

Sodium and

A GUIDE FOR CONSUMERS,
POLICYMAKERS AND THE
MEDIA



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The Association of Food, Beverage
and Consumer Products Companies

The **Grocery Manufacturers Association (GMA)** represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over \$1 trillion in added value to the nation's economy. For more information, visit the GMA website at www.gmabrands.com

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FOREWORD

This paper addressing dietary salt and sodium is one in a series published by the Grocery Manufacturers Association (GMA) to evaluate and explore the science behind some of the most talked-about food-related issues of importance to consumers and policymakers.

The Grocery Manufacturers Association represents the world's leading food, beverage and consumer products companies. The Association promotes sound public policy, champions initiatives that increase productivity and growth, and helps to protect the safety and security of the food supply through scientific excellence. One of the Association's goals is to ensure that the laws and regulations governing food marketing and production are feasible, practical and based on sound information.

Each of our science policy papers includes a review of key scientific peer-reviewed published articles, regulatory considerations, food and beverage applications and market insights. The Association's goal in publishing these white papers is to provide current, scientifically accurate resources to journalists, health professionals, policy makers, interested consumers and other stakeholders.

For more information, visit the Grocery Manufacturers Association website at www.gmabrands.com

Robert Brackett, Ph.D.
*Senior Vice President and
Chief Science and Regulatory Affairs Officer*
Grocery Manufacturers Association

EXECUTIVE SUMMARY

The food industry takes seriously its commitment to develop products that provide choices for consumers interested in managing their intake of salt (sodium chloride) and sodium. The element sodium naturally occurs in a variety of foods and beverages, including drinking water. However, the majority of salt in the U.S. diet comes from manufactured foods and from restaurant foods away from home. Thus, the food industry can play a key role in offering consumers lower-salt food choices with conventional and modified levels of salt or sodium. It is important to remember that salt plays a critical role in the flavor, texture and safety of foods, so approaches to reduce the salt content of foods or beverages must consider these key functions.

Sodium is an essential nutrient, in other words, required for life and health; dietary inadequacy can lead to serious consequences. Present in biological systems as a major element in the space surrounding cells (extracellular space), sodium maintains extracellular fluid volume and balance.

The food industry is committed to helping consumers find ways to meet the daily intake goal of 2,300 mg daily sodium, the upper level recommended in the Dietary Guidelines for Americans, 2005. Companies are achieving lower sodium in products through extensive research, reformulation, new salt reduction technology, and new product development. Today, thanks to industry efforts, more and more sodium- or salt-modified products appear in the marketplace. In fact, the top health and wellness claims by product category and their associated sales include foods and beverages with salt- and sodium-related labeling claims. For the year ending April 2008, annual sales of such products topped \$15.9 billion, following products bearing claims about fat, and those with “natural” or calorie claims. With “silent” and incremental reductions over time, sales of products that have modified sodium content are much greater. Further, individual companies’ efforts and industry collaboration have produced education programs encouraging consumers to make incremental changes to reduce sodium intake.

Amendments to the Federal Food, Drug and Cosmetic Act (FDCA; the Act) in 1958 established the statutory safety standard of GRAS (Generally Recognized as Safe) and established a list of “prior sanctioned” food commodities and ingredients. Salt, pepper, sugar, flour, corn meal and many other products are prior sanctioned by their long-term history of safe use. The Act requires that scientific experts make a GRAS determination of an ingredient’s or substance’s safety, as shown by established scientific procedures or experience based on common use in foods before 1958, under the intended conditions of use of that substance. Salt is a common food ingredient that clearly meets the above definition of GRAS and “prior sanctioned,” as the naturally occurring mineral has been safely used in foods since antiquity.

All nutrients can be present in the diet at levels that cause deficiencies, provide for optimal intake, or lead to excessive intake. Similar to sodium, many nutrients, even essential nutrients, can have adverse effects at high levels of intake. Sodium at normal dietary levels, or even at levels modestly above the current Daily Value used in food labeling of 2,400 milligrams (mg) per day (the Dietary Guidelines for Americans, 2005

[commonly referred to as the 2005 Dietary Guidelines] recommends 2,300 mg/d), is completely safe for humans from a toxicological point of view. Thus, no scientific, medical, or clinical basis exists to abandon the millennia of safe use of salt and almost 50 years as a “prior sanctioned” GRAS ingredient.

In November 2007, the U.S. Food and Drug Administration (FDA) held a hearing to consider aspects of regulation of salt and sodium. This sodium and salt review summarizes scientific research, regulatory history, consumption levels, patterns and trends, uses in foods and beverages, health considerations and marketplace trends.

After considering, in total, evidence-based dietary guidance, epidemiological and clinical studies, consumer behavior, and applications in food manufacture and processing, the following points are critical when considering sodium and salt in foods:

- The addition of salt and other sodium-containing ingredients to many foods is critical for functional and safety reasons.
- An overarching priority in food policy should be improving overall food choices and dietary patterns, rather than singling out specific ingredients or foods.
- Federal policies should be compatible with and should advance the 2005 Dietary Guidelines and MyPyramid food guidance system, to encourage the public to adopt the recommended “pattern of eating.” In addition, educational efforts to encourage changes in food and dietary patterns (e.g., MyPyramid food patterns or DASH dietary patterns) also are critical to help meet sodium intake recommendations.
- Consumers who take small steps to gradually reduce their salt and sodium intakes and incremental changes by the food industry can result in the greatest overall success in reaching a daily sodium intake of 2,300 mg (about 1 teaspoon of salt).
- Additional research related to taste mechanisms, use of salt alternatives, success in meeting food and dietary patterns, health outcomes, and consumer understanding and behavior is required.
- Although salt and sodium are related to blood pressure, and blood pressure is related to risk of heart disease and other conditions, a large-scale human-heart-disease outcomes study needs to be funded and conducted to evaluate the role of salt and sodium in health and disease for various subpopulations. ■

INTRODUCTION

Dietary salt (sodium chloride) and sodium have long garnered interest with consumers, researchers, policy makers, consumer advocacy groups, professional organizations, and other key stakeholders. When it comes to public health and sodium, much of the discussion centers on the relationship between salt and hypertension (high blood pressure). However, many factors contribute to the development of hypertension beyond salt or sodium, including genetics, advancing age, weight, obesity, sedentary lifestyle, stress, smoking and insufficient potassium intake.⁽¹⁾ Research also reveals that potassium, magnesium, calcium and, especially, chloride can produce greater effects, both up and down, on blood pressure than salt or sodium.⁽²⁻⁴⁾

Scientific consensus does not exist to advocate reducing daily sodium intake below the 2,300 milligram (mg) per day level currently recommended in the Dietary Guidelines for Americans, 2005 (2005 Dietary Guidelines). In fact, too much sodium restriction can have adverse effects, actually raising blood pressure.⁽⁵⁾

Salt, as an ingredient, is paramount in the taste, texture, and safety of many processed foods. Thus, any attempts to reduce sodium in processed foods need to consider salt's key functional roles.

