extreme limits to control microbial growth, food manufacturers may employ hurdle technology (Leistner, 1994). Using this approach, manufacturers control multiple factors of a food product to develop food formulations and production methods that create an unfavorable environment for microbial growth during the shelf life of the food product (Betts et al., 2007).

#### Water activity and microbial growth and survival

Salt predominantly reduces the water activity ( $a_w$ ) of food, rendering water unavailable for use by microorganisms. The term  $a_w$  is defined as the amount of water available for microorganisms to grow and is based on a scale of 0 to 1.0, with pure water at 1.0. Reducing  $a_w$  of a food matrix can dramatically affect the growth and survival of microorganisms. It can extend the lag phase (the period of cellular adaptation to the environment before exponential growth begins) and reduce bacterial growth. Microbial cells may undergo osmotic shock<sup>4</sup> in a low  $a_w$  environment, resulting in water loss and thereby either retarding growth or resulting in cell death (Davidson, 2001). In spite of these effects, lowering the  $a_w$  of a food product is not necessarily enough to ensure that all microorganisms are killed, because affected cells may remain viable.

The  $a_w$  of food matrices is greatly influenced by the concentrations of dissolved substances such as salts and sugars (Chirife and del Pilar Buera, 1996). The decrease in  $a_w$  mediated by salt is thought to be based on association of sodium and chloride ions with water molecules (Fennema, 1996; Potter and Hotchkiss 1995). Each microorganism cannot grow below its minimum  $a_w$ . The minimum  $a_w$  limits for growth of microorganisms are shown in Table II of the Appendix. Notably, these limiting  $a_w$  levels apply only when other growth conditions are favorable. If factors such as pH, oxygen levels, or temperature are suboptimal for microorganisms, growth or viability may not occur without a greater  $a_w$ .

#### Effect of $a_w$ on pathogenic microorganisms

Most foodborne bacterial pathogens cannot grow when  $a_w$  is less than 0.83. *Clostridium botulinum* strains require a minimum  $a_w$  of approximately 0.94 for optimal growth, while *Escherichia coli* strains require a minimum  $a_w$  of approximately 0.95 (Doyle et al., 2001; Sperber 1983). Most *Listeria monocytogenes* strains require an  $a_w$  that is less than or equal to 0.97 for optimal growth. *Salmonella enterica* serovars<sup>5</sup> Typhimurium, Enteritidis, and others require a minimum  $a_w$  of 0.93. Pathogenic *Staphylococcus aureus* strains, which are considered to be tolerant to osmotic stress, can grow in a minimum  $a_w$  of 0.86 (Doyle et al., 2001).

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redox potential of their local environment.

<sup>4</sup> Osmotic shock is a sudden change in the concentration of substances dissolved in water. Because bacteria are single-celled organisms with cell membranes directly exposed to their environment, they are particularly vulnerable to osmotic shock, which can disrupt many biological processes.

<sup>5</sup> A serovar (serological variant or serotype) is a group of closely related microorganisms distinguished from other serovars by characteristic surface antigens.

### Effect of $a_w$ on spoilage microorganisms

Spoilage-causing *Pseudomonas* spp. cannot grow at  $a_w$  less than 0.92. Some groups of spoilage microorganisms tolerate  $a_w$  under 0.92, including lactic acid bacteria (LAB) (0.90) and yeasts (0.62). Molds (*Aspergillus* and *Penicillium*) also tolerate lower  $a_w$  than most bacteria, ranging from 0.80 to 0.83 (Betts et al., 2007; Christian, 2000).

### Other Modes of Activity

For some microorganisms, salt may limit oxygen solubility, interfere with cellular enzymes, or force cells to expend energy to remove sodium ions from the cell. All these effects can reduce the growth rates of microbes (Shelef and Seiter, 2005).

## **Food Categories at Risk for Reduced Microbiological Safety and Stability**

Food categories are discussed in the **Supplementary Memorandum to the Draft Guidance**. Our category structure has the following major groupings:

- Cheeses
- Fats, Oils, and Dressings
- Fruits, Vegetables, and Legumes
- Nuts and Seeds
- Soups
- Sauces, Gravies, Dips, Condiments, and Seasonings
- Cereals
- Bakery Products
- Meat and Poultry
- Fish and Other Seafood
- Snacks
- Sandwiches
- Mixed Ingredient Dishes
- Salads
- Other Combination Foods
- Baby/Toddler Foods

We identified a number of categories for which added salt plays a particularly important role in microbiological safety and stability. Below we list these categories<sup>6</sup>, in order of the group to which they belong.

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<sup>6</sup> These categories exclude meat and poultry products, which are discussed in a separate memorandum.

- Cheeses
  - Natural<sup>7</sup> cheeses
  - Processed cheeses
- Fats, Oils and Dressings
  - Butter
  - Margarine and vegetable oil spreads
  - Salad dressings
- Fruits, Vegetables and Legumes
  - Fermented vegetable products
- Sauces, Gravies, Dips, Condiments, and Seasonings
  - Sauces
  - Condiments
- Bakery Products
  - Breads
- Fish and other Seafood
  - Smoked fish

Similar microbiological considerations would apply to combination product categories (such as sandwiches, mixed ingredient dishes, etc.) where they contain components from one or more of the categories listed above.

## **Methodology**

We searched primary scientific literature using large search engines such as PubMed, Google Scholar, and Science Direct. Our initial literature search included the terms “sodium reduction” or “salt reduction” in conjunction with “safety”, “preservation”, or “microbiological stability.” We reviewed these results to identify relevant and useful material. Additional relevant studies were subsequently identified and reviewed as a result of this initial round of literature search and review.

## **Review of Sodium Reduction Studies in Key Food Categories**

### ***Cheeses***

#### Natural cheeses

Natural cheeses are highly standardized foods, as described in FDA regulations at 21 CFR part 133. These standards include moisture and fat content, as well as permissible ingredients, including salt. Salt enhances the flavor and texture of cheese, but also inhibits the growth of pathogenic microorganisms and extends a product’s shelf life. Other critical factors applied to ensure the control or elimination of microbial pathogens in cheese include pH, cold temperature storage, and use of competing microflora (Guinee and O’Kennedy, 2007).

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<sup>7</sup> In cheesemaking, the word “natural” is a purely technical term to distinguish one type of cheese from processed and imitation cheese with no qualitative meaning attached to the term. It is not meant to illustrate FDA’s thinking about the overall use of the term “natural.”

