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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

Draft Guidance

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

**U.S. Department of Health and Human Services
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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

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I. Introduction

Sodium¹ is widely present in the American diet (most commonly, but not exclusively, as a result of eating or drinking foods containing salt). Average sodium intake in the U.S. is approximately 3,400 milligrams/day (mg/day²). The 2015-2020 Dietary Guidelines for Americans (Dietary Guidelines) (Ref. 1) and Healthy People 2020 (Ref. 2) advise people to consume less than or equal to 2,300 mg of sodium per day.

Purpose and Scope

Approximately 75 percent of total sodium intake comes from processed and commercially prepared (e.g., restaurant) foods (Ref.3). This voluntary guidance aims to help Americans achieve the Dietary Guidelines-recommended sodium levels by encouraging food manufacturers, restaurants, and food service operations to reduce sodium in foods. It is intended to complement existing efforts by food manufacturers, restaurants, and food service operations to achieve these goals.

¹ In this document, we refer primarily to “sodium,” a component of sodium chloride, commonly known as “salt.” 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.

² The 2015-2020 Dietary Guidelines for Americans indicate that only 11% of the current population is meeting sodium recommendations.

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FDA recognizes the important role of sodium in food for microbial safety, stability, and other functions. This guidance is not intended to undermine these functions, but to provide³ measurable voluntary draft short-term (2 year) and long-term (10 year) goals for sodium content⁴ (from sodium chloride, commonly called “salt,” as well as other sodium-containing ingredients) in commercially processed, packaged, and prepared foods⁵ to reduce excess population sodium intake. FDA’s approach to establishing these goals was grounded in research, review, and expert consultation.⁶ The draft goals are intended to allow both FDA and the food industry to have a common system for defining and measuring progress in reducing sodium and to encourage public comment and input on the proposed goals. Decreasing population sodium intake is expected to reduce the rate of hypertension, a major risk factor for heart disease and stroke, the first and fifth leading causes of death in the U.S. (Ref. 4).

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

- Support increased food choice for consumers seeking to consume a diverse diet that is consistent with recommendations of the 2015-2020 Dietary Guidelines by encouraging food reformulation and new product development for Americans;
- Support the 2015-2020 Dietary Guidelines and the Healthy People 2020 recommendations of sodium intake of less than 2,300 mg per day for many individuals⁷;
- Provide shared goals as metrics (mg/100g) for voluntary sodium reduction for industry stakeholders;
- Focus on total amount of sodium in a given food as opposed to any individual sodium-containing ingredient; and
- Support and extend industry’s voluntary efforts to reduce sodium across the range of commercially processed, packaged, and prepared foods.

This guidance does not:

- Recommend specific methods and technologies for sodium reduction;
- Prescribe how much of a sodium-containing ingredient, such as salt or sodium nitrite, should be used in a formulation (we focus on the total amount of sodium⁸ in a given food);

³ References 17-20 provide record of the research, review, information, and decisions that went into development of our draft voluntary sodium reduction goals.

⁴ 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.

⁵ “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.

⁶ References 17-20 as well as FDA’s memorandum, “Target Development Example,” provide a record of the research, review, information, and decisions that went into development of our draft voluntary sodium reduction goals.

⁷ The 2015-2020 Dietary Guidelines for Americans recommendation to limit intake of sodium to less than 2,300 mg per day is the upper intake level (UL) for individuals ages 14 years and older set by the IOM. The recommendations for children younger than 14 years of age are the IOM age- and sex-appropriate ULs.

⁸ 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

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- Focus on foods that contain only naturally occurring sodium (e.g., milk); or
- Address salt that individuals add to their food⁹.

Overview:

The voluntary sodium reduction goals are based on the following criteria:

- Population-level sodium intake reduction should occur gradually to allow time for voluntary product reformulation;
- Population-level sodium intake reduction should occur at a pace such that consumer preferences and expectations for saltiness in foods can adjust over time;
- Change should not negatively affect the nutritional quality of the foods by modifying other nutrient levels (e.g., added sugars or saturated fat) to less-healthy levels (e.g., taking 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 stakeholders¹⁰;
- Goals should be expressed in a way that supports ongoing efforts to track modifications to the sodium content of the food supply over time;
- Change is contingent upon broad participation by, and evenly distributed impact upon, the food industry;
- 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.