Throughout history, humans and other mammals have exhibited an inherent affinity for salt, which may be a principal reason for the popularity of the salty taste in foods. Consumer acceptance of sodium-reduced foods is an important consideration for scientific, industry and policy stakeholders. After all, a "healthy food" will not promote health if it is not eaten.

Sodium occurs naturally in a variety of plant- and animal-based foods as well as in beverages, including drinking water. In general, fruits contain the least sodium, followed by vegetables, and then meat, fish and eggs.⁽⁶⁾ Milk and, subsequently, other dairy products, such as yogurt, naturally contain more sodium. Salt also is added to process dairy ingredients into cottage cheese, cheese, etc.

Salt is added to a number of foods and beverages for flavor, preservation and texture, making salt (sodium chloride) the world's most-established food additive and one of the most common and important food preservatives. Widely used as a seasoning, salt improves the palatability of bland foods, such as bread and pasta, and also enhances foods' natural flavors.

Historically, salt curing is one of the earliest recognized preservation forms for meat, fish and vegetables. And today, salt still plays an important food safety role in many foods. For example, salt acts as a microbial control agent in cheeses, sausages and smoked fish.

Salt also aids in foods' color development, such as in cured meats, pickled vegetables and bread products.

Sodium-containing ingredients are critical for leavening of most breads and baked goods. Salt also is used to improve the texture of many foods, such as development of rind in cheeses, uniform grain in breads and tenderness in cured meats.⁽⁷⁾

SODIUM AND SALT — THE BASICS

What is Sodium?

Though technically incorrect, people often use the terms "sodium" and "salt" or "table salt," interchangeably. However, common salt (NaCl) comprises the elements sodium (Na⁺) and chloride (Cl⁻) that form microscopic cubes tightly bound together through ionic bonding. By weight, salt is 40 percent sodium and 60 percent chloride.⁽⁸⁾ In common household-measurement terms, 1 teaspoon of salt—weighing about 6,200 mg—contains about 2,400 mg sodium.

Human Requirements for Sodium

Sodium, a mineral, is an essential nutrient, which is an element or compound that humans need to consume for life and health. In the body, sodium is involved in fluid and electrolyte balance and is required for normal cellular functions (i.e., ion channels, neurotransmission). Due to sodium's natural, widespread occurrence in foods, dietary deficiency of sodium is very uncommon; however, dietary inadequacies may lead to serious consequences.⁽⁹⁾ For North America (United States and Canada), the Institute of Medicine (IOM) Dietary Reference Intake (DRI) report on water and electrolytes identifies 1,500 mg/day of sodium as an "Adequate Intake" (AI) for normal human body functions in adults, with higher levels appropriate for individuals who are very active.⁽⁹⁾ In addition, the IOM's DRI report establishes a Tolerable Upper Intake Level (UL) for sodium at 2,300 mg sodium per day for adults. The DRI reports define the UL as "The maximum level of daily nutrient intake that is likely to pose no risk of adverse effects."⁽⁹⁾

Roles and Uses of Salt in Foods and Beverages

Salt adds enjoyment to eating, and by increasing palatability of nutrient-dense foods/beverages, salt can

contribute to a healthful eating pattern. Furthermore, salt and other sodium-containing ingredients also serve multiple, critical purposes in food processing.

Preservative: Salt preserves foods by creating a hostile environment for certain microorganisms. Within foods, salt brine dehydrates bacterial cells, alters osmotic pressure, and inhibits bacterial growth and subsequent spoilage. Historically, salting fish made long-range explorations possible in the age of sailing ships.

Texture Aid: Salt strengthens gluten in bread dough, providing uniform grain, texture and dough strength. With salt present, gluten holds more water and carbon dioxide, allowing the dough to expand without tearing. Salt improves the tenderness in cured meats, such as ham, by promoting protein's binding-water capabilities. Salt also gives a smooth, firm texture to processed meats. Salt develops cheeses' characteristic rinds and helps produce the desirable, even consistency in cheese and other foods such as sauerkraut.

Binder: Salt helps extract the proteins in processed and formed meats, providing binding strength between adjacent pieces of meat. Water-binding properties are increased and, as a result, cooking losses are reduced. Salt increases the solubility of muscle proteins in water. In sausage making, stable emulsions are formed when the salt-soluble protein solutions coat the finely-formed globules of fat, providing a binding gel consisting of meat, fat and moisture.

Fermentation Control: In baked products, salt controls leavening by slowing and controlling the rate of fermentation, important in making a uniform product. During pickle making, salt-brine concentration gradually increases, reducing the fermentation rate as the process proceeds to completion. Salt is also used to control fermentation in making cheese, sauerkraut and summer sausage.

Color Developer: Salt promotes color development in ham, bacon, hot dogs and sauerkraut. Used with sugar and nitrate or nitrite, salt produces a color in processed meats, which consumers find appealing. Salt enhances the golden color in bread crust by reducing sugar destruction in the dough and increasing caramelization (browning).⁽¹⁰⁾

Salt also is critical to ensure food safety:

Smoked fish: Salt is required for prevention of *C. botulinum*. Regulations require the water-phase salt level to be above 3.5 percent to prevent the growth of this potentially deadly organism.

