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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0055]

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Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance entitled "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods." The draft guidance, when finalized, will describe our views on voluntary short-term and long-term goals for sodium reduction in a variety of identified categories of foods that are commercially processed, packaged, or prepared. These goals are intended to address the excessive intake of sodium in the current population and promote improvements in public health.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on Issues 1 through 4 listed in section IV of this document by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on Issues 5 through 8 listed in section IV of this document by [INSERT DATE 150 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-0055 for "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Kasey Heintz, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1376.

SUPPLEMENTARY INFORMATION:

I. Introduction

Many expert advisory panels have concluded that scientific evidence supports the value of reducing sodium intake in the general population (Ref. 1). Recent analysis, including the findings of the 2013 Institute of Medicine (IOM) report, "Sodium Intake in Populations: Assessment of Evidence" (IOM report), continue to support this conclusion (Ref. 2). The 2013 IOM report confirmed a positive relationship between higher levels of sodium intake and the risk of heart disease, and found substantial evidence of population benefit and no evidence of

negative health effects associated with reductions in sodium intake down to 2,300 milligrams of sodium per day (mg/day) (Ref. 2). Members of the committee which authored the 2013 IOM report also clarified in a subsequent publication that different groups using a variety of methods and data have obtained results consistent with the committee's analysis that current U.S. intake is excessive, that it should be reduced, and that reduction is expected to have significant public health benefit (Ref. 3). Moreover, the 2015 Dietary Guidelines Advisory Committee Sodium Working Group examined the relationship between sodium and blood pressure and other cardiovascular outcomes in adults, as well as sodium and blood pressure in children. The Committee's recommendations concurred with previous reports that sodium intake among the U.S. population remains high and that higher levels of sodium intake are associated with increased blood pressure and risk of cardiovascular disease (Ref. 4).

Multiple researchers have estimated the public health benefits associated with broad reduction in sodium intakes in the United States (Ref. 1). Reasonable reductions in average intake (modeled at a variety of intake levels below current intake, down to an average level of roughly 2,200 mg/day) have been estimated to result in tens of thousands fewer cases of heart disease and stroke each year, as well as billions of dollars in health care savings over time. A recent study (Ref. 5) used three epidemiological datasets to forecast the separate public health benefits of reducing the population's average sodium intake to 2,200 mg/day over 10 years. (This 2,200 mg/day final mean intake level was derived from intake values embedded in the sources of evidence used for the study.) Researchers found that this pattern of reduction would save between 280,000 and 500,000 premature deaths over 10 years; sustained sodium reduction would prevent additional premature deaths.

FDA is not conducting rulemaking with regard to sodium, and these goals are voluntary. Given the potentially significant benefits to public health, as well as FDA's role in safeguarding America's food supply and enabling consumers to choose healthy diets, we are committed to exploring effective and efficient strategies to promote sodium reduction in the food supply. We believe that these voluntary goals can be an effective means to achieve significant benefits to public health through sodium reduction in commercially processed, packaged, and prepared foods.

II. Background

We are announcing the availability of a draft guidance for industry entitled "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods." (For purposes of this draft guidance, "commercially processed, packaged, and prepared foods" refers to processed, multiple-ingredient foods that have been packaged by a member of the food industry for direct sale to consumers or for use in restaurants and similar retail food establishments including, but not limited to, restaurants, or for resale to other members of the food industry, as well as foods that are prepared by food establishments for direct consumption.) The draft guidance provides information to the food industry on sodium reduction, expressed as measurable voluntary goals for sodium content (from sodium chloride, commonly called "salt," as well as other sodium-containing ingredients) in commercially processed, packaged, and prepared foods. Approximately 75 percent of sodium consumed by Americans is added to foods before they are sold (Ref. 6). Thus, the goals are intended to promote reductions in the amount of sodium added during processing, manufacturing, and preparation, especially for uses not necessary for microbial safety, stability, and/or physical integrity. We particularly encourage attention by food manufacturers whose

products make up a significant proportion of national sales in one or more categories and restaurant chains that are national or regional in scope.

Broad adoption of these voluntary recommendations by the industry members would create a meaningful reduction in population intake over time and support adjustment of consumer taste preferences. We recognize that many companies have initiated sodium reduction efforts and have made commitments on their own. The voluntary goals are intended to support ongoing efforts, including progress that has already been made by industry. This approach also builds on other efforts such as a an initiative by New York City in partnership with local and State health departments and health organizations and international approaches from foreign governments such as Canada and the United Kingdom. The voluntary goals are intended to provide a shared framework for describing and analyzing the success of voluntary reduction efforts by various industry stakeholders and to promote continued discussion on sodium reduction opportunities. The guidance is intended to help achieve public health goals and see safe, gradual, and broadly distributed change over time across the full range of commercially processed, packaged, and prepared foods. To accomplish these goals, discussion and collaboration among FDA, Federal partners, the food industry, consumers, and other stakeholders will be essential.

