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# **Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry**

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this guidance, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1200.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

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# **Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## **I. Introduction**

This guidance is intended to provide measurable voluntary short-term (2.5-year) goals for sodium content<sup>1</sup> in commercially processed, packaged, and prepared foods<sup>2</sup> to reduce excess population sodium intake, while recognizing and supporting the important roles sodium plays in food technology and food safety.

Sodium is widely present in the American diet (most commonly, but not exclusively, as a result of eating or drinking foods to which sodium chloride, commonly referred to as “salt,” has been added). More than 70 percent of total sodium intake is from sodium added during food manufacturing and commercial food preparation (Refs. 1, 2). Average sodium intake in the U.S. is approximately 3,400 milligrams/day (mg/day) (Ref 3). The *Dietary Guidelines for Americans, 2020-2025 (Dietary Guidelines)* (Ref. 3) advises individuals 14 years and older to limit their consumption to 2,300 mg/day; this aligns with recommendations from the National Academies

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<sup>1</sup> In this document, we refer primarily to “sodium,” a component of sodium chloride, commonly known as “salt” (21 CFR 101.22(h)(4)). Most, but not all, sodium is added to food in the form of salt, and we are interested in all sources of sodium added to foods. The focus of this guidance is on foods to which sodium has been added, not those foods, such as milk, that contain only intrinsic sodium.

<sup>2</sup> “Commercially processed, packaged, and prepared foods” refers to processed, multiple-ingredient foods that have been packaged for direct sale to consumers, for use in food establishments including, but not limited to, restaurants, or for resale to other members of the food industry, as well as foods that are prepared by food establishments for direct consumption. The guidance addresses certain conventional foods, and not dietary supplements.

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of Sciences, Engineering and Medicine (NASEM), which set the Chronic Disease Risk Reduction Intake (CDRR) for sodium at 2,300 mg/day<sup>3</sup> for those 14 years and older (Ref. 4).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

### A: Purpose and Scope

This guidance aims to help Americans reduce average sodium intake to 3,000 mg/day by encouraging food manufacturers, restaurants, and food service operations to gradually reduce sodium in foods over time. Although we recognize that a reduction to 3,000 mg/day still would be higher than the recommended sodium limit of 2,300 mg/day, the 2.5-year goals are intended to balance the need for broad and gradual reductions in sodium and what is publicly known about technical and market constraints on sodium reduction and reformulation. The guidance provides short-term goals that include both a target mean concentration and an upper bound concentration of sodium for various specified categories of food. The target mean sodium concentration is our goal for the food category as a whole rather than for every product in that category. The upper bound concentration is our goal for the highest sodium concentration for any product in that food category.

FDA recognizes the important role of sodium in food for microbial safety, stability, and other functions. FDA's approach to establishing these voluntary, short-term goals is grounded in research, review, and expert consultation (Refs. 5-9). The goals are intended to provide both FDA and the food industry with a common system for defining and measuring progress in reducing sodium. The goals are intended to complement existing efforts by food manufacturers, restaurants, and food service operations to achieve sodium reduction.

The voluntary sodium content goals in this guidance are intended to:

- Support increased food choice for consumers seeking a diverse diet that is consistent with recommendations of the *Dietary Guidelines* by encouraging food reformulation and new product development for Americans;
- Support the *Dietary Guidelines*, and NASEM CDRR recommendations of limiting sodium intake to 2,300 mg/day<sup>4</sup> by encouraging sodium reduction over the short term to achieve an average intake of 3,000 mg/day;

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<sup>3</sup> Above this level, sodium intake should be reduced in order to reduce the risk for hypertension and cardiovascular disease; lower levels are recommended for children younger than 14 years of age (Ref. 4).

<sup>4</sup> The *Dietary Guidelines* recommendation is for individuals aged 14 and older to limit intake of sodium to less than 2,300 mg/day. The CDRR level for individuals ages 14 years and older set by the NASEM 2019 Dietary Reference Intakes for sodium and potassium report is 2,300 mg of sodium per day (Ref. 4). The recommendations for children younger than 14 years of age are the NASEM age- and sex-appropriate CDRRs.

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- Provide uniform metrics (mg of sodium per 100 g of food) for voluntary sodium reduction for industry stakeholders;
- Focus on the total amount of sodium in a given food as opposed to individual sodium-containing ingredients; and
- Support and extend industry's voluntary efforts to reduce sodium across the range of commercially processed, packaged, and prepared foods.