Pathogens of concern in cheese include *L. monocytogenes*, *S. aureus*, *E. coli*, and salmonellas. Pathogens may be present in raw milk or may be introduced through post-pasteurization contamination (Fox et al. 2000, Donnelly 2004). Pasteurized milk, used as the base for cheese or other food products, should be free from pathogens. However, post-pasteurization contamination is possible (Donnelly, 2004). Salt acts as a food safety critical factor in cheese directly in the case of post-pasteurization contamination and indirectly as a mechanism to control  $a_w$  and growth of competing microorganisms (Guinee and O'Kennedy, 2007). For the higher salt cheese types, salt plays important roles in controlling the microorganism environment. The high salt content of blue cheese is one aid in selecting growth of the desired mold, *Penicillium roquefortii*, rather than allowing salt sensitive and sometimes defect-causing microorganisms to grow. In the case of feta, a rather high-moisture cheese, salt slows the growth of undesirable microorganisms and slows the undesirable proteolytic activity that would eventually result in a cheese with excessive softness. Parmesan cheese is a low-moisture cheese and, together with a high salt content, has an extended shelf life of several years (Johnson et al 2009). During cheese manufacturing, salt aids in removing water from the curd, resulting in desirable moisture content for ripening. Salt concentrations above optimal levels may disrupt the starter microbial culture and reduce its ability to out-compete any pathogens in the matrix.

Generally, reducing added salt will stimulate growth of the starter culture, resulting in a lower pH. While this may be undesirable from a flavor stand-point, it would not be harmful from a food safety perspective. However, reduction will also result in a lower salt percentage in the aqueous phase of food, which could make the environment more hospitable for pathogens.

Soft cheeses and surface-ripened cheeses often have a higher pH and more moisture than other cheeses, and are handled frequently prior to aging, which increases the chance of contamination. Fresh unaged cheeses at low salt concentrations have been specifically implicated in outbreaks (Fox et al., 2000). Manufacturers must maintain safe practices when reducing sodium levels in high moisture cheeses to avoid pathogen growth.

One study investigated sodium reduction in a feta-type brined cheese (Aly, 1995). The author compared 4 percent salt (1540 milligrams (mg) of sodium per 100 grams (g)) to 2 percent salt (740 mg sodium per 100 g) cheese formulations, and found limited increases in microbial counts in the lower-sodium cheese. Organoleptic properties were not affected. In the author's view, it is possible to manufacture quality feta-type cheeses with a 2 percent salt concentration.

In a study on cheddar cheeses (hard cheese), the authors compared a typical 1.8 percent salt (700 mg of sodium per 100 g) cheese to a 0.7 percent (280 mg per 100 g) cheese (Shrestha et al., 2011). They inoculated the cheeses with *L. monocytogenes* and found that pathogen growth was not supported in either formulation, at both cold and room temperature. They concluded that lower salt cheeses may be as safe as their full salt counterparts with respect to post-aging contamination of *L.monocytogenes*.

### Processed cheese and cheese products

Processed cheeses are mixtures of cheese and other dairy ingredients, cooked and emulsified.<sup>8</sup> Like natural cheeses, they are defined by food standards that specify fat and moisture content, permissible ingredients, and processing procedures. Non-standardized processed cheeses (often referred to as “processed cheese products”) are also sold.

The role of sodium in processed cheeses is somewhat more complex than in natural cheeses. The 3 major ingredients that contribute to sodium in processed cheese are sodium-based emulsifying salts (approximately 44% to 48%), natural cheese (approximately 28% to 37%), and added salt (approximately 15% to 24%). Therefore, sodium reduction efforts in processed cheese involve mainly the modification of 1 or all 3 ingredients during processed cheese formulation and manufacture ((Johnson et al 2009). Emulsifiers, like disodium phosphate, can be added at levels up to 3% (percentage weight/weight (w/w)). Thus, the sodium content of processed cheese and processed cheese products is generally much higher than that of natural cheeses because of the addition of salt at 0.4 to 1.05% (w/w) (Guinee and O’Kennedy, 2007). Processed cheeses have a pH above 4.6 and  $a_w$  above 0.85.

Most organisms of concern would be inactivated during pasteurization and aging of the cheese component, but *C. botulinum* control remains a concern. Consequently, to minimize the risk of *C. botulinum* growth and to eliminate the risk of toxin production, they must either be refrigerated or commercially sterilized (Hutton, 2002; Sperber, 1982). Use of intense heat treatment to commercially sterilize processed cheeses would diminish the quality of the finished products. Therefore, formulations are manipulated to prevent the growth of *C. botulinum* and ensure safety. Moisture content, pH, salt, and disodium phosphate levels have been shown to be the most important variables in controlling toxin formation. One study indicates that sodium (from salt and disodium phosphate) must be higher than 800 mg sodium per 100 g cheese in shelf-stable cheese spread products to ensure microbiological safety (Tanaka et al., 1986).. Another study found potassium-based emulsifiers to be less effective at inhibiting *C. botulinum* toxin production than sodium-based emulsifiers (Karahadian et al., 1985). However, potassium-based emulsifying salts could replace up to 75% of sodium-based emulsifiers (on a molar basis) in reduced-fat processed cheese without reducing *C. botulinum* control (Glass and Doyle, 2005).

Several models to examine the interactions between ingredient levels and safety exist, though it is difficult to account for all variables (Glass and Doyle, 2005). As a result of this, large changes in processed cheese formulations must be validated for safety through processing tests and challenge studies (see "Techniques to evaluate the effect of sodium reduction on food safety and quality" below).

### ***Butter, margarine and vegetable oil spreads***

Salt was originally a preservative in butter, but with advances in manufacturing hygiene and refrigeration (as well as preservatives allowed in products that do not have ingredients defined by

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<sup>8</sup> Emulsification is the process of suspending small drops of one liquid in a second liquid when the two would not normally mix; e.g., water in oil.



regulation), its role is less critical (Guinee and O'Kennedy 2007; Hutton, 2002). Taste and flavor development are now more important considerations (Brady, 2002; Hutton, 2002). Salt-free butter, margarine, and low-sodium vegetable oil spreads are currently available on the market. Fat, the major ingredient of margarine and other spreads, is not an ideal environment for microorganisms to proliferate and thrive. The water phase is generally pasteurized prior to the emulsification step to destroy any microbes that may have been introduced through the dry ingredients (whey, buttermilk, spices, etc.).

