DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: June 1, 2016

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

Subject: Supplementary Memorandum to the Draft Guidance

To: Administrative Record - Sodium Reduction Voluntary Guidance

FDA's Voluntary Sodium Reduction Goals

Supplementary Memorandum to the Draft Guidance

Table of Contents

1. Introduction

1.1 Draft Guidance Overview

The U.S. Food and Drug Administration (FDA) has developed a draft guidance document intended to promote broad, gradual reduction of excessive sodium in the U.S. food supply through the development of voluntary sodium reduction goals (target mean concentrations and upper bound concentrations)[1]. The guidance presents our views on sodium reduction in the food supply, expressed as voluntary goals for reduced sodium content (from sodium chloride, commonly called "salt") as well as other sodium-containing ingredients in commercially processed, packaged, and prepared foods.

This sodium reduction effort is consistent with the recommendations of the Institute of Medicine (IOM) 2010 Report entitled "Strategies to Reduce Sodium Intake in the United States" and supports the objectives of the Million Hearts Initiative announced by the Department of Health and Human Services, as well as the objectives of the 2015- Dietary Guidelines for Americans (Dietary Guidelines) (Ref. 1) and Healthy People 2020 (Ref. 2). Experience suggests that no single tool will be enough to promote reductions in intake sufficient to meet the recommendations of the Dietary Guidelines for Americans. Reduction of sodium in foods, improved labeling and communication methods, and changes in dietary patterns are all necessary parts of an effective effort to achieve the recommendations. Our guidance focuses on the development of sodium reduction goals for the U.S. food supply; however, the overall sodium reduction initiative will also include an essential education component.

The goals described have been developed to support reductions in excess sodium added to the food supply, keeping in mind the importance of sodium in food for microbial safety, stability, and other technical effects. Both target mean and upper bound sodium concentration target values apply to a broad variety of food categories comprising the majority of processed foods containing added sodium in the food supply. Sodium concentration goals and measurements will be used to measure and discuss industry-wide efforts at reformulation and sodium reduction, with the ultimate goal of promoting lower sodium intake at the population level in order to reduce elevated blood pressure, as well as the rates of heart disease and stroke.

Our goals should be applicable to all foods with respect to technical challenges and opportunities; however, we particularly encourage attention by food manufacturers whose products make up a significant proportion of national sales in one or more of our food categories, as well as restaurant chains that are national or regional in scope. This focus on market leaders reflects our desire to guide any reformulations that may be undertaken by

[1] In this document, 'goals' refers to the overall framework of target mean sodium concentrations and upper bound sodium concentrations for each of our categories. 'Category goals' refers to the combined target mean concentration and upper bound concentration for each category. When discussing either the target mean concentration or the upper bound concentration, the specific term or a shortened version ('target', 'upper bound') will be used.

industry, and the effort they represent, toward the products that will have the greatest impact on population sodium intake and public health. The guidance is intended to promote a level playing field among industry sectors and among similarly situated firms, and to complement and coordinate existing efforts by food manufacturers and restaurant/food service establishments[2].

Development of the draft guidance document requires assessing and making judgments on a wide range of technical and policy issues with input from many federal partners and external stakeholders. We sought input from external stakeholders through the establishment of dockets and a public meeting (see 76 FR 57050). Both were developed in collaboration with federal partners and were announced in the Federal Register. In an effort to ensure clarity and transparency, the process and methods for developing the draft guidance and the sodium reduction goals are captured in this document. Drafts of the sections in this document have served as crucial tools for detailed discussion with federal partners with regard to issues associated with sodium reduction goals.

Development of the Draft Guidance for Industry (Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods) involved three main steps:

(1) Development of Food Categories for Sodium Reduction
(2) Development of Sodium Content Baseline Levels
(3) Development of Sodium Reduction Goals (Target Mean Concentrations and Upper Bound Concentrations)

This document serves both as the primary background material for the draft guidance as well as a detailed record of the information and decisions that went into development of our draft voluntary sodium reduction goals.

2. Development of Food Categories for Sodium Reduction

2.1 Overview

To promote gradual and stepwise sodium reduction in the food supply, FDA sought a systematic and efficient approach that could be adopted by both government and the private sector, including but not limited to the food industry. A first step in this approach is the organization of foods into categories. Different types or groups of foods rely on sodium-containing ingredients for different purposes (e.g., microbiological control, texture, taste, etc.) and often for multiple purposes. A system of categories allows us to account for the varying amounts of sodium in foods and to be more effective in identifying and pursuing

[2] The term "Food Service Establishment" in the context of the draft guidance means: 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.(Table 2 of the draft guidance Appendix)

specific opportunities for sodium reduction. An uncategorized approach that does not account for variable patterns of sodium content in different foods would not provide a feasible or useful approach for reduction. The food supply can be categorized in many ways, depending on the intended purpose. This section describes the food categories developed to support our sodium reduction efforts. These categories are also intended to capture all foods commonly consumed in the U.S. according to the United States Department of Agriculture (USDA) Food and Nutrition Database for Dietary Studies (FNDDS), which is the food composition database used for What We Eat in America (WWEIA), the dietary intake component of the National Health and Nutrition Examination Survey (NHANES). These proposed categories would provide a framework for:

- Establishing baseline sodium values for sodium concentration
- Defining quantitative goals for changes in the sodium concentration of foods, expressed as reference mean and upper bound concentrations for each category, and
- Monitoring changes in the food supply over time with reference to our target means and upper bounds (discussed in section 4).

The full list of food categories with descriptions is provided in the Appendix to this document in two tables. The first table lists food categories for which we have developed draft voluntary sodium reduction goals (target mean and upper bound concentrations) (Table 2).The second table contains food categories for which we have not developed draft goals ("non-target" categories) (Table 3). Non-target categories either did not contain meaningful amounts of added sodium (i.e. foods with no sodium or with intrinsic sodium that is not added), or did not contribute 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.[3,4]

2.2 Criteria and Goals in Developing Food Categories

Development Criteria

To guide development of the food categories, we identified criteria which are listed here and described in detail below.

Optimal categories would:

- Have similar functional roles for sodium containing-ingredients
- Have similar sodium concentrations (within a range for the food category)
- Be compatible with existing industry and regulatory categories, and government databases
- Have similar technological potential for sodium for sodium reduction

[3] As measured by an analysis of the food sources of sodium intake using 2007-2008 WWEIA/NHANES data.
[4] As assessed by a sensitivity analysis to determine if food categories shifted, looking at percent consumer, per user mean, and per capita mean.

- Enable convergence of sodium concentrations in comparable packaged and restaurant foods

We recognize that it is not possible to ensure that all criteria are perfectly met due to a number of factors including limited information on food technology challenges and opportunities associated with sodium reduction, as well as the tension between limiting the number of categories to a manageable number and keeping every category populated by nearly identical foods.

The first two criteria reflect the recognition that reduction goals would be more achievable and meaningful if foods with similar ingredients and sodium content (within reason), based on both USDA nutrient data and label data, were grouped together. This approach served as a starting point for developing the proposed categories and allowed FDA to reuse some of the structures of other food category systems where they were consistent with these criteria. We also wanted to maintain compatibility among FDA categories and other nutrient composition and food intake databases, particularly FNDDS, in order to complement other government efforts for sodium reduction and facilitate future monitoring activities.

Another criterion for categorization was the potential for technological changes in formulation and production to accommodate sodium reduction. A review of the literature and data for different foods informed choices in some category assignments. Finally, to promote equitable treatment of industry sectors, FDA included both packaged and prepared (e.g., restaurants and other food establishments) foods in the same category system.

Category Development Goals

Our primary goal was that the criteria and methods used to establish food categories be clear, understandable, and equitable. In addition, we aimed for the food categories themselves to be well-defined, easy to understand and apply, and consistent with relevant regulatory food categories. We reviewed and compared alternative food grouping systems to help define categories succinctly and sought to input from other federal stakeholders on the categories once they were developed.[5]

2.3 Data Sources and Referenced Information

In developing the food categories, we wanted to learn from and take advantage of existing examples and research, while still developing a fully documented categorization structure explicitly designed to support federal-level sodium reduction efforts. We therefore reviewed three primary types of information:

- Existing food category systems;
- Scientific literature on food technology (related to sodium reduction); and

[5] We sought input from staff at multiple Federal agencies, including the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and USDA's Food Safety and Inspection Service (FSIS), Center for Nutrition Policy and Promotion (CNPP), and Agricultural Research Service (ARS).

- Technical comments from interested persons (on approaches to reducing sodium consumption)

Existing Food Category Systems

Extensive work has been done on organizing the diversity of the food supply for different purposes, and many categorization systems already exist. Our review included the following types of food category systems, which are described further below:

- Government Food Category Systems;
- Private-Sector Food Category Systems; and
- Sodium Reduction Initiative Category Systems.

Government Food Category Systems

Codex Alimentarius: General Standard for Food Additives (GSFA):

The Codex Alimentarius Commission, created by Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), developed the commodity-oriented "Codex General Standard for Food Additives" (GSFA, Codex STAN 192-1995) food category system. This food category system is used to set forth the conditions under which permitted food additives may be used in various foods. The system is hierarchical and encompasses all foods, including those in which no food additives are permitted. The system includes 16 main categories (and approximately 250 sub-categories), a description of the foods covered by each food category, and relevant food additive provisions. The GSFA food categories include a category for prepared foods which is defined as foods with mixtures of multiple components (e.g., meat, sauce, grain, cheese, vegetables). Prepared foods are also defined as requiring minimal preparation by the consumer (e.g., heating, thawing, rehydrating). There is not a category specific to restaurants, however. Additional detail on food categories is available at http://www.codexalimentarius.net/gsfaonline/foods/index.html.

U.S. FDA: Title 21, Code of Federal Regulations, § 170.3 (21 CFR 170.3):

21 CFR 170.3 describes 43 general food categories that group specific related foods together for the purpose of establishing tolerances or limitations for the use of direct human food ingredients. Restaurant foods are not a separate category, but are included in pertinent categories. For example, the category for egg products includes “liquid, frozen, or dried eggs, and egg dishes made therefrom, i.e., egg roll, egg foo young, egg salad, and frozen multicourse egg meals, but not fresh eggs”. Additional detail on these food categories for food additives is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=170.3.

U.S. FDA: Title 21, Code of Federal Regulations, § 133 (21 CFR 133):

21 CFR 133, subpart B describes requirements for specific standardized cheese and related products, breaking out cheese or related products into 94 sections. Additional details are

available at:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=133&showFR=1&subpartNode=21:2.0.1.1.22.2

U.S. FDA Total Diet Study (TDS):

TDS provides data from an analysis of nutrients, contaminants, and pesticides based on current national consumption surveys on 280 foods sampled from 4 regions, 4 times a year. Foods analyzed in TDS are categorized into 12 general categories (beverage, baby food, dairy product, egg, fruits and fruit juice, grain product, legume, meat/poultry/fish, mixture, oil/fat, sweet, vegetable). Thirteen restaurant foods from fast food or "carry out" are analyzed in TDS (i.e. chicken nuggets, fast-food; beef with vegetables in sauce, from Chinese carry out, etc.). These foods are categorized in the meat/poultry/fish, mixture, and vegetable (i.e. French fries, fast-food) categories. The foods collected in the TDS (referred to as the TDS food list) represent the major components of the diet of the U.S. population. The food list is based on results of national food consumption surveys and is updated from time to time to reflect changes in food consumption patterns. Additional detail on TDS and the TDS food list is available at:
http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184970.htm.

USDA Food and Nutrient Database for Dietary Studies (FNDDS) Food Groups:

FNDDS is a database of foods, their nutrient values, and weights for specified food portions. FNDDS is used to analyze data from the WWEIA survey. FNDDS presents a food grouping scheme with 9 major food groups (1) milk and milk products, (2) meat, poultry, fish, and mixtures thereof, (3) eggs, (4) legumes, nuts, and seeds, (5) grain products, (6) fruits, (7) vegetables, (8) fats, oils, and salad dressings, and (9) sugars, sweets, and beverages) developed by the USDA Food Survey Research Group (and 296 subgroupings). In FNDDS, the included restaurant foods are mainly fast-food items that are identified either by brand name or by food ingredients when the brand is not reported. Each food is categorized according to the groupings listed above. Additional detail on FNDDS food categories can be found in the FNDDS documentation. The most recent documentation is available at:
http://www.ars.usda.gov/SP2UserFiles/Place/12355000/pdf/fndds/fndds5_doc.pdf#title.

USDA National Nutrient Database for Standard Reference (SR):

SR is the foundation of most food and nutrition databases in the U.S. and is used in food policy, research and nutrition monitoring. SR categorizes foods into groups for ease of use. The names of 36 food groups are available at:
http://www.ars.usda.gov/Services/docs.htm?docid=24911. Restaurant food is one of these food groupings. Data on these foods can be found at:
https://www.ars.usda.gov/SP2UserFiles/Place/80400525/Data/SR27/reports/sr27fg36.pdf

Private-Sector Food Category Systems

Mintel:

Mintel is a global consumer, product, and market research company. The firm offers various proprietary databases and trend reports related to the food and drink industries. Mintel categorizes foods to track trends and provide both market intelligence and food product label information. Although Mintel tracks restaurant data as part of their Menu Insights offering, the food categories focus on packaged foods. Additional detail on Mintel's food categories (30 food-related) is available at: http://foodanddrink.mintel.com/about-categories.

Select Prominent Sodium Reduction Initiative Category Systems

New York City National Salt Reduction Initiative (NSRI):

On April 26, 2010, NSRI announced voluntary guidelines for salt reduction for 62 categories of packaged food and 25 categories of restaurant food, which are contributors to salt intake and that correspond to those generally recognized by consumers and industry. The goal was to reduce salt in packaged and prepared foods by 25 percent with a 20 percent reduction in sodium intake over 5 years (2009-2014). NSRI structured their categories so that foods in any given category can be produced and marketed with lower average salt levels than they contained at baseline. Industry participated in refining category definitions and some of their comments were reflected in the final release. Additional detail on food categories is available at: http://www.nyc.gov/html/doh/downloads/pdf/cardio/cardio-salt-nsri-packaged.pdf and http://www.nyc.gov/html/doh/downloads/pdf/cardio/cardio-salt-nsri-restaurant.pdf.

United Kingdom (UK) Food Standards Agency Salt Reduction Strategy:

Since 2003, the Food Standards Agency and the Department of Health in the UK have been working with the food industry and other stakeholders to reduce the amount of salt in a wide range of foods to achieve reductions in the salt intake of the population. Their goal was to reduce salt intake to 6g per person per day by 2010. In 2005, the Food Standards Agency developed proposals for targets for salt levels in 85 product categories, three of which were for "take-away" foods (i.e. take away, meat based; take away, fish based; take away, vegetable and potato based). These targets were the subject of a public consultation in August 2005 and were published in March 2006. In 2008, after a series of sector-specific meetings to review and discuss salt target categories and a public consultation on proposals to revise targets, new targets for 2012 for most foods were established and the number of categories was reduced from 85 to 80. Additional updates to categories were made in 2014 to 76 categories. Additional detail on food categories is available at https://www.food.gov.uk/northern-ireland/nutritionni/salt-ni/salt_targets.

Health Canada Sodium Reduction Initiative:

In September 2009, Health Canada (HC) and the Food Supply Sub-Committee of the Sodium Working Group (SWG) held meetings with the food industry and other interested stakeholders to gather information about reducing the amount of sodium in commercially prepared foods and to discuss the work being conducted by the SWG. In November and December 2009, HC's Food Directorate conducted meetings with food industry stakeholders to inform them of HC's approach to reducing sodium in foods, and to initiate discussion on

the proposed draft sodium reduction targets for the first set of food categories (Group I). Between February and March 2010, the Food Directorate sought written feedback from industry on the draft sodium reduction targets that were developed for Group I. This feedback was used to help revise the Group I targets and to develop targets for the second set of food categories (Group II). In June 2012, HC issued voluntary Guidance for the Food Industry on Reducing Sodium in Processed Foods. Benchmark sodium reduction levels for processed foods were set for further refined food categories over three phases, with final l goals for sales-weighted average level and maximum level sodium in 2016. HC asked that manufacturers apply the guidance "to all processed food products regardless of whether the foods are destined for consumers, other food manufacturers, for the foodservice and restaurant sectors." There are 15 final main food categories with 94 subcategories for which interim and 2016 guiding benchmark sodium reduction levels have been established. Maximum levels for sodium were also established for 2016. Additional detail on this process and original food categories is available at the following links: http://www.hc-sc.gc.ca/fn-an/nutrition/sodium/prev-cont-prec-eng.php, http://www.hc-sc.gc.ca/fn-an/consult/2011-sodium/append-a-eng.php, http://collections.europarchive.org/tna/20100927130941/http://food.gov.uk/healthiereating/salt/saltreduction. The final categories (and benchmark sodium reduction levels) can be found at: http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/legislation/guide-ld/2012-sodium-reduction-indust-eng.pdf.

Scientific Literature on Food Technology

We reviewed literature and available data on issues related to sodium reduction in dairy products, grain products, meat products, and canned foods. We concluded that available public literature and data did not provide enough information for a systematic assignment of targets and upper bounds across our food categories. However, our review informed our assessment of the potential for reduction for different food products based on areas including food safety, technical effects (e.g., texture, palatability, etc.), and processing and manufacturing. Separate memoranda, "**Salt Taste Preference and Sodium Alternatives**," "**Survey of Microbiological Issues in FDA-Regulated Products,**" and "**Survey of Microbiological Issues in Meat and Poultry Products**" provide a survey of these findings and have been reviewed by staff at other agencies, including FSIS. We acknowledge that, in some cases, sodium reduction that may technically be possible may be less feasible for industry to implement due to various factors. For example, replacing a sodium-based additive with a potassium based version of the same class of additive or for another substance entirely to achieve the desired technical function may not always be as cost effective.