The voluntary sodium content goals in this guidance are not intended to:

- Recommend specific methods and technologies for sodium reduction;
- Recommend how much of a sodium-containing ingredient, such as sodium chloride or sodium nitrite, should be used in a formulation (our recommendations focus instead on the total amount of sodium<sup>5</sup> in a given food);
- Focus on foods (e.g., milk) that contain only naturally occurring sodium; or
- Address the sodium chloride or other sources of sodium that individuals add to their food at the table or through cooking.<sup>6</sup>

### B: Overview

This sodium reduction guidance is based on the following principles:

- Reduction in sodium levels should progress gradually to allow time for product reformulation;
- Population-level sodium intake reduction should progress at a pace such that consumer preferences and expectations for saltiness in foods adjust;<sup>7</sup>
- Reduction in sodium levels should not lead to reformulation that negatively affects the nutritional quality of the foods by modifying other nutrient levels (e.g., by increasing added sugars or saturated fat content) and should take into account all *Dietary Guidelines* recommendations and FDA policies;
- Population-level sodium intake reduction will involve ongoing voluntary efforts led by the food industry, in collaboration with FDA, our Federal partners, and other stakeholders;<sup>8</sup>
- Goals should be expressed in ways that support ongoing efforts to track modifications to the sodium content of the food supply over time;
- Successful sodium reduction is contingent upon broad participation by and distribution of impacts across the food industry; and

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<sup>5</sup> We recognize that total sodium in a food may include some intrinsic sodium and that this contribution to the food's total sodium does not represent deliberate introduction of a sodium-containing ingredient. However, total sodium is the most practicable measure of the food's composition and is strongly correlated with the use of sodium-containing food ingredients in the foods that are the focus of this guidance.

<sup>6</sup> FDA supports public education efforts on how consumers can reduce sodium in their diet, including salt they add to their food.

<sup>7</sup> Consumer preferences and expectations for salty taste can adjust based on dietary changes (Ref. 8).

<sup>8</sup> This includes states, tribes, consumers, international governments, academic institutions, and other organizations as appropriate.

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- Population-level sodium intake reduction can be advanced through both the categorization of the food supply based on relevant data and information (e.g., ingredient similarity, technical effects in the food, role in food safety, and range of sodium concentrations in marketed products) and the use of voluntary objectives.

### C: FDA's Approach to Voluntary Sodium Reduction in the Food Supply

Multiple public health efforts have attempted to reduce sodium intake over the past 40 years (Ref. 10). However, these efforts, which mainly included education initiatives, have generally not been successful. The Institute of Medicine (IOM, now the Health and Medicine Division of NASEM) thus concluded that without an overall reduction of the level of sodium in the food supply, consumers will not be able to reach intakes recommended by the *Dietary Guidelines* (Ref. 10). As more than 70 percent of Americans' sodium intake comes from foods where sodium is added during food manufacturing and commercial food preparation (Refs. 11, 12), lowering population intake of sodium to more moderate levels must involve lowering the amount of sodium added to commercially processed, packaged, and prepared foods in the U.S. marketplace (Refs. 2, 10).

Various food manufacturers, retailers, and food service firms have initiated voluntary efforts to reduce sodium, with some success (Refs. 11, 12). However, consumers who are trying to consume less sodium continue to face significant challenges. The 2010 National Academies report "Strategies to Reduce Sodium Intake in the United States" noted that the food supply itself is a key obstacle for consumers: "The sodium densities of available foods—both in the marketplace and from restaurant/food service operations—make it difficult for consumers to meet dietary recommendations" (Ref. 10). Given the emphasis on sodium reduction by the public health community over the last several decades, the available evidence demonstrating little progress in reducing sodium intake on a population level over this time (Ref. 10), and the number of foods in the marketplace that are high in sodium, additional strategies are warranted to reduce sodium consumption. To assist consumers who want to lower the total sodium content of their diets, this guidance aims to support voluntary, coordinated, and gradual reduction of sodium across the food supply.

Below, we provide guidance to industry in the form of specific targets for a broad sector of the market for sodium content in categories of commercially processed, packaged, and prepared foods. These categories are compatible with existing industry and regulatory categories and with government databases (Ref. 5). This guidance is intended to inform general industry thinking about sodium content in their foods. This guidance is not intended to limit industry's use of any appropriate methods or technologies to achieve sodium reduction.

FDA, in cooperation with other agencies, intends to monitor the prevalence of sodium in the food supply over time using the measures described in this guidance and supporting documents. To avoid the potential for unintended consequences, we plan to monitor the levels of other nutrients (e.g., added sugars and saturated fat); such monitoring will be done by, for example, consulting product nutrition information and ingredient lists to ensure that no broad trends emerge that negatively affect the nutritional quality of foods. We will continue to discuss with industry the appropriate use of ingredients added to food as part of sodium reduction efforts

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during product development or reformulation. Our goal is to encourage gradual, efficient reduction of overall sodium content using effective and sustainable strategies that maintain other measures of nutritional quality. Because many higher-selling products currently marketed are at or below the category means presented in this guidance, it should be possible to avoid disruptive changes to individual products that might result in noticeably altered taste, greatly reduced shelf life, or other undesirable product outcomes.<sup>9</sup>