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

According to the 2010 Institute of Medicine (IOM) Report, “Strategies to Reduce Sodium Intake in the United States” (Ref. 5), multiple public health efforts have attempted to reduce sodium intake over the past 40 years. However, these efforts, which mainly included education initiatives, have not been successful. The IOM noted this and 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. Approximately three-quarters of sodium in the diet of the U.S. population is added during food manufacturing and commercial food preparation (Refs. 3 and 4). Therefore, 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. 1 and 5).

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.

⁹ FDA supports public education efforts on how consumers can reduce sodium in their diet, including salt they add to their food.

¹⁰ This includes states, tribes, consumers, international governments, academic institutions, and other organizations as appropriate.

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Various food manufacturers, retailers, and food service firms have initiated voluntary efforts to reduce sodium, with some success (Ref. 6). However, consumers who are trying to make healthier choices or who are attempting to follow their physician's instruction to consume less sodium continue to face challenges. The 2010 IOM report, "Strategies to Reduce Sodium Intake in the United States" notes 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." Given the emphasis on sodium reduction by the public health community over the last several decades and the available evidence demonstrating that there has been no reduction in sodium intake on a population level over this time (Ref.5), additional strategies are warranted to reduce sodium consumption if so many foods in the marketplace remain high in sodium. To assist consumers who want to eat healthfully and 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 on voluntary sodium reduction, in the form of specific goals for a broad sector of the market for sodium content in various identified categories¹¹ of commercially processed, packaged, and prepared foods. We designed these categories to be compatible with some existing industry and regulatory categories and with government databases¹². These goals are intended to inform general industry thinking about sodium content in their foods. These goals are not intended to limit industry use of any appropriate methods or technologies to achieve sodium reduction.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and 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.

Intended Audience

We believe that the goals contained in this guidance are of interest to all members of the food industry. Broad adoption of these voluntary recommendations by members of industry can create a meaningful reduction in population sodium intake over time and support adjustment of consumer taste preferences. However, we recognize that the great majority of food consumption in the U.S. comes from a fairly small number of products and menu items and that many of these products are produced by a limited number of companies. It is possible that reformulation by these companies 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 eventually be more readily able to provide lower-sodium products. Given the

¹¹ For categories where the same food is often sold to the consumer in more than one form (e.g. dry mix mashed potatoes and ready-to-eat/heat mashed potatoes) or storage method (frozen or shelf stable), Table 2 in the Appendix of the draft guidance provides the category baseline values for both forms, with the distinction of a/b after the number.

¹² FDA's Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) describes our process for establishing food categories.

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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.

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 the foods. We will continue to discuss with industry the appropriate use of ingredients added to food as part of sodium reduction efforts during product development or reformulation. Our goal is to promote gradual, efficient voluntary reduction of overall sodium content using effective and sustainable strategies that maintain other measures of nutritional quality. The extent and speed of reduction will be different for different products and categories, since the 10-year targets set were designed to allow for flexibility in reformulation based on differences in food categories and products. Our preferred approach is intended to avoid large, abrupt changes to individual products that might result in noticeably altered taste, greatly reduced shelf life, or other undesirable product outcomes.

II. Background

Sodium and Health

Research shows that excess sodium consumption is a contributory factor in the development of hypertension (Ref.7), which is a leading cause of heart disease and stroke, the first and fifth leading causes of death in the United States, respectively (Ref. 4). 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 (Refs. 8 and 9) and that the U.S. population consumes far more sodium than recommended (Ref. 1 and 5). Moreover, dietary reduction of sodium can lower blood pressure, as has been demonstrated in the Dietary Approaches to Stop Hypertension (DASH)-Sodium trial (Ref. 10). Many expert advisory panels have concluded that scientific evidence supports the value to public health of reducing sodium intake in the general population (Ref. 5).