Cured and fermented meats: For critical microbial control, salt and other sodium-based compounds are required for production of sausage, ham and other cured meats, even with refrigeration requirements for these types of foods.

Sodium, bound with other elements besides a chloride ion—for example, as sodium nitrate, sodium phosphate and monosodium glutamate—also can be added to foods for various processing enhancements.⁽⁶⁾

Sources of Dietary Sodium

On average, naturally occurring sodium in foods accounts for only about 10 percent of total intake, while discretionary use of salt at the table and in cooking contributes another 5–10 percent of total sodium intake. The remainder of salt and sodium in foods and beverages comes from manufactured foods and from food service items in restaurants.⁽⁵⁾

Within food commodities and manufactured foods, sodium is distributed throughout the food supply. As dietary practices change over time, so have the principal food sources of sodium in the American diet. Factors include food choices, quantity consumed (portion), frequency of consumption and product formulation. Data from the U.S. National Health and Nutrition Examination Survey (NHANES) from 2003–2004 (see Table 1) shows that the amounts of sodium contributed through foods to the diet is more dependent upon frequency of consumption than upon the specific amount in a serving of an individual food. Of these top 20 sources of sodium by frequency of consumption in the diet, three are food commodities for which sodium levels cannot be changed, over half have sodium levels below the FDA "Healthy" level (480 mg), and three qualify for "low sodium." Therefore, total sodium intake is more about food choices and dietary pattern over a day than the sodium content in an individual serving of a food.

TABLE 1. Top 20 Individual Food Sources of Sodium in the American Diet (Based on the Combination of Frequency of Consumption and Sodium Content)

1. Meat pizza	11. Salty snacks/corn chips
2. White bread	12. Whole milk
3. Processed cheese	13. Cheese pizza
4. Hot dogs	14. Noodle soups
5. Spaghetti w/sauce	15. Eggs (whole/fried/scrambled)
6. Ham	16. Macaroni w/cheese
7. Catsup	17. Milk, 2%
8. Cooked rice	18. French fries
9. White roll	19. Creamy salad dressings
10. Flour (wheat) tortilla	20. Potato chips

Source: NHANES 2003–2004 (Data analysis provided by General Mills Bell Institute of Health and Nutrition.)

Current Consumption Levels

Dietary sodium consumption varies from country to country, with average adult salt intake ranging between 9 and 12 grams salt (3,600–4,800 mg sodium) per day in industrialized countries.⁽¹²⁾ NHANES 2005–2006 data show that the average daily U.S. intake of sodium is 3,436 mg (2,933 mg/d for adult females 20 years of age and older; 4,178 mg/d for adult males 20 years of age and older).⁽¹³⁾

Because of huge cultural diversity and variations in dietary patterns, individual countries' recommendations for daily salt intake also vary. Each country's recommendation is a target for reduction in average daily sodium intake (see Table 2).⁽⁶⁾

TABLE 2. Recommended Daily Sodium Intake by Country

Country	Recommended Daily Sodium Intake
France	8 g salt (3,200 mg sodium)
UK, Germany, Denmark	6 g salt (2,400 mg sodium)
Sweden	5.6 g salt (2,240 mg sodium)
Greece	5 g salt (2,000 mg sodium)
Finland	3–5 g salt (1,200–2,000 mg sodium)

Dietary Guidance

For more practical, average daily consumption, the 2005 Dietary Guidelines advise daily consumption of less than 2,300 mg sodium—about 5.75 g of salt (about one teaspoon). For individuals with hypertension, blacks, and all other middle-aged and older adults, the *Guidelines* suggest no more than 1,500 mg of sodium per day, and, to meet daily potassium recommendations, consumption of foods that, together, provides 4,700 mg potassium daily.⁽⁵⁾

The 2005 Dietary Guidelines' sodium and potassium recommendations are based on the premise that nutrient needs are met by consuming foods that shape overall dietary patterns. Both USDA's MyPyramid and the DASH (Dietary Approaches to Stop Hypertension) diet focus on eating a variety of foods from food groups that are rich in nutrients and fiber and that provide adequate amounts of nutrients that are expected to lower blood pressure, mainly minerals potassium, calcium, and magnesium.^(5, 14)

Prior research with the DASH-diet overwhelmingly support the premise that modifying total diets to include more fruits, vegetables and low-fat dairy products can fairly easily reduce risk of hypertension as well as offer potential for reducing the risk of other chronic diseases.^(9, 15–21)

The Debate — U.S. Regulation of Salt and Sodium in Foods

The federal government regulates salt as an ingredient, requiring it in specified amounts in certain foods for food safety reasons. Sodium content is also required on food labels, and claims about reduced content are regulated via content labeling claims. Dietary guidance calls for intake levels that are somewhat lower than many adults' intakes. However, the scientific evidence showing benefits of further sodium reduction is conflicting (see Health Considerations).

Public health policy needs to be aimed at promoting public health, using the best scientific data available. And, a number of important questions arise related to population approaches to reducing sodium through government regulation:

- Will such an approach benefit most of the population, including a significant benefit for the general population?
- Will sodium reduction be safe across the U.S. population (i.e., considerations for special populations or conditions such as infants' requirements and goiter prevention)?
- Will sodium reduction improve cardiovascular disease outcomes?
- Will unintended consequences occur with increased regulation?

In 1981, the Center for Science in the Public Interest (CSPI), a consumer advocacy group, submitted a petition to the FDA seeking warning labels on salt packages. The FDA denied that petition in 1982, indicating that an isolated warning appearing on the label of one class of food products would be inappropriate given that many foods contribute to an individual's sodium intake.

In 2005, CSPI filed a formal petition with the U.S. Food and Drug Administration (FDA), urging the agency to remove sodium from its list of Generally Recognized as Safe (GRAS) food ingredients.⁽²²⁾ In November 2007, the FDA held a public hearing to address questions related to sodium, including its relationship to human health, federal regulation and labeling, and salt's uses in the U.S. food supply.