### D: Intended Audience

This guidance is intended for members of the food industry (e.g., food manufacturers and other establishments that commercially prepare foods), and also may be of interest to public health groups and consumers. Broad industry adoption of these voluntary recommendations can create a meaningful reduction in population sodium intake over time and support adjustment of consumer taste preferences. However, we recognize that most of the food consumption in the U.S. comes from a relatively small number of products and menu items in the marketplace that are produced by a limited number of food manufacturers. It is possible that reformulation by these food manufacturers could lead to increased demand for lower-sodium versions of ingredients used to produce packaged and prepared foods. As a result, such actions could help all members of the food industry be more readily able to provide lower-sodium products. Given the resources involved in successful reformulation to achieve voluntary sodium reduction and to have the most public health impact, we specifically encourage attention by:

- Food manufacturers whose products make up a significant proportion of national sales in one or more categories, and
- Restaurant and similar retail food chains that are national or regional in scope.

## **II. Background**

### A: Sodium and Health

Research shows that excess sodium consumption is a contributory factor in the development of hypertension (Refs. 4, 13-15), which is a leading cause of heart disease and stroke, the first and fifth leading causes of death in the United States, respectively (Ref. 16). Decreasing population sodium intake is therefore expected to reduce the rate of hypertension. Research also shows that the increase in blood pressure seen with aging, common to most Western countries, is not observed in populations that consume low sodium diets (Ref. 17) and that the U.S. population consumes far more sodium than recommended (Refs. 3 and 18). Moreover, dietary reduction of sodium can lower blood pressure, as has been demonstrated in the Dietary Approaches to Stop Hypertension (DASH)-Sodium trial (Ref. 19) and other experimental studies (Refs. 4 and 20).

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<sup>9</sup> We provide information about products relative to category means on our sodium reduction webpage at [www.fda.gov/sodiumreduction](http://www.fda.gov/sodiumreduction).

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### B: U.S. Sodium Intake and Recommendations

Currently, the average sodium intake for Americans 2 years and older is approximately 3,400 milligrams per day (mg/day) (Refs. 3, 18). The recommendations of scientific groups that are charged with examining the totality of the evidence, including scientific bodies, qualified experts and governments around the world, support limiting sodium intake to about 2,300 mg/day (Refs. 3, 4, 21-24). Ninety-six countries have implemented a national strategy for sodium reduction (Ref. 25). A systematic review evaluating the effects of sodium reduction in high-income countries found no evidence of adverse effects from initiatives to reduce sodium intake (Ref. 26).

This guidance supports the goal of reducing sodium intake as recommended by scientific consensus groups, by focusing on short-term reduction to 3,000 mg/day as a gradual approach to sodium reduction in the food supply. The guidance reflects the broad consensus among experts regarding the direct relationship between sodium and blood pressure, as well as the relationship between blood pressure and cardiovascular disease events (Ref. 4). With average sodium intake in the U.S. over 3,400 mg/day, there is considerable work to do to reduce intake to the recommended limit of 2,300 mg/day in order to reduce the risk of hypertension and cardiovascular disease. Thus, the overall goal of this guidance is to support reduction of average sodium intake to 3,000 mg/day as we continue the dialogue on sodium reduction.

### C: Potential Public Health Impact of Sodium Reduction

Multiple studies have estimated the public health and economic benefits associated with broad reduction in sodium intakes in the U.S. (Refs. 27-30). Those studies have shown that reductions in average intake (modeled at a variety of intake levels below current intake, down to an average level of roughly 2,200 mg/day) have been estimated to result in tens of thousands fewer cases of heart disease and stroke each year, as well as billions of dollars in health care savings over time. One study (Ref. 27) used three epidemiological datasets to estimate the separate public health benefits of reducing the population's average sodium intake to 2,200 mg/day over 10 years. The researchers estimated that this pattern of reduction would prevent between 280,000 and 500,000 premature deaths over 10 years and that sustained sodium reduction would prevent additional premature deaths.

### D: Other Initiatives with the Goal of Reducing the Sodium Content of Foods

This guidance is informed by domestic and international initiatives to reduce sodium in the food supply. In the United States, the New York City Department of Health and Mental Hygiene initiated the National Salt Reduction Initiative (NSRI),<sup>10</sup> a partnership of 70 local and state health departments and health organizations, to set voluntary targets to reduce sodium in restaurant and processed foods. The goal of NSRI was to decrease average sodium intake by 20 percent over five years (2009 through 2014) by developing stepwise reductions from 2009 base levels. More than 25 companies, including packaged food corporations and restaurants, responded to NSRI by committing to reductions in the sodium content of some of their products (Ref. 31). According to the most recent report, some participating food companies achieved the

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<sup>10</sup> This initiative was updated to the National Salt and Sugar Reduction Initiative (NSSRI) in 2019.



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2012 NSRI targets for various categories (Ref. 11). By 2014, NSRI reported that 26 percent of packaged food categories met 2012 targets and 3 percent met 2014 targets (Ref. 12).