Additionally, microbiological stability of spreads is largely dependent on the droplet size of water emulsified into the fat (Delamarre and Batt, 1999). In margarines, the average droplet size is 4-5 micrometers with a range from 1 to 20 micrometers. Water droplets less than 10 micrometers largely preclude microbial growth due to limited interior area available for microbial growth and the low quantity of nutrients available in a droplet.

Salt is concentrated in these water droplets relative to the oil that surrounds it; 2% salt in the overall product may mean up to 8% salt in the water droplets (Delamarre and Batt, 1999). Reducing added salt could affect the behavior of proteins in the emulsion, causing instability and coalescence of the dispersed water droplets. One potential strategy for countering this instability at lower sodium concentrations is to use hydrocolloids, which can increase the viscosity of the dispersed water and make it less likely for the droplets to coalesce.

### ***Fermented vegetable products***

Historically, salt plays a central role in fermented vegetable products. Fermentation can transform fresh foods to desirable foods that can be maintained for a longer time than their fresh counterparts (Potter and Hotchkiss, 1995). Pickles, sauerkraut, olives, and soy sauce and other condiments owe many of their characteristics to the actions of LAB such as *Lactobacillus plantarum* and *Leuconostoc mesenteroides*. Salt favors the growth of these more salt-tolerant, desirable organisms, while inhibiting the growth of undesirable spoilage bacteria and fungi naturally present in or on these foods (Doyle et al., 2001; Reddy and Marth, 1991; Panagou et al., 2011). Salt also helps to draw water and sugars out of plant tissues during fermentation of vegetables. Water aids fermentation by filling air pockets in fermentation vats, yielding reduced oxygen conditions that favor growth of LAB. The release of water and sugars also promotes fermentation reactions in the resulting brine, increasing the rate of the fermentation process (Doyle et al., 2001; Potter and Hotchkiss, 1995).

Partially replacing salt with alternative compounds like potassium chloride and calcium chloride in fermented vegetable products may be possible (Bautista-Gallego et al., 2008; Reddy and Marth, 1991; Yumani et al., 1999). In one study, cucumbers were fermented in closed jars using calcium chloride in place of salt. The authors did not detect production of propionic or butyric acids, which would be suggestive of growth of spoilage bacteria that often produce these acids. Cucumber fermentations with and without salt in the fermentation brine were similar in both the chemical changes caused by the fermentative microorganisms and in the retention of firmness in the fermented cucumbers (McFeeters and Perez-Diaz, 2010).

Another study compared sauerkraut fermentation in a 1.2 or 0.5 percent salt solution, or a 0.5 percent mineral salt solution (57 percent sodium chloride NaCl, 28 percent potassium chloride

KCl). LAB grew most rapidly in the high salt solution. However, after two weeks of fermentation, all formulations had similar LAB counts, pH, and acetic acid concentrations. Juice from the mineral salt formulation was rated most highly of the three by a trained taste panel. (Viander et al., 2003).

Panagou et al. (2011) compared olive fermentation in a control brine solution (8% NaCl) to a number of other brines with mixtures of sodium, potassium, and calcium salts. The pH and growth profile of LAB and yeasts were similar in all formulations. A trained taste panel evaluated each formulation after six month of storage. Brines containing only potassium or calcium resulted in unacceptably bitter olives; olives fermented in a mixture of 4% NaCl and 4% KCl were reported to be similar in quality to the control formulation.

### ***Dressings, sauces, and condiments***

Sauces, salad dressings, and condiments are often high in sodium. Reasons for sodium use include flavor, preservation, and improved stability of emulsions by improving the solubility of emulsifiers. Flavor is a main reason for adding salt to these products, and saltiness is often one of the major characteristics of these items. Many sauce formulations typically rely on a combination of salt, sugar, and acetic acid to provide microbiological safety and stability. In most condiments, salt plays a role in preservation (Brady, 2002) combined with other hurdle technologies such as pH control and use of chemical preservatives. With appropriate levels of these ingredients, sauces can be formulated to be shelf-stable at ambient temperature without the need for additional preservatives or heat processing (Hutton, 2002). Sodium-containing ingredients other than salt also may be added to salad dressings, sauces, and condiments to act as emulsifiers or preservatives. However, it may be possible to achieve lower sodium concentrations in these products without sacrificing safety by adjusting other hurdles. For example, sugar<sup>9</sup> or vinegar can be added to the formulation, or lower sodium products can be refrigerated to extend their shelf life.

### ***Bakery products***

Water activity is the most important factor influencing microbiological spoilage of bakery products. Low  $a_w$  baked products ( $a_w < 0.6$ ) such as crackers, are not ordinarily subject to microbial spoilage. Intermediate  $a_w$  products ( $a_w 0.6-0.85$ ) such as cakes and filled pastries can spoil, predominantly by osmophilic yeasts and molds. High  $a_w$  products ( $a_w 0.94-0.99$ ) such as crumpets and pies are subject to spoilage by bacteria, yeasts, and molds. Mold spoilage often limits the shelf life of bakery products and results in economic loss to the bakery industry.

Therefore, bakeries often use preservatives to reduce spoilage. Propionic, sorbic, acetic, and benzoic acids and their salts are among the most commonly used chemical preservatives (Legan, 1993). Microbiological spoilage can also be reduced by other practices, including attention to hygiene to limit mold spore exposure, pasteurization of sourdough breads once packaged, use of

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<sup>9</sup> An optimal sodium reduction strategy would seek to maintain overall nutritional quality when reducing sodium concentrations.

certain preservatives such as raisins prune juice concentrate or LAB, and modified atmosphere packaging (MAP) (Gerez et al., 2009).

Salt also helps control the growth of molds and bacilli, thus extending the shelf life of baked goods (Betts et al., 2007). Bacilli are capable of forming rope-like structures, off-flavors, and discoloration, especially in baked goods high in sugar or fats (Doyle et al., 2001). However, sugar, not salt, is the primary means of controlling  $a_w$  in many baked products; therefore, many food preservation concerns with bakery products are not dependent on salt for control (Smith et al., 2004).

Challenge tests with or without partial replacement of salt with salt substitute ingredients were performed on white bread to determine the consequences of reducing the amount of added salt on the growth of *Penicillium roqueforti*, the most common mold in bread spoilage. The results revealed that differences in the growth of *P. roqueforti* on standard white bread (507 mg per 100 g), bread with 30% less salt (353 mg per 100 g), and bread in which 30% of the salt has been partially replaced by a mixture of potassium chloride (KCl) and a commercial salt substitute (a mixture of salt, KCl, and sodium gluconate that has 35% less sodium than the same quantity of salt) (413 mg per 100 g). The authors found no significant difference between growth curves of *P. roqueforti* in the three different bread formulations (Samapundo et al. 2010).