Technical Comments from Interested Persons

On September 15, 2011, FDA and FSIS published a notice in the Federal Register (76 FR 57050) establishing a docket and seeking comments, data and information to inform future agency activities regarding the reduction of dietary intake of sodium. The notice requested comments on a variety of issues, including methods for sodium reduction targets as they related to food categories. On November 10, 2011, we held a public meeting on sodium reduction (76 FR 63305) where interested persons had additional opportunity to provide

thoughts on category development. FDA and FSIS received a number of substantive comments, but relatively little information pertinent to systematic organization of food categories or other food technology considerations.

2.4 General Process and Rationale

Food Group Systems and Survey Data

We began by reviewing a variety of food category systems to compare how foods were categorized. These systems, described in detail above, included:

- Codex GSFA,
- 21 CFR 170.3 FDA food categories for the use of food additives,21 CFR 133 FDA cheeses and related cheese products,
- FDA TDS,
- USDA SR and FNDDS, and
- NYC, Health Canada, and UK sodium reduction initiative food categories.

Based on our review of these food categorization structures, we concluded that too few food categories would not provide the detail needed to achieve sodium reduction, but that too many categories would not be practical. We adopted the general categories from the Codex GSFA food category system as a preliminary organizing structure that was intuitively clear and widely used. We developed 16 general categories with more specific underlying categories, which were condensed by grouping items with similar content, feature ingredients, and/or similar sodium concentration (expressed as milligrams per 100 grams (mg/100 g)). For example, most white breads have similar ingredients and sodium concentrations and can be considered as a single category for the purposes of this categorization strategy. Our initial category development process resulted in over 100 food categories.

Cheeses are a particularly complex part of the food supply. They are diverse, heavily standardized by federal regulation in the United States, and salt is a key component of manufacturing and identity. To develop dairy categories, we reviewed various classification systems, including those by the National Dairy Council, the US Dairy Export Council, and the American Cheese Society to understand industry perspectives on cheese categorization. The FDA product code cheese categories, which were designed based on common risk profiles of cheese, were also reviewed. Some of these cheeses are categorized based on the type of milk, which is not directly useful for our purposes; the categories are also fairly broad. The FDA standards of identity (SOI) for cheeses are listed in the Code of Federal Regulations (21 CFR part 133, subpart B), and specify the moisture content and other factors defined for different traditional and processed cheeses. The SOIs were also used as a reference point for our classification process. We considered the range of sodium concentrations in each cheese category, and adjusted the category structure to narrow these ranges to the extent possible without creating an undue number of categories. Subject matter experts in the Division of Plant and Dairy Food Safety at FDA reviewed the category

structure and provided additional input. Our cheese category structure was also compared to those of other sodium reduction initiatives (e.g. UK, HC, and NYC).

After developing a preliminary category structure, we integrated it with the FNDDS 4.1 food codes that describe specific foods consumed in the U.S. FNDDS 4.1 contains over 7,000 unique 8-digit USDA food codes.[6] These food codes were captured in our categories by creating a mapping file in which each food code was manually sorted into one of the food categories we had developed. This work enabled us to align our category structure with the most widely used and robust data set used to estimate food intake by U.S. consumers and will facilitate future estimates of sodium intake. Foods labeled with no, low, or reduced sodium in FNDDS were included and mapped to our food categories. Use of no, low, or reduced sodium foods in our baseline calculations is discussed in section 3.

Contribution to Sodium Intake

Once the initial category structure was complete, we reviewed the categories and split them into those for which we had developed draft sodium reduction goals ("target categories") and those that did not require goals ("non-target" categories). Non-target categories were comprised of foods that fell in the lower 10 percent of consumption when foods were binned in categories and ranked (described in more detail below). These foods also tended to be foods containing only naturally occurring sodium. We identified non-target foods by assessing the contribution of each category to total sodium intake, using FNDDS sodium content and NHANES 2007-2008 24-hour dietary recall (combined day 1 and day 2 dietary intake files; ages 2 and above[7]). The 2-day dietary weights provided by NHANES were used in the analysis.

To derive sodium intake from each food category consumed by each person, we aggregated the milligram values over all foods in each food category (including no/low/reduced sodium foods) that were reported to be consumed during his/her 24-hour recall. We next conducted the food sources analyses to calculate mean intake from each food category, and the percent that each food category contributed to the total dietary intake of sodium (from all foods and water). We then ranked all food categories in descending order by their percent contribution. This ranked list was then split: one group containing the top 90% of sodium contribution (155 food categories) and one containing the lower 10% of sodium contribution (80 categories). We reorganized both parts of the original list by grouping foods into general food categories for greater clarity. The end products of this process are a table of categories receiving targets and a table of non-target foods/categories, which are provided in the Appendix (see Tables 2 and 3)

[6] USDA, Agricultural Research Service, Food Surveys Research Group, 2009

[7] Ages 2 and above were initially used in analysis to be consistent with approaches used in various reports by USDA WWEIA, CDC, and Healthy People 2020and to capture consumers of foods not specially designed for infants. Although specially designed toddler foods are not a large contributor to sodium intake in the toddler population based on our analysis, we decided to add a toddler food category to the list of targeted categories to be more inclusive of all age groups.

Food Technology Considerations

As a second step in prioritization of categories, we also reviewed the tables (with input from FSIS staff) to determine whether any targeted categories had prohibitive technical constraints and should be excluded from goal assignment.[8] We considered whether any products in the non-target table had sufficient potential for sodium reduction to merit inclusion in the target table.[9] Finally, we considered whether there were technical reasons to condense or expand specific food categories. The qualitative assessment of food technology issues was based on published literature. Criteria used to address the overall potential for sodium reduction were the following:

- food safety,
- technical feasibility,
- food processing and form (e.g. frozen, liquid, dry mix, canned foods, etc.), and
- potential reformulation and manufacturing limitations for reduction.

The category table in the Appendix includes information on how food technology was considered qualitatively for each category by addressing the role of sodium for each category. We documented the non-target categories to make clear that all foods were considered and to provide reasoning for non-target status. Additional details on the development of targets can be found in section 5.

Food Combinations and Commercially Prepared Foods

Restaurant and other commercially-prepared foods represent a major portion of the American diet, and restaurant foods make a significant contribution to sodium intake. The 2010 IOM Report indicates that foods consumed away from home can have higher sodium density than foods purchased and prepared at home. In our view, it was important to consider commercially prepared foods when formulating categories. Our initial approach was to develop a "mixed products" category within the packaged foods categories, which would encompass various food items (e.g. pasta, pizza, sandwiches, salads, meat and poultry entrees), and which was designed to include restaurant menu items. However, this approach produced heterogeneous and poorly defined categories not conducive for developing targets, since there was so much variation in the kinds of foods within a category. We ultimately chose to use publicly available menus to identify common menu items consumed frequently from leading quick-service and casual dining restaurants to develop restaurant-specific categories (and then baseline sodium content values), using brand-specific menu nutrition information as our primary source of sodium values, which is further described in the section 3**.**

[8] For example, fluid milk contains meaningful quantities of sodium and is consumed in substantial quantities, but the sodium is intrinsic rather than added and so is not an appropriate target for reduction.

[9] A limited number of foods below the cutoff were reintroduced due to their high sodium content; these included aged Mexican cheese, goat cheese, cottage cheese, olives, cooked cereals, sauerkraut, fruit/vegetable dips, and "other" grain based snacks, crackers, and salad dressings. Further modifications during development resulted in removal or regrouping of some of these foods.

We reviewed comprehensive lists of the leading restaurant chains from various outlets to identify major restaurant chains. These included QSR Magazine, NY Jobsource, Mintel Menu Insights, and Technomic data, each described below. We sought to capture menu items from the nation's top restaurant chains, which represent the majority of restaurant foods consumed in the U.S. Because data from Technomic on the "Top 100 U.S. Chain Restaurants" was consistent with the other sources mentioned above and also provided corresponding 2010 total restaurant sales, we opted to use these data as a way to roughly weight restaurant data for establishing baseline sodium values and subsequent targets and upper bounds (described in section 5). Further discussion of baseline sodium value calculation for restaurants can be found in the section 3. We used restaurant menus for the top 100 U.S. chain restaurants reported by Technomic in 2010,[10] as well as data from Mintel Menu Insights on the frequency of product sales, to identify the most commonly consumed restaurant foods in the U.S. The top 100 U.S. chain restaurants represent about one-third of fast-casual and traditional quick-service restaurants sales in 2010.[11]

We obtained nutrition data, including sodium concentrations, primarily from publicly available restaurant nutrition information. We accessed the databases and websites listed below to obtain data on top restaurants, most frequent menu items, nutrition and sales information, and to gain general insight into the restaurant industry. The Technomic top 100 U.S. chain restaurant list had the most comprehensive restaurant list; it captured 96 percent of the QSR top 50 list; 92 percent of the Mintel list, and 88 percent of the NY Jobsource list.

- **QSRMagazine.com** – A major fast food industry media outlet that covers quick-service and fast casual restaurant news and trends. They produce a top 50 quick service restaurant list.
- **NYJobsource.com** – A job listing site that also has news stories and 'top' lists of restaurant by sales (in US dollars). (Since updates to this date could not be referenced, the list was used as a comparison to other more reliable lists.)
- **Mintel Menu Insights** – A Mintel database that provides information on menu trends, market insights, and actual menus from the restaurants under Mintel's surveillance. Trends tracked include top menu item cuisine type, top menu item dishes, average menu item price per restaurant, among others. Limited information on fast food restaurant market share is also provided. We consulted Mintel Menu Insights for data on menu items and top restaurant chains based on number of outlets as well as to get an idea of market share and insight on different restaurant segments.
- **Restaurant Websites** – Nutrition data, which was confirmed to be current, was obtained for the top 100 U.S. restaurant chains, from corresponding company websites when available. Nutrition information from casual dining restaurants proved to be particularly limited.
- **Technomic.com** – Technomic is a consulting and research firm serving the food industry. We used their publicly available data on the top 100 U.S. restaurant chains

[10] http://www.technomic.com/Resources/Industry_Facts/dynTop_100.php
[11] Estimate based on total sales from top 100 US quick service restaurants and a 2010 National Restaurant Association Industry Sales Forecast.

with 2010 U.S. sales numbers.

- **Other Nutrition Websites** – We considered other public nutrition websites as possible sources for obtaining additional data on sodium for specific restaurant foods that were unavailable elsewhere. Data from these websites, however, are not validated, so we did not rely on this information.

In collaboration with federal partners (the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH),and FDA), the Nutrient Data Laboratory of USDA-ARS runs the National Food and Nutrient Analysis Program (NFNAP) to improve nutrient values in the National Nutrient Databank System. One program goal is to institute a monitoring program for key (high-priority) foods, including some restaurant foods, and critical nutrients, including sodium. As of 2009, NFNAP had sampled and analyzed approximately 1,400 foods, some of which were restaurant foods. Thus, additional data may be of use in future baseline and target development as updated information becomes available. Additionally, as the menu labeling provisions of the Patient Protection and Affordable Care Act of 2010 are implemented, nutrition information may become more broadly and readily available.

After considering various organizational schemes for our food categories that involved complex or mixed dishes, we concluded that there was substantial overlap between the categories that emerged from our analysis of restaurant foods and the base categories developed for packaged foods. Thus, the food categories presented in the appendix are intended to encompass both packaged and restaurant foods. In practice, some categories would apply primarily to foods from food service establishments, some to packaged foods, and some to both.

Category Refinement Based on Public Comment

With an evolving food supply and new information gained from research, public discussion, and monitoring of foods, we expect that modifications will continue to be made over time.2.5 Targeted Food Categories Based on the considerations and data discussed above, we developed the following target categories, which will be monitored for changes in sodium over time:

- Cheeses (13 categories)
- Fats, Oils, and Dressings (4 categories)
- Fruits, Vegetables, and Legumes (14 categories, including fried, battered, canned and pickled vegetables)
- Nuts and Seeds (2 categories)
- Soups (6 categories)
- Sauces, Gravies, Dips, Condiments, and Seasonings (15 categories)
- Cereals (5 categories)
- Bakery Products (25 categories)
- Meats and Meat Products (26 categories)
- Fish and Other Seafood (4 categories)
- Snacks (9 categories)

- Sandwiches (10 categories)
- Mixed Ingredient Dishes (10 categories)
- Salads (5 categories, including grain, vegetable, green, and meat salads)
- Other Combination Foods (7 categories, including pizza, tacos, burritos, and enchiladas)
- Baby/Toddler Foods[12] (3 categories)

In Table 2 in the Appendix, for categories where the same food is often sold to the consumer in more than one form (ex: dry mix mashed potatoes and ready-to-eat/heat mashed potatoes) or storage method (frozen or shelf stable), the table provides the category baseline values for both forms, with the distinction of a/b after the number.
In an initial analysis looking at food consumption by infants and toddlers (ages 0-2 years), we found that foods commonly consumed by adults are major contributors to sodium intake for the toddler population as well. While most infant foods are low in sodium, a subset of toddler foods does contain relatively high sodium concentrations. We captured this limited set of toddler foods in our target categories.

2.6 Data Limitations and Assumptions

Of necessity, many calculations and judgments made in developing the categories relied on assumptions and incomplete information. Where possible, we sought to obtain sufficient information to assure that the result was reasonably representative. In many cases, precise data were not available or available data was of unknown accuracy. When assumptions, extrapolations, or proxy values were necessary, we have identified them and explained our rationale. Given the fundamental challenges of organizing the extraordinarily large, complex, and dynamic U.S. food supply, our primary goal was to develop a structure that was reasonably comprehensive, representative, and sufficient to support the development of a fair and equitable sodium reduction effort.

U.S. Consumption Data

When sodium food sources analyses were conducted to determine the highest ranked contributors that collectively contribute 90% of sodium intake, we assumed that WWEIA/NHANES, 2007-2008, data were representative of intake at that time. Although restaurant foods are limited in FNDDS, we also assumed these to be representative of intake. We conducted subgroup analysis by race, ethnicity, and age to also determine whether foods contributing to intake were different by subgroup.

U.S. Sodium Content

We worked with the best data available to us to determine sodium content for food categories, namely USDA FNDDS, the USDA Nutrient Database for Standard Reference (SR), and consumer package label data. Although the majority of FNDDS and SR data are

[12] Products specifically identified for toddlers

analytical (ranging between 60-75 percent depending on the SR release[13]), some foods in the databases from previous years need to be updated. In addition, foods in the databases may not capture the full range of sodium values that could be found in various food products. Likewise, consumer package label data may include sodium content information based on SR and FNDDS values alone, rather than listing manufacturer analytical values, and therefore, these data may not be fully representative of sodium in the marketplace. Furthermore, analysis of food products has indicated that label values are typically higher than chemical analysis values.

Technical Feasibility of Sodium Reduction

Because data on the potential for sodium reduction in different food categories, especially relating to food safety, were not readily available from industry, we conducted a survey of the public scientific literature. We concluded that the available public literature and data did not provide enough information for a systematic assignment of targets and upper bounds across our food categories. However, this data and information, which informed our assumptions about the available tools and potential for innovation in food technology and microbiology, is summarized as supportive information in the memoranda "**Salt Taste Preference and Sodium Alternatives**," "**Survey of Microbiological Issues in FDA-Regulated Products,"** and **"Survey of Microbiological Issues in Meat and Poultry Products**." As additional data and information become available to us through public comment, we will be able to refine goals (targets and upper bounds) and more accurately monitor the sodium levels in the food supply.

Foods from Food Service Establishments

After considering various approaches to categorizing foods from food service establishments, we concluded that these foods could be addressed in the same format as packaged foods. Some foods from food service establishments can be more sodium dense than packaged foods, but overlap with packaged food categories in regard to food ingredients and similar technological potential for sodium reduction made the use of the same categorization scheme viable. Sections 3 and 5 provide additional detail on this approach.

3. Development of Sodium Content Baseline Levels

3.1 Overview

This section describes FDA's proposed process for assigning baseline sodium concentrations (baseline sodium) to the food categories we developed in order to assist us in assigning sodium reduction goals and measuring future progress. It also describes the sources of data used to determine our mean baseline sodium concentration values. Multiple data sources and

[13] Holden, Joanne, USDA Monitors Levels of Added Sodium in Processed and Prepared Foods, Presentation at the 36th National Nutrient Databank Conference, Empowering Consumers through Advances in Food Composition, March 25-28, 2012, Houston, TX, Available at www.nutrientdataconf.org/pastconf/NDBC36/2-4_Holden_NNDC2012.pdf. [Accessed on Dec 9, 2012]

methods were used in the analyses. We recognize that no currently available data sources and methods are simultaneously comprehensive, accurate, and current.

Effective sodium reduction efforts focused on the food supply require granular information about how the food supply is changing over time. This information allows measurement of progress and informed adjustment as needed over time. We chose 2010 as our initial baseline year because relevant data were available for this time period. We reviewed and evaluated currently available food composition datasets (both public and private) useful for calculating nationally representative baseline values for total sodium content (all sodium containing ingredients) in the food supply.

The baseline sodium concentration values were calculated from both packaged and restaurant sources in a way that reflects the most popular products and most commonly consumed foods in the U.S. These calculations excluded products labeled as no-sodium-added, low-sodium, and reduced-sodium. .[14] To justify the exclusion of these products from the calculations, FDA analyzed baseline sodium concentration values which included these no-sodium-added, low-sodium, and reduced-sodium products. Several of the food categories did not contain no-sodium-added, low-sodium, or reduced-sodium products; however, these categories had low sales volumes and did not impact the sales-weighted mean sodium concentrations (see below). As such, it was felt that these products could be excluded from the calculations for baseline.