Internationally, of the 96 countries with sodium reduction strategies, more than 50 countries have developed initiatives to support the reduction of sodium in the food supply (Refs. 25, 32). These initiatives have included both voluntary and mandatory efforts. In an approach developed by the United Kingdom's (UK) Food Standards Agency, many companies voluntarily pledged to reduce sodium in their foods. The UK initiative resulted in a decline in average sodium intake from 3,800 to 3,240 mg/day between 2003 and 2011, and researchers concluded that decreases in blood pressure in the UK during this time were largely attributable to the reduction in sodium intake (Ref. 33). In 2020, the UK government issued revised voluntary targets to be achieved by 2024 (Ref. 34). Health Canada, the department within the Canadian government responsible for helping Canadians maintain and improve their health, also developed a voluntary approach to sodium reduction. Health Canada collated information from the food industry and other stakeholders to inform their "guiding benchmark" sodium reduction levels for processed foods, which were issued in 2012 to be achieved by 2016.<sup>11</sup> In 2017, Health Canada evaluated the food industry's efforts to meet sodium reduction targets in processed foods. Results showed that 52 percent of food categories met the Canadian Phase I, II, or III targets, indicating that voluntary efforts can reduce sodium in packaged foods (Ref. 35). In 2020, Health Canada also issued updated voluntary targets to be achieved by 2025 (Ref. 36).

### E: Food Ingredient Regulation

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that a food additive be approved for use in food and used in accordance with its approved conditions of use (see generally 21 U.S.C. 348). Certain food substances are exempt from these requirements because they are exempt from the definition of a food additive. These food substances include substances that are generally recognized as safe (GRAS) for their intended use (see 21 CFR 170.30) and substances that have been prior sanctioned (21 U.S.C. 321(s)). FDA's food additive and GRAS regulations may establish certain limitations for the use of these food substances. Moreover, these regulations are predicated on usage of the substances under conditions of good manufacturing practices (21 CFR 170.30(h) and 21 CFR 172.5). In addition to the safety requirements of the FD&C Act, the intended use of a food ingredient in meat, poultry, or egg products must be verified as efficacious and suitable by the United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS).<sup>12</sup> FDA regards salt (sodium chloride) as a common food ingredient that is GRAS for its intended use (see 21 CFR 182.1(a)), and salt (sodium chloride) is an optional or required ingredient in many food standard regulations promulgated by FDA or by USDA.<sup>13</sup>

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<sup>11</sup> Additional information on Health Canada's sodium reduction initiative can be found in FDA's Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 5).

<sup>12</sup> Related Documents for FSIS Directive 7120.1 - Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products, <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series/safe-suitable-ingredients-related-document>

<sup>13</sup> For discussions of FDA's regulation of sodium, see generally 72 FR 59973 (Oct. 23, 2007) and 47 FR 26590 (June 18, 1982).

### **III. Discussion**

A gradual and voluntary approach to reducing sodium in the food supply is intended to create flexibility for industry members interested in supporting the public health goals of this guidance. By encouraging action with respect to the products that are the market leaders (i.e., products sold in the greatest numbers) in each category, we hope to stimulate innovative product reformulation that maintains market share while also having the most significant public health impact and minimizes the impact on low-market share products in the food category.

FDA has developed quantitative target mean concentrations and upper bound concentrations for sodium levels in various identified food categories. The target mean concentrations (target means) are goals for sodium levels for the category, calculated as the sales-weighted mean sodium level (in milligrams per 100 grams of food). In setting these target means, FDA has taken into account concentrations necessary to achieve important food safety functions (e.g., antimicrobial) and functionality roles. The short-term targets are intended to be feasible using existing technology and are within the range of currently available top-selling commercial products. The upper bound sodium concentrations (upper bounds) are goals for the highest level of sodium for products in each food category (in milligrams sodium per 100 grams of food).

In Table 1 in the Appendix of this guidance, we summarize the results of our analysis of the sodium content of the food supply and identify short-term target mean (average) sodium concentrations for a wide variety of food categories, as well as the upper bound sodium concentration for products in these food categories.<sup>14</sup> These sodium concentration goals were informed by the distribution of sodium from packaged products and menu items in the food supply in 2010, as well as by publicly available data and information about the formulation of sodium-reduced foods. Nutrition data came from Nutrition Facts labels for packaged foods and from restaurant nutrition information.<sup>15</sup>

Food industry manufacturers, particularly the firms described earlier (e.g., food manufacturers whose products make up a significant proportion of national sales in one or more categories and restaurants and similar retail food chains that are national or regional in scope), may consider using the voluntary goals in Table 1 to inform decisions about the use of sodium in products or menu items.

Table 1 contains four key elements:

- Foods and food categories;
- Baseline sodium concentrations;
- Target mean sodium concentrations; and

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<sup>14</sup> See also FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5) for a detailed discussion of target and non-target categories of foods. Non-target categories of foods either did not contain meaningful amounts of sodium or did not contribute meaningfully to sodium intake in the general population because they were consumed rarely and thus provided little contribution relative to other food groups.