### ***Fish Products***

Salt can be a significant factor in preserving both hot and cold-smoked fish to prevent *C. botulinum* toxin production. For refrigerated, reduced-oxygen packaged (e.g. vacuum or modified atmosphere packaged) cold smoked or smoke-flavored fish, 3.5 % water phase salt, or, where permitted, the combination of 3.0 % water phase salt and not less than 100 parts per million nitrite, appear sufficient to prevent *C. botulinum* toxin production (Hutton, 2002; Betts et al. 2007). In another study, the shelf life of cold-smoked vacuum-packed salmon was reduced at 2.2% salt compared to 4.6 %, at both 5 and 10 °C (Hansen et al., 1995). In hot-smoked fish products, one study found that NaCl and NaCl/KCl mixtures were similar in their ability to inhibit outgrowth and toxin production by *C. botulinum* (Pelroy et al., 1985).

*L. monocytogenes* is another pathogen of concern for smoked fish. Salt and temperature control alone appear inadequate to suppress *L. monocytogenes* growth in these products. Additional control measures such as vacuum packaging and the addition of sodium nitrite are considered necessary (Peterson et al 1993).

In salted fish, the preservative action of salt occurs through a combination of direct microbial inhibition, enzyme inhibition, and a significant dehydration effect in the fish tissue (Connell 1995). Immersion in a 5% salt solution incorporating modified atmosphere packaging extended the shelf life of the fish by 8 days (Pastoriza et al. 1998). Salt can also kill fishborne parasites. Storage of herring in 21% salt brine for ten days destroyed the herring worm (*Anisakis simplex*), implicated in infections of humans who ate raw or lightly cured fish (Ranken 1997).

***Summary***

Within the food categories discussed above, salt contributes either to food safety, extended shelf life, or both. Table 2 below summarizes the role of salt in these foods, as well as microbiological safety and spoilage concerns. The key control measures used during sodium reduction in those foods are also included. Table 3 highlights the available microbiological safety and stability studies in sodium-reduced food products from each of the categories above.

**Table 2: Salt Contribution to Microbiological Stability and Potential Compensatory Control Measures in Reduced-Sodium Foods**

Category	Salt role	Microbiological safety		Microbiological stability
		Key pathogen of concern	Potential compensatory control measure for sodium reduction	Spoilage microbes
Natural cheese	<ul style="list-style-type: none"> <li>Control fermentation</li> </ul>	<i>L. monocytogenes</i> +	pH≤4.4, a <sub>w</sub> ≤0.92, WPS >10%, preservatives	Bacteria, mold, and yeast
Processed cheese and cheese food	<ul style="list-style-type: none"> <li>Extend shelf life,</li> <li>Inhibit pathogen growth</li> </ul>	<i>C. botulinum</i>	pH≤4.6, a <sub>w</sub> ≤0.94, WPS >10% , preservatives	
Cheese spread				
Butter, margarine, salad dressing	Extend shelf life	<i>L. monocytogenes</i>	pH≤4.4, a <sub>w</sub> ≤0.92, preservatives, refrigeration	Bacteria, mold, and yeast
Fermented vegetable products	<ul style="list-style-type: none"> <li>Control fermentation</li> <li>Extend shelf life,</li> <li>Inhibit pathogen growth</li> </ul>		pH control, a <sub>w</sub> , preservatives	Acid tolerant bacteria, mold, and yeast spoilage
Sauces, gravies, dips, condiments, and seasonings	Extend shelf life		pH, a <sub>w</sub> , preservatives	Bacteria, mold, and yeast
Bread products	<ul style="list-style-type: none"> <li>Control fermentation</li> </ul>		pH, a <sub>w</sub> , preservatives (propionates, sorbate, acetic acid, etc.), etc.	<i>Bacillus subtilis</i> . Yeast
Pastries with filling, pie, cakes *	<ul style="list-style-type: none"> <li>Extend shelf life</li> </ul>			
Refrigerated dough/ batter	<ul style="list-style-type: none"> <li>Extend shelf life</li> <li>Inhibit pathogen growth</li> </ul>	<i>L. monocytogenes</i>	pH, a <sub>w</sub> , preservatives (propionates, sorbate, acetic acid, etc.), etc.	Psychrotrophic anaerobic bacteria, mold, and yeast

Category	Salt role	Microbiological safety		Microbiological stability
		Key pathogen of concern	Potential compensatory control measure for sodium reduction	Spoilage microbes
Salted fish/seafood	<ul style="list-style-type: none"> <li>Extend shelf life</li> <li>Inhibit the growth of pathogens</li> <li>Kill parasites</li> </ul>	<i>C. botulinum</i>	pH ≤ 4.6, a <sub>w</sub> ≤ 0.85, salt > 20% in shelf-stable salted products	Bacteria, mold, and yeast
Smoked fish/seafood	<ul style="list-style-type: none"> <li>Extend shelf life</li> <li>Inhibit the growth of pathogens</li> </ul>	<i>C. botulinum</i> <i>L. monocytogenes</i>	pH < 5, a <sub>w</sub> ≤ 0.97, salt > 5% in refrigerated products	Bacteria, mold, and yeast
			Salt > 3.5% or 3.0% + 100 ppm nitrite in refrigerated, reduced oxygen packaged smoked fish or smoke-flavored fish	

+Salmonellas, *E. coli*, and *S. aureus* in raw milk-made cheese (use of pasteurized milk avoids this issue).