3.2 Sodium Content in Food Categories

As described in section 2, we used sodium concentrations as one criterion for grouping foods into categories. During this process, we reviewed sodium values from various sources. The data sources we considered are described in more detail in a later section of this memorandum and include the following:

- United States Department of Agriculture (USDA) Nutrient Database for Standard Reference (SR),
- USDA Food and Nutrient Database for Dietary Studies (FNDDS),
- FDA Total Diet Study (TDS),
- Gladson Nutrition Database (Gladson),
- Mintel Global New Products Database (Mintel),
- Restaurant company nutrition websites; and
- Manufacturer and other websites

[14] These products are excluded as a practical matter because they do not sell in high volumes and rarely if ever appear in the top 80% of sales for a given category. In some cases, they may also not be representative of the broader category in which they would naturally appear (e.g., certain standardized low-sodium cheeses, which are permitted ingredients not allowed in other cheeses).

3.3 Selection of Data Sources

No single source provided an ideal combination of comprehensiveness, accuracy, and timeliness. TDS values are derived from direct chemical analysis and are available on an annual basis, with the most recent available analyzed sodium data from 2011[15]. However, by design TDS is intended to provide a comprehensive survey of the food supply, rather than product-specific sodium information for a large array of products over time. Although values in the National Nutrient Databank System (SR and FNDDS) may date back a decade or more, many sodium values in these data sets are being actively updated as part of the National Food and Nutrient Analysis Program (NFNAP). This effort involves frequent surveys and substantial direct chemical analysis of individual foods. Thus, each individual updated value is more accurate and reliable than comparable label data. Ultimately, we concluded that on a broad scale, sodium values from label data (Gladson, Mintel) and from restaurant nutrition information would provide a more comprehensive picture of the full array of products offered in a particular category at any point in time[16], with some cost to accuracy. Use of label data also means that sodium concentrations in the food supply are assessed by relying on representations of sodium content made by each manufacturer or vendor. We considered this consistent with the goals of promoting sodium reduction and reformulation. Label data are available for the majority of packaged foods offered for sale and comparable data are available from many of the restaurant menus and websites for the top 100 chain restaurants. Restaurant chains that currently provide limited data may provide more data in the near future, in light of recent menu labeling requirements derived from the 2010 Patient Protection and Affordable Care Act.

Based on the considerations discussed above, we chose to use label data for packaged foods and publicly available restaurant nutrition information for restaurant foods as the primary reference sources for calculating baseline sodium concentrations. In addition to this primary measure, we expect to track measures of sodium concentration based on other data sets, most notably USDA nutrient data from the National Nutrient Databank System that is being actively updated at this time with a focus on key sodium-containing foods in both the packaged and restaurant sectors, using direct analysis of sodium content. We anticipate close review of the new USDA data to see any trends in the primary label-based dataset can be replicated. Multiple measures of the same underlying system (the U.S. food supply) should allow us to more readily and confidently identify trends in sodium content.

3.4 Measurement of Baseline Sodium Concentrations

We propose calculating and monitoring sodium values on a concentration basis (milligrams (mg) per 100 grams (g) of food) rather than a per-serving basis. Our review of other sodium reduction initiatives suggested that this measure had the fewest drawbacks in terms of clarity,

[15] http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm184293.htm (Individual nutrients available annually; latest analysis completed for 2008; data summaries available in 5 year increments, i.e. 2011-2015).

[16] We did not filter Gladson and Mintel data by entry date, though this information is available. Updates to these databases are completed based on market research concerning product updates as well as requests from individual users, rather than systematic re-examination of all label records.

equitable treatment of products within a category, and promotion of healthier taste preferences.[17] We wanted to avoid the additional complexity of variable serving sizes. We also concluded that concentration-based goals would more effectively promote taste adaptation because flavor perception is more directly related to concentrations than to absolute quantity of sodium per eating occasion. Our rationale for this proposal is discussed in more detail in section 4.

3.5 Methods for Weighting Baseline Data

While developing sodium concentration baselines for the proposed food categories, we considered sales-weighted and non-weighted approaches, and ultimately selected a sales-weighted approach. A non-weighted approach results in an average sodium concentration baseline to which all products in a category contribute equally, regardless of amount sold relative to other products in the category. A sales-weighted approach provides an average sodium concentration for each category that takes into account the sales volume of each food product compared to other products in the category. Each food product is assigned a weight based on sales units and the weights determine the relative impact of each product's sodium concentration on the category average. Therefore, products purchased in greater volume had more weight when calculating the baseline sodium concentration for a category. A weighted mean measurement which is influenced most strongly by the most popular products in a category is more useful and relevant in understanding the relationship between changes in the category and potential effects on population sodium intake.

Example: A hypothetical food category has only two products. Product 1 from Company A has 200mg sodium/100g food. Product 2 from Company B has 600mg sodium/100g food. National sales data indicate that four packages of Product 2 are sold for every equally sized package of Product 1. The unweighted mean sodium concentration for the category is 400 mg/100 g ((200 + 600)/2). The weighted mean sodium concentration, however, is 520 mg/100 g (((200*1) + (600*4))/5). The weighted mean sodium concentration more accurately reflects the average consumer's experience of the food supply, which is strongly biased towards consumption of Product 2.

Sales data were available in both the form of dollars and units. The appropriate weighting mechanism used to calculate mean sodium was based on sales units rather than dollars. For packaged foods, we used direct sales data from Nielsen[18], expressed as what we termed, "total equivalized units" (TEU; sales units all adjusted to an equivalent product mass prior to calculation, as mass is more relevant to consumption-weighting than price-based measures).

Since data of this kind were not available for restaurant foods, total annual restaurant chain sales were adopted as a proxy weighting measure for foods from different chains in a single food category. Using this strategy, the average sodium concentration of two similar products

[17] One drawback is the need for conversion from serving size data, which would be unintuitive for consumers and may not be possible where serving weight is not available.

[18] Nielsen examines business trends by product (including private-labels), category or market using retailer scanner-based sales and gathers information from tens of thousands of retail outlets.

is more heavily influenced by the sodium concentration of the product from the larger chain. The underlying assumption is that given any two similar products from different chains, the larger chain's product is likely to be more frequently consumed. However, products within a single chain cannot be weighted relative to each other.

Figure 1 illustrates the methods used to develop baselines for packaged and restaurant foods, which are described in more detail in the paragraphs below. Weighted values for packaged and restaurant foods were kept separate as shown in Appendix 1 of the Draft Guidance.

Figure 1

Baseline Sodium Concentration Calculations for Packaged and Restaurant Foods
Similar Methods, Different Data Sources

	Aggregate Data ⇨	**Assign Product Weights** ⇨	**Associate Sodium Data[19]** ⇨	**Calculate Weighted Sodium** ⇨	**Calculate Baseline Sodium[20]**
Packaged Foods	2010 Nielsen UPC list	2010 Nielsen sales data	• Gladson • Mintel • Public data	Multiply sodium by product sales for each product	Calculate average of weighted sodium values per category
Restaurant Foods	Menu items from Technomic Top 100 chains	2010 total sales, per chain	Publicly available menu nutrition data	Multiply sodium by total chain sales for each product	Calculate average of weighted sodium values per category

Methods for Weighting Package Nutrition Label Data

We combined all available sales and nutrition (product label) data for each product in a category in order to assign appropriate weighting and calculate baseline average sodium concentrations on a category basis. All 2010 Nielsen (Scantrack) sales data were merged by UPC with Gladson and Mintel packaged food label data through import into SAS9.3 (SAS Institute Inc., Cary, NC). We then created a Microsoft Access database containing all resulting merged data in tables by Nielsen-specified department (Dry Grocery, Frozen Foods, Deli, Dairy, and Refrigerated Meats)[21]. As noted above, we used TEUs as the weighting

[19] Sodium content data was expressed "as purchased."
[20] Expressed as milligrams of sodium per 100 grams of food (concentration).
[21] Data sources available to us did not include 2010 Nielsen market sales data for refrigerated meats. Instead, we used 2006 Nielsen market sales data to which we had access. We anticipate that development of final guidance will

variable. This allowed us to compare the relative total mass of each food in the category that was sold, which is a good proxy for how frequently each food is eaten relative to others in the category. The final database includes all sales data for each department, the summed TEUs per product, and any available corresponding product label data.

Nielsen market sales data for packaged products that met category criteria as specified in section 2 were aggregated by food category. This required both Access queries and manual filtering of data. Once filtered to the appropriate set of products that pertain to a given food category, we exported the data into an Excel spreadsheet specific to that food category. We then sorted this spreadsheet in descending order by TEUs. While Nielsen sales data included a very extensive list of products in each category, significant limitations prevented these lists from being truly comprehensive. In addition to the limitations in regards to the levels of national representativeness of the datasets themselves (see Data Sources section), other constraints included:

1. Encrypted private label data: While there were sales figures for private label (store brand) products, the description of the product and the UPC were both coded/hidden. This prevented us from both categorizing the products correctly and merging sodium data with the sales data.

2. Missing sodium data for products in the Nielsen data set: While the label databases contained sodium data on the vast majority of high-selling products, available label data tended to be sparse for products with relatively fewer sales. In some categories, only a few sodium values were missing from the final aggregated data. However, other categories that happened to contain a large variety of low-selling product options were missing a substantial number of values. We addressed this issue through a combination of market share-based filtering and manual data collection.

Our goal in establishing proposed baseline values was to use a clear, reproducible process that resulted in a representative measure of sodium concentrations in the food supply. Given resource and time constraints, we chose to calculate baselines using the products with available nutrient and sales data that made up the vast majority of sales in a category. To implement this choice, we selected a cutoff value of 80%[22] of total sales volume in each category. This filtering process generates a sodium concentration value which provides a reasonable proxy for sodium content in a given food category, given practical limitations on data availability. In particular, the bottom 20% of sales is typically comprised of a very large number of low-selling products, often without label data available from any of our data

include use of matched-year Nielsen market sales data for calculation of revised baselines and measurement of progress.

[22]This "80% filter" is distinct from the "90% filter" discussed in Section 2. The "90% filter" is based on the contribution to total sodium intake from a preliminary set of food categories. The "90% filter" was used to rapidly eliminate unprocessed and/or rarely consumed classes of foods in an objective way by retaining only food categories that represented the top 90% of sodium sources. The "80% filter" is based on relative sales of each product within a final food category, and doesn't involve the product's sodium content.

sources.[23] We concluded that an attempt to develop a baseline measure including these products would require substantial additional effort on a regular basis without a corresponding benefit in terms of identifying and tracking meaningful changes in a food category over time. To determine baselines for each category, the following steps were taken:

- filter list of products to eliminate private label products given absence of linked sales data,
- rank the remaining products by relative TEU sales,
- divide the product list into a smaller group making up the top 80%[24] of sales and a larger group making up the bottom 20% of sales, and finally
- calculate a weighted average[25] of the sodium content of all products making up the top 80%

Methods for Weighting Restaurant Nutrition Label Data

Expanded discussion relating to the various data sources and categorization approaches that we considered can be found in Section 2. For restaurant foods, a 2010 Technomic list of the top 100 U.S. chains (quick-service and fast casual) was used as a guide for selection; these data were used in the creation of food categories as well as baseline sodium concentrations. We obtained sodium values for each restaurant food or menu item from publicly available parent company menu nutrition data. We aggregated these data into Excel spreadsheets by food category. While some product data were available in the mg/100g format, other product sodium data were only presented on a per serving basis. We converted these restaurant product mg/serving values to mg/100g, to be consistent with the way packaged product label data were converted to a per 100 g basis. Since sales by product were not available for the restaurant foods, the corresponding restaurant chain's 2010 total reported sales were used as

[23] In many product categories, approximately 10% or less of the total number of products made up 80% of the TEU sales. For the total product lists, 50% or more of the products did not have available nutrient data. However, for the products in the top 80%, both the percentages (typically 0-10%) and the absolute numbers of products without nutrient data were sharply lower. Thus, the sales-filtered lists were more both complete and more amenable to manual data collection.

[24] Manual data collection has been used to supplement purchased label data for those categories where purchased label data were incomplete, balancing completeness against ready availability of public information. However, not every category contains a complete set of sodium data for every product in the top 80% of sales. For these instances, we noted the current percent of sales for which sodium data is available. Planned internal sensitivity analysis will be used to quantify the potential significance of these data gaps when determining the weighted average concentration for the relevant categories.

[25] The Gladson database, which was the major source of label data, does not provide all serving sizes in grams, but does provide sodium content per serving, total package size in grams, and the number of servings in each total package. From this available data, we calculated a mg/100g sodium concentration for each product. The TEU weights were then applied to each product's concentration value, and the weighted baseline mean concentration was calculated for each category. If two different sizes of the same product were in the top 80%, they were both counted. Use of TEUs converts all products to the same units. Adding different package sizes of the same product together is not a concern when calculating a weighted average based on sales volume.

a proxy weighting system to represent the relative consumption of products from different chains in a category. These sales figures were also obtained from the 2010 Technomic list.

Example: Only two chains (A and B) sell a particular menu item that is the sole member of a hypothetical food category. Chain A has total sales of $400 million in 2010. Chain B has total sales of $100 million in 2010. Chain A's menu item has 200mg sodium/100g food. Chain B's menu item has 600mg sodium/100g food. The unweighted mean for the category is 400 mg/100 g ((200 + 600)/2). The weighted mean would be 280 mg/100 g (((200*4)+(600*1))/5). This same relative weighting (four to one in favor of Chain A) of sodium concentrations would be applied whenever both Chain A and Chain B both offered a menu item in a particular category, because it is derived from total chain sales.

We considered alternative weighting measures such as the number of outlets per chain; however, we found inconsistencies between various data sources when investigating these other measures and concluded that total sales were an acceptable proxy for relative consumption given the available options. Using Technomic restaurant chain sales figures as a proxy for unit-sales values enabled us to calculate baselines in a way that was conceptually similar across both packaged and restaurant foods.[26] Both packaged and restaurant food sodium values were compared to those from the USDA's FNDDS (5.0) as well as to other available analytical data, including FDA TDS data, to provide a sense of how our label-based data compared to other widely used data sources. In general, values derived from these different data sources were comparable.

3.6 Baseline Sodium Intake Estimates from WWEIA/NHANES

The dietary component of the CDC's National Health and Nutrition Examination Survey (NHANES), conducted in partnership with USDA, is called What We Eat in America (WWEIA). It provides essential information about the dietary intake by Americans, and the WWEIA data is used to estimate sodium intake. The most widely used and recognized estimate of sodium intake is derived from the joint use of WWEIA data combined with sodium food composition data from the USDA with the USDA Food and Nutrition Database for Dietary Studies (FNDDS). The FNDDS is specifically designed and updated every two years by USDA for use with WWEIA intake data, as it provides the complementary nutrient composition data for all foods reported by participants of the WWEIA survey.

Each sample person's sodium (mg/d) intake was determined by summing the sodium intake derived from the amounts of each food and water reported during his/her 24-hr dietary recall interview. The mean and standard error of the distribution of sodium intake by age-gender subgroups of the population were then estimated using SUDAAN 11.0.1 (Research Triangle

[26] We recognize the limitations of using chain sales as a proxy for relative consumption weighting within a category; certain menu items of a chain may be relatively more popular and commonly consumed than others and our approach cannot take such facts into account. Unfortunately, available data comparable to Nielsen sales values is limited both in scope and quality. We considered purchasing these data but ultimately concluded that it would not be an effective use of resources.

Institute, Research Triangle, NC). Mean sodium intake was determined using the dietary intake data from the first of two 24-hour recall interviews, thus, with the use of dietary sampling weights, estimates are representative of intake by the U.S. population on any one day during 2009-2010, which was the period of time when the most recently available WWEIA/NHANES was conducted. The mean population sodium intake in 2009-2010 by persons aged 2 years and older was 3,463 mg/day (See Table 3 in the Appendix). This is reasonably comparable to the somewhat higher 2010 baseline intake produced by our model (3,590 mg/d), given that the model assumes 100% of all foods consumed are either packaged or from restaurants.

This estimated value is familiar to and readily reproducible by external stakeholders. However, because this intake estimate is not derived from our calculated baseline concentration data, it is not directly comparable to modeled intake that was determined to inform our expectations about the potential impact of the proposed target concentrations. Nevertheless, it provides important context for our category-derived intake model (see Section 5) and allows us to relate our internal measures to historical and current consensus measures of sodium intake.

3.7 Discussion

In this document, we describe a process for characterizing the sodium concentrations of foods in the food categories proposed in Section 2. The results of this process (baseline sodium concentrations) are not intended to provide a definitively accurate measure of the entire universe of products in each category, as available data regarding both sodium content and sales have significant limitations. Instead, the baseline concentrations do provide a reasonably representative measure of sodium in each category of foods.

We have also estimated mean sodium intake using WWEIA/NHANES, 2009-2010 data to provide population mean intake values best associated with our baseline year of 2010. Modeled intake was estimated to make a tentative, approximate assessment of the impact of our model using target concentrations (see Section 5), which uses the same consumption data and methodology as described for assessing WWEIA/NHANES, 2009-2010 intake. However, the modeled intake is not intended to represent a definitive measure of sodium intake in the U.S. population.

None of the proposed baseline concentrations described in this document are intended to supplant standard and widely accepted measures of the sodium content of foods. These estimates were developed for specific purposes to support this particular sodium reduction effort. The value of baseline sodium concentrations as described in this document is twofold. First, they integrate a wide variety of product-specific nutrition data to provide a reasonable representation of the concentration of sodium present in the food supply at a granular level. Second, they allow us to track patterns of change in that representation of sodium content related to properties of individual food products, as well as the relative popularity of each product over time. Our parallel establishment of both baseline intake estimates and food

category baseline concentrations emphasizes that both are essential tools used to help understand relationships between the sodium content of our proposed food categories and the outcome of actual public health interest: population sodium intake.