U.S. Sodium Intake and Recommendations

Current average adult intake of sodium is approximately 3,400 milligrams per day (mg/day). Recent analysis, including the findings of the 2013 Institute of Medicine (IOM) report, “Sodium Intake in Populations: Assessment of Evidence,” continue to support the conclusion that sodium intakes are too high (Ref. 11). The 2013 IOM report confirmed a positive relationship between higher levels of sodium intake and the risk of heart disease. It also found both substantial evidence of population benefit and no evidence of harm associated with reductions in sodium

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intake down to 2,300 mg/day (Ref. 11). Some of the members of the committee that authored the 2013 IOM report also clarified in a subsequent publication that different groups using a variety of methods and data have obtained results consistent with the committee's analysis that current U.S. intake is excessive, that it should be reduced, and that reduction is expected to have significant public health benefit (Ref. 12). Moreover, the 2015 Dietary Guidelines Advisory Committee Sodium Working Group examined the relationship between sodium and blood pressure and other cardiovascular outcomes in adults, as well as sodium and blood pressure in children. The Committee's recommendations concurred with previous reports that U.S. sodium intake remains high and that higher levels of sodium intake are associated with increased blood pressure and risk of cardiovascular disease (CVD) (Ref. 13). This voluntary guidance supports the goal of reducing sodium intake to 2,300 mg/day (Ref. 1) and the broad consensus on the direct relationship between sodium and blood pressure, as well as the relationship between blood pressure and cardiovascular disease events. When considering the recommendations of scientific groups that are charged with examining the totality of the evidence, among scientific bodies, qualified experts and governments around the world, a consensus exists that reducing sodium intake to 2,300 mg/day is a viable, achievable, and effective strategy to reduce the incidence of CVD. With average sodium intake in the U.S. at over 3,400 mg/day there is considerable work to do to slowly reduce intake to the recommended level of 2,300 mg/day. Thus, the overall goal of this guidance is to reduce sodium intake in the general population to 2,300 mg/day.

Potential Public Health Impact of Sodium Reduction

Multiple researchers have estimated the public health benefits associated with broad reduction in sodium intakes in the U.S.) (Ref. 5). They 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. A recent study (Ref. 14) 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.

Other Initiatives with the Goal of Reducing the Sodium Content of Foods

FDA's sodium reduction voluntary 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), 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. To date, over 25 companies, including packaged food corporations and restaurants, have responded to NSRI committing to reductions in the sodium content of some of their products (Ref. 16). According to the most recent report, many of the food companies participating made commitments for reduction, and some achieved the 2012 NSRI targets for various categories (Ref.6).

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Internationally, more than 35 countries have developed initiatives to support the reduction of sodium in the food supply. These initiatives have included both voluntary and mandatory efforts. In an approach developed by the United Kingdom's (UK) Food Safety Authority, over 8,080 companies have voluntarily pledged to reduce salt in their foods; the UK initiative has resulted in a decline in average sodium intake from 3,800 to 3,440 mg/day, and researchers concluded that decreases in blood pressure in the UK between 2003 and 2011 were largely attributable to the reduction in sodium intake (Ref. 15). Health Canada, the department within the Canadian government responsible for public health, also developed a voluntary approach. Health Canada collated information from the food industry and other stakeholders to inform guiding benchmark sodium reduction levels for processed foods, which were issued in 2012.¹³

A Federal Register notice published on September 15, 2011, announced that we were opening a docket and soliciting comments, data, and information on approaches to reducing sodium consumption (see 76 FR 57050). The notice requested information on the following:

- Public and private initiatives to reduce sodium intake over the past few decades;
- Data on current sodium intake in the United States;
- The health effects and costs associated with sodium intake; and
- The functional role of sodium in food (e.g., in improving food safety, extending shelf life, and providing functional and physical properties such as improving texture or melting properties).

Comments we received were general and emphasized the importance of a gradual approach to sodium reduction, that all sectors of the food industry be involved to support changes in consumer taste preferences, and that we consider the technical and regulatory constraints related to sodium reduction.

Food Ingredient Regulation and Good Manufacturing Practices

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. This includes substances for which the intended use meets the criteria for general recognition of safety (GRAS) (see 21 CFR 170.30) or is prior sanctioned (21 U.S.C. § 321(s)). In addition to these safety requirements for all food ingredients, 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).¹⁴ FDA has regarded salt as GRAS for

¹³ 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. 17).