<sup>15</sup> Additional information on data sources is available in FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5).

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- Upper bound sodium concentrations.

We describe each of these elements in more detail below.

### A: Foods and Food Categories

In developing sodium reduction goals, FDA reviewed various food categorization systems,<sup>16</sup> identified significant contributors to the intake of sodium in the United States, and organized foods into various identified food categories. We identified and categorized the foods in these categories on the basis of:

- Contribution to sodium intake;
- The total amount of sodium in the food (foods with added sodium, i.e., not just naturally occurring);
- Similar functional roles for sodium-containing ingredients;
- Similar sodium concentrations;
- Similar technical potential for reduction in sodium content;
- Compatibility with existing industry and regulatory categories; and
- Comments received to the draft guidance docket.

Many food categories have recommended targets (listed in Table 1; e.g., various bakery products, meats, cheeses, and types of sauces, etc.). However, we did not suggest targets for certain categories that do not contribute meaningfully to overall sodium intake<sup>17</sup> (e.g., salted dried fish and organ meat) either because they were consumed rarely (by all ages and ethnicities) or because they provided little contribution to sodium intake relative to the other food groups.<sup>18</sup>

### B: Baseline Sodium Concentrations

Table 1 presents baseline sodium concentrations for each of the identified food categories. Each baseline should be interpreted as our assessment of the approximate “state of the market” regarding sodium concentrations in each food category in 2010,<sup>19</sup> based on public representations of sodium content by the food industry through food labels and menus, rather than as representing a precise measurement of sodium concentrations in the food supply. We derived these baseline values from a large, market-weighted array of products in each category.

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<sup>16</sup> The food categorization systems mentioned refer to various government food category systems, private-sector food category systems, and sodium reduction initiative category systems that are further described in the FDA’s Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5).

<sup>17</sup> See FDA’s Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5) for a table with foods for which targets were not developed, and Tables 1 and 2 of this guidance.

<sup>18</sup> For more detail about the process we used to identify and categorize these foods, see FDA’s Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5), as well as our expanded definitions for categories in this guidance.

<sup>19</sup> For our rationale in selecting 2010 as our baseline year and for more detail about the data sources used, see FDA’s Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5). For this guidance, baseline values for categories include the full year of 2010 data (Ref. 37).

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We include them in the tables to provide context for the target mean concentrations and upper bound concentrations.

We developed the baselines for sodium concentrations using label data for packaged foods sold directly to the consumer and menu nutrition data for foods sold in large restaurant chains. We used these data because they are available for each individual product and they are the manufacturer's or restaurant chain's representation of the sodium content of their products. We also developed these baselines using sales volume data for the products involved, so that more widely consumed products in a category would have more influence on the final sodium concentration for the category. In other words, we used sales volume data to give extra weight to higher-selling foods in a category and to eliminate very low-volume foods from our calculations.<sup>20</sup>

We developed baselines for packaged foods by reviewing label data on sodium content for the individual food products within a category. We focused on foods making up the top 80 percent of sales by volume in each category. Using both label and sales data for packaged foods, we calculated a sales-weighted average sodium concentration for the category; products with higher sales volume counted for more in the final average.

We developed baselines for commercially prepared foods by reviewing public menu data for the largest national and regional restaurant chains, capturing only those menu items with added sodium. Because sales data on individual products within each restaurant chain were not available, we calculated a sales-weighted average sodium concentration for each category using the total sales of each chain as a proxy value; products from a chain with greater total sales of all products counted for more in the final average. Because sodium concentrations are not always similar in packaged and restaurant versions of a food, we developed two separate baselines for packaged and restaurant (prepared) foods.<sup>21</sup>

### C: Target Mean and Upper Bound Sodium Concentrations

For our draft guidance, we developed a model of sodium intake based on our food categories and the 2009-2010 What We Eat in America (WWEIA) survey<sup>22</sup> consumption data (Ref. 5). We estimated that a reduction in mean population intake to near 3,000 mg/day could be attainable if the food industry achieved the short-term goals presented in the draft guidance.

We recognize that any potential changes in the sodium content of the food supply will take time. Table 1 identifies our 2.5-year goals for sodium concentrations in the food supply, both for the

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<sup>20</sup> See FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5) for a detailed discussion of our use of sales volume data to give extra weight to higher-selling foods and eliminate low-volume selling foods from our calculations.

<sup>21</sup> See FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5) for more detail about the development of baseline sodium concentrations.

<sup>22</sup> The National Health and Nutrition Examination Survey is a program of studies designed to assess the health and nutritional status of adults and children in the United States. It is a major program of the National Center for Health Statistics, which is part of the Centers for Disease Control and Prevention (CDC). More information about NHANES can be found at <http://www.cdc.gov/nchs/nhanes.htm>.