Generally Recognized as Safe (GRAS)

The 1958 amendments to the Federal Food, Drug and Cosmetic Act (FDCA; the Act) established the statutory definition of GRAS (Generally Recognized as Safe). This definition requires that scientific experts make a GRAS determination of safety, as shown through scientific

toxicological procedures or through experience based on a substance's common use in foods before 1958, under the intended conditions of use of that substance. For 50 years, the GRAS process has been a widely accepted and effective tool to evaluate the safety of a wide array of common food ingredients. Because salt has been used for millennia in food preservation and production, and is required in many foods with standards of identity established by FDA, salt is a "prior sanctioned" ingredient. Thus, salt is a common food ingredient that clearly meets the above definition of GRAS and has been safely used in foods since antiquity.

All nutrients can be present in the diet at levels that cause deficient, optimal, or excessive nutrition. Salt, at normal dietary levels, is safe from a toxicological point of view. Similar to sodium, many other essential nutrients can have adverse effects at high levels of intake.

Labeling

Since the implementation of the 1990 Nutrition Labeling and Education Act (NLEA), all packaged food product labels, through the "Nutrition Facts" panel, are required to provide the amount of sodium per labeled serving (expressed in mg) and the percentage contribution to a daily amount in a model 2,000-calorie dietary pattern—percent Daily Value (appearing on labels as % Daily Value, or %DV). Also regulated are nutrient content claims related to sodium or salt. These claims provide a method for food and beverage products to offer, via labeling, ways to communicate about expanded food options for consumers (see Table 3). Products with claims related to sodium or salt offer a positive approach for consumers attempting to make dietary changes for health, along with information from the "Nutrition Facts" panel.

In addition to nutrient content claims about sodium or salt, FDA's "Healthy" nutrient content claim requires foods bearing the claim to contain 480 mg sodium or less (meals and main dishes, 600 mg or less).⁽²³⁾ In any food product that bears a nutrient content claim about a nutrient other than sodium, if the sodium level in the food is more than 480 mg (more than 720 mg for main dishes; more than 960 for meal products), it must provide a disclosure statement in conjunction with the nutrient content claim—"See nutrition information for sodium content."⁽²⁴⁾

The amount of sodium in a food must be controlled in order to bear an FDA health claim. To bear a health claim, a food must contain 480 mg sodium or less (720 mg or less for main dishes; 960 mg or less for meal products); and contain specified amounts, or less, of fat, saturated fat and cholesterol (unless specifically exempted).⁽²⁵⁾ The link between sodium and hypertension is the subject of an FDA health claim authorized by regulation, "Diets low in sodium may reduce the risk of high blood pressure, a con-

dition associated with many risk factors" (requires meeting FDA's definition of "low sodium" at 140 mg sodium or less).⁽²⁶⁾ The FDA health claim (FDA Modernization Act [FDAMA] health claim) regarding the relationship between potassium and reduced risk of blood pressure and stroke, "Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke," requires that a food must provide at least 350 mg potassium and sodium level must not exceed FDA's definition of "low sodium."⁽²⁷⁾

Regulatory Issues

Salt in the United States may be fortified with iodine, the addition of which has essentially eradicated goiter over the decades since the public health strategy was implemented. Thus, recommendations or petitions to place a warning label on salt packages may be counterproductive to the public health goal of maintaining healthy intake levels of iodine.

Additionally, consideration should be given to lesser sodium-reduction levels than currently allowed by federal regulations for claims that characterize less sodium in a food—such as 10 percent or 15 percent—rather than the full 25-percent reduction now required to make nutrient content claims "reduced" or "less." The industry believes that claims about smaller sodium reductions would provide added incentives for food companies to offer reformulated and new products with lower-sodium content labeling claims that would alert consumers to additional food options.

The "Healthy" nutrient-content claim is important for encouraging the food industry to modify the sodium content of foods, as exhibited by the number of manufacturers recently introducing and promoting additional "Healthy" product options to consumers.⁽²⁸⁾ This trend of introducing "Healthy" foods and reformulating established foods is one of the intended consequences that the FDA noted in its 2005 final rule on the "Healthy" nutrient content claim. Together, foods with label claims about sodium or salt, "Healthy" products, portion-controlled products, and those with stepwise, incremental reductions in sodium over time, with or without label statements about such reductions, meet consumer demands for taste and health and wellness, and may increase acceptance of sodium-modified products over time.

Evaluation of a program such as that being implemented in the United Kingdom against foods in the U.S. food supply shows that most popular foods (and those contained in the USDA National Nutrient Database, Standard Reference 20) already meet the UK targets for average sodium levels. Said alternatively, the current UK effort is lowering sodium in food categories to average levels that exist in the U.S. food supply.

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HEALTH CONSIDERATIONS

Sodium in the Body

Sodium is essential in regulating water balance, pH (acid balance), normal pressure in the fluids surrounding cells (extracellular) and in nerve transmission. Because of these essential functions, sodium levels are tightly

regulated by the body. Thus, sodium intake can vary widely, yet the human body remains healthy by maintaining relatively constant levels of sodium.⁽⁹⁾ However, advancing age, various health conditions, consumption of other nutrients, and certain other variables can affect the body's normal handling of sodium.

TABLE 3. FDA Regulations for Nutrient Content Claims about Sodium and Salt (21 CFR §101.61 and 21 CFR §101.56)