4. Sodium Reduction Goal Framework Development

4.1 Overview

This section is concerned with the third step of quantitative goal assignment. In particular, this section discusses potential frameworks for sodium reduction goals and their advantages and disadvantages. A hybrid framework involving both target mean sodium concentrations and upper bound sodium concentrations is explored. For members of the food industry who choose to take action based on FDA's voluntary draft guidance, the hybrid framework has the advantage of providing flexibility to industry for reducing sodium in their portfolios, combined with clear reference values for all products in a portfolio.

Role of Sodium Reduction Goals

The function of quantitative sodium reduction goals is to define clear, specific, measures for change in the food supply. By publishing sodium reduction targets for food categories that contribute meaningful quantities of added sodium to U.S. intake, we will be able to:

- Influence expectations for the magnitude of change;
- Promote reformulation and innovation while maintaining awareness of overall nutrient quality (e.g., avoid compensatory increases in fats or sugars);
- Promote dialogue and sharing of data on obstacles to change in particular food categories; and
- Measure and report any changes in the food supply over time with respect to specific reference sodium concentrations on a food category basis.

General Requirements

Quality metrics for the sodium reduction goals make sure to:

- Make every effort to account for food safety considerations;
- Address both packaged and restaurant foods in order to avoid noticeable differences in taste as well as inequitable economic impacts across industry sectors;
- Extend broadly across the food supply to processed, packaged, and prepared foods that add salt and other sodium-containing ingredients;
- Encourage gradual change to facilitate acceptance by all stakeholders, including consumers and the food industry;
- Be sufficiently achievable to encourage voluntary engagement by the food industry;
- Be ambitious enough to create momentum for change in the food supply;
- Reflect the market success of product introductions and reformulations within a category;

- Allow stakeholders the opportunity to reconstruct our measures and assess performance over time, using either public or purchasable data;
- Allow for updates/improvements/alterations during reassessment periods if metric is found to be strong; and
- Avoid discouraging voluntary adoption by members of the food industry who have already independently begun to reformulate their portfolios.

General Limitations

There are a number of constraints associated with development of quantitative sodium reduction goals, derived both from data limitations as well as advancement of food technology. These include the following:

(1) ***Quality of data-*** Sodium reduction goals are dependent on available baseline data used to formulate points of departure, and assessment of changes in the food supply with reference to these goals can only be as accurate and current as the underlying data (see Section 3 for more details). For example, assessment based on label data is constrained by the fact that labels reflect compliance values and actual sodium content may be up to 120% of the label value[27]. Additionally, some values from the United States Department of Agriculture (USDA) Food and Nutrient Database for Dietary Studies (FNDDS) or other databases are derived by calculation from recipes which may not accurately correspond to the actual sodium value of a food product, or reflect analytical values that are not updated on a yearly basis.[28]

(2) ***Timeliness -*** Many data sets that could be used for developing goals and monitoring the food supply have a lag of up to two years and thus may not reflect the latest levels of nutrients in foods. It is important to recognize that different data sets have different degrees of lag and that timeliness may not align with precision, comprehensiveness, or other desired attributes. Thus, monitoring of goals is subject to the limitations of available datasets.

(3) ***Compatibility of data*** - Quantitative sodium reduction goals should be expressed in a format compatible with existing data on food composition and intake, primarily the datasets managed by USDA/ARS (Standard Reference and FNDDS). These ARS data sets constitute a widely used standard for assessing food composition and dietary intake in the U.S. and provide a valuable resource for parallel and comparative analysis of changes in food composition and intake over time. One issue to address is that some label nutrient values from commercial datasets being used to assess category baselines are provided in the "as packaged" form (e.g. sodium listed on the package), while almost all FNDDS nutrient data values are in the "as prepared" (e.g. sodium in the final recipe preparation, as consumed) format. Ideally, quantitative

[27]http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm063113.htm

[28] This situation is being addressed by USDA's Agricultural Research Service (ARS) with a focus on key food items, but remains an important consideration for efforts to set baselines and assess progress of the industry as a whole.

goals would be expressed in the “as prepared” format, but some underlying nutrient data may provide the mg/100g value in the “as packaged” format. For food product types such as dry sauce mixes and dry baking mixes, this format may be more appropriate to provide to industry. When monitoring change over time and making comparisons to USDA/ARS nutrient data, conversion to “as prepared” will be required. Recipe calculations would be used to estimate the “as prepared” sodium concentrations for products initially labeled with dry-base nutrient information.

(4) ***Technological feasibility*** - Technological and economic limitations place significant constraints on feasible reduction goals. In specific cases, reduction goals may be shaped by the food technologies available. Food safety in particular should not be compromised. Spoilage and shelf life issues, as well as reformulation frequency, may impose significant economic burdens on the food industry. Some issues may be mitigated by providing sufficient time for new product development and reformulation. Nevertheless, it is important to recognize that technological constraints do exist and that we have limited information about their impact in any specific food category.

4.2 Options for Expression of Quantitative Goals

The actual value used as the quantitative goal for each category could represent a value desired for:

(1) the total sodium in the package,
(2) the total sodium per serving, or
(3) the concentration of sodium in the product (e.g., mg/100g).

Total sodium levels are easily understandable, but are difficult to apply across different product sizes, or would require separate targets for each product size (e.g., a block versus pre-sliced cheddar cheese). The second option, total sodium per serving, helps to resolve the issues of various sizes of food products within a category, since serving sizes are generally standardized based on the Reference Amounts Customarily Consumed (RACC). However, it introduces another variable (RACC) which may not remain stable over time, creating more complexity and less reliability in tracking over time. For example, the serving size of a 15 ounce frozen meal could change from 2 servings per container to 2.5 servings per container. If no changes to the physical product are made, the milligrams of sodium per serving would be reduced because the serving size has changed while the sodium content has not necessarily been modified and thus could inaccurately appear as reduction in sodium content during potential product labels reviews. It is difficult to predict the extent to which this would occur, but the possibility deserves consideration.

The third option, expression of quantitative goals as sodium concentrations (e.g., mg/100g), allows products of variable size to receive an equal reduction target. This measure would provide the most confidence that labeling changes reflected formulation changes. The issues of food safety and product functionality can also be taken into account for products within the same food category that may differ in size. Furthermore, concentration relates most

directly to the sensory properties of a food product, a key variable in the effort to encourage gradual reductions in sodium taste preference. One disadvantage of this approach is that target levels will not correspond directly to the sodium per serving size as shown on a product label. However, the advantages of consistency across different products and direct relationship to technical functions and flavor recommend this option as the most useful of the three considered. The remainder of this memorandum will assume the use of concentration-based quantitative goals.

4.3 Goal Framework Options and Implementation

Quantitative sodium concentration goals can be expressed in a variety of ways. We identified four options:

- set an upper bound concentration;
- apply a fixed percent reduction;
- calculate an unweighted target mean concentration; and
- calculate a sales-weighted target mean concentration.

Below we describe each of these options in more detail, including their potential to affect the distribution of product sodium concentrations in a food category.

The discussion below represents an attempt to understand and compare the potential benefits and problems associated with each goal framework. Our sodium reduction draft guidance is a voluntary; we encourage the food industry to pursue the concentration goals. For the purposes of this assessment, however, we may assume that all food industry members choose to adopt a particular goal framework. This assumption simplifies our analysis and clarifies potential negative incentives a particular firm might experience. Nothing in this document should be construed to imply that any goal framework is required.

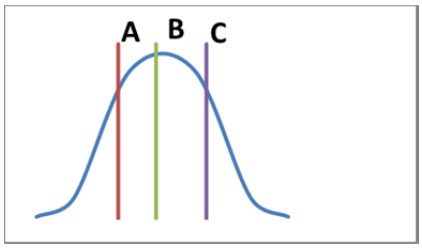
Goal Framework Option #1: Set an Upper Bound Concentration

In this approach, we would promote reformulation efforts with the aim that all products within a category fall below an upper bound sodium concentration. A firm voluntarily adopting the goals of FDA's voluntary guidance would not reformulate products already below the upper bound. Assessment of the food supply with respect to this reference concentration would be simple; any individual product is either below or above the upper bound concentration. One key advantage of this approach is its clarity and applicability to individual products.

The upper bound concentration could be set based on a combination of factors, including the current distribution of product sodium concentrations in the category and our preferred new distribution. An upper bound concentration can be thought of as more or less challenging for those food industry members who choose to adopt this goal framework based on how much of the sodium concentration distribution curve for a category is to the right of the upper bound concentration; increasingly lower upper bound concentration place more of the current

products in a category above the cutoff. Figure 1 illustrates three increasingly higher potential upper bound concentrations (A, B, and C) placed on a distribution curve of current sodium product concentrations in a hypothetical food category. The area under the frequency curve on the right of each upper bound shows the increasing proportion of the market that is affected as the upper bound value moves lower (from C to A). We cannot predict whether any industry members who voluntarily adopted this goal framework would decrease the sodium content of their products only to the upper bound concentration provided or lower. It is also possible that some firms might interpret an upper bound as encouragement to increase sodium up to this level. Therefore, we cannot know whether any voluntary changes by food industry members would actually affect the final distribution of sodium concentrations in a given category. [29]

Figure 1: Potential placement for upper bound concentrations



Example: The upper bound concentration in a category is 600 mg/100 g. Firm X has a product with a sodium concentration of 670 mg/100 g and chooses to reduces it to 550 mg/100 g. Firm Y has a product with 670 mg/100 g and chooses to reduce it only to 600 mg/100 g. Firm Z has a product with 520 mg/100 g and chooses to *increase* it to 600 mg/100 g.

While predicting the effects of this approach is challenging, we can assume that the potential impact on the distribution of product concentrations as well as mean sodium concentration in the category is related to the restrictiveness of the upper bound. A lower upper bound (Figure 1, max A) may motivate food industry members who choose to adopt this goal framework to reduce their sodium concentrations substantially while a higher upper bound (Figure 1, max C) may not encourage sodium reduction for most products. Because products below the upper bound concentration will not be explicitly encouraged to reformulate under this approach, the upper bound's effect on the mean sodium concentration in the category depends strongly on the distribution of sodium concentrations among products that are included in the category. An upper bound concentration would have little effect in a category where most products are clustered around the center of the curve.

[29] The hypothetical sodium concentration curves (both current and desired) are portrayed as normal distributions; this is a simplification adopted for these examples. We would expect both the shape and the mean of the sodium concentration curves to change in response to goals.

Example: The soup category[30] has a calculated 2010 baseline concentration of 450 mg of sodium per 100 grams. The short-term upper bound is 550 mg per 100 grams. Approximately 15% of the soups on the market are above this upper bound, based on 2010 data, so firms who manufacture soups above the upper bound who choose to adopt this goal framework would voluntarily reduce the sodium concentrations in those soups to be consistent with the upper bound concentration.

Goal Framework Option #2: Percent Reduction

This measure involves a fixed percentage reduction that would be applied equally to all individual products within a category. The percentage would be chosen based on broad judgments about technological feasibility. It is possible to assess the status of any individual product over time with respect to the goal, as long as the product's starting sodium concentration is known. This approach is conceptually simple and transparent, and the predicted impact on sodium in the category may be readily calculated. However, the rigidity of this approach may discourage voluntary adoption of the goal framework. It assumes similar potential for reduction in all products in a food category regardless of starting sodium concentration.[31] It might be possible to compensate for this by introducing cutoff sodium concentrations below which no reduction would be recommended (a "gated" percent reduction), or by creating a sliding percentage reduction requested relative to current sodium concentration, but this would introduce substantial additional complexity without a clear public health benefit.

Example: Consider a short-term reduction target of 20% applied to the soup category: For Soup A with a baseline concentration of 450 mg/100g in 2010, the short-term reduction target would be 360 mg/100g if the manufacturer chose to adopt this goal framework. For Soup B with a baseline concentration of 500 mg/100g, the short-term reduction target would be 400 mg/100g if the manufacturer chose to adopt this goal framework

Goal Framework Option #3: Unweighted Target Mean Concentration

This approach would use a target representing a desired sodium concentration associated with a food category that is measured by comparison to an unweighted mean of sodium concentrations in that category. In other words, the target represents a desired result when the simple average of all measured products is taken. This target could be used as a point of reference when assessing all products within a category, or the portfolio of products from any individual manufacturer in that category, but not for any individual product. The target mean concentration for a category would be developed on the basis of judgments about technical feasibility, cost, product safety, and the range of sodium concentrations of commercially available products in the category.

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[30] All numbers in this and subsequent examples are for illustrative purposes only.

[31] A fixed percentage reduction of a smaller absolute sodium concentration does have some benefit for products that are already relatively lower in sodium in a category; the absolute reduction would be lower than for higher-sodium products. However, the benefit did not appear sufficient to compensate for the disincentives associated with this approach.

We recognize each firm is best suited to understand the relative potential for reduction across their own product lines. The less rigid nature of this goal framework could increase the number of industry members who would voluntarily choose to adopt it. One disadvantage of this goal framework is that an unweighted mean may not accurately reflect actual changes in consumer consumption patterns, but instead diversification of product portfolios to include more low-volume low-sodium products. For this reason, estimates of impact of sodium intake based on unweighted targets would be of limited use and relevance.

Goal Framework Option #4: Sales-weighted Mean Concentration

This measure expresses a desired mean sodium concentration for an entire food category, including all firms and weighted by the relative sales of individual products. In other words, each product's contribution to the mean is greater or smaller depending on its total sales compared to other products in the category. The weighted mean, although not explicitly mentioning brand names or companies, does implicitly characterize the top producers within each category when a substantial proportion of the market within a food category is commonly known to be driven by only a few companies[32] (see section 3 for more details). Like the unweighted mean, it is a reference value for groups of food products (e.g., an entire category or a company portfolio within a category), not individual products. It can be used as a reference when assessing sodium concentrations for all products in an entire food category sector or if a firm voluntarily chooses to assess their own portfolio of products in a particular food category. The targets themselves would be expressed identically in an unweighted and sales-weighted approach; only the calculations used to assess the state of sodium concentrations in the selected population of food products would differ.

As with the unweighted mean, the sales-weighted mean approach does not address the formulation of any particular product in a category portfolio. For this reason, food industry members may be more likely to choose to voluntarily adopt this goal framework relative to other approaches.

Because each product is weighted by sales, products that are not frequently purchased would be given little weight in measuring the performance of a selected population of food products. It is important to note that this approach to assessment of sodium concentrations will sometimes appear to report smaller changes than the unweighted mean. However, this approach is both more representative of the actual food supply encountered by consumers and may encourage more sustainable results by focusing attention on widely purchased products.

Example: Consider a 2010 baseline concentration of 450 mg/100g of sodium for the soup category, with a short-term reduction target of 400 mg/100g. When the soup category is assessed on the short-term target date, the sales-weighted mean of all reported sodium concentrations for the category is 420 mg/100g. The corresponding unweighted mean is 380

[32] A weighted approach takes into account the proportional contribution of each component, in this case, the sales volume of each food product in a category. Each food product is assigned a weight based on sales volume and the weights determine the relative importance of each product's sodium concentration on the category mean.

mg/100g. The weighted mean happens to be higher than the unweighted mean because the soup products that lowered their sodium concentrations were not the highest selling soups. As described above, the weighted mean is a more relevant estimate of the actual reduction of sodium from a public health perspective because it emphasizes frequently purchased products.

The sales-weighted mean approach can also account for shifting consumption patterns, including those that may be caused by reformulation.

Example: In 2010, Product A (500 mg/100 g) has 30% of the market and Product B (500 mg/100 g) has 70% of the market in a particular category. By 2014, Product A has reduced sodium to 350 mg/100 g but now only has a market share of 15%. Product B has reduced sodium to 450 mg/100 g and now has a market share of 85%. Product A's reformulation is greater but counts for less than it did in 2010 because of falling market share.

Other approaches and variations are also possible. However, we consider that the four options discussed above are representative of the range of feasible options.

4.4 Approach Taken by the FDA

Based on the discussion above, one approach that may be useful for promoting sodium reduction goals would be a hybrid goal framework. Each food category would be assigned both a sales-weighted mean concentration target and an upper bound concentration. The mean target concentrations will communicate a quantitative reference point for assessment of broad change within food categories, while upper bound concentrations will provide a clear reference point for assessing individual products.

This approach has a number of advantages:

- Directly communicates information about desired changes in sodium concentrations in the category.
- Ties the target reduction goal to actual sales of successful products, and does not encourage simple diversification of a portfolio or sector with low-volume niche products among food industry members that choose to adopt this goal framework.
- Offers a conceptually simple approach and can be used as a reference point for individual products.

One significant limitation of this approach includes reliance on proprietary data for internal calculations; the aggregation of data in reporting may be perceived as less than fully transparent. Despite this limitation, we consider that this hybrid goal framework offers a useful approach for defining points of reference with respect to sodium concentrations in the food supply. The framework and the methods embedded in it are capable of assessing detailed trends in the food supply over time that are directly relevant to population intake of sodium, establish milestones for evaluating and communicating these changes over time, and include measures applicable to both individual and aggregated products.

5. Development of Sodium Reduction Goals

5.1 Overview

FDA's draft quantitative goals, which are target mean concentrations for food categories, and upper bound concentrations for individual products, are provided in Appendix 1 of the Draft Guidance. In this section we describe the following:

- the objectives and considerations that influenced draft goal development,
- the timing of the goals,
- our methodology for developing draft goals,
- a general introduction to technical considerations, and
- the predicted impact on sodium intake for both short-term and long-term target mean concentrations in a hypothetical scenario for which all members of the food industry chose to voluntarily adopt these sodium reduction goals.

5.2 Objectives and Considerations

We developed draft goals with a number of specific objectives and considerations in mind.

- First, these goals should be capable of producing meaningful (i.e., sufficient to confer a public health benefit) reductions in sodium intake, if, in a hypothetical scenario, all members of the food industry chose to voluntarily adopt them.