\*Salmonellas, *B. cereus* and *S. aureus* in egg and dairy ingredients in filled bakery product. However, sugar is generally the primary means of controlling a<sub>w</sub> in these products.

a<sup>v</sup>(water activity)

WPS (water phase salt - the end-product water-phase salt level (amount of salt compared to the amount of moisture (water)))

**Table 3**  
**Comparative Studies on Microbiological Stability of**  
**Conventional and Reduced-Sodium Food Products**

Category group	Tested Foods	Relative microbiological stability	Sodium level tested (mg/100g)	Literature Citation
Natural cheese	Feta	Low salt Feta-type cheese (740 mg Na/100 g cheese) has stable shelf life; Acceptable quality feta cheese ) could be manufactured using 2% of a mixture of NaCl:KCl=1:1, resulting in 410 mg Na/100 g	740	Aly 1995
	Cheddar	Low salt cheeses (0.7%) appear as safe as their full salt counterparts (1.8%); salt may only be a minor food safety hurdle regarding the post-aging contamination and growth of <i>L. monocytogenes</i> .	280	Shrestha et al. 2011
Processed cheese and cheese products	Cheese spread	Salt and disodium phosphate final concentration in shelf-stable cheese spread product must be > 4% to be microbiologically safe	800	Tanaka et al. 1986
Fermented vegetable products	Sauerkraut	No significant differences among 0.5% mineral salt (28% KCl, 57% NaCl resulting in a NaCl concentration of 0.3%), 0.5%, and 1.2% salt in terms of fermentation, shelf life.	120	Viander et al. 2003
	Olive	4% NaCl +4% KCl good fermentation without spoilage	1600	Panagou et al. 2011
	Cucumber	Cucumber fermentation is completely inhibitory to undesirable microbes and enables a successful fermentation at pH≤3 regardless of salt concentration; if pH >3 salt must be >2%	800	Kim and Breidt 2007
		Fermentation of cucumbers brined with CaCl <sub>2</sub> instead of salt in closed jars does not result in detectable propionic or butyric acids, indicating growth of spoilage bacteria (pH≤3.5)	no added sodium	McFeeters and Perez-Diaz 2010

Category group	Tested Foods	Relative microbiological stability	Sodium level tested (mg/100g)	Literature Citation
Bread products	White bread	No significant difference occurred in the growth of <i>P. roqueforti</i> on standard white bread (sodium 507 mg/100g), bread with 30% less NaCl (sodium 353 mg/100 g) and bread in which 30% of the NaCl has been partially replaced by a mixture of KCl and Sub4Salt	353	Samapundo et al. 2010
Salted fish/seafood	Salted herring	Storage of herring in 21% salt brine for 10 days destroys parasites, the herring worm ( <i>Anisakis simplex</i> )	8000	Ranken et al. 1997
Smoked fish/seafood	Slices of hake	Immersion in a 5% salt solution incorporating MAP extended the shelf life of the fish by 8 days compared with those obtained for air-stored samples and for MAP-stored samples in the absence of NaCl.	2000	Pastoriza et al. 1998
	Cold-smoked salmon	The shelf life of cold-smoked vacuum-packed salmon was reduced to 4-5 weeks at 2.2% salt from 7-8 weeks with 4.6 % salt at 5°C and to 1-2 weeks at 2.2% salt from 5-6 weeks at 10 °C.	1400	Hansen et al. 1995
	Cold-smoked salmon	Neither 3% nor 5% salt by itself is sufficient to prevent the growth of <i>L. monocytogenes</i> in vacuum-packaged or O <sub>2</sub> -permeable film-packaged, cold-processed salmon at refrigerator temperatures. Adding sodium nitrite to NaCl, was suggested to inhibit <i>L. monocytogenes</i> in cold-smoked fish.	1400	Peterson et al. 1993
	Smoked whitefish	Challenge tests: Similar inhibition on toxic outgrowth of <i>C. botulinum</i> type E in hot-process (smoked) whitefish when KCl substituted for all or part of the NaCl at the abuse temperature of 25°C. 3.5% NaCl, 4.3% KCl, 4.2% equimolar NaCl: KCl	1400	Pelroy et al. 1985



## **Use of Other Microbial Control Measures in Reduced-Sodium Foods**

Typically, sodium is often used as a preservative to retard microbial growth and survival by lowering the critical factor  $a_w$ . Reducing sodium may impact the microbial safety and stability of the foods because other critical factors (pH, temperature, etc.) may only be effective at original sodium levels. Reducing added salts in some foods results in a higher  $a_w$  which presents potential reformulation challenges.

To ensure safe foods with acceptable shelf lives, reformulation may have to incorporate additional microbial control measures or modify the parameters of critical factors. By using a number of different means of microbial inhibition, it is possible to apply each individual control measure and critical factor at a reduced intensity or concentration and still produce foods that are safe, have adequate shelf lives, and are acceptable to consumers (Leistner and Gorris, 1995). Examples of control measures and critical factors include increased concentrations of preservatives other than added salt, and modified cooking, packaging, and storage temperatures. Some additional control measures, which could help maintain quality and safety in reduced sodium products, are described below.

### ***Botanically-derived antimicrobials***

Many plant-derived substances have antimicrobial properties. Examples include vegetable extracts, mustard, onion, garlic, horseradish, and a range of other herb and spice ingredients, including their extracts and essential oils (Benkeblia, 2004; Lund et al., 2006; Nadarajah et al. 2005a, 2005b; Raybaudi-Massilia et al., 2006). Active components from plants or essential oils exhibit antimicrobial activity against molds and bacterial pathogens in numerous laboratory broths (Burt, 2004). Such compounds with antimicrobial activity may have potential as food preservatives if there is adequate evidence of their safety (Smid and Gorris, 1999). Botanically-derived antimicrobials are increasingly popular with consumers who prefer foods that they perceive as natural and healthy. However, these compounds are often more effective under laboratory conditions compared to actual foods matrices, where fats or other food components may inactivate or impair their antimicrobial properties (Gupta and Ravishankar, 2005). In addition, the strong flavor of those compounds may negatively alter the organoleptic properties of the foods, affecting consumer acceptance (Doyle and Glass, 2010).

### ***pH reduction***

Microorganisms have optimum pH ranges for growth and survival. In general, bacteria associated with food grow at pH between 4 and 8, whereas yeasts and molds associated with food grow at a wider pH range. In some instances, the range is between pH 2 and 11 (Wheeler et al., 1991). However, microorganisms may survive at low pH, remaining viable without growth. Generally, reduced pH environments are complemented by the use of salt in preservation systems. Predictive models or challenge tests can be used to determine optimal pH to ensure the microbial safety and stability of reduced-sodium foods.

### ***Preservatives***

A number of chemical preservatives can be used to inhibit growth of microorganisms in foods. The following are some examples.

#### ***Organic Acids***

Organic acids have been widely used to suppress microbial growth in low pH foods including pickled vegetables, salad dressings, fruit juices, beverages, and wines. The main organic acids used in food manufacture that have been shown to be effective in controlling microbial growth include acetic, citric, malic, tartaric, and lactic acids (Betts et al., 2007). These organic acids are able to penetrate bacterial cell walls and disrupt the normal physiology of certain types of pH-sensitive bacteria. They also inhibit yeasts and molds.