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target mean and for the upper bound sodium concentrations (defined in the discussion above and further discussed below).<sup>23</sup>

The 2.5-year goals are intended to balance the need for broad and gradual reductions in sodium and what is publicly known about technical and market constraints on sodium reduction and reformulation. The distribution of sodium concentrations in currently available products in each category was a significant factor in developing these quantitative sodium concentration goals. We developed the goals with a particular emphasis on maintaining concentrations needed for food safety, given the function of salt as a food preservative. These short-term goals are within the range of concentrations found in currently marketed foods and are feasible using existing technical strategies.

We acknowledge that small businesses may not have the same resources as larger companies for reaching these goals. However, we anticipate that these goals would ultimately be within reach for all firms, given time and the spread of innovations in food ingredients and manufacturing methods.

We consider it likely that the amount of a sodium-containing ingredient needed to achieve various technical effects (including flavor) in foods could decrease over time, due to advances in food technology, such as flavor science and food preservation. Changes in consumer taste preferences are also possible, and may be more likely, should reformulation occur. Reformulation strategies are expected to take time to implement; as a result, we expect sustainable reductions in the amount of sodium in the food supply to happen gradually. The reformulation strategies will likely vary; for example, sodium concentrations in processed and packaged foods are not always parallel to the sodium concentrations in comparable foods prepared at restaurants and other retail food establishments. The short-term (2.5-year) goals (which include both the target mean concentrations and upper bound concentrations) reflect this differentiation.

We do not provide detailed guidance on the technical details of reducing sodium in this document, although we reviewed the publicly available scientific literature on potential opportunities and technologies for reducing sodium (Refs. 6-8). Experts from the food industry are well-positioned to innovate by exploring combinations of strategies and technologies that are most appropriate for each food category and each food product reformulation while maintaining food safety. However, we want to make clear that broader public health goals and maintenance of nutritional quality are important considerations in developing sodium reduction or reformulation strategies. For example, sodium reduction that relies on increases in added sugars would not be consistent with the public health goals of this guidance.<sup>24</sup>

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<sup>23</sup> See FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5) for further discussion on the target mean and upper bounds.

<sup>24</sup> We also recognize that in reformulating products, firms may need to balance additional public health goals, such as reducing acrylamide formation in certain foods (see FDA's Guidance for Industry: Acrylamide in Foods, March 2016, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-acrylamide-foods>).

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### 1. Voluntary Target Mean Sodium Concentrations

Table 1 identifies voluntary target mean sodium concentrations for each food category. The voluntary target mean indicates the desired average sodium concentration in each category, weighted by relative sales volume so that more popular products have a greater influence on the category average. Target assignment was based on a default reduction percentage modified by available category-specific information. The extent of targeted reduction in each food category is influenced by the functions of sodium-containing ingredients in the category, as well as the distribution of sodium concentrations we found in products within that category.<sup>25</sup> These values are FDA's goals for each food category as a whole, not necessarily for individual manufacturers who choose to pursue these goals voluntarily. These mean target concentrations represent the benchmarks that we will use to assess the impact of any voluntary efforts by members of the food industry on the overall composition of the food supply. However, individual members of the food industry choosing to pursue sodium reduction may find it helpful to assess the sales-weighted status of their product portfolio in a particular category with reference to the target mean concentration in order to inform decisions about where to focus their voluntary reformulation efforts.<sup>26</sup>

### 2. Voluntary Upper Bound Sodium Concentrations

Table 1 also identifies voluntary upper bound sodium concentrations for each food category. The upper bound is a standard that could be applied to every individual product in a category, in contrast to the target means, which apply to average concentrations in a food category. Food industry members can compare any of their products in a category to the upper bound concentration for every product in that category. The upper bound for each category is influenced by the corresponding target mean concentration and the current distribution of sodium concentrations for products in that category.<sup>27</sup> The upper bound sodium concentrations are goals and do not represent maximum allowable levels for sodium.

## **IV. Appendix**

Table 1. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (see attached Excel table)

Table 2. Non-Target Categories

The non-target categories are food categories for which we have not developed goals. Non-target categories include those that either did not contain meaningful amounts of added sodium (i.e., are foods with no sodium or with intrinsic sodium that is not added) or did not contribute

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<sup>25</sup> FDA consulted with FSIS staff during the development of the meat and poultry categories and target mean concentrations.

<sup>26</sup> See FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5).

<sup>27</sup> See FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance (Ref. 5) for more details about the calculation of upper bound concentrations.

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meaningfully to overall sodium intake because they were consumed rarely (by all ages and ethnicities) and because they provided little contribution relative to the other food groups.<sup>28 29</sup>

Table 3. Definition of Terms Used in This Document (for the purposes of this guidance only)

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<sup>28</sup> As measured by an analysis of the food sources of sodium intake using 2007-2008 WWEIA/NHANES data.