- Second, we sought to ensure that the hypothetical reductions implied by our goals were technologically feasible. In particular, we reviewed the short-term target mean concentrations to assess whether they were achievable using currently available and well-understood food technologies, without raising food safety concerns. We also reviewed comments submitted in response to a notice, "Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information," (76 FR 57050, Sept. 15, 2011) that we published in the Federal Register and from a public meeting on sodium reduction in November 2011 sponsored by FDA, the Centers for Disease Control and Prevention, and the United States Department of Agriculture's Food Safety and Inspection Service, Agricultural Research Service, and Center for Nutrition Policy and Promotion (76 FR 26371, Oct. 12, 2011).

- Third, our sodium reduction goals were intended to be compatible with incremental changes that were near or within the threshold of consumer acceptance and would not necessitate extensive use of novel supplementary flavor technologies, should any member of the food industry choose to voluntarily adopt these goals. As discussed in the 2010 Institutes of Medicine report on sodium reduction strategies, our expectation is that, if broad sodium reduction in the food supply were to occur gradually over time, population salt preference would also gradually shift. Our long-term goals

reflect our understanding of both these adjustments as well as the potential for advances in food technology over a ten-year span.

- Fourth, we developed a timeline that encompasses sufficient time for reformulation and marketplace adjustments for any member of the food industry who voluntarily chooses to adopt our sodium reduction goals.

- Finally, we hope to receive extensive technical comments on the specific considerations particular to individual food categories in response to draft guidance on voluntary sodium reduction goals. These comments may provide us with additional data and information that are not readily available in the published scientific literature. We expect to revise and recalibrate voluntary sodium reduction goals on a category-by-category basis with the help of whatever technical information we receive.

5.3 Timing

As discussed in section 3, we have calibrated our reduction goals to a 2010 baseline. In anticipation of publication of a final guidance document in 2016, we would suggest a short-term milestone for 2018, and long-term goals for 2026. This timeframe would also recognize the substantial voluntary efforts in food reformulation and sodium reduction by many members of the food industry that are currently ongoing. We acknowledge that some products already have concentrations within range of the draft goals, and we expect that many product portfolios would exhibit noticeably lower sodium concentrations as a result of voluntary reduction efforts relative to the 2010 baseline at the time of publication of the draft guidance.

5.4 Goal Assignment Methodology

As discussed in Section 4, we explored the use of both sales-weighted mean concentrations and upper bound concentrations to express the short-term and long-term goals. The methodology that we suggest for each of these measures is discussed below.

Methodology: Sales-Weighted Mean Concentration Targets

We began our development of long-term sales-weighted mean concentration targets by conducting a preliminary modeling exercise to determine whether a 40% reduction of the sodium intake from targeted food categories might have the potential impact of lowering the population sodium intake to a level that is less than 2,300 mg/d. This preliminary modeling was solely to understand the impact of targets derived by reducing the sales-weighted mean sodium concentration of all targeted food categories by 40%, if, in a hypothetical scenario, all members of the food industry chose to voluntarily adopt such targets. Accordingly, we applied a flat 40% reduction to the sodium intake from all foods in the targeted food categories that were reported in USDA's What We Eat In America (WWEIA/NHANES,

2007-2008).[33] This preliminary modeling exercise showed that the mean sodium intake by all aged 2+ years in 2007-2008 of about 3,460 mg/d could indeed be lowered to a level that makes substantial reductions (approximately 2,300 mg/d) as a result of the default 40% reduction.

This initial modeling step was intended only as a range-finding exercise. We were interested in understanding how a particular reduction percentage would relate to predicted sodium intake. This relationship informed our starting point for target assignment, although long-term target assignment was additionally informed by food technology data when available. This modeling exercise suggested that 40% reduction would be an appropriate starting point when assigning a long-term reduction target for each category. Should all members of the food industry hypothetically choose to adopt such sodium concentration goals, it would produce a meaningful impact on sodium intake, and by extension, this reduction would provide a recognized public health benefit.

Thus, the default 40% percentage reduction was used as a starting point for each category to determine a recommended long-term sales-weighted mean concentration target. The following category-specific considerations were involved in adjusting initial targets to arrive at long-term mean concentration targets for each food category:

- Equity: similar reduction goals for food categories that are similar from the standpoint of food technology and manufacturing;
- Technical feasibility: identifying all possible opportunities for reduction based on the specific roles played by salt and other sodium-containing ingredients of foods in the category;
- Safety: absolute sodium concentrations that available data and information indicate are consistent with food safety, given known food technologies; and
- Regulatory requirements: certain sodium reduction technologies are not available to food industry members who wish to label their foods in accordance with particular standards of identity. This in turn influences the feasibility of reducing the sodium concentration of those foods.

Choosing to voluntarily pursue sodium reduction goals similar to these draft long-term targets will likely necessitate replacement of sodium-containing ingredients and may require the adoption of new technological innovations, for those foods where regulatory standards permit. However, based on our review of the available literature, we conclude that it should be possible to achieve these reductions over time without compromising safety, functionality, or taste.

Similar considerations informed our assignment of short-term mean targets. While the long-term targets were developed in the context of a 30-40% reduction of population sodium intake, we estimated that short-term targets might potentially result in a 15% intake

[33] At the time of this preliminary modeling exercise, WWEIA/NHANES, 2007-2008, provided the most recent dietary intake data available.

reduction. We do not expect that voluntarily choosing to adopt the short-term sales-weighted mean concentration targets would necessitate major technical innovations or raise significant concerns with respect to safety, functionality, or taste. In general, these short-term sales-weighted mean concentration targets are within the range of commercially available products we observed in development of 2010 baseline concentrations.

Methodology: Upper Bound Concentrations

We originally considered two potential approaches for development of upper bound concentrations. First, we considered an approach where upper bound concentrations were derived only from percentiles of the 2010 sodium concentration distributions (e.g., the long-term upper bound for a category would be the 60th percentile of the 2010 distribution). However, we found that some food categories currently have either a compressed range of baseline concentration data or right-skewed distributions. In these cases, upper bound concentrations based on specified distribution percentiles result in recommendations that would be insufficient to promote reformulation even if members of the food industry voluntarily chose to adopt these recommendations.

We then considered a second approach where upper bound concentrations were derived as a percentage of the target mean concentration (e.g., 130% of the target mean concentration). However, we found that some category baseline distributions exhibited a relatively very wide range of concentrations. In this scenario, a target percentage approach might make members of the food industry more reluctant to choose to adopt these upper bound concentrations because of the extent of voluntary reformulation implied.

We ultimately adopted a hybrid approach that incorporated both baseline percentiles and target percentages. By allowing target mean concentrations to influence upper bounds, we incorporate implicit information about the potential for sodium reduction in a particular category. By allowing current concentration distributions to influence upper bounds, we incorporate implicit information about the number of products that would be reformulated if a member of the food industry chose to voluntarily adopt the upper bound concentration.

For each food category's frequency distribution of baseline sodium concentrations on a per-product basis, we calculated the 60th and 80th percentile values of the distribution of sodium concentrations. The 60th and 80th baseline percentiles were used in calculating the long-term and short-term upper bound concentrations, respectively.[34] We also calculated the concentrations equivalent to 130% of the long-term and short-term target mean concentrations.[35] To derive the long-term upper bound concentration, we calculated the average of the 60th percentile and 130% of the long-term target mean concentration. To derive the short-term upper bound concentration, we calculated the average of the 80th percentile and 130% of the short-term target mean concentration. We used this method of

[34] The 60th and 80th percentiles were selected because they were viewed as reasonable goals, and not because of any specific mathematical property of a given percentile.

[35] We selected 130% of the target mean to strike a balance between the status quo and prohibitively difficult reduction, and not because of any specific mathematical property of this percentage.

combining two variables from the baseline datasets (a percentile of the distribution and the desired target mean concentration) to assign upper bound concentration values for all food categories so that there was consistency of approach considering the variety of products available within categories.

The averaged values (the percentile and 130% of the target mean) represented starting points when determining upper bound concentration for each category. However, adjustments were made as needed on a category-by-category basis. For those categories that contained both packaged and restaurant products, two separate distribution curves were created. Where these curves were meaningfully[36] different, separate short-term upper bound concentrations were created to reflect the distinct starting points for these two industry sectors. However, long-term upper bound concentrations were set to be the same, to be compatible with long-term convergence of sodium levels between these sectors in the event that members of the food industry voluntarily chose to adopt these goals.

Each category's upper bound was reviewed with respect to issues of safety, taste, and technological feasibility, however, these factors were weighed in light of the fact that even the long-term upper bound concentrations were generally at or above the 2010 market-weighted mean sodium concentrations.

Technical Considerations

The three general technical factors that we considered in our target mean assignment process were:

- Microbiological stability (safety and spoilage),
- Flavor, and
- Functionality related to manufacturing or physical properties of the food (e.g., texture).

There are also costs associated with sodium reduction efforts. These costs may involve research and development, new ingredients, or processing (e.g., less tolerance for process deviations due to reduced margin of safety). We did not have adequate data to make detailed cost estimates at the food category level, and did not attempt to adjust goal assignments based on cost considerations. However, our focus on technical feasibility of our short-term goals (within the range of currently commercially available products) and the final goals'

[36] The averaged values (percentiles and 130%) represented starting points for each upper bound concentration. However, adjustments were made as needed on a category-by-category basis. For those categories that contained both packaged and restaurant products, two separate distribution curves were created. Where these curves were sufficiently different, to suggest different typical use levels between comparable packaged and restaurant foods, separate short-term upper bound concentrations were created to reflect the distinct starting points for these two industry sectors. However, long-term upper bound concentrations were set to be the same, to be compatible with long-term convergence of sodium levels between these sectors in the event that members of the food industry voluntarily chose to adopt these goals.

long time horizon are intended partly as mitigating factors that would reduce the economic burden for any food industry member who chose to voluntarily adopt our sodium reduction goals.[37]

With regard to safety and spoilage issues, we were able to gather significant, though very incomplete, data from the scientific literature. These data therefore represented a supplementary and not primary basis for our decision-making. A survey of the some of the available literature is discussed on a category basis in the memoranda **Survey of Microbiological Issues in FDA-Regulated Products** and **Survey of Microbiological Issues in Meat and Poultry Products**. We concluded that short-term target means would generally remain within the bounds of sodium concentrations that did not raise safety or spoilage concerns, based on both our literature review and the general availability of commercial products in the relevant concentration ranges. With respect to long-term targets, in some cases data were available to support the safety of the target concentration if other currently available technologies were used. In other cases, little data are available. We anticipate that both technical input from stakeholders as well as technological innovations will allow us to refine these targets in the future.

With respect to taste and consumer acceptance, little food-specific data are available. We made a general assumption based on our review of the literature as described in the memorandum **Salt Taste Preference and Sodium Alternatives** that a reduction of 15-20% of the sodium content of specific foods would often be possible without significantly impairing consumer acceptance, although in some cases adjustment of other flavoring ingredients might be necessary. The above memorandum also discusses many developing or recently available technologies and strategies used to emulate current flavor profiles while using less sodium. We hope more substantial reductions will be feasible over a decade timespan, both due to technological innovation and the potential impact of broad reductions in sodium content on consumer taste expectations.

Very limited data are currently available on the specific sodium concentrations required for key functional roles in food manufacturing, although in many cases we were able to identify the basic roles played by sodium-containing ingredients of foods in a particular food category. Much of the detailed information in this area is proprietary and was not available to inform target assignment.

In addition to these general technical factors, which were informed by scientific literature, we used other sources of information to judge the viability of our target assignments, including market data, the range of sodium concentrations in currently available commercial products,

[37] We conducted a limited cost-benefit analysis of the interim and long-term target mean concentrations. This analysis was based on a hypothetical scenario in which all members of the food industry voluntarily chose to adopt our sodium reduction goals. Considered costs included labeling, new ingredients, and reformulation. Benefits included both improvements in public health as well as direct medical cost savings. This analysis suggests there is a significant net benefit.

and targets set by other sodium reduction initiatives. Considerations specific to a few broad food types that represent major sources of added sodium in the diet are described below.

- **Dairy:** Salt is an important functional ingredient in many cheeses.[38] There is some literature available, which was considered in target assignment (see the memorandum **Survey of Microbiological Issues in FDA-Regulated Products** for further information). Subject matter experts within CFSAN were also consulted due to the complexities of product manufacture and technical effects that vary across the diverse array of cheeses available in the United States. We reviewed market data and FNDDS values to identify commercial ranges. In addition, the target mean concentrations set by Canada and the UK were considered because many of the cheese categories were found to be relatively similar.
- **Meat and Poultry:** The antimicrobial effect of salt contained in meat and poultry is complex and variable, depending on the product category. We focused on the use of salt in representative products such as frankfurters/hotdogs, corned beef, and sausages. Emphasis was placed on these products because they generally rely on salt for microbiological safety (See the memorandum on **Survey of Microbiological Issues in Meat and Poultry Products** for more information). Limited data regarding the impact of salt on microbiological product stability of other types of meat products are available. For example, although sodium is added to uncooked poultry for moisture retention, there is limited availability of data regarding its microbiological effects in this system. We considered the sodium concentrations of commercially available products as supplementary data with respect to safety and spoilage issues. We also consulted with subject matter experts at the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) regarding our overall approach and appropriate sodium concentrations. FSIS noted that some products have standards of identity[39] that includes specific levels of salt that must be contained in the product. For example, the standard for cured meat products packed in brine requires that a 10 percent salt concentration must be maintained in the brine solution. These standards must be considered in developing reduction strategies for meat and poultry products.
- **Grain Products:** Sodium plays a variety of roles in breads, cereals, and other baked goods. Salt controls fermentation and affects the texture of yeast-raised breads. It also helps to control the growth of molds and *Bacillus* bacterial species, thus extending the shelf life of baked goods. However, in many sweet baked products, sugar, rather than salt, is the primary means of controlling water activity. Therefore, techniques used for preservation of many bakery products are not primarily dependent on salt content (see the memorandum **Survey of Microbiological Issues in FDA-Regulated Products** for further information).
- **Mixed Dishes:** The heterogeneity of mixed dishes in each of these categories accounts for the wide range of their sodium content distributions. The assigned

[38] Standards of identity for almost all named cheeses preclude the use of mineral salt substitutes and many other technologies at this time. These standards can be found in Title 21 of the Code of Federal Regulations, Part 133.
[39] Found in Title 9 of the Code of Federal Regulations, Part 319 (for meat) and Part 381 (for poultry).

targets were not as ambitious as for other general categories due to the limited availability of data and research about the mixed dishes categories. Target assignment was informed by reductions for similar mixed dish food categories that were deemed feasible by other sodium initiatives and potential reductions of constituent ingredients (i.e. sauce on pizza).

Case Studies

In this section, we discuss the application of the methods discussed above as an illustration of our approach used to assign targets for a few food categories. In general, we began by surveying available data on both concentrations and technical functions of sodium contained in these foods. We then attempted to define a literature-derived lower bound for the sodium concentrations of foods in the category, based on safety or other technical considerations. This lower bound was compared to the range of currently available products as an additional proxy for technical feasibility. Literature-based lower bounds often involved sodium replacement. Although we did not systematically examine product labels, our assessment of a limited sample suggested that many commercial products also use other ingredients as partial replacements or substitutes for various technical effects of sodium.

Ham and Canadian Bacon

The key role of salt (the primary source of sodium in ham and Canadian bacon) is as a preservative, and a secondary role is as a flavor ingredient. The first step in our assignment process was to review available data on sodium content.

- Market and label data
  - 13 values
  - Range: 776-1376 mg/100 g
  - Weighted[40] mean: 1065 mg/100 g

We identified three studies that assessed the microbiological stability of reduced-sodium hams. These studies suggested that sodium concentrations could be safely reduced to as low as 600 mg/100 g if other ingredients (such as lactates and diacetates) were introduced. We assigned a short-term target of 900 mg/100 g (15% reduction) and a long-term target of 800 mg/100 g (25% reduction). The short-term and long-term targets are both within the range of currently available products.

Cooked Sausages

The key role of salt (the primary source of sodium in cooked sausages) is as a preservative, and its use as a flavor ingredient is a secondary role. The first step in our assignment process was to review available data on sodium content.

- Market and label data

[40] For the draft guidance, meat baseline concentrations are based on 2006 Nielsen data, as described in Section 3.

- 254 products
- Range: 312-1529 mg/100 g
- Weighted[41] mean: 936 mg/100 g

We identified two studies that assessed the microbiological stability of reduced-sodium sausages. These studies suggested that sodium could be safely reduced to as low as 560 mg/100 g if calcium ascorbate was added. Market and label data, however, suggest that even lower concentrations may be commercially feasible. We assigned a short-term target of 850 mg/100 g (9% reduction) and a long-term target of 750 mg/100 g (20% reduction). Both targets are within the range of currently available products. Based on the available data, the long-term target still provides an ample margin of safety, even when products are formulated using only currently available food technologies.

White Bread

Salt (the primary source of sodium in white breads) plays multiple roles, including:

- taste and flavor,
- control of yeast fermentation,
- strengthening of dough gluten,
- improving texture, and
- controlling water activity of the final product (which limits microbial growth).

The absolute level of sodium in white breads is not particularly high; their prominence as a source of sodium intake results from relatively high consumption rates relative to other foods.

The first step in our assignment process was to review available data on sodium content.

- Market and label data
  - 55 products
  - Range: 297-688 mg/100 g
  - Weighted mean: 523 g/100 g
- Public restaurant data
  - 53 menu items
  - Range: 238-801 mg/100 g
  - Weighted mean: 519 mg/100 g

We identified and reviewed one study on spoilage of reduced sodium breads, four studies on consumer acceptability of reduced-sodium breads, and one study on the technical effects of sodium in breads. The spoilage study suggest that sodium concentrations as low as 353 mg/100 g do not increase growth of bread molds; other studies also make clear that many

[41] For the draft guidance, meat baseline concentrations are based on 2006 Nielsen data, as described in Section 3.

methods are widely available to inhibit microbial growth in bread. Consumer acceptance studies indicate that significant reductions from the current baseline can be achieved without detection by consumer acceptance tests; in one study, a 25% reduction was achieved in six weeks without changes in consumer acceptance. Other studies suggest that techniques such as uneven salt distribution within the bread increase sensory contrast and perceived saltiness at lower absolute sodium concentrations. Finally, the study of sodium's technical effects in breads did not identify significant effects on dough rheology, baking quality characteristics, or sensory attributes as a result of a 75% reduction in sodium content (from 480 mg/100 g to 120 mg/100 g).