The desired flavor for the final product determines the acid chosen. Although acetic acid is the most effective antimicrobial of the organic acids, it imparts a strong taste. Tomato-based products naturally contain citric acid. Therefore, citric acid is added most often to these products to further lower the pH. Other preservatives such as sorbic acid and its potassium salt are widely used throughout the food industry for the preservation of cheese and in bakery products, vegetable-based products (pickles, olives, fresh salads), fruit-based products (dried fruits, fruit juices), beverages, and additional products such as smoked fish, margarine, and mayonnaises (Betts et al., 2007). Sorbate is usually more efficient at inhibiting yeasts and molds but not bacteria. Moreover, it is selective and does not inhibit growth of LAB used for fermentations. Yeast inhibited by sorbate include species of *Brettanomyces*, *Candida*, *Cryptococcus*, *Saccharomyces*, *Zygosaccharomyces*, and *Debaromyces*. Molds inhibited by sorbates include species of *Alternaria*, *Aspergillus*, *Cladosporium*, *Penicillium*, and *Fusarium*. Bacteria inhibited by sorbate include *Bacillus*, *Clostridium*, *Enterobacter*, *Pseudomonas*, salmonellas, and *Serratia* (Sofos and Busta, 1983).

#### ***Sodium Benzoate***

Sodium benzoate is another preservative commonly used in low pH products such as mayonnaise, pickled vegetables, fruit products and drinks. It is commonly combined with potassium sorbate in mayonnaise-type products to enhance effectiveness. Benzoate acts primarily upon yeasts and molds, but also inhibits many bacteria. However, clostridia and LAB are resistant to benzoate (Betts et al., 2007).

#### ***Propionate***

Sodium and calcium propionate are generally used in cheese production to prevent mold growth on cheese surfaces. They are also used widely in bakery products as common mold inhibitors, due to their efficacy in higher pH environments. Propionate inhibits mold and some bacteria, such as *Bacillus* species, which cause rope spoilage in bread. Propionate only has a weak effect on yeast, so it does not inhibit yeast fermentation in bakery products (Betts et al., 2007). Sodium and calcium propionate are typically used at relatively lower levels and contribute much less sodium to products compared to sodium chloride (Doyle et al, 2010).

#### ***Lactates***

Lactates (sodium or potassium) can reduce  $a_w$  of foods to a greater degree than salt does. When pH is low, lactates take on the form of nondissociated lactic acid. Lactic acid can create leaks in bacterial cell membranes and inhibit growth, separately from the drop in  $a_w$ . For these reasons, lactates are useful for inhibiting growth of *C. botulinum* and *L. monocytogenes* (CTAC, 2009). Sodium lactate contains 50% less sodium than salt, which provides needed inhibition of pathogen growth while keeping sodium levels low.

#### *Other Preservatives*

Other preservatives such as sodium diacetate, sodium nitrite, and sodium phosphate compounds are also added alone or in combination to foods to prevent microbial growth and improve texture. The amount of sodium contributed by common sodium-containing additives compared to sodium chloride is summarized in Table III of the Appendix.

#### *Heat treatment*

The delivery of an adequately lethal thermal process is central in food preservation, both to prevent a public health risk and to achieve commercial sterilization for the food (Zeuthen and Bøgh-Sørensen, 2003). The choice of heat treatment depends on the product characteristics, target microorganisms likely to present, survive and growth under the product characteristics, and heat resistance characteristics of the target organism (Betts et al., 2007). One of the most heat resistant spores is *C. botulinum*, which unless inactivated will produce the lethal botulin toxin under the anaerobic conditions when in a container. Consequently most processes are chosen on the basis of the destruction of this microorganism.

There are two main categories of heat treatment: pasteurization and sterilization. Pasteurization is a thermal process used to eliminate specific pathogenic microorganisms from a food. Most pasteurization systems are designed for liquid foods with specific attention to achieving a specific time-temperature process.

The use of a thermal process to achieve a shelf-stable food product is referred to as commercial sterilization. The systems used to accomplish a thermal process are designed to increase the product temperature to high magnitudes for specified periods of time. The process could be batch, continuous and aseptic. Metal cans, glass or pouches are available packages for this process.

If the salt level of a food is changed then this could change the product characteristics and reduce its inherent antimicrobial properties. Likewise for reformulation efforts such as replacing salt with other preservations. If any changes happen in the microorganism environment of the product, heat treatment may need to be adjusted to ensure the safety.

#### *Nonthermal processing treatments*

A number of physical treatments can be used to inactivate microorganisms without heat. These include:

(1) *High Pressure*: The use of high pressures to achieve food preservation has evolved as a potential commercial process. Historically, there have been demonstrations of inactivation of microbial populations by using ultra-high pressures in the range of 300 to 800 MPa (Singh and Heldman, 2009). High pressure is used for liquid and fruit products such as jams, pâtés and guacamole. It is also used for heat sensitive products where a pasteurization or sterilization effect is required but where the application of heat may damage the product (Betts et al., 2007).

(2) *High-intensity light*, also described as pulsed broad-spectrum white light, including ultraviolet (UV) light, is a decontamination or sterilization technology that can be used for the rapid inactivation of microorganisms on food surfaces, equipment, and food packaging materials. It is a nonthermal food preservation intervention that minimizes the deleterious effects of thermal processing and chemical treatments on quality and sensory attributes. It is cost-effective and regarded as a relatively safe and nontoxic treatment (FDA, 2000). Disadvantages to using high-intensity light include production of off-colors, flavors, and odors (Colchin et al., 2001). Additionally, it can be difficult to reach an even UV light exposure level on food surfaces that are not smooth; thus UV light treatment may not be as effective for such foods (Zeuthen and Bøgh-Sørensen, 2003).

(3) *Microfiltration* is a well-established filtration process in which contaminants (i.e. microorganisms - vegetative and spore forms) are removed from a fluid (liquid and gas) by passage through a microporous membrane to produce a sterile fluid. Microfiltration of milk can replace, or be used with heat treatment to produce liquid milk with extended shelf life. Additionally, microfiltered milk with reduced bacterial numbers can be used as an alternative to pasteurized skim milk in cheese manufacture. In one semi-skimmed milk product available in the U.K., Cravendale 'Purfiltré' milk (marketed by Arla Foods, DK), microfiltration appears to remove 99.7% of the bacteria (Zeuthen and Bøgh-Sørensen, 2003).

(4) *Pulsed electric fields (PEF)*, which use short bursts of electricity for microbial inactivation, permit operation at low or moderate temperatures and, therefore, represent a promising nonthermal preservation alternative to heat pasteurization. Food sanitation, reduction of the microbial load, and extension of storage life can be obtained without notable effects on food constituents or quality. However, PEF works well only with homogeneous fluid foods without gas bubbles or large particles (Zeuthen and Bøgh-Sørensen, 2003).