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You may use an alternate approach to reducing sodium as long as these approaches satisfy the requirements of the applicable statutes and regulations.

The draft guidance provides our tentative views with respect to identifying challenging, yet feasible, target mean and upper bound concentrations of sodium (referred to in this document as "sodium concentration goals") across a wide variety of food categories. Our targets are based on our analysis of the current minimum and upper bound levels of sodium in a variety of identified food categories, available literature on the amount of salt needed for different functions in food, and discussions with experts on different food categories. Our milestone date for the short-term goals is the second year after publication of the final guidance. Our milestone date for the long-term goals is the 10th year after publication of the final guidance. The short-term targets are intended to be more easily achievable and as many as half of all products may already have achieved these interim targets. We recognize that the longer term targets are more difficult to achieve. We are aware that new ingredients capable of replacing some salt as well as other innovative strategies are being explored and more research and development may be needed. We also want to make clear that broader public health goals and maintenance of nutritional quality are important considerations in developing sodium reduction or reformulation strategies. For example, sodium reduction that relies on increases in added sugars would not be consistent with the public health goals of this guidance.

The sodium concentration goals in this voluntary draft guidance are intended to:

- Support increased food choice for consumers seeking to consume a diverse diet that is consistent with recommendations of the 2015-2020 Dietary Guidelines for Americans;
- support the 2015-2020 Dietary Guidelines and the Healthy People 2020 recommendations of less than 2,300 mg per day for many individuals;
- provide shared goals as metrics (mg/100g) for voluntary reduction efforts by various industry stakeholders;

- support successful efforts already underway in the private sector to reduce sodium content;
- focus on total amount of sodium in a given food as opposed to any individual sodium-containing ingredient; and
- support and extend industry's voluntary efforts to reduce sodium across the range of commercially processed, packaged, and prepared foods.

This guidance does not:

- Recommend specific methods and technologies for sodium reduction;
- prescribe how much of any individual sodium-containing ingredient, such as salt or sodium nitrite, should be used in a formulation (in other words, we focus on the total amount of sodium in a given food);
- focus on foods that contain only naturally occurring sodium (e.g., milk); or
- address salt that individuals add to their food.

As described in the notice "Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information" (76 FR 57050, September 15, 2011, referred to in this document as the 2011 request for comment), current sodium intake is substantially higher than what scientific and public health agencies and organizations have recommended in recent years. There have been a number of public and industry initiatives to reduce sodium intake, as well as initiatives in other countries (76 FR 57050 at 75051). In April 2010, IOM released a report titled "Strategies to Reduce Sodium Intake in the United States" which concluded that sodium intake, with the greatest contribution from salt, remains well above recommended levels (Ref. 1).

We recognize that a successful effort to reduce sodium intake requires information on a wide variety of topics, resulting from a genuine dialogue with all interested persons. To begin this dialogue, in 2011, FDA and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) opened parallel dockets for public comment and described the rationale for sodium intake reduction and identified 15 specific issues for comment by all interested persons (76 FR 57050). These issues concerned multiple aspects of sodium reduction, including technical challenges and opportunities, implementation of reduction targets, and potential unintended consequences of reduction.

In November 2011, FDA and FSIS, in conjunction with other Federal agencies interested in sodium reduction efforts, including the Centers for Disease Control and Prevention and USDA's Agricultural Research Service and Center for Nutrition Policy and Promotion, sponsored a public meeting to provide a forum for discussion of the issues raised in the 2011 request for comment. FDA and FSIS together received approximately 1,500 comments, which addressed the following key themes:

- The need for slow and gradual change;
- the importance of acknowledging technical and regulatory constraints;
- the need for consumer acceptance and market viability of new or reformulated products;
- the critical importance of maintaining a safe food supply;
- the potential health consequences of broad sodium reduction;
- the costs associated with broad reductions in sodium;
- the potential for positive incentives to promote reformulation; and
- reports of successful reduction efforts.