¹⁴ 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>

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direct use in food (see 21 CFR 182.1), and salt is an optional or required ingredient in many food standard regulations promulgated by FDA or USDA.¹⁵

FDA's food additive and GRAS regulations may establish certain limitations for the use of these food substances. Moreover, these regulations predicate usage under conditions of good manufacturing practice (21 CFR 170.30(h) and 21 CFR 172.5). For example, a substance that is listed or affirmed as GRAS must be of an appropriate food grade; perform an appropriate function in the food or food-contact article in which it is used; and be used at a level no higher than necessary to achieve its intended purpose (21 CFR 170.30(h)).

III. Discussion

The gradual and voluntary approach to reducing excessive sodium in the food supply is intended to create flexibility for industry members interested in supporting the goals of this guidance. By emphasizing reformulation of the products that are the market leaders in each category, our approach focuses innovative reformulation on products that maintain market share while having the most significant public health impact and minimizing the impact on low-market share products in the food category.

FDA has developed quantitative target mean concentrations for various identified food categories. In setting these target mean concentrations, FDA took into account maintaining concentrations that achieve important food safety functions (e.g., antimicrobial functionality). The proposed short-term targets are intended to be feasible using existing technology and are within the range of currently available commercial products.

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 the target mean (average) sodium concentration in a wide variety of food categories,¹⁶ as well as the upper bound sodium concentration for products in these food categories. We developed both short-term (2-year) and long-term (10-year) targets. These sodium concentration goals were informed by the distribution of sodium in current packaged products and menu items¹⁷, as well as by publicly available data and information about the formulation of sodium-reduced foods.

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

¹⁵ See generally for discussions of FDA's regulation of sodium, 72 FR 59973 (Oct. 23, 2007) and 47 FR 26590 (June 18, 1982).

¹⁶ See FDA's Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) 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.

¹⁷ Nutrition data came from Nutrition Facts Panels for packaged foods and from restaurant nutrition information for restaurants. Additional information on data sources is available in FDA's Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17).

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using the voluntary goals in Table 1 to inform decisions about the use of sodium in products or menu items. The goals are a reference for industry members when considering the following questions: “Are each of my products below the highest level recommended for its category?” “Do my products help achieve the overall mean levels for their respective categories?”¹⁸

Table 1 contains four key elements:

- Food categories;
- Baseline sodium concentrations;
- Target mean sodium concentrations; and
- Upper bound sodium concentrations.

We describe each of these elements in more detail below.

Key Elements of the Guidance

Foods and Food Categories

In developing sodium reduction goals, FDA reviewed various food categorization systems,¹⁹ 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 amount of sodium in the food (rather than only naturally occurring);
- Similar functional roles for sodium-containing ingredients;
- Similar sodium concentrations;
- Similar technical potential for reduction in sodium content; and
- Compatibility with existing industry and regulatory categories.

Many food categories have proposed 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 intake²⁰ (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. In addition, see FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) for more detail about the process we used to identify and categorize these foods.²¹ We seek comment on the proposed categorization and targets.

¹⁸ Sales-weighted means for categories can be calculated using market share (sales) data and nutrition data. The data sources we used are further described in FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17).

¹⁹ The food categorization systems mentioned refers 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. 17).

²⁰ See FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) for table with foods for which targets were not developed.

²¹ As this memorandum explains, we also did not include targets for food that contains sodium which is not added, such as milk.

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Baseline Sodium Concentrations

Table 1 presents baseline sodium concentrations for each of the identified food categories. Each baseline should be interpreted as our tentative assessment of the approximate “state of the market” regarding sodium concentrations in each food category in 2010,²² 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 and market-weighted array of products in each category. We include them in the table to provide context for the target mean concentrations and upper bound concentrations. We seek comment on this method and the suggested baselines.

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.²³

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% 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 when both packaged and restaurant (prepared) foods were represented in a category. We seek comment on this approach. See FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) for more detail about the development of baseline sodium concentrations.

²² 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. 17).

²³ See FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) 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.