Sodium Free	Very Low Sodium	Low Sodium	Reduced Sodium	"Light" or Salt Claims
<p>Less than 5 mg per reference amount customarily consumed (RACC) and per labeled serving (or for meals and main dishes, less than 5 mg per labeled serving)</p> <p>No ingredient that is sodium chloride or generally understood to contain sodium except as noted below*</p> <p>If the food is inherently sodium free without special processing or formulation, the claim must be stated, "[name of food], a sodium-free food."</p>	<p>35 mg or less per RACC greater than 30 g or 2 T (and per 50 g if the RACC is less). For meals and main dishes, 35 mg or less per 100 g.</p> <p>If the food meets the criteria for very low sodium without special processing or formulation, the claim must be stated, "[name of food], a very low-sodium food."</p>	<p>140 mg or less per RACC greater than 30 g or 2 T (and per 50 g if the RACC is less). For meals and main dishes, 140 mg or less per 100 g.</p> <p>If the food meets the criteria for low sodium without special processing or formulation, the claim must be stated, "[name of food], a low-sodium food."</p>	<p>At least 25% less sodium per reference amount than an appropriate reference food. For meals and main dishes, 25 percent reduced sodium per 100 g.</p> <p>Reference food may not be "Low Sodium"</p> <p>Language must accompany the claim that describes the percent (or fraction) reduction as compared to the reference food, "reduced sodium (name of food), [x percent (or fraction) less sodium than (reference food)], and quantitative information describing the sodium reduction, "sodium content has been lowered from [x] to [y] mg per serving".</p>	<p>"Light" (for sodium reduced products): if food is "Low Calorie" and "Low Fat" and sodium is reduced by at least 50%</p> <p>"Light in Sodium" may be used if sodium is reduced by at least 50% per reference amount. Entire term "Light in Sodium" must be used in same type, size, color & prominence. Light in Sodium for meals = "Low in Sodium"</p> <p>"Salt Free" must meet criterion for "Sodium Free" and not contain salt as an ingredient.</p> <p>"No Salt Added" and "Unsalted" may be used if the food does not contain salt; salt is not used in processing. If not sodium free, the product must declare, "Not A Sodium Free Food" or "Not for control of sodium in the diet."</p> <p>"Lightly Salted": 50% less sodium than normally added to reference food and if not "Low Sodium", so labeled on information panel with the statement, "Not a low sodium food."</p>

* The ingredient in the product must be followed by an asterisk (*) and one of the following statements below the ingredient declaration:

"Adds a trivial amount of sodium," "Adds a negligible amount of sodium," or "Adds a dietarily insignificant amount of sodium."

Hypertension

About 50 million Americans have hypertension— 32 percent of black adults compared with 23 percent of whites and 23 percent of Mexican Americans.^(29, 30) Hypertension incidence advances with age. People exhibiting normal blood pressures (normotensive) at age 55 have a 90 percent risk of developing high blood pressure.⁽²⁹⁾ Hypertension is twice as common among obese, as among non-obese, people. Reducing the high incidence of hypertension in the United States and globally and deterring its adverse impact on other health outcomes, including heart attacks and strokes, has long been a public health priority.

Causes of hypertension are multifactorial, but genetics greatly influence an individual’s risk. Obesity, sedentary lifestyle, stress, smoking, and excessive amounts of alcohol or salt in the diet all can play a role in developing high blood pressure in people who have a related, inherited tendency.⁽¹⁾

Blood pressure is recorded as systolic pressure/diastolic pressure, for example, 120/80 mm Hg (millimeters of mercury). The higher value reflects the highest measurable pressure in the arteries, which is reached when the heart contracts (during systole). The lower value reflects the lowest pressure measurable in the arteries, which is reached just before the heart begins to contract again (during diastole). *High blood pressure* is defined as 140/90 mm Hg or higher (see Table 4).

TABLE 4. Categories for Blood Pressure Levels in Adults (Ages 18 Years and Older)⁽²⁹⁾

Blood Pressure Level (mmHg)			
Category	Systolic		Diastolic
Normal	< 120	and	< 80
Prehypertension	120–139	or	80–89
High Blood Pressure			
Stage 1 Hypertension	140–159	or	90–99
Stage 2 Hypertension	≥160	or	≥100

Note: When systolic and diastolic blood pressures fall into different categories, the higher category should be used to classify blood pressure level. For example, 160/80 mmHg would be stage 2 hypertension (high blood pressure).

Blood Pressure’s Relationship to Dietary Salt/Sodium Intake

Some facts and research results related to dietary salt/sodium intake:

- While common explanation has it that dietary sodium/salt raises blood pressure, physiologically, serum

sodium (sodium content in the body’s fluids) raises blood pressure by causing the body to retain water to maintain normalcy. The heart then has to pump harder, raising blood pressure, to handle the extra fluids. But, with the exception of people who are “sodium sensitive,” there is little evidence that dietary sodium raises serum sodium.

- Scientific consensus exists that sodium reduction decreases blood pressure. More than 100 well- designed and -executed randomized clinical trials and subsequent meta-analyses [“studies of studies” that take into account statistical analyses of many previous studies; each meta analysis relates to one subject or question] have unequivocally demonstrated that, in adults, a 75–100 mmol (1,725–2,300 mg) reduction in daily sodium intake can, on average, reduce blood pressure by 3–4 mm Hg systolic and less than 1 mm Hg diastolic—more in older, hypertensive, or black persons. Such reductions are modest and less than the variance seen in routine blood pressure measurement.^(31, 32)
- Yet, blood pressure response to dietary changes in sodium is hardly consistent. In some individuals, blood pressure actually rises with dietary sodium reductions, and in most people, a change in pressure is undetectable.⁽³²⁾
- For example, three recent NHANES follow-up studies involving a large, demographically representative group within the total number of participants was analyzed using a highly regarded methodology of the National Center for Health Statistics. These analyses demonstrated that no subgroup benefited from a low-sodium diet, and, instead, these findings add to the evidence that for the broad general U.S. population, higher sodium is unlikely to be independently associated with higher all-cause or cardiovascular disease mortality.^(33–35)
- Most salt/blood pressure trials have been of short duration, and more extended study suggests that despite continued adherence to lower salt regimens, the beneficial effect tends to weaken over time. What’s more, individual responses to sodium reduction vary and can include both a substantial fall or, actually, an increase in pressure, reflecting the body’s “defense” responses to a drop in sodium intake that protect pressure and flow.⁽³⁶⁾
- A number of additional factors contribute to the development of hypertension, including genetics, advancing age, obesity, sedentary lifestyle, stress, smoking, excessive amounts of alcohol or sodium, and insufficient potassium intake.⁽¹⁾ Research also reveals that, in addition to the beneficial blood-pressure-lowering effects of potassium, magnesium and

calcium, chloride can produce the greatest increases in blood pressure, even higher than sodium's effects. In fact, when sodium is combined with other elements besides chloride, blood pressure does not increase.⁽²⁻⁴⁾

- In addition, sodium restriction generates other, sometimes undesirable effects, including increased insulin resistance, activation of the body's complicated, natural defenses to preserve its sodium level within tight parameters, and increased sympathetic nerve activity.⁽⁴⁾

Blood Pressure and Children

While the relationship of dietary sodium to blood pressure in adults is well established by substantial epidemiological and clinical data, as well as through various disease-related studies, not surprisingly, considerably less is known about the relationship in children.⁽³²⁾ Compared to adults, hypertension in children generally is associated with other serious health issues and diseases. Thus, putting healthy and medically compromised children on research diets with sodium levels lower than those recommended to meet the *Dietary Guidelines* and MyPyramid may be unethical and could threaten their general health.