(5) *Ultrasonication*, or use of ultrasound, is energy generated by sound waves, which can be used to disrupt biological structures. There is evidence for ultrasound effects on a great variety of microorganisms, some enzymes, and even bacterial spores, especially in combination with heat. The use of ultrasound treatments could lead to shorter process times and/or lower temperatures and subsequent improvement in product quality and convenience to the consumer. Although the efficacy of ultrasound in isolation to reduce or kill microbes has been questioned, in some cases, synergistic effects with other hurdles, such as heat and/or pressure have been reported and may have promise (Zeuthen and Bøgh-Sørensen, 2003).

### ***Modified atmosphere packaging***

Modified atmosphere packaging (MAP) is a food preservation technique that has been studied for many years by the food industry and now plays an extremely important role in microbial control. MAP is defined as “the enclosure of food products in a high barrier film in which the gaseous environment has been changed or modified to slow the respiration rates, reduce microbiological growth, and retard enzymatic spoilage with the intent of extending the shelf life” (Young et al., 1988). MAP has been widely used for meat, seafood, minimally processed fruits and vegetables, pasta, cheese, bakery goods, poultry, refrigerated ready meals, and dried foods.

Refrigerated foods are also often stored in a mixture of gases where oxygen is excluded via MAP. However, there is the potential for growth of anaerobic pathogens such as *C. botulinum* under reduced oxygen conditions. For example, the industry code of practice in the U.K. recommends that the shelf life of refrigerated MAP or vacuum packaged (VP) foods, therefore, be restricted to 10 days or fewer if the foods do not incorporate sufficient controlling factors, i.e. pH of 5.0 or less,  $a_w$  of 0.97 or lower, aqueous salt level of 3.5% or higher, or heat treatment equivalent to 90°C for 10 minutes (Betts 1996). This recommendation applies to all MAP foods stored between 3°C and 8°C. The reduction of salt from certain MAP and VP foods can therefore have large implications for safety and shelf life unless additional preservative factors are addressed (Betts et al., 2007).

For many processed foods, reducing sodium levels while maintaining microbiological safety and stability will depend on the use of new or altered hurdles. Skillful manipulation of factors mentioned above, including pH,  $a_w$ , acid salts, thermal and nonthermal processing, proper packaging and storage temperature, will be critical to future successes. Replacement of salt with other mineral salts such as potassium chloride, or with no- or low-sodium additives, herbs or spices, may also be valuable in some scenarios.

### **Techniques to evaluate the effect of sodium reduction on food safety and quality**

Any change in food formulation or processing conditions must be analyzed to identify new potential hazards and food manufacturers should take appropriate actions to manage these hazards as required. Reducing sodium levels in foods could lead to more rapid growth of microorganisms if other factors used in manufacturing those foods are not adjusted accordingly. Reducing sodium levels across the board without careful consideration of compensatory measures could increase the risk of foodborne illness. A well-known example of this general principle was an outbreak attributed to sugar-free hazelnut conserve in reduced-calorie yogurt products in the United Kingdom (Entis 2007). The conserve maker substituted aspartame for sugar without altering the rest of the formulation and without altering processing. The sugar in the original formulation reduced  $a_w$ , preventing the growth of *C. botulinum*, but without it, this organism grew and eventually led to the death of one person and serious illness in 25 others. This outbreak is an example of the types of possible unfortunate outcomes that can occur when safety-related functions of ingredients are not considered during reformulation. However, events like this are preventable when adequate food safety expertise and product testing are employed. Food companies evaluate the potential for reduced sodium to increase food safety risks. In doing so, they engineer additional hurdles into the product manufacturing to mitigate the survival and

growth of undesired microorganisms. Techniques such as the ones described below, can be used to ensure product safety.

### ***Shelf life testing***

It is standard practice for the food industry to validate the safety of new and reformulated products using shelf life testing (IOM 2010). It is designed to determine how long a product remains within the designed quality parameters during normal production and storage conditions. Any changes to the level of salt in a formulation should lead to reevaluation of the shelf life of the food product. The results of the shelf life tests will determine the limits of sodium reduction for specific foods and provide information to define acceptable conditions of use. Shelf life testing in foods that have extended shelf life (such as processed cheese) can be time-consuming. Small firms may need consulting support to undertake such testing.

### ***Challenge tests***

Challenge testing is designed to determine whether the product formulation and storage conditions would control growth of pathogens during the designated shelf life of a food if they were present in the food through accidental contamination. When designing and carrying out a microbiological challenge study, some factors to be considered include the selection of appropriate pathogens or surrogates, the level of the challenge inoculum, the inoculum preparation and method of inoculation, the duration of the study, formulation factors, storage conditions, and sample analyses (Vestergaard 2001). Challenge tests are specific to the particular food and can be very expensive, particularly if a range of products, formulations, and different bacteria are tested. A well designed challenge study can provide critical information on the microbiological safety and stability of a food formulation.

### ***Predictive modeling***

Predictive models are powerful tools to look at the effect of environmental conditions on growth of pathogens and spoilage organisms. These models typically relate the microbial growth, survival or death response to the levels of the controlling factors, such as temperature, pH, water activity, etc. Predictive microbiological models are developed from laboratory data obtained under a defined set of experimental conditions. These models are used to predict the likely responses under new combinations of conditions or under conditions not previously tested. For example, data describing the effect of 4%, 2%, and 1% salt concentrations on an organism can be used to predict the likely growth at 3%. Predictive models can provide a cost-effective means to minimize microbiological testing in determining shelf life (Grummer and Schoenfuss, 2011). They are also powerful in new product development. Modifications of new or existing recipes can be modeled *in silico* to see if the change will have any effect on the safety and shelf life of the products before embarking on expensive laboratory experiments or pilot-scale production runs.

There are a number of publicly available modeling systems available to the food industry. These include, Growth Predictor (based on the data formerly used to create Food Micromodel, available at [www.ifr.ac.uk/Safety/GrowthPredictor](http://www.ifr.ac.uk/Safety/GrowthPredictor)), Pathogen Modeling Program (PMP available at [www.arserrc.gov/mfs/pathogen.htm](http://www.arserrc.gov/mfs/pathogen.htm)), and combined database, ComBase-PMP ([www.combase.cc](http://www.combase.cc)). The ComBase-PMP database draws from a vast collection of literature to

provide useful information on predicted growth as affected by product temperature, pH, and salt (0 to 70%) (Baranyi and Tamplin, 2004).