<sup>29</sup> As assessed by a sensitivity analysis to determine if food categories shifted, looking at percent consumer, per user mean, and per capita mean.

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<b>Table 2. Non-Target Categories</b>	
<b>General Food Category</b>	<b>Category and Product Examples</b>
Dairy	All milk except buttermilk and dry milk
Dairy	Buttermilk
Dairy	Dry milk
Dairy	Yogurt
Dairy	Ice cream/frozen yogurt
Dairy	Hot Cocoa
Dairy	Ice cream bars/cones/sundaes
Dairy	Whipped topping
Dairy	Cream and cream substitute
Dairy	Sour cream
Dairy	Custards/flans
Dairy	Mousse-type pudding
Dairy	Mascarpone cheese
Dairy	Ricotta cheese
Dairy	Fresh Mozzarella cheese
Dairy	Cheese fondue (packaged food)
Dairy	Cream-based fruit dips
Fats, Oils, and Dressings	Animal fats
Fats, Oils, and Dressings	Natural oils
Fats, Oils, and Dressings	Raw commodities
Fats, Oils, and Dressings	Butter – unsalted
Fats, Oils, and Dressings	Margarine, vegetable oil spreads – unsalted
Fruits, Vegetables, and Legumes	Fruit - raw/fresh
Fruits, Vegetables, and Legumes	Fruit – frozen
Fruits, Vegetables, and Legumes	Fruit filling
Fruits, Vegetables, and Legumes	Fruit – canned
Fruits, Vegetables, and Legumes	Fruit - salads/cocktails
Fruits, Vegetables, and Legumes	Fruit – cooked
Fruits, Vegetables, and Legumes	Fruit – juice
Fruits, Vegetables, and Legumes	Fruit – dried
Fruits, Vegetables, and Legumes	Fruit - misc. (sauces, juice bars, etc.)
Fruits, Vegetables, and Legumes	Coconut products
Fruits, Vegetables, and Legumes	Vegetables - raw and/or no added sodium
Fruits, Vegetables, and Legumes	Boiled/baked/raw potatoes, no toppings
Fruits, Vegetables, and Legumes	Dried beans and dried peas
Fruits, Vegetables, and Legumes	Instant potatoes, unseasoned
Fruits, Vegetables, and Legumes	Dried vegetables
Fruits, Vegetables, and Legumes	Vegetable pastes/purees
Fruits, Vegetables, and Legumes	Peppers, Shelf-Stable
Fruits, Vegetables, and Legumes	Pickled Vegetables, excluding pickled cucumbers (pickles)
Fruits, Vegetables, and Legumes	Fruit – pastes/cubes



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Fruits, Vegetables, and Legumes	Tomato – puree
Fruits, Vegetables, and Legumes	Crispy fried onions
Fruits, Vegetables, and Legumes	Grape leaves – stuffed/non-stuffed
Nuts and Seeds	Nuts/seeds, unsalted
Nuts and Seeds	Dessert/sweet seed/nut spreads (almond paste, chocolate hazelnut spread, caramel paste, etc.)
Nuts and Seeds	Miso (soy bean paste)
Soups	Liquid/paste bouillon
Soups	Refrigerated soup bases/starters/mixes
Soups	Wet broth/stocks – concentrate/base/starter
Soups	Frozen soups
Sauces, Gravies, Dips, Condiments, and Seasonings	Seasoned salt and seasoning salt
Sauces, Gravies, Dips, Condiments, and Seasonings	Relish
Sauces, Gravies, Dips, Condiments, and Seasonings	Hummus dip, dry-mix
Cereals	Ready-to-eat cereals, shredded
Cereals	Ready-to-eat cereals, granola
Cereals	Ready-to-eat cereals, muesli
Bakery Products	Pie crust/shells
Bakery Products	Soda bread
Bakery Products	Bread pudding
Bakery Products	Tortillas and wraps, corn
Bakery Products	Brownie dough
Bakery Products	Dry mix brownies and cookies
Bakery Products	Liquid bakery batters
Bakery Products	Graham cracker crumbs
Bakery Products	Wrappers – egg roll/won ton/gyoza/spring roll
Bakery Products	Ice cream bowl/cone
Bakery Products	Other desserts (panna cotta, crème brûlée)
Meat and Poultry (and substitutes)	Organ meat, not cured/smoked
Meat and Poultry (and substitutes)	Organ meat, cured/smoked
Meat and Poultry (and substitutes)	Veal
Meat and Poultry (and substitutes)	Lamb and goat
Meat and Poultry (and substitutes)	Game meat, not cured/smoked
Meat and Poultry (and substitutes)	Game meat, cured/smoked
Meat and Poultry (and substitutes)	Prosciutto
Meat and Poultry (and substitutes)	Ground meat/poultry, raw patties
Meat and Poultry (and substitutes)	Pâté/Meat Spreads
Meat and Poultry (and substitutes)	Vegetarian Pâté/ & Terrines
Fish and Other Seafood	Fresh/raw fish and seafood
Fish and Other Seafood	Salted/pickled/dried/smoked fish and other seafood
Fish and Other Seafood	Escargot
Fish and Other Seafood	Seafood pastes/pates