To study the relationship between salt intake and blood pressure in children and adolescents, researchers in Great Britain analyzed the data of a large study (the National Diet and Nutrition Survey for young people) in a nationally representative sample of children aged 4 to 18 years. A total of 1,658 participants had both salt intakes, via seven-day dietary records, and blood pressures recorded. Salt intake increased with age, and by the age of 18 years, salt intake had increased from 4.7 ± 0.2 g/day to 6.8 ± 0.2 g/day.

The researchers concluded that salt intake was strongly associated with systolic blood pressure as well as with pulse pressure after adjusting for age, sex, body mass index and dietary potassium intake. Specifically, a difference in salt intake of 1g (1,000 mg salt contributing 400 mg sodium) was associated with a 0.4 mm Hg rise in systolic blood pressure.³⁷ In a commentary to the research, it was noted, *the significance of this relationship disappeared after correcting for increasing energy intakes as the children grew older*. Interestingly, discretionary salt use, either at table or in cooking, was not associated with blood pressure in these children.⁽³²⁾

In the above-mentioned study, the researchers noted that the magnitude of the association of salt intake with systolic blood pressure was very similar to that observed in a meta-analysis of controlled trials in which dietary salt intake was reduced, as was blood pressure. Surprising to many experts, considering the disappearance of the sodium/blood pressure relationship when energy-intake

adjustments were made, was the co-authors' conclusion that the results supported a call for reduced salt intake in children and adolescents.⁽³⁷⁾

Limits of Epidemiological, Mortality Studies

The theory that dietary sodium intake might influence cardiovascular disease outcomes has been based upon sodium's relationship with blood pressure.⁽³⁸⁾ However, in an extensive analysis of studies addressing the impact of dietary salt and sodium on blood pressure in adults, researchers concluded that the historical impact of a few articles with refutable data drove the thinking on the relationship of dietary sodium to blood pressure, as well as blood pressure to mortality.

In fact, more recent work progressively narrowed the lowering of dietary salt's true influence on blood pressure to the current concept of a dietary-sodium impact of about 1 mm Hg blood-pressure reduction in non-hypertensive people as determined from nearly a century of collected research. In hypertensive individuals, Graudal notes that supporters and skeptics have, via meta-analyses, agreed that sodium reduction decreases blood pressure by about a modest average of 4/2 mm Hg (systolic/diastolic). And, hypertension's relationship to death rates is even less established.⁽³⁹⁾

Other research examples refuting broad-brush theories concerning salt and sodium and their effects on hypertension, cardiovascular disease and death rates further confuse cause-and-effect relationships:

- A retrospective-analysis of a highly regarded European database, which has generated multiple, previously published papers, is likely the best database of the relationship of sodium intake to cardiovascular disease (CVD) and death from all causes. While the sample of people was not large, various researchers consider the CVD and mortality data precise and the other research procedures complete. However, a quick review suggests that, from the research results, any individual would prefer to be in the higher sodium group! Only in overweight subjects did the researchers find a positive relationship between sodium intake and death rates.⁽⁴⁰⁾
- Another very large study of more than 40,000 Japanese men and women in a subgroup followed for more than seven years documented that a higher sodium intake could be associated with a higher blood pressure but a lower CVD and death from all causes, even considering their life-long consumption of the high-sodium, hypertension-related Japanese diet.⁽²⁹⁾ Stroke incidence, however, increased among males with the highest salt intake; yet, the dietary pattern was again associated with a lower risk of CVD deaths. Researchers on two studies found a

direct relation of sodium intake to cardiovascular mortality only in an obese minority of the group studied.

- To assess the association between sodium intake with CVD and death from all causes, as well as the potential impact of dietary sodium intake less than 2,300 mg per day, U.S. researchers examined data from the First, Second, and Third National Health and Nutrition Examination Survey (NHANES I, II, and III). Taken together, the inconsistencies in these study results suggested a wide variability in humans' response to dietary sodium and CVD-related death. The researchers concluded that higher sodium intakes, yet lower CVD death rates, raised questions regarding the likelihood of a survival advantage accompanying a lower-sodium diet.^(33–35)
- Canadian researchers undertook a vast analysis of studies reported over three decades. The scientists, in 1999, concluded that restricting salt intake for the population with normal blood pressures (normotensive) was not recommended, because of insufficient evidence demonstrating that such restrictions would lead to a reduced incidence of hypertension.⁽⁴¹⁾
- These large, high-quality studies employed intensive behavioral/diet interventions. Yet, the researchers concluded that the degrees of dietary sodium reductions and changes in blood pressures were not related. They also concluded that intensive interventions, unsuited to medical care or population-prevention programs, provided only small reductions in blood pressure. Plus, effects on deaths and cardiovascular incidences were unclear.⁽⁴¹⁾
- In a study of the effects of a no-added-salt diet for 80 patients with mild-to-moderate hypertension, researchers concluded that this simple diet significantly decreased both systolic and diastolic blood pressure. The researchers advised that hypertensive patients should follow such a basic diet, which helped reduce hypertension without the use of drugs.⁽⁴²⁾
- To determine whether restriction of dietary sodium lowers blood pressure in hypertensive and normotensive individuals, a meta-analysis of 56 trials that met the researchers' criteria for good studies was performed. Decreases in blood pressure were larger in trials of older hypertensive individuals, yet were small and not significant in trials of normotensive individuals whose meals were prepared and who lived outside institutional settings. The researchers suggested that dietary sodium restriction for older hypertensive individuals might be considered, but the evidence in the normotensive population did not support current recommendations for universal dietary-sodium restriction.⁽⁴³⁾

Cancer

Recently, a world-wide scientific panel judged that salt intake is limited to stomach cancer risk but not to other forms of cancer.⁽¹²⁾ Regarding stomach cancer, the panel concluded that salt, and also salt-preserved foods, are probable, but not convincing, causes of stomach cancer. Evidence only was limited or suggestive for stomach cancer and consumption of processed meats, smoked foods, and grilled or barbecued meat or poultry products.