We also considered specific commercial products. One major national brand of white bread contains 338 mg/100 g of sodium, which supports the conclusion that this level does not pose problems from spoilage, technical, or consumer acceptance perspectives. This suggests that current commercially available food technology is sufficient to formulate products with minimal sodium content that do not pose problems from a spoilage or technical perspective (though not necessarily from the standpoint of consumer acceptance).

We assigned a short-term target of 440 mg/100 g (approximately 15% reduction) and a long-term target of 300 mg/100 g (approximately 40% reduction). A separate target was not developed for restaurant white breads, given the similar range and weighted mean. Based on our survey of the scientific literature and commercially available products, we do not anticipate major obstacles from a spoilage, technical, or consumer acceptance perspective.

Grain Snacks - Puffed Corn[42]

Salt is the primary source of sodium in savory snacks and it contributes to overall flavor in varying degrees. It is also used as a vehicle to evenly distribute minor ingredients, flavors, and colors. In some extruded products, salt also helps develop puffy texture and color.

The first step in our assignment process was to review available data on sodium content.

- Market and label data
  - 23 products
  - Range: 496-1307 mg/100 g
  - Weighted mean: 1075 mg/100 g

We did not identify any spoilage or other sodium-specific technical concerns in our review of the literature. The primary constraint appears to be an acceptable flavor profile.
We assigned a short-term target of 880 mg/100 g (approximately 20% reduction) and a long-term target of 550 mg/100 g (approximately 50% reduction from the weighted mean). Our expectation is that long-term consumer acceptability could be maintained through the use of other flavor technologies. This would be particularly effective against a background of broad

[42] E.g., Cheetos, Cheez Doodles

sodium reductions in the overall food supply, which would promote adaptation of consumer tastes.

Acrylamide: A Non-microbiological Food Safety Consideration

Acrylamide is a substance commonly formed during food processing that is considered a potential carcinogen. There is significant research interest regarding the degree of risk posed by the presence of this substance in food, as well as strategies to limit or inhibit acrylamide formation. The FDA Draft Guidance "Guidance for Industry – Acrylamide in Foods"[43] describes a variety of food manufacturing practices that may reduce acrylamide formation. Some of these methods involve sodium-containing ingredients. The impact of these methods on the sodium content of most of the foods described in this guidance does not appear significant. However, one strategy described in the draft guidance for baked goods involves the presence of sodium at concentrations of approximately 2%, similar to the levels currently found in many commercial baked goods. Other strategies are available, and many baked goods are currently sold with significantly lower sodium concentrations. However, the potential for acrylamide formation and available mitigation strategies are additional factors that some food industry members may need to consider if voluntarily choosing to adopt sodium reduction goals for baked goods.

5.5 Estimated Impact

It is useful to understand whether our sodium reduction targets are consistent with reductions in sodium intake expected to positively influence public health, if, in a hypothetical scenario, all members of the food industry chose to voluntarily adopt these goals.[44] The preliminary modeling work referred to above showed that a flat 40% reduction of all targeted food categories' mean baseline sodium concentration level is consistent with a reduction in the population mean intake to a level that is less than 2,300 mg/d. We conducted more detailed modeling to predict the impact of our draft short-term and long-term targets on sodium intake by both the total U.S. population and subgroups of the total population. We have calculated modeled mean intake using the same methodology that was used to determine baseline intake in 2009-2010 as presented in section 3.

The dietary component of CDC's National Health and Nutrition Examination Survey (NHANES), called What We Eat in America (WWEIA), is conducted by the U.S. Department of Agriculture (USDA). WWEIA provides essential information about the dietary intake by Americans, and the WWEIA data is used to estimate sodium intake. The most widely used and recognized estimate of sodium intake is derived from the joint use of

[43]http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm374524.htm

[44] Universal voluntary adoption of our goals by the food industry is unrealistic. However, this scenario is helpful for understanding the theoretical potential of our overall approach, and it is also consistent with FDA's approach to cost-benefit analysis.

WWEIA dietary intake data combined with sodium food composition data from the USDA Food and Nutrition Database for Dietary Studies (FNDDS). The FNDDS is specifically designed for use with the WWEIA intake dataset, as it provides the complementary nutrient composition data for all foods reported by participants of the WWEIA survey.

To understand the potential impact of sodium reduction goals, we developed an intake model that was compatible with the structure of those goals. We constructed such a model by combining our internally developed sales-weighted label and restaurant menu food composition data (baseline sodium concentrations) with 2009-2010 WWEIA dietary intake data. By design, our proposed food categories are compatible with a FNDDS food grouping scheme that we developed in order to use the WWEIA dietary intake data to assess the modeled sodium intake that would be contributed from each targeted food category.[45] This model was used to calculate the 2010 modeled sodium intake value derived from our mean baseline sodium concentration values. Given that food label and restaurant menu data will be tracked to assess changes in the baseline sodium concentration values, the modeling would allow us to measure the impact of future progress, by assessing changes in future modeled sodium intake compared to the 2010 modeled sodium intake. We have also predicted the modeled sodium intake in 2016 and 2022, by replacing the mean baseline sodium concentrations with the short-term and long-term targeted mean concentrations, respectively, if, in a hypothetical scenario, all members of the food industry chose to voluntarily adopt these goals.

The rationale for modeling sodium intake values derived from the baseline sodium concentration data is to directly correlate the modeled intake in 2010 from the voluntary guidance food category baselines to predictive intake data. The 2010 modeled intake value could be a key analytical benchmark for use during future monitoring efforts, because it is based on the baseline sodium concentrations. For this approach, we applied our packaged and restaurant baseline sodium concentration (mg/100 g) data to the amount (g) of foods each participant reported that they consumed during their 24-hr dietary recall interview. Information collected in WWEIA/NHANES was used to determine the sources of consumed foods (i.e., where the foods were purchased or obtained) in order to align packaged and restaurant baseline means accordingly.

FNDDS 5.0 contains nutrient composition data for all foods reported to be consumed in the WWEIA/NHANES, 2009-2010, 24-hr dietary recall and dietary intake files. To model sodium intake from each targeted categories' mean baseline sodium concentrations, we migrated the sales-weighted mean sodium concentrations that were derived from label and restaurant menu data into a format compatible with the WWEIA dietary intake data, by first classifying all of the foods reported in the WWEIA (i.e., FNDDS food codes) into mutually exclusive food groups that represented each of the targeted food categories. While mapping all food categories to FNDDS 5.0 food codes, several considerations were made, as follows.

[45] We have data on other nutrients, including potassium, iodine, sugars, saturated fat, and calories. Parallel modeling of intake for these nutrients will allow us to determine whether any unintentional nutrition-related consequences of sodium reduction are occurring.

If some FNDDS food codes were to overlap with our category structure (e.g. "Cheese, not further specified" could potentially belong to more than one of our cheese food categories), we assigned proportions of the FNDDS food to the relevant food categories using proportional weights provided in the SR-link file of the FNDDS (which provides a "recipe" for survey foods by linking each FNDDS food code to "ingredient" food codes found in the Nutrient Database for Standard Reference). We retained the FNDDS 5.0 sodium concentration of food codes in non-target categories that were not assigned sodium reduction goals (e.g., game meat, milk, raw commodities[46], etc.). The mapping process resulted in a new sodium concentration data set, which contained our migrated baseline sodium data. The mapping also included the mean sodium concentration values that represented our short-term and long-term targets, and the short-term and long-term sodium concentration targets were then used to model predicted sodium intake in 2016 and 2022, respectively.

We then applied our mapping of the packaged and restaurant baseline, short-term and long-term sodium concentration (mg/100 g) data to the amount (g) of each food that each participant reported that they consumed during their 24-hr dietary recall interview. We applied this dataset to the WWEIA/NHANES, 2009-2010, dietary intake data using SAS9.3 and MATLAB2009b software. Each sample person's sodium (mg/d) intake was then determined by summing the sodium intake derived from the amounts of each food and water reported during his/her 24-hr dietary recall interview. The mean and standard error of the distribution of sodium intake by age-gender subgroups of the population were then determined using SUDAAN 11.0.1. Mean sodium intake was determined using 1-day dietary intake and the day-1 dietary sampling weights, thus estimates are representative of intake by the U.S. population on any one day during the predicted time period.[47] Usual intake[48] was also modeled as part of our portfolio of intake calculations, in order to estimate percentiles of the usual sodium intake distributions, and percentages of the population having sodium intakes <2,300 mg/d (data not shown).This analysis of modeled intake was based on sales-weighted mean baseline and target concentrations to predict the impact of the sodium reduction goals. While it would be possible to develop a model that incorporates the upper bound levels as well, we have concluded that this would not add significant predictive power. Table 1 below presents modeled intake predictions used to assess the potential impact of both short-term and long-term targets on sodium intake. The 2010, 2018, and 2024 intakes are modeled using mean baseline, short-term and long-term sodium concentrations, respectively.

Table 1. Mean modeled sodium intake from food and water with 2010 sales-weighted mean baseline sodium concentrations replaced by short-term and long-term sodium concentration targets in 2018 and 2026, respectively

[46] "Enhanced" or brine-injected meat and poultry were not considered raw commodities and are included in our reduction goals.

[47] The analytic sample included participants of all ages who had a complete, reliable, 24-hour recall on the first of two days, and because the amount of breast milk fed to breast-fed infants and toddlers was not quantified, their 24-hour recall was judged incomplete, and they were therefore excluded from the analytic sample.

[48] Using the National Cancer Institute method: http://riskfactor.cancer.gov/diet/usualintakes/method.html

Age (y) and Gender	N	Modeled 2010 Intake (mg/d)	Modeled 2018 Intake (mg/d)	Modeled 2026 Intake (mg/d)
All ages	9618	3525	3136	2384
Male	4777	4079	3632	2764
Female	4841	2998	2665	2023
0-1	576	1222	1110	905
Male	276	1171	1069	883
Female	300	1270	1149	926
2-3	477	2227	1988	1539
Male	256	2235	1980	1521
Female	221	2218	1998	141559
4-8	958	2748	2448	1868
Male	499	2788	2482	1894
Female	459	2702	2410	1838
9-13	887	3216	2848	2148
Male	438	3305	2930	
Female	449	3138	2775	2087
9-13	887	3169	2799	2094
Male	438	3357	2966	2217
Female	449	3002	2631	1986
14-18	802	3809	3367	2515
Male	428	4534	4020	3018
Female	374	3130	2756	2043
19+	5918	3723	3315	2524
Male	2880	4400	3920	2989
Female	3	3091	2750	2091

Source: What We Eat in America, NHANES, 2009-2010, individuals of all ages (excluding breast-fed children), day 1 dietary intake data, weighted.

Several limitations have to be taken into account when developing a model to predict the impact that the target levels could hypothetically have on sodium intake. The primary issue is

that the current National Health and Nutrition Examination Survey dietary intake data are used to calculate the short-term and long-term mean intakes. Because only current consumption data are available, we assume that consumption patterns remain the same as future sodium concentration data change. The other main limitation of our model is that we cannot predict how individual members of the food industry will actually respond to the sodium reduction goals, because there is no obligation for any firm to follow any part of the guidance and any adoption of these goals is entirely voluntary. Some or all food industry members may choose to disregard sodium reduction entirely. For those who voluntarily choose to adopt sodium reduction goals, a variety of responses are still possible. Some food industry members may aggressively seek to shift their entire portfolio in a category in the direction of the category target. Some food industry members may focus their efforts only on products in a portfolio that are above the target mean, resulting in a smaller shift in the overall portfolio mean. Some food industry members may simply seek to ensure that all products are below the upper bound level. Our current intake predictions are based on a hypothetical scenario in which all members of the food industry voluntarily choose to act so that the overall target mean for the category is achieved. More complex models of industry behavior are possible, and could be developed if desired.

5.6 Discussion

In this section, we have described methods for developing voluntary sodium reduction goals for various identified food categories[49], consisting of both upper bound concentrations and sales-weighted target mean concentrations. We suggest assignment of both short-term (2018) as well as long-term (2026) targets to promote gradual change over time. The short-term targets are intended to represent reductions that are currently feasible with respect to safety, consumer acceptance, and manufacturing, and within the range of commercially available products. The long-term targets are intended to represent achievable goals that do not compromise safety but may challenge food industry members who voluntarily adopt these goals to adopt new technical innovations to meet taste and manufacturing preferences.

6. Data Sources

6.1 Description of Public and Private Data Sources

FDA has used various data sources, both public and private, in the development of categories, sodium content baselines, and goals (target mean concentrations and upper bound concentrations) and that will be used in monitoring efforts. These include food composition and consumption databases, a food market share database, company nutrition data, and industry trend data. The following information provides additional descriptions of some of these key databases.

[49] For categories where the same food is often sold to the consumer in more than one form (ex: 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.

6.2 Data Sources Used for Packaged and Restaurant Foods

Food Composition Data

USDA National Nutrient Database for Standard Reference (SR)

SR contains information on the composition of United States foods, including food descriptions, nutrient content, weights and measures, and additional information about the sources of data. It is updated and released annually by USDA's Nutrition Data Laboratory, and it provides the foundation for FNDDS composition data. Over half of the SR data is analytical, and less than half of the data are derived from product labels, industry submissions, and other imputations.

As part of the USDA's efforts to monitor sodium content in foods one indicator for prioritizing foods to reanalyze was the identification of a list of 125 Sentinel Foods. Sentinel foods are a subset of a much larger set of key foods, and were chosen particularly to monitor sodium levels. The Sentinel Foods cover approximately 35% of total dietary sodium intake in 2007-2008 WWEI/NHANES and have been noted as having potential for possible reduction of sodium content. Led by the Food Surveys Research Group (FSRG) of ARS, the foods were each analyzed beginning in 2010 through the National Food and Nutrient Analysis Program (NFNAP). Analysis of the 125 foods completed since 2010 have been incorporated into SR, providing valuable information on sodium content. FSRG will continue to generate new sodium data which will be disseminated in the successive releases of the SR[50].

USDA Food and Nutrient Database for Dietary Studies (FNDDS)

FNDDS is a database of foods, their nutrient values, and weights for typical food portions used for coding and analysis of food consumption surveys and other dietary studies. FNDDS contains multiple data files (including codebook, food amounts, recipe, and food composition) from a variety of sources, including SR[51]. The nutrient intake information provided in the WWEIA/NHANES dietary intake files are developed by combining food consumption information reported during the 24-hour dietary recall interviews with information contained in the FNDDS files. The FNDDS are released every two years in parallel with WWEIA. FNDDS can be used to code food and amounts eaten and calculate amounts of nutrients/components in foods. It translates NHANES food codes into ingredients to estimate nutrient content (foods as consumed). FNDDS foods are fully represented in our food categories. A limitation is that all products need to be reviewed for each version of FNDDS to the level of refinement that may be of interest in monitoring the food categories.

[50] http://ac.els-cdn.com/S2211601X13000114/1-s2.0-S2211601X13000114-main.pdf?_tid=950f02ac-7e52-11e4-9fad-00000aab0f26&acdnat=1417985568_a155d436defdcab99641d4943d866d44

[51] About 3,000 items from SR are used to determine nutrient values for about 7,000 commonly consumed foods in FNDDS 4.1

Also, specific brand and restaurant information desired for this project is limited and/or not available.

FDA Total Diet Study (TDS)

The FDA TDS project provides analytical data of selected nutrients, contaminants, and pesticides for commonly consumed foods in the U.S., as identified through nationally representative dietary surveys. The sampling methodology involves the purchasing of about 280 foods from throughout the U.S. four times a year. The purchased foods are prepared prior to analysis; thus, providing data on foods as they are consumed. The primary purpose of TDS is to monitor the concentrations of a broad array of constituents contained in common foods to aid in estimations of exposure levels to these constituents at a national level. The known sodium variation between similar products and the need for data at the individual product level limits the capability of TDS data to fulfill the data needs for the voluntary guidance. Additional information about the US FDA TDS program is available at: http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy.

Gladson Nutrition Database (Gladson)

The Gladson Nutrition Database covers over 90% of all major product categories in industry. It provides syndicated consumer packaged goods, product images and nutrition information with UPC codes. It is the main source of sodium values in our database and is used in combination with Nielsen data to generate sales weighted mean sodium values. A limitation of the Gladson Nutrition Database is that it does not have product information for some of the Nielsen-derived food items necessary for the sales weighted sodium concentration calculations and some product information may not be current. Also, products are associated with their date of entry into the database and it must be assumed that the date of entry represents the sales data time frame.

Mintel Global New Products Database (Mintel; GNPD)

Mintel is a global consumer, product and market research company, which produces the GNPD. GNPD monitors product innovation and retail success in the consumer packaged goods market and provides product records containing up to 80 fields, which include label data (nutrition information and full ingredient list), bar codes (including UPC codes), positioning claim information, product images, pricing information and data on product launch success from Information Resources, Inc. (IRI). Data is available from 1996 forward for 49 countries in 32 food categories. Sodium values from nutrition labels for U.S. products, available in GNPD, were used to populate missing data for packaged food that were available to us from Nielsen sales data but were not found in Gladson. A limitation of GNPD is that it provides nutrition information (e.g. sodium) for only a limited number of currently selling U.S. food products, some products may not be up-to-date, and at this time it does not facilitate a way to readily monitor product reformulations over time.