The effect of sodium reduction varies from food to food, so each food type has to be considered individually. For foods that are partially preserved by salt, predictive models may be helpful to assess the potential effect of sodium reduction. If available, models can greatly aid product design and reduce the number of challenge tests required. However, model predictions in general should be interpreted with caution and should not replace laboratory based assessments of foods, especially in foods with substantial formulation changes (Black and Davidson, 2008). Further development of predictive models could extend their usefulness (Stringer and Pin 2005).

### **Conclusion**

Sodium, primarily in the form of salt, plays a significant role in the microbiological safety and stability of many products in the food supply. In this memorandum, we have reviewed the microbiological effects of salt in food, identified some key categories with respect to salt's microbiological role, and discussed research on sodium reduction in these categories. These studies suggest that there is some potential for sodium reduction in many foods. This conclusion is consistent with our observations of the range of sodium content in comparable commercial food products currently available. However, it is important to remember that many of the studies available in peer-reviewed literature use small scale production or laboratory experiments. Not all findings in these studies translate well to large scale production environments. Additional validation may be necessary to ensure that scaled-up processes based on literature findings can continue to produce a safe product. Safety must remain a paramount consideration in the development of all new foods and reformulation of existing products.

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## Appendix

**Table I.**  
**Critical factors influencing growth of microorganisms**

<b>Factor</b>	<b>Effect on microorganism</b>
<b>pH or acidity</b> Either achieved by adding organic acids such as citric, acetic or formed naturally due to fermentation process	Diverts the cells' energy to removing the hydrogen ions in order to maintain homeostasis and thus reduces microbial growth. If the pH is low enough the cell death may occur
<b>Water activity (a<sub>w</sub>)</b> Removal of moisture by drying or evaporation or addition of solutes, e.g. salt and sugar	Lack of moisture will dry out the cell and reduce its growth. Microorganisms can survive in dry environments for a long time
<b>Salt</b> Lowers the water activity but has some antimicrobial action due to the ion	Cells will lose water in a high salt environment and divert energy to accumulate solutes in the cell to reach a balance with the conditions in the food. Growth will slow down or stop
<b>Sugars</b> Lowers a <sub>w</sub> . Less effective than salt and requires larger amounts	Effects are similar to salt but it requires a high level of sugar to achieve similar effects
<b>Preservatives</b> Addition of chemical preservatives such as sorbate, benzoate, propionate	Preservatives will divert the cells' energy to remove or counteract the effects of preservatives in the cell. Microbial growth will slow down. Death may occur if levels of preservatives are high enough
<b>Heat treatment</b> Application of heat during cooking	Dependent on times and temperatures achieved the heat treatment should destroy the microorganisms, i.e. those capable of growth in the product
<b>Other non-thermal treatments</b> Application of UV light, high pressure, ultrasound	Dependent on times and temperatures achieved the treatment should destroy the target microorganisms, i.e. those capable of growth in the product
<b>Modified atmosphere</b> Changing the atmospheric oxygen level, addition of CO <sub>2</sub>	Removal of oxygen and addition of CO <sub>2</sub> will slow down/prevent the growth of aerobic organisms
<b>Storage temperature</b> Use of fast cooling and chill storage conditions	All microorganisms have a minimum temperature below which they cannot grow. Use of chill temperatures slow down/prevent microbial growth

*Source: Adapted from Betts et al, 2007.*

**Table II.****Minimum water activity ( $a_w$ ) limits for growth of microorganisms of concern in food**

$a_w$	Bacteria	Molds	Yeast
0.97	<i>Clostridium botulinum</i> E <i>Pseudomonas fluorescens</i>		
0.95	<i>Escherichia coli</i> <i>Clostridium perfringens</i> Salmonellas <i>Vibrio cholerae</i>		
0.94	<i>Clostridium botulinum</i> A, B <i>Vibrio parahaemolyticus</i>	<i>Stachybotrys atra</i>	
0.93	<i>Bacillus cereus</i>	<i>Rhizopus nigricans</i>	
0.92	<i>Listeria monocytogenes</i>		
0.91	<i>Bacillus subtilis</i>		
0.90	<i>Staphylococcus aureus</i> (anaerobic)	<i>Trichothecium roseum</i>	<i>Saccharomyces cerevisiae</i> <i>Candida</i>
0.88			
0.86	<i>Staphylococcus aureus</i> (aerobic)		
0.85		<i>Aspergillus clavatus</i>	
0.84		<i>Byssochlamys nivea</i>	
0.83		<i>Penicillium expansum</i> <i>Penicillium islandicum</i> <i>Penicillium viridicatum</i>	<i>Debarymyces hansenii</i>
0.82		<i>Aspergillus fumigatus</i> <i>Aspergillus parasiticus</i>	
0.81		<i>Penicillium cyclopium</i> <i>Penicillium patulum</i>	
0.80		<i>Penicillium citrinum</i>	<i>Saccharomyces bailii</i>
0.79		<i>Penicillium martensii</i>	
0.78		<i>Aspergillus flavus</i>	
0.77		<i>Aspergillus niger</i> <i>Aspergillus ochraceous</i>	
0.75		<i>Aspergillus restrictus</i> <i>Aspergillus candidus</i>	
0.71		<i>Eurotium chevalieri</i>	
0.70		<i>Eurotium amstelodami</i>	
0.62			<i>Saccharomyces rouxii</i>
0.61		<i>Monascus bisporus</i>	
<0.60	No microbial proliferation		

Source: Tapia et al, 2007

**Table III.**  
**Amount of sodium contributed by some common sodium-containing substances**

<b>Sodium compound</b>	<b>Typical use %</b>	<b>% sodium compound</b>	<b>mg of Na/100 g food</b>
Chloride	1.5 to 2	39.3	590 to 790
Benzoate	0.1	16.0	16
Diacetate	0.1 to 0.4	16.2	16 to 65
Lactate	1.5 to 3	21.0	310 to 620
Propionate	0.3	23.9	70
Sorbate	0.3	17.1	50
Nitrite	0.012	33.3	4
Acid pyrophosphate (SAPP)	0.35	20.7	100
Triphosphate (STPP)	0.35	31.2	160
Pyrophosphate (TSPP)	0.35	34.6	170
Hexametaphosphate (SHMP)	0.35	22.6	110

*Source: Adapted from Doyle and Glass, 2010.*