Infection with the bacterium, *H. pylori*, is a necessary but not sufficient cause for stomach cancer. The report also stated that non-starchy vegetables, and specifically allium vegetables (i.e., onion family and garlic), and fruits probably protect against stomach cancer. Given that dietary factors both increase and decrease risk of stomach cancer, dietary and food patterns that follow the 2005 Dietary Guidelines and MyPyramid can help reduce risk, not avoidance of salt or reduction sodium intake alone.

SODIUM REDUCTION STRATEGIES AND TRENDS

As supporters of evidence-based health policy, food manufacturers are faced with the challenge of reducing the salt content of foods without compromising palatability. While the marketplace for foods and beverages boasting health attributes continues to grow, consumers consistently rank taste as “very important” to purchase decisions. A number of companies have set business goals to reduce the sodium content in their products and have been conducting extensive product and consumer research to achieve such goals.

Some manufacturers are simply choosing to add less salt to their products without replacing the salt with other ingredients. Taste and chemical-senses research has revealed that humans are accustomed to the flavor of salt at their own particular dietary-intake levels, but research subjects who followed various reduced-sodium level diets, over time, grew used to the flavor of lower-sodium diets and continued to consume less sodium than previously.^(44–48) Along these lines of changing salt-taste preferences, some food processors are actively following step-down plans to gradually reduce the sodium contents of their products. These reductions, over various lengths of time, simultaneously help “reshape” and reduce loyal consumers' salt-taste preferences toward those foods.

Sodium-replacement Ingredients in the Food Industry

Recognizing consumer loyalty and sensitivity to brands and products developed with specific formulations, manufacturers are wary of alienating customers by drastically and too-quickly altering flavor and texture profiles. Thus, research on alternative ingredients and technologies has expanded in recent years and continues to grow. Current options available and promising areas of research include salt substitutes and taste enhancers. In addition to research on salt substitutes, substantial research is required to define the physiologic mechanisms related to salt, sodium, and taste.⁽⁴⁹⁾

Potassium Chloride

A substitute for sodium chloride, potassium chloride is one of the most common substitution ingredients used to reduce the sodium content of foods. Potassium chloride can help maintain a salty taste; however, potassium may leave a bitter or metallic aftertaste, and some blood pressure medications actually require limiting dietary potassium.

Taste Enhancers

In a 2006 article in *Food Technology*, Brandsma reviewed numerous taste enhancer ingredients available to food manufacturers.⁽⁷⁾ The following information on taste enhancers is adapted from his review.

Taste enhancers function by activating receptors in the mouth and throat, which helps offset the taste effects of salt reduction. These ingredients also elicit the “umami” taste receptor, improving balance and taste perception of foods.

Umami (pronounced “you-mommy”), which means “flavorful” in Japanese, is now recognized as a fifth taste, joining salt, sweet, bitter and sour. Substances that add the umami taste to foods can help impart fuller, “rounder” flavors in the presence of less sodium. Several naturally occurring compounds impart umami taste. Certain vegetables like peas and tomatoes naturally contain umami constituents, such as glutamic acid, while foods such as shiitake mushrooms and tuna offer other components, such as nucleotides, which work along with glutamic acid.

Monosodium glutamate (MSG), primarily derived from molasses and containing high levels of glutamic acid, is the most frequently used taste enhancer. Food manufacturers and many chefs include the ingredient in a wide range of savory foods, and the ingredient can dramatically amplify the umami intensity of a food. MSG is a GRAS food ingredient in the United States, and is approved by international food regulatory bodies. As one of the most

intensely studied food ingredients world wide, allegations of negative health effects have been refuted consistently by academic, health, and governmental scientific evaluations.⁵⁰

Soy sauce is used as an umami-enhancing ingredient. Soy sauce also enhances sweetness in bitter foods and balances acidic taste.

Hydrolyzed vegetable protein (HVP), another taste enhancer, is chemically treated protein broken down into its amino acid components. These amino acids help enhance foods’ flavors, making HVP another ingredient useful in low-sodium food formulations.

Yeast extracts, considered all-natural ingredients, are finding favor with food processors striving to meet consumer demands for processed foods boasting “clean” labels—the absence of chemical-sounding names and other ingredients classified as artificial. In fact, these extracts may hold the greatest promise in the search for low-sodium and low-salt products.

New Product Introductions

According to Information Resources Inc.’s new supermarket product tracking, the most successful new-product launch in 2007 was the line extension of a company’s canned soups with 25 percent less sodium. These reduced-sodium soups notched \$101 million in sales, excluding vending machines, convenience stores, and Wal-Mart. The nearest competitor, with \$87 million in sales, was the introduction of steam bags for frozen vegetables with no added salt.⁽⁵¹⁾

As for seemingly old-fashioned canned soups, these new versions finally struck a chord with consumers. The new soups, using a proprietary recipe and sea salt, perform well rather than fail, as was the case with consumers’ rejection of 1960s-era low-sodium soups with 150 mg sodium per serving. These new-millennia soups with new recipes and use of sea salt are exceeding consumer acceptance over earlier versions of sodium-modified soups in the late 1980s and 1990s.

Food companies in the United States recognize that new and reformulated products, including sodium-modified foods, are a key to helping consumers achieve healthy dietary patterns. In fact, products with modified-sodium levels comprise one of the top categories of new-product introductions.

According to 2008 product-marketing and product-sales data from The Nielsen Company, a global information and media company, growth in various food categories, including sodium-modified products, continue to offer impressive statistics.⁽²⁸⁾ Annual figures related to retail sales for the year ending April 19, 2008 appear in Table 5.