Food Consumption Data

National Health and Nutrition Examination Survey/What We Eat in America (NHANES/WWEIA)

CDC's NHANES is the largest national source of interview and laboratory data that objectively measures indicators of the health and nutrition status of adults and children. WWEIA is the dietary interview component of NHANES, which is used to assess intake of individual foods and nutrients for 2 nonconsecutive days based on 24-hour recall data[52]. WWEIA provides data to determine exposure estimates. Limitations of this dataset include the usual biases associated with recall data (e.g. under- and over-estimation of portion sizes and intake of certain reported foods) and the fact that data may not capture all products consumed in the U.S.

Market Share Data

AC Nielsen Scantrack (Nielsen)

Nielsen Scantrack examines business trends by product (including private-labels), category or market using retailer scanner-based sales and gathers information from tens of thousands of retail outlets. Product data, including brand, category, dollar sales, and unit sales are provided at the barcode level. A limitation of this data is that it does not contain grocery chains with less than $2 million in sales. Also, Walmart, a leading food retailer, was not included in datasets prior to the year 2012. The masking of private label products and missing information for products without barcodes also require the use of assumptions when describing the representativeness of the data. A limitation with these data is that it is resource intensive to disaggregate the Nielsen datasets into the FDA voluntary guidance food categories.

Restaurant-Specific Data

Technomic

Technomic is a consulting and research firm serving the food industry. It conducts and presents information on proprietary research, trend analysis, forecasts, and common-interest studies as well as providing state-of-the-industry reports. In addressing restaurant foods, we used Technomic's publicly available 2010 list of top 100 U.S. restaurant chains, which was complete with total sales numbers for each restaurant. Data gathering and development of weighted means were based on these data.

Company Information

[52] 24-hr recall data is obtained using the Automated Multi-Pass Method Approach (AMPM). This data is then used to estimate mean food and nutrient amounts consumed by individuals in the US.

Restaurant websites and available nutrition materials were used to gather sodium and other nutrition information pertaining to the top 100 chain restaurants. A limitation is that some restaurant nutrition information is currently unavailable.

6.3 Additional Data Sources Considered

FDA Food and Label and Package Survey (FLAPS)

FLAPS is an FDA study of processed, packaged food labels in the United States food supply. FDA uses the FLAPS data to monitor the food industry's response to its food labeling regulations and to support agency policy, regulatory, and food safety decisions. Data includes Nutrition Facts panels, scanned images of complete label, product images, and sampling weights. There are limitations to using FLAPS in that tracking sodium content would require expansion of the sampling frame and data collection of packaged and prepared foods.

NPD Group's National Eating Trends (NET) 14-day Food Diary Data

NET monitors the eating and drinking habits of thousands of individual household members, and this multiple-day dataset is used to determine how often thousands of food and beverage products are consumed. This consumption data can be cross-linked to sodium content information. Data representing approximately 4,400 complete diaries is collected through the year (representing all seasons and all U.S. regions) and released annually. Limitations include the fact that amounts of foods are generalized in the diaries, and the actual amounts consumed need to be estimated. It may be a potential data source for comparison purposes, but the need for additional resources and assumptions to quantify sodium intake need to be taken into account.

QSRMagazine.com

This website is a fast food industry media outlet that provides publicly available information on quick-service and fast casual restaurant news and trends. Information obtained from the site was used to verify decisions made based on the Technomic top 100 U.S. restaurant list that pertained to fast food.

NYJobsource.com

This website is a job listing site that also contains 'top' lists. Information obtained from the site was used to verify decisions made based on the Technomic top 100 U.S. restaurant list that pertained to restaurant chains.

Mintel Global Market Navigator (GMN)

GMN is a Mintel database that provides market size, market share and forecast data for thousands of consumer goods worldwide. GMN generates trend reports on topics including U.S. restaurants, fast food, takeaways, and coffee shops, providing market segmentation information and limited assessment of market shares by volume and by value. GMN data on

restaurant segments and market share were compared to data from Technomic while developing our internal database.

Mintel Menu Insights

Menu Insights provides information on menu trends, market insights, and actual menus from the restaurants under Mintel's surveillance. Tracked trends include top menu item cuisine type, top menu item dishes, average menu item price per restaurant, among others. Mintel also has limited information on fast food restaurant market share. Data from Mintel Menu Insights on menu items and top restaurant chains based on number of outlets or market share, and insight on different restaurant segments were considered while developing our internal database.

7. Monitoring

Successful implementation of quantitative sodium reduction goals requires ongoing understanding of the changes in sodium concentrations in key food categories, relative to both original baselines and to each other. Such information allows FDA to assess the impact and effectiveness of the targeted reduction process, and also informs potential refinements and revisions of the targets based on observation of marketplace developments. It also allows us to identify which manufacturers are making an effort to reduce sodium or not, as well as the ability to see which manufacturers are the greatest offenders of using excess sodium in foods.

The public health outcome associated with sodium reduction targets is reduction in sodium intake, which can lead to reduction in blood pressure, a contributor of cardiovascular disease and stroke. Experience suggests that no single tool will be enough to promote reductions in intake sufficient to meet the recommendations of the Dietary Guidelines for Americans. Reduction of sodium in foods, improved labeling and communication methods, and changes in dietary patterns are all necessary parts of an effective effort to achieve the recommendations of the Dietary Guidelines. Thus, measures of sodium intake over time will provide essential data to inform the effectiveness of the overall sodium reduction initiative.

To monitor the impact of this voluntary guidance, we will work with available data sources, relevant measures, and key metrics that can be used to assess the impact of the voluntary guidance. In collaboration with other agencies (e.g. USDA, CDC), measures of sodium content will include baseline-parallel calculations, analysis of sentinel foods, and comparative analysis of sodium content distributions in a category over time. Sodium content of the food supply is the variable over which FDA has the most direct influence. However, we will also track estimated sodium intake, the proximal measure of the public health impact of our reduction efforts. Measures of sodium intake include exposure estimates using USDA What We Eat in America (WWEIA) intake data in conjunction with either our internal baseline content data or FNDDS sodium content data. In addition, we expect to closely follow NHANES measures of urinary sodium analysis, which represent a direct biological measurement of sodium intake. CDC and other data sources will inform on public health outcomes, including blood pressure, cardiovascular disease events and overall mortality.

Ongoing monitoring of the impact of the voluntary guidance will require attention to potential unintended consequences, including the potential for adverse effects on the overall nutritional quality of reformulated foods (e.g., increases in sugar or solid fats to compensate for reductions in sodium). We expect to assess these general nutritional issues as part of our overall monitoring of reformulation.

8. Conclusion

We have shared the issues, challenges, and recommendations associated with the development of draft guidance on voluntary sodium reduction goals in this memorandum. The information reflects input from a wide variety of stakeholders, including industry comments, federal partners, and CFSAN subject matter experts, and serves as a record of the key information and decisions that led to the draft guidance.

9. References

1) U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015 – 2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at http://health.gov/dietaryguidelines/2015/guidelines/.
2) Mattes RD and Donnelly D. Relative contributions of dietary sodium sources. J Am Coll Nutr. 1991 Aug;10(4):383-93.

10. Appendix

Table 2. Food Categories and Descriptions (Target Categories)

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

Food Category ID	Food Category Name	Food Category Description
Category 1: Dairy – Cheese		
1	**Blue/Blue-Veined Cheese (Semi-soft)**	Blue, Gorgonzola and other Blue-veined cheeses, e.g. Roquefort.
2	**Gouda and Edam Cheese (Semi-soft)**	Gouda and Edam cheeses.
3	**Processed Cheese/Cheese Food (Semi-soft)**	Pasteurized processed non-spreadable cheeses, e.g. American cheese slices and processed cheese loaf.
4	**Monterey Jack and Other Semi-soft Cheese**	Monterey Jack and other semi-soft cheeses, e.g. Havarti, Muenster, Provolone, and Fontina. Includes Mexican soft-cheeses, e.g. Casero, Panela and Cotija.
5	**Cream Cheese (Soft)**	All cream cheese spreads.

6	**Cheese Spreads/Other Spreadable Cheese (Soft)**	Pasteurized spreadable cheeses, pimento spreads, and other cheese spreads.
7	**Brie and Other Ripened Cheese (Soft)**	Brie, Camembert, chevre/goat cheese, and other mold-ripened cheeses.
8	**Pasta Filata Cheese (Soft)**	Mozzarella cheeses and other Pasta Filata cheeses. Excludes "fresh Mozzarella".
9	**Feta Cheese (Soft)**	Feta and Feta-style cheeses (salted in brine).
10	**Cottage and Other Soft Cheese**	Cottage cheese and other soft cheeses, e.g. Mascarpone and queso fresco.
11	**Cheddar and Colby Cheese (Hard)**	Cheddar and Colby cheeses.
12	**Swiss and Swiss-type Cheese (Hard)**	Swiss, Gruyere, and Emmentaler cheeses.
13	**Parmesan and Other Hard Cheese**	Parmesan, Romano, Asiago, and other hard cheeses.
Category 2: Fats, Oils, and Dressings		
14	**Butter**	Frozen and refrigerated butter; e.g. sticks and whipped products. Excludes vegetable oil and butter blends (see 15).
15	**Margarine and Vegetable Oil Spreads**	Semi-solid and solid vegetable oil products. Includes blends.
16	**Mayonnaise and Other Sandwich Spreads**	Mayonnaise and other sandwich spreads/dressings. Includes vegan products.
17	**Salad Dressing**	Shelf stable and refrigerated salad dressing. Includes oil and vinegar based dressings and creamy dressings. Excludes salad dressing dry mixes (see 52).
Category 3: Fruits, Vegetables, and Legumes		
18	**Frozen Vegetables and Legumes**	Frozen vegetables and legumes in sauce and/or seasoning. Excludes frozen french fries.
19	**Canned Vegetables**	Canned and bottled vegetables, legumes, and creamed vegetables in sauce and/or seasoning. Includes canned potatoes.
20	**Sauerkraut**	Refrigerated and canned sauerkraut.
21	**Olives without Additions**	Olives in brine or water. Excludes stuffed olives with additions (see 22)
22	**Olives with Additions**	Stuffed olives and olives in oil or sauce. Excludes olives without additions (see 21)
23	**Pickled Vegetables**	Pickled vegetables, e.g. peppers, cucumbers, and beets. Excludes sauerkraut (see 20) and olives (see 21 and 22).
24	**Vegetable Juice**	Vegetable-based juices and cocktails, e.g. tomato juice.
25	**Battered/Breaded Vegetables**	Fried or baked vegetables, e.g. onion rings, fried jalapeños, and fried green beans.
26	**Fried Potatoes without Toppings**	Fried, seasoned potatoes without additions, e.g. French fries, tater tots, and sweet potato fries. Excludes fried potatoes with toppings such as cheese, meat, and/or condiments (see 27).

27	**Fried Potatoes with Toppings**	Fried, seasoned potatoes with additions and/or toppings, such as cheese, meat, and/or condiments etc. Excludes fried potatoes without toppings (see 26).
28	**Hash Browns and Home Fries**	Baked, fried, or pan-fried hash browns and home fries.
29	**Potato Side Dishes**	Potato side dishes, e.g. mashed potatoes with gravy or sauce, scalloped potatoes, and baked potatoes with toppings such as cheese. Excludes fried potatoes (see 26), mashed potatoes (see 30.a and b), and hash brown and home fries (see 28).
30.a	**Mashed Potatoes, Prepared**	Prepared, seasoned mashed potatoes without gravy or sauce.
30.b	**Mashed Potatoes, Dry Mix**	Dry mix mashed potatoes with or without additions.
Category 4: Nuts and Seeds		
31	**Nuts and Seeds**	Nuts and seeds.
32	**Nut/Seed Butters and Pastes**	Nut butters and seed pastes. Includes tahini.
Category 5: Soups		
33	**Canned, Condensed Soup**	Condensed canned soup.
34	**Canned, Ready-to-Eat Soup**	Ready-to-eat canned soup. Excludes chili (see 129).
35	**Dry Mix Soup**	Dry mix soup. Includes instant Asian-style noodles.
36	**Shelf Stable Liquid Broth and Stock**	Shelf stable liquid stocks and broths, e.g. chicken, beef, and vegetable-based stocks or broths.
37	**Frozen Soup**	Frozen soup as prepared.
38	**Refrigerated Soup**	Refrigerated soup as prepared.
Category 6: Sauces, Gravies, Dips, Condiments, and Seasonings		
39	**Soy Sauce**	Soy sauce.
40	**Asian-style Sauce**	Asian-style sauces and condiments, e.g. teriyaki, hoisin, sweet and sour, stir-fry, and duck sauces. Excludes soy sauce (see 39).
41	**Mexican-style Sauce**	Mexican-style sauce, e.g. mole, taco sauce, and enchilada sauce. Excludes dry seasoning mixes (see 52), cheese-based sauces (see 44), and dips (see 48).
42	**Pesto**	Pesto sauces, e.g. standard pesto, basil sauce, and sun-dried tomato pesto sauce.
43	**Tomato-based Sauce**	Tomato-based sauces with and without meat, vegetables, and/or cheese added. Includes pizza sauce and tomato-based pasta sauces.
44	**Cheese-based Sauce**	Cheese-based sauces, e.g. nacho cheese sauce. Includes cheese sauces with and without additions.
45	**Cream-based Sauce**	Cream-based sauces, e.g. alfredo sauce. Includes cream sauces with and without additions.
46	**Gravy**	Gravy, e.g. ready-to-eat, refrigerated, and frozen gravy. Excludes gravy in dry-mix form (see 52).
47	**Condiments**	Condiments, e.g. catsup/Ketchup, mustard, barbecue sauce, tartar sauce, Worcestershire sauce, steak sauce, and hot pepper sauce.

48	**Cheese-based Dips**	Processed or other cheese-based dips, e.g. salsa con queso and cheese fondue.
49	**Cream-based Dips**	Dips with sour cream, cream cheese, yogurt, oil-based emulsion, and/or mayonnaise bases.
50	**Bean-based Dips**	Bean-based dips, e.g. hummus and refried bean-based dips.
51	**Vegetable/fruit-based Dips**	Dips with vegetable and fruit bases, e.g. salsa, chutney, and guacamole.
52	**Dry Seasoning and Dry Sauce Mixes**	Dry seasoning mix and dry sauce mix, e.g. spice rubs, dry dip mix, dry salad dressing mix, and dry gravy mix.
53	**Batters and Coatings**	Batter mixes for coating. Excludes bread crumbs (see 62).
Category 7: Cereals		
54	**Ready-to-Eat Cereal, Flakes**	Ready-to-eat, flaked cereal, e.g. corn flakes, wheat flakes, and other extruded flakes.
55	**Ready-to-Eat Cereal, Puffed**	Ready-to-eat, puffed cereal, e.g. puffed whole grain cereal, extruded gun-puffed cereal, oven-puffed cereal, and extruded expanded cereal.
56.a	**Prepared Cooked Cereal**	Cooked cereal as prepared, e.g. oatmeal, grits, cornmeal, whole wheat cereal, wheat cereal, bulgur, and couscous.
56.b	**Dry Mix Instant Cereal**	Dry mix instant cooked cereal, e.g. oatmeal, cornmeal, bulgur, and farina.
57	**Cereal and Granola Bars**	Bars with cereal and/or granola.
Category 8: Bakery Products		
58	**White Bread**	White bread and rolls, ready-to-eat and frozen, e.g. sourdough, potato, and pita bread. Includes white bread with fruit added.
59	**Wheat and Mixed Grain Bread**	Wheat and mixed grain bread and rolls, ready-to-eat and frozen, e.g. bread made from whole wheat, multigrain, oatmeal, and cornmeal. Includes wheat, mixed grain breads and rolls with additions.
60	**Garlic and Cheese Bread**	Seasoned garlic bread or rolls with and without cheese. Includes breadsticks.
61	**Rye Bread**	Rye and pumpernickel breads.
62	**Breadcrumbs and Croutons**	Breadcrumbs, croutons.
63	**Bagels and Soft Pretzels**	Ready-to-eat and frozen bagel and soft pretzels.
64	**English Muffins**	Ready-to-eat English muffins.
65	**Sweet Rolls**	Ready-to-eat and frozen sweet rolls, e.g. cinnamon buns and Danish pastry. Includes sweet rolls with nuts, fruit, and sweet toppings such as glazes and icing.
66	**Croissants**	Ready-to-eat and frozen croissants. Includes croissants with additions, toppings, and/or fillings. Excludes croissant dry mix (see 79).