We reviewed the comments submitted to the 2011 request for comments as well as other available information. In particular, we have considered the 2013 IOM report, "Sodium Intake in Populations: Assessment of Evidence." The IOM report concluded that evidence from studies on direct health outcomes associated with sodium intake was sufficient to support reducing excessive sodium intake, noting a benefit for cardiovascular disease outcomes if population sodium intake came down to a level of 2,300 mg/day. Ultimately, this report reaffirmed the association between sodium intake and health outcomes, which supports the need to engage in population-based efforts to lower excessive dietary sodium intakes (Ref. 2).

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 101 have been approved under OMB control number 0910-0381. The collections of information in 21 CFR 101.11 have been approved under OMB control number 0910-0783.

IV. Issues for Consideration

We developed the sodium targets using the best available representation of sodium in the food supply, based on product nutrition data from manufacturers and widely used sales data. We welcome comment on any issues related to the methods for developing the sodium targets and for implementation of this guidance. In particular, we are interested in comments on collecting and organizing these data into food categories, our methods for quantifying sodium content, refinements to the specific mean and upper bound targets based on adjustments of our category

structures and data, and any challenges of implementing the voluntary goals. Please provide the reasoning behind your comments, including, where available, any data you may have.

1. Are there categories where foods have been grouped together that should be separated on the basis of different manufacturing methods or technical effects relating to the potential for sodium reduction? Conversely, are there categories which could be merged due to similar sodium functionality and potential for reduction? Are there foods that contribute to sodium intake that we have not effectively captured? Are the categories amenable for use by restaurant chains and if not, how should they be modified to make them amenable for use by restaurant chains?

2. Are the baseline sodium concentration values reasonably representative of the state of the food supply in 2010? For categories that do not appear representative, what food products are not adequately represented? Are there situations in which our method of quantification could lead to unrepresentative baseline values?

3. Are there categories for which the 2-year target concentration goals are infeasible? If so, why are these targets not feasible, e.g., for technical reasons? What goals would be feasible in the short-term (2-year), and why? For reference, a supplementary memorandum to the docket is provided to further describe the type of information needed, "Target Development Example: Supplementary Memorandum to the Draft Guidance" (Ref. 7).

4. Are the short-term (2-year) timeframes for these goals achievable? If the timeframes are not achievable, what timeframes would be challenging, but still achievable?

5. Are there categories for which the 10-year target concentration goals are infeasible? If so, why are these targets not feasible, e.g., for technical reasons? What goals would be feasible in the long-term (10-year), and why? For reference, a supplementary memorandum to the docket

is provided to further describe the type of information needed, "Target Development Example: Supplementary Memorandum to the Draft Guidance" (Ref. 7).

6. Are the long-term (10-year) timeframes for these goals achievable? If the timeframes are not achievable, what timeframes would be challenging, but still achievable?

7. What specific research needs or technological advances (if any) could enhance the food industry's ability to meet these goals? What are possible innovations in the area of sodium reduction and are there any unintended consequences associated with their use?

8. What amendments to FDA's standard of identity regulations in 21 CFR parts 130-169 are needed to facilitate sodium reduction by permitting alternative ingredients to be used in standardized foods? For example, amendments could include revisions to specific standards (e.g., cheese or cheese products) and to the general requirements for foods named by use of a nutrient content claim (e.g., "reduced sodium") and a standardized term under 21 CFR 130.10.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/FoodGuidances, or http://www.regulations.gov. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

VI. References

The following references are on display in FDA's Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.

1. IOM. "Strategies to Reduce Sodium Intake in the United States," Washington DC: The National Academies Press (2010).

2. IOM. "Sodium Intake in Populations: Assessment of Evidence Institutes of Medicine (IOM) Report," Washington DC: The National Academies Press (2013).

3. Strom, B. L., C. A. M. Anderson, and J. H. Ix. "Sodium Reduction in Populations: Insights From the Institute of Medicine Committee." Journal of the American Medical Association. July 3, 2013; 310(1): 31-32.

4. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee," Part B, Chapter 6. http://www.health.gov/dietaryguidelines/2015-scientific-report/. Accessed March 9, 2015.

5. Coxson, P. G., N. R. Cook, M. Joffres, Y. Hong, et al. "Mortality Benefits From U.S. Population-Wide Reduction in Sodium Consumption." Hypertension. March 2013; 61:564-570.

6. Mattes, R. D. and D. Donnelly. "Relative Constitutions of Dietary Sodium Sources." Journal of the American College of Nutrition. August 1991;10(4):383-93.

7. FDA. "Memo: Target Development Example: Supplementary Memorandum to the Draft Guidance (2016)."

Dated: May 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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