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Target Mean and Upper Bound Sodium Concentrations

The long-term public health goal associated with our sodium concentration goals is to reduce sodium intake in the U.S. population. We have developed a model of sodium intake based on our food categories and current What We Eat in America (WWEIA) survey²⁴ consumption data (Ref. 17). Based on this model, we estimate that a reduction in mean population intake to near 2,300 mg/day (from approximately 3,400 mg/day, currently) could be attainable if the food industry were able to achieve the final sodium concentration goals outlined in the Appendix. This goal is consistent with reductions in sodium intake sufficient to confer a public health benefit (Ref. 5). Reductions of this extent are also consistent with the findings of the 2013 IOM report on Sodium Intake in Populations. This report concluded that evidence was sufficient to support an association between lower sodium intake (i.e., intake at 2,300 mg/day) and lower cardiovascular-related events (Ref. 11).²⁵

We recognize that any potential changes in the sodium content of the food supply will take time and that progress in certain categories on the 10-year targets may require technical innovation. Table 1 identifies both short- and long-term goals for sodium concentrations in the food supply, both for the target mean and for the upper bound sodium concentrations (described further below). Our milestone date for the short-term goals is the second year after final publication of this guidance. Food manufacturers and ingredient suppliers have informed us that the average time from the start of a project to market is approximately 2 years. Our milestone date for the long-term goals is the tenth year after final publication. This longer timeframe considers the time, effort, and innovation required for voluntary large-scale reformulation of the food supply, should members of the food industry voluntarily pursue these goals. See FDA's Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) for further discussion.

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 certain areas of food technology, such as flavor science and food preservation. Changes in consumer flavor preferences are also possible, and may be more likely, should reformulation occur. Reformulation strategies are expected to take time to implement, and as a result sustainable reductions in the amount of sodium in the food supply are expected 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 year) goals (target mean concentrations and upper bound concentrations) reflect this differentiation; however, the long-term (10 year) goals for both sectors of the food industry converge.

²⁴ 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>.

²⁵ The 2013 IOM Report also concluded that current literature does not provide evidence to support treating population subgroups with health conditions (e.g., diabetes) differently from the general population.

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The goals are intended to balance the need for broad and gradual reductions in sodium against 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. Short-term goals in particular are within the range of concentrations found in currently marketed foods and are intended to be feasible using existing technical strategies. We recognize that the long-term goals are more challenging and would need more time and effort to achieve. We also acknowledge that small businesses may not have the same resources as larger companies for reaching short-term and long-term target 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 do not provide detailed guidance on the technical details of reducing sodium in this document, although we have reviewed the scientific literature that is publicly available on potential opportunities and technologies for reducing sodium (Refs. 18-20). Experts from the food industry are well positioned to provide valuable insights into what combination of strategies and technologies would be most appropriate for each food category and each food product reformulation they are involved in 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.²⁶

Voluntary Target Mean Sodium Concentrations

Table 1 identifies voluntary target mean sodium concentrations for each food category, including both short-term and long-term targets. The voluntary targets indicate 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.²⁷ These values are FDA's goals for each food category as a whole, not necessarily for an individual manufacturer who may 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

²⁶ 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," published March 2016).

²⁷ FDA consulted with FSIS staff during the development of the meat and poultry categories and target mean concentrations.

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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. See FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) for more detail about the assignment of target mean sodium concentrations. We believe that in almost all cases the short- and long-term target concentration goals identified in this draft guidance are achievable by building on existing methods and technologies. We seek comment on this assessment.

Voluntary Upper Bound Sodium Concentrations

Table 1 also identifies voluntary upper bound sodium concentrations for each food category, including both short-term and long-term upper bound concentrations. 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 long-term upper bounds are lower than the short-term upper bounds, and are intended to reflect potential continued sodium reduction efforts over time. 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. See FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (Ref. 17) for more detail about the calculation of upper bound concentrations.

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. Definition of Terms used in This Document (for the purposes of this guidance only)

Term	Definitions in this Draft Guidance
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. Nielsen ScanTrak 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 draft 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

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Term	Definitions in this Draft Guidance
	purchase.
Food Service Establishment	An operation that stores, prepares, packages, serves, and sells food directly to the consumer. FDA specifically encourages attention to this guidance by restaurant and similar retail food chains that are national or regional in scope.
Food Group	High level food category grouping for the list of draft 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 and 10 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 (21 CFR 101.74).
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.
Salt	Salt or sodium chloride is a chemical compound comprised of 39 percent sodium and 61 percent chloride by weight. The majority of sodium intake in the American diet comes from salt.
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, etc.
Seasoned	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 (milligrams per 100g).
Upper Bound	The goal upper bound sodium content of an individual food product or menu item included in a food category measured by milligrams per 100 grams of food.

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V. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of [June 1, 2016], FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after [June 1, 2016].

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