TABLE 5. Products Promoting Health & Wellness Claims

Label Claim	Annual Retail Sales
Salt/Sodium (all)	\$15.9 billion
Low Salt/Low Sodium	\$11.9 billion
No Salt/No Sodium	\$ 3.8 billion
No Salt/Sodium Added	\$ 0.2 billion

In fact, the top four health and wellness claims by product-labeling-claim category and their associated sales included foods and beverages with salt- and sodium-related labeling claims. Sales reached \$15.9 billion, and these sales registered behind only claims related to fat, natural ingredients, and calories, and ahead of products bearing claims about the absence of preservatives or cholesterol, or presence of whole grain.

Introductions of new food and beverage products, totaling 1,343 new items, sported key health and wellness characteristics and included products in the low- and no-sodium category. These represented 2.7 percent of all new food and beverage introductions, ahead of new products with claims such as low fat, fat free and cholesterol free and behind new-product categories with claims for natural, organic, absence of trans or saturated fats, presence of vitamins/minerals, preservative free, and presence of whole grain.

Consumer Education and Behavior

Sodium content in food labeling, expressed both in mg and as percent Daily Value (%DV), is useful for consumers to make food and food consumption choices. Further, the food industry has been successful over several decades, and since implementation of mandatory nutrition labeling, in providing American consumers with a variety of foods addressing salt and sodium content. Numerous “reduced,” “low,” “very low,” or sodium “free” labeled food products have been introduced. Consumers also may choose products without “added salt,” “lightly salted,” and those that are “light” in sodium. Further, the selection and breadth of products that qualify for the FDA “Healthy” nutrient content claim are expanding. As industry, government, and health professions’ educational efforts focus on eating patterns consistent with the 2005 Dietary Guidelines (e.g., MyPyramid or the DASH dietary pattern), dietary sodium intake falls.

Just as the federal government has encouraged consumers to make small steps toward health and dietary improvements, the food industry is addressing sodium levels in foods, both by quietly, or “silently,” making incremental reductions in food products over time, and by utilizing labeling statements from the toolbox of nutrition claims for new and reformulated food products.

The Grocery Manufacturers Association’s (GMA) 2007 *Industry Report on Health and Wellness* notes that 98 percent of responding GMA member companies are reformulating and introducing new products aimed at meeting consumer preferences for nutrition, health, and wellness. Over 10,000 new or reformulated products have been introduced, with attention to portion size, calories, saturated fat, *trans* fat, sugars, and salt or sodium.⁵²

Under the theme of “small steps” toward healthier Americans, GMA, along with the Food Marketing Institute and MatchPoint Marketing, developed the *Take A Peak* in-store MyPyramid promotion program. Along with *Take A Peak*, GMA conducted an evaluation to determine how gradual and incremental changes to meet MyPyramid and 2005 Dietary Guidelines goals would alter the diet through purchasing and consuming foods listed in the program.⁵³

The evaluation assessed baseline diet and incremental changes to sample menus over three weeks for an average adult female against MyPyramid, the 2005 Dietary Guidelines, and USDA’s Healthy Eating Index. Making small, incremental changes in food choices that meet the criteria for the *Take A Peak* program resulted in the following positive changes:

- Increased Health Eating Index (HEI) score (a dietary evaluation tool developed by USDA) from an average of 41 to an average of 93.5 (excellent);
- Decreased sodium by nearly a third (32 percent); and,
- Met all other 2005 Dietary Guidelines and MyPyramid consumption recommendations for food patterns, macronutrients, and most common “shortfall” nutrients.

The *Take A Peak* menu-modeling exercise demonstrates that incremental changes, over time using foods in the U.S. marketplace, can successfully address food and nutrient goals, including substantial reductions in sodium.

Another stair-step-down example is consumers’ altering their consumption of dairy products that feature different fat levels, encouraged through dietary guidance, public education and improved product availability. In making dietary choices to cut dietary fat, as well as to meet MyPyramid patterns and the 2005 Dietary Guidelines, many consumers, over time, have moved down the “fat ladder” from whole milk to 2 percent milk to 1 percent, 0.5 percent, or fat free milk.

ADDITIONAL RESEARCH NEEDS

Before mandating policy changes in the United States related to increased regulation of salt or sodium levels in foods that will affect the entire population, more research is needed in several areas, including cardiovascular outcomes related to sodium intake, consumer behavior, salt-taste mechanisms, and development of salt alternatives and enhancers.

- Although salt and sodium are related to blood pressure, and blood pressure is related to risk of heart disease and other conditions, a large-scale human-heart-disease outcomes study needs to be funded and conducted to evaluate the role of salt and sodium in health and disease for various subpopulations.
- Additional research is needed on the physiology of taste, and mechanism of taste.
- Current food composition databases require updating to keep abreast of food product formulation changes related to sodium.
- Government and industry should collaborate on development of acceptable salt alternatives.

Several aspects of consumer behavior in connection to labeling remain unanswered and require further study prior to possibly implementing new policy:

- Consumer research should address taste acceptance of sodium-modified products with and without label statements about sodium reduction.
- Warning messages on containers of salt may be counterproductive to the positive, required public health message of iodized salt—"Iodine, a required nutrient." Conflicting consumer messages may lead to unintended consequences for infants, goiter prevention, or other nutrient and dietary factors.
- Consumer research is required to determine whether any proposed, required label statements about salt/sodium would be effective in positively affecting consumers' food choices or food consumption related to sodium intake.

SUMMARY

1. Salt, used since antiquity, clearly meets FDA standards as a safe food ingredient.
2. Sodium is an essential nutrient necessary to maintain health. However, many people in the United States consume more than the 2,300 mg daily level recommended in the 2005 Dietary Guidelines.
3. Gradual changes in sodium consumption often are more acceptable to consumers in achieving long-term healthful dietary patterns.
4. The marketplace for sodium-reduced foods is on the rise, thanks to efforts by the food industry to provide consumers with new product introductions and line extensions. Many of these products bear nutrition or health claims related to sodium.
5. USDA's MyPyramid food patterns and the DASH Diet encourage consumption of fruits, vegetables, and low-fat dairy products rich in potassium, calcium, and magnesium, which together, helps promote healthful blood-pressure levels.

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