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Fish and Other Seafood	Caviar
Eggs and Egg-based Dishes (and substitutes)	Eggs and egg substitutes, no additions during preparation (packaged)
Snacks	Popcorn kernels
Snacks	Sweet popcorn (kettlecorn, caramel, chocolate covered, etc.)
Snacks	Roasted vegetable snacks – corn nuts/wasabi peas, etc.
Snacks	Wheat nuts
Mixed Ingredient Dishes	Sushi
Toddler/Baby Foods	Toddler/baby meat sticks
Confectionary (Sweets)	Sugar and sugar substitutes
Confectionary (Sweets)	Syrups
Confectionary (Sweets)	Gelatin desserts, jellies, jams
Confectionary (Sweets)	Chewing gum
Confectionary (Sweets)	Fudges
Confectionary (Sweets)	Candy and chocolate with nuts
Confectionary (Sweets)	Candy and chocolate without nuts
Confectionary (Sweets)	Non-dairy based bakery desserts
Confectionary (Sweets)	Non-dairy frozen/prepared desserts
Confectionary (Sweets)	Frosting
Confectionary (Sweets)	Chocolate syrup
Confectionary (Sweets)	Chocolate fondue
Confectionary (Sweets)	Chocolate-covered potato chips
Confectionary (Sweets)	Halva
Confectionary (Sweets)	Brittles
Other Foods	Infant food products, infant formula
Other Foods	Meal replacement powders, and supplements
Other Foods	Pasta – shelf-stable
Other Foods	Matzo balls, in broth
Beverages	Non-alcoholic
Beverages	Alcoholic
Beverages	Water

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<b>Table 3. Definition of Terms Used in This Document (for the purposes of this guidance only)</b>	
<b>Term</b>	<b>Definition in this Guidance</b>
As prepared	Sodium concentration of the product after the food product is prepared according to the product’s specific preparation and cooking directions provided on the product label.
Baseline level	The amount of sodium in a category representing the 2010 U.S. food supply. The levels are provided as sales-weighted mean concentrations (sodium in mg per 100 g). Baseline levels were calculated using product nutrition information from commercially available databases and public websites. Scanner data was used for sales weighting packaged foods and restaurant total dollar amounts were used for weighting items at major restaurant chains.
Food Category	A grouping of food products at the level for which a sodium reduction target is suggested. Unless otherwise noted, each category includes all relevant food items containing added sodium. The category product inclusions are not confined to a specific industry sectors (e.g., packaged foods, prepared foods) or point of purchase.
Food Service establishment	An operation that stores, prepares, packages, serves, and sells food directly to the consumer.
Food Group	High level food category grouping for the list of sodium reduction targets (e.g., Dairy; Fats, Oils, and Dressings; etc.).
Goals or “Sodium Reduction Goals”	Refers to both target mean and upper bound concentrations that have been established for 2.5 years after final publication of this guidance.
Hypertension	Hypertension, or high blood pressure, generally means a systolic blood pressure of greater than 140 millimeters of mercury (mm Hg) or a diastolic blood pressure of greater than 90 mm Hg.
Ready-to-eat food	Packaged or prepared food that is ready for human consumption at time of purchase. Ready-to-eat food does not require further addition of ingredients, preparation, or cooking by the consumer to achieve food safety.
Sales-weighted mean	A measurement of sodium content calculated by weighting individual products by volume sales given as the average sodium content in milligrams per 100 grams. A sales-weighted mean gives more weight to items that sell more, thereby providing a preferred monitoring metric for evaluating future sodium reduction progress.
Sodium	Sodium is specified here as the chemical entity or electrolyte “sodium” and is distinguished from sodium chloride, or salt, which is 39 percent sodium by weight (21 CFR 101.74). Examples of other sodium-containing ingredients found in foods include sodium propionate, sodium lactate, and sodium benzoate.

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<b>Table 3. Definition of Terms Used in This Document (for the purposes of this guidance only)</b>	
<b>Term</b>	<b>Definition in this Guidance</b>
Seasoned (and seasoning)	Addition of salt, herbs and spices to food for the purpose of flavor enhancement.
Target (mean)	The goal sodium level for the category, calculated as the sales-weighted mean sodium level (in milligrams per 100 grams of food).
Upper bound	The goal upper bound sodium content of an individual food product or menu item included in a food category (in milligrams per 100 grams of food).

<sup>ii</sup> This is based on the definition of “food establishment” in FDA’s Food Code (2013).

<http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm374275.htm>

## **V. References**

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction or are not publications. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff or, in the case of non-publication references, at any website listed. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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