67.a	**Frozen Biscuits**	Frozen biscuits and biscuit dough. Includes frozen biscuits with cheese and other additions.
67.b	**Prepared Biscuits**	Prepared biscuits. Includes prepared biscuits with cheese and other additions.
68	**Cornbread**	Prepared cornbread. Includes prepared cornbread muffins.
69	**Muffins**	Includes all frozen, ready-to-eat, and prepared muffins. Excludes cornbread (see 68) and dry muffin mix (see 79).
70	**Tortillas and Wraps**	Tortillas and wraps made from wheat and other flours.
71	**Hard Taco Shells**	Hard taco shells made from corn, wheat, and other flours.
72	**Crackers**	Crackers, e.g. graham crackers and soda crackers. Includes cheese flavored and crackers with other flavors. Excludes animal crackers (see 76).
73	**Cheesecake**	Cakes made with soft and/or fresh cheeses with or without grain crust.
74	**Cake**	Ready-to-eat cakes, cupcakes, and snack cakes. Includes cakes with and without icing and/or sweet fillings. Excludes dry cake mix (see 79).
75	**Pastries, Pie, and Cobbler**	Ready-to-eat and frozen pies and other pastries with fruit-based and other sweet fillings e.g. cobbler, tarts, and turnovers. Includes puff pastry-based products.
76	**Donuts**	Cake donuts, yeast-raised donuts, and donut holes. Includes donuts with toppings and glazes.
77	**Cookies**	Ready-to-eat cookies. Includes sandwich cookies with filling, wafers, and animal crackers.
78.a	**Frozen/Refrigerated Breakfast Bakery Products**	Frozen or refrigerated pancakes, waffles, French toast, and other similar breakfast bakery products.
78.b	**Prepared Breakfast Bakery Products**	Prepared pancakes, waffles, French toast, and other similar breakfast bakery products.
79	**Frozen/Refrigerated Dough and Batter**	Frozen or refrigerated dough and batters for bread/rolls, cookies, croissants, pancakes, pie shells, pizza crust, etc. Excludes frozen biscuit dough (see 67.a).
80	**Bakery Dry Mixes**	Shelf stable dry mixes for bread, cakes, cookies, pancakes, etc.
Category 9: Meat and Poultry		
81	**Deli Meats - Ham**	Sliced ham luncheon meat. Excludes bone-in hams.
82	**Deli Meats - Beef**	Sliced beef luncheon meat, e.g. roast beef, corned beef, and pastrami.
83	**Deli Meats -Turkey/Chicken**	Sliced chicken and turkey luncheon meat.
84	**Deli Meats - Loaves/Mixtures**	Meat-based loaves and mixtures. Includes canned luncheon meat and meat-based loaves with cheese.
85	**Frankfurters, Hot Dogs, and Bologna**	Beef, pork, and poultry-based frankfurters, hot dogs, wieners, and bologna. Includes mixed meat products. Excludes corn dogs and hot dogs with bun (see 121).

86	**Uncooked Sausage**	Fresh meat and poultry sausages not precooked. Includes both breakfast and dinner-type products in patty, link, and ground form.
87	**Precooked Sausage**	Precooked meat and poultry sausages. Includes both breakfast and dinner-type products in patty and link form.
88.a	**Uncooked Bacon**	Frozen or refrigerated, uncooked cured and uncured bacon. Excludes Canadian bacon (see 95).
88.b	**Cooked Bacon**	Cooked cured and uncured bacon. Excludes Canadian bacon (see 95), bacon bits, and bacon bits/pieces (see 102).
89	**Salami and Pepperoni**	Hard, dry beef and pork products, e.g. salami and pepperoni. Excludes salami cotto.
90	**Jerky and Prosciutto**	Meat/poultry/fish jerky and pork prosciutto.
91	**Bone-in, Non-Breaded/Battered Poultry**	Frozen, refrigerated, or prepared bone-in poultry without breading or batter. Includes products in sauce.
92	**Bone-in, Breaded/Battered Poultry**	Frozen, refrigerated, or prepared breaded and/or battered poultry containing the bone, e.g. breaded chicken wings. Includes products in sauce.
93.a	**Boneless, Non-Breaded/Battered, Uncooked Poultry**	Frozen or refrigerated, uncooked boneless poultry without breading and/or batter. Includes products in sauce.
93.b	**Boneless, Non-Breaded/Battered, Precooked Poultry**	Frozen, refrigerated, precooked, or prepared boneless poultry without breading and/or batter. Includes products in sauce.
94	**Boneless, Breaded/Battered Poultry**	Frozen, refrigerated, or prepared breaded and/or battered boneless poultry pieces. Includes products in sauce.
95	**Reformed/Restructured, Breaded/Battered Chicken**	Frozen and prepared reformulated/restructured cooked chicken products, e.g. nuggets and breaded patties.
96	**Cured/Smoked Pork and Canadian Bacon**	Cured or smoked hams, and pork loins. Includes Canadian bacon. Excludes uncooked and fully cooked bacon (see 87.a and b).
97	**Whole Muscle Pork**	Whole muscle pork with sauce/marinade or preseasoned, e.g. ribs and pork chops.
98	**Whole Muscle Beef**	Frozen beef cuts with sauce/marinade or preseasoned.
99	**Reformed/Shaped Beef**	Refrigerated or frozen precooked beef patties, burgers, and meatballs.
100	**Canned Meat**	Shelf stable canned beef, e.g. canned corned beef.
101	**Canned Sausage**	Shelf stable canned meat sausages, e.g. Vienna sausages.
102	**Canned Poultry**	Shelf stable canned poultry, e.g. canned chicken breast chunks. Excludes canned poultry sausages (see 100).
103	**Bacon Bits/Pieces**	Shelf stable real and imitation bacon bits and pieces.
104	**Meat Substitutes and Analogues**	Frozen or refrigerated vegetarian meat substitutes, e.g. veggie bacon, veggie meatballs, and veggie patties etc. Includes marinated or seasoned soy products, e.g. tofu.

Category 10: Fish and Other Seafood		
105	**Non-Breaded Fish and Other Seafood**	Frozen, uncooked, and not breaded fish fillets and shellfish.
106	**Breaded Fish and Other Seafood**	Frozen, precooked, and breaded fish fillets and shellfish.
107	**Canned Fish and Seafood**	Canned fish and shellfish, e.g. tuna, sardines, crab, and clams in water, oil or sauce, e.g. tomato or mustard sauce. Excludes canned anchovies (see 107).
108	**Canned Anchovies**	Canned anchovies. Includes canned anchovies with additions.
Category 11: Snacks		
109	**Unflavored Potato and Vegetable Chips**	Salted potato and other vegetable chips. Includes both reformed chips/crisps and sliced chips. Excludes chips with other seasonings in addition to salt (see 109).
110	**Flavored Potato and Vegetable Chips**	Salted potato and other vegetable chips with additional flavor seasonings, e.g. barbeque or sour cream. Includes both reformed chips/crisps and sliced chips.
111	**Unflavored Grain Chips**	Salted corn, wheat, multigrain, and rice chips, e.g. salted tortilla chips. Excludes grain chips with other seasoning in addition to salt (see 111).
112	**Flavored Grain Chips**	Salted and seasoned corn, wheat, multigrain, and rice chips, e.g. cheese flavored salted corn chips.
113	**Puffed Corn Snacks**	Seasoned, extruded/puffed corn snacks, e.g. puffed corn snack with cheese or onion seasonings.
114	**Puffed Rice Snacks**	Seasoned puffed rice, e.g. puffed rice cakes and puffed rice snacks. Includes sweet and savory flavored/seasoning puffed rice snacks, e.g. caramel, cheese, or butter flavor.
115	**Popcorn**	Microwave-ready, stove-top, and ready-to-eat flavored popcorn, e.g. butter flavor microwave-ready popcorn and cheese flavor ready-to-eat popcorn. Excludes unseasoned kernels.
116	**Pretzels**	Salted hard pretzels. Includes sweet and savory flavored, filled, and unfilled pretzels snacks, e.g. chocolate covered pretzels and pretzels filled with cheese.
117	**Snack Mixes**	Multiple component dry snack mixes containing cereal, nuts, pretzels, and/or dried fruits. Includes trail mix.
Category 12: Sandwiches		
118	**Beef/Pork-based Sandwiches**	Sandwiches and wraps primarily containing beef and/or pork. Includes sandwiches and wraps containing sausages. Excludes sandwiches and wraps containing dry/cured meat (see 119) and luncheon meat (see 120).

119	**Poultry/Fish-based Sandwiches**	Sandwiches and wraps primarily containing poultry, fish and/or seafood. Includes sandwiches and wraps containing poultry/seafood based salads, e.g. chicken salad and tuna salad. Excludes luncheon meat sandwiches and wraps (see 120).
120	**Dry/Cured Meat-based Sandwiches**	Sandwiches and wraps primarily containing dry/cured meats, e.g. salami and pepperoni.
121	**Deli Meat-based Sandwiches**	Sandwiches and wraps primarily containing luncheon meats. Excludes sandwiches and wraps containing dry/cured meat (see 119).
122	**Hot Dogs on Buns and Corn Dogs**	Frozen or prepared corn dogs, hot dogs, or frankfurters on buns or other breads. Includes prepared meat and/or poultry, and veggie hot dogs and frankfurters.
123	**Breakfast Sandwiches On Biscuits**	Frozen, refrigerated, or prepared breakfast sandwiches on biscuits.
124	**Breakfast Sandwiches Not on Biscuits**	Frozen, refrigerated, or prepared breakfast sandwiches not on biscuits, e.g. bagel, croissant, and English muffin breakfast sandwiches. Includes breakfast burritos.
125	**Vegetarian Sandwiches**	Sandwiches without meat, poultry, or seafood, e.g. grilled cheese sandwiches, sandwiches with meat substitutes, and peanut butter and jelly sandwiches.
126	**Hamburgers/Ground Meat Sandwiches: Without Cheese**	Hamburgers/ground meat sandwiches without cheese and with or without toppings, e.g. bacon, vegetables, and condiments. Includes hamburgers and ground meat sandwiches made with poultry or seafood patties.
127	**Hamburgers/Ground Meat Sandwiches: With Cheese**	Hamburgers/ground meat sandwiches with cheese and with or without toppings, e.g. bacon, vegetables, and condiments. Includes hamburgers and ground meat sandwiches made with poultry or seafood patties.
Category 13: Mixed Ingredient Dishes		
128	**Frozen Meals/Entrees**	Frozen meals and entrees ready-to-eat after heating, e.g. frozen pot pies, frozen lasagna, and frozen burritos. Excludes frozen pizzas (see 144a, 145a).
129	**Grain-based Meals/Entrees, Dry- Mix**	Shelf stable meals from dry mix which contain grains, e.g. pasta, rice, couscous, wheat, legumes, and dry seasoning mixes or sauces, e.g. macaroni and cheese, seasoned rice, and tabouli. Includes mixes that require the addition of other ingredients, e.g. meat, butter, milk, etc.
130	**Canned Meals**	Shelf stable canned meals, e.g. pasta in sauce with or without meat, chili, and baked beans with or without meat.
131	**Combination Meals/Platters**	Prepared meals presented/listed as combination meals or platters, e.g. breakfast platters and "surf and turf" meals. Excludes frozen entrees (see 127) and dry mix meals (see 128).

132	**Grain-based Dishes**	Prepared noodle, rice, and pasta dishes, e.g. fried rice, macaroni and cheese, and fried noodles. Includes dishes with meat, poultry, seafood, dairy, and/or vegetable additions. Excludes frozen entrees (see 125), dry mix meals (see 126), and sushi.
133	**Vegetable-based Dishes**	Prepared vegetable-based or vegetarian mixed ingredient dishes and entrees, e.g. green bean casserole, stuffed eggplant, and vegetable stir-fry. Includes vegetarian dishes with meat substitutes. Excludes frozen entrees (see 125) and dry mix meals (see 126).
134	**Egg-based Dishes**	Prepared egg-based mixed ingredient dishes, e.g. omelets, quiche, and soufflés. Excludes frozen entrees (see 125) and dry mix meals (see 126).
135	**Meat/Poultry-based Dishes**	Prepared meat and/or poultry mixed ingredient dishes and entrees, e.g. meat/poultry pot pies and pot roast. Excludes frozen entrees (see 125) and dry mix meals (see 126).
136	**Seafood-based Dishes - With Breading**	Prepared, breaded seafood based mixed ingredient dishes and entrees, e.g. fried breaded shrimp, fish sticks and crab cakes. Excludes frozen meals/entrees (see 127) and dry mix meals (see 128).
137	**Seafood-based Dishes -Without Breading**	Prepared, not breaded seafood based mixed ingredient dishes and entrees, e.g. grilled fish, shrimp scampi, and steamed mussels. Excludes frozen meals/entrees (see 127) and dry mix meals (see 128).
Category 14: Salads		
138	**Lettuce/Green Salads: With Additions - With Dressing**	Green salads with dressing and additions/toppings containing added sodium, such as cheese, croutons, meat, and salted nuts. Excludes taco salads.
139	**Lettuce/Green Salads: With Additions - Without Dressing**	Green salads without dressing and with additions/toppings containing added sodium, such as cheese, croutons, meat, and salted nuts. Excludes taco salads.
140	**Lettuce/Green Salads: Without Additions - With Dressing**	Green salads with dressing and without additions/toppings containing added sodium, such as cheese, croutons, meat, and salted nuts.
141	**Seafood/Meat-Based Salads**	Refrigerated, prepared seafood, meat, and poultry-based salads, e.g. chicken salad and tuna salad. Excludes lettuce and other leafy green based salads (see 137-139).
142	**Grain/Vegetable-Based Salads**	Refrigerated, prepared grain and vegetable-based salads, e.g. pasta salad, potato salad, and legume based salads. Excludes lettuce and other leafy green based salads (see 137-139).
Category 15: Other Combination Foods		
143	**Filled Dough Appetizers**	Savory, prepared filled dough appetizers, e.g. dumplings, egg rolls, potstickers, samosas, savory turnovers, and sandwiches in pastry. Excludes sweet and/or fruit filled dough prepared snacks.
144	**Cheese-based Appetizers**	Breaded, baked or fried prepared cheese-based appetizers and snacks, e.g. fried mozzarella sticks and

		baked cheese curds.
145.a	**Pizza: With Meat/Poultry or Seafood - Frozen**	Frozen pizza with meat, poultry, and/or seafood toppings. Includes pizza without cheese, pizza snacks, Stromboli, and calzones with meat, poultry and/or seafood.
145.b	**Pizza: With Meat/Poultry or Seafood - Not Frozen**	Prepared pizza with meat, poultry, and/or seafood toppings. Includes pizza without cheese, Stromboli, and calzones with meat, poultry and/or seafood.
146.a	**Pizza: Without Meat/Poultry or Seafood - Frozen**	Frozen pizza without meat, poultry, and/or seafood toppings, e.g. pizza with cheese only or pizza with vegetable or fruit toppings. Includes pizza without cheese, pizza snacks, Stromboli, and calzones with no meat, poultry or seafood.
146.b	**Pizza: Without Meat/Poultry or Seafood - Not Frozen**	Prepared pizza without meat, poultry, and/or seafood toppings, e.g. pizza with cheese only or pizza with vegetable or fruit toppings. Includes pizza without cheese, Stromboli, and calzones with no meat, poultry or seafood.
147	**Tacos, Burritos, and Enchiladas**	Tacos, burritos, enchiladas, fajitas, taquitos, nachos, quesadillas, etc.
Category 16: Baby/Toddler Foods		
148	**Toddler Meals and Entrees**	Frozen and shelf stable meals and entrees labeled for toddlers.
149	**Baby/Toddler Snacks: Cookies/Biscuits**	Cookies, biscuits, and grain-based bars labeled for babies and toddlers.
150	**Baby/Toddler Snacks: Seasoned Puffs**	Seasoned extruded snacks labeled for babies and toddlers.

Table 3. Non-Target Categories

General Food Category	Sub-Category
Dairy	All milk except buttermilk and dry milk
	Buttermilk
	Dry milk
	Yogurt
	Ice cream/frozen yogurt
	Hot Cocoa
	Chocolate syrup
	Ice cream bars/cones/sundaes
	Whipped topping
	Cream and cream substitute
	Sour cream
	Custards/flans
	Bread Pudding
	Mousse-type pudding
Fats, Oils, Raw Commodities	Animal fats
	Natural oils
	Raw commodities
	Butter - unsalted
	Margarine, vegetable oil spreads - unsalted
Fruits, Vegetables, Legumes	Fruit - raw/fresh
	Fruit - frozen
	Fruit filling
	Fruit - canned
	Fruit - salads/cocktails
	Fruit - cooked
	Fruit - juice
	Fruit - dried
	Fruit - misc. (sauces, juice bars, etc.)
	Coconut products
	Vegetables - raw and/or no added sodium
	Boiled/baked/raw potatoes, no toppings
	Dried beans and dried peas
Nuts and Seeds	Nuts/seeds, unsalted
Cereals	Ready-to-eat cereals, shredded
	Ready-to-eat cereals, granola
Bakery Products	Pie crust
	Quick breads - soda bread
	Tortillas and wraps, corn
Meat Products	Organ meat, not cured/smoked
	Organ meat, cured/smoked
	Veal

	Lamb and goat
	Game meat, not cured/smoked
	Game meat, cured/smoked
Fish and Other Seafood	Fresh/raw fish and seafood
	Salted/pickled/dried fish and other seafood
Eggs	Eggs and egg substitutes, no additions during preparation
Confectionery (Sweets)	Sugar and sugar substitutes
	Syrups
	Gelatin desserts, jellies, jams
	Chewing gum
	Fudges
	Candy and chocolate with nuts
	Candy and chocolate without nuts
	Non-dairy based bakery desserts
	Non-dairy frozen/prepared desserts
Snacks	Pretzels, unsalted/uncovered/uncoated
Mixed ingredient dishes	Sushi
Foods for Specific Nutritional Purposes	Infant food products, infant formula
	Meal replacement bars, powders, and supplements
Beverages (excluding juice and milk)	Non-alcoholic
	Alcoholic
	Water

Table 3. Mean Sodium Intake from Food and Water in the United States, 2009-2010

Age (years) and gender	n	Mean (mg/d)	Standard Error
All ages	9618	3408	(19.8)
Males	4777	3951	(33.4)
Females	4841	2893	(14.2)
0-1	576	1186	(63.4)
Males	276	1146	(80.4)
Females	300	1225	(89.6)
2+	9042	3463	(19.4)
Males	4501	4019	(31.6)
Females	4541	2934	(15.4)

2-3	477	2151	(44.0)
Males	256	2140	(56.3)
Females	221	2164	(70.4)
4-8	958	2696	(58.0)
Males	499	2735	(68.5)
Females	459	2652	(66.8)
9-13	887	3100	(66.8)
Males	438	3339	(103.1)
Females only	449	2888	(83.4)
14-18	802	3711	(155.1)
Males	428	4408	(191.8)
Females	374	3059	(147.6)
19+	5918	3590	(28.6)
Males	2880	4249	(40.8)
Females	3038	2975	(29.3)

Source: What We Eat in America, NHANES, 2009-2010, individuals of all ages (excluding breast-fed children), day 1 dietary intake data, weighted.