



AMERICAN PUBLIC HEALTH ASSOCIATION

For science. For action. For health.

October 14, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: 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

Dear Commissioner Califf:

The American Public Health Association, a diverse community of public health professionals who champion the health of all people and communities, strongly supports the Food and Drug Administration's proposal to set voluntary sodium reduction targets and upper bound concentrations for commercially processed, packaged and prepared foods.

On average, Americans consume far more sodium than is recommended. With the products available in the current marketplace it is difficult for people not to consume too much sodium. About three-quarters of sodium consumed by people in the U.S. is already added to foods before purchase during processing, manufacturing and preparation. There is a strong and clear relationship between habitual sodium intake and blood pressure levels. Elevated blood pressure levels are a major cause of cardiovascular diseases. We believe that the sodium reduction targets are an effective approach to achieving significant public health benefits. Industry adherence to the targets would enable consumers to choose healthier diets and have the potential to prevent hundreds of thousands of premature deaths and illnesses in a decade. APHA strongly urges FDA to swiftly finalize the sodium reduction guidance for industry.

As companies work toward achieving sodium reduction and developing reformulation of processed, packaged and prepared foods, we agree with FDA that broader public health goals and nutritional quality are important considerations, and should not be compromised during this process.

APHA would like to highlight the following major points:

- APHA strongly believes the sodium reduction targets are feasible and should even be strengthened. Given the urgent need to start reducing the harm from excessive sodium in foods, the modest 2-year sodium reduction targets should be finalized by the end of this year. APHA supports maintaining the upper bounds for categories to provide industry

with specific guidance and to ensure that foods do not contain unsafe levels of sodium. The maximums also enable consumers and health officials to identify foods with excessive sodium and to determine whether companies are complying with this element of the program.

- Although the amount of sodium per 100 grams might meet FDA's targets, many restaurant meals contain one or even several days' worth of sodium. Therefore, FDA should set maximum sodium levels for three major food categories (sandwiches, mixed ingredient dishes and other combination foods) for a whole serving, as well as per 100 grams. FDA should also urge restaurants to publish the weight, in grams, of their dishes.
- The Secretary of the Department of Health and Human Services should seek funding for a national, comprehensive public education campaign that includes all stakeholders and focuses on the communities most at risk of consuming excessive sodium.
- The Secretary of HHS should also establish comprehensive surveillance activities, including biennial nationally representative 24-hour urinary sodium tests, to monitor sodium intake. Moreover, the surveillance should provide for sufficient power to monitor at-risk communities and populations. These activities are necessary to maximize the potential public health benefits that could be achieved by significantly reducing sodium intake.

APHA respectfully submits the following comments to address specific questions in FDA's June 2, 2016 Federal Register notice.

I. Sodium intake and health consequences

The 2015–2020 Dietary Guidelines for Americans recommend that healthy adults limit sodium consumption to no more than 2,300 mg per day. In FDA's update to the Nutrition Facts Label, the Daily Value for sodium was reduced to 2,300 mg per day. The Dietary Guidelines also note that those with hypertension and pre-hypertension may wish to limit their sodium consumption to 1,500 mg per day for greater blood pressure reduction.¹ On average, Americans consume more than 3,400 mg of sodium per day according to the 2011–2012 National Health and Nutrition Examination Survey,² and average sodium intake is likely higher due to underreporting. A recent pilot study by the Centers for Disease Control and Prevention to assess the feasibility of NHANES' collection of 24-hour urine samples found average estimates of sodium intakes of 3,657 mg (first day of urine collection) and 3,773 mg (second day of collection) per day.³ Therefore, the proposal to set voluntary targets to reduce sodium intake by the 10-year targets to 2,300 mg per day is both warranted and necessary for both packaged and restaurant foods, which both contribute to the high levels of sodium consumption. The goal of 3,000 mg per day with the 2-year targets is reasonable.

Excess sodium consumption boosts blood pressure, and high blood pressure, or hypertension, is a leading cause of cardiovascular disease, accounting for two-thirds of all strokes and half of all cases of heart disease.⁴ Reducing sodium intake helps lower blood pressure, and blood pressure responds with greater decreases at increasingly lower levels of dietary sodium intake.⁵ Researchers estimate that reducing current sodium intake by 1,200 mg a day – which would bring most people close to the 2,300 mg per day goal of FDA's long-term targets – would

prevent 60,000 to 120,000 cases of coronary heart disease, 32,000 to 60,000 cases of stroke and save 44,000 to 92,000 lives per year.⁶ Reducing sodium intake to 2,300 mg per day would save an estimated \$10 billion to \$24 billion in health care costs annually.⁷

II. Representing sodium concentration in the food supply

While FDA did not include no-, low- or reduced-sodium products in its baseline calculations, APHA supports including them in future assessments of the marketplace to better represent the sodium concentration in the food supply.

About 50 percent of chain restaurants were excluded from FDA's baseline and target calculations due to missing serving-size weights. The omissions are critical, given that restaurant foods largely make up the top three contributors to sodium intake – sandwiches, mixed ingredient dishes and other combination foods. Therefore, APHA strongly recommends that FDA urge restaurants to provide gram weights in their nutrition data, and that FDA establish maximum sodium levels *per serving* of restaurant foods to encourage restaurants to reduce sodium levels or serving sizes of large portions that are high in sodium.

A. Establishing maximum sodium levels *per serving* of food for sandwiches, mixed ingredient dishes and other combination foods.

To encourage sodium reductions in restaurant foods, APHA recommends that FDA set long-term maximum sodium levels *per serving* for foods under sandwiches (Food Category ID: 118–127), mixed ingredient dishes (ID: 128–137) and other combination foods (ID: 143–147). Setting a maximum sodium level per serving of menu item addresses two major issues. First, it would extend the sodium reduction efforts to all restaurant foods in these categories, regardless of whether the restaurants have gram weights available. Secondly, this recommendation would address the large portion sizes of restaurant foods, which, unlike multi-serving packaged foods, are often consumed in one sitting. A large sandwich, burger, individual pizza, burrito or serving of fried rice, pad Thai, spaghetti and meatballs, and many other mixed dishes may contain an unhealthy level of sodium even if the sodium content per 100 grams of food is within the proposed targets.

APHA encourages FDA to evaluate the distribution of sodium *per serving* in each of the three categories using the restaurant data used to calculate the mean targets and upper-bounds. The distributions should help inform the maximum sodium targets, just as similar distributions did for the sales-weighted-mean targets.⁸

As documented in FDA's June 21 webinar, sandwiches, mixed ingredient dishes and other combination foods contribute a total of 45 percent of U.S. sodium intake.⁹ The three categories are subdivided into 27 subcategories and include primarily restaurant foods, indicated by the proportion of packaged foods (683 items) and restaurant foods (3,314 items) used in the baseline calculations. Those three categories are the greatest contributors of sodium, and limiting their sodium levels would yield the greatest public health impact.

Setting a maximum sodium level *per serving* might also discourage the growing portion sizes—and sodium content—of restaurant foods and meals.¹⁰ Portion sizes have grown since the 1970s, and some table-service and fast-food restaurant menu items are now two to five times larger than similar foods were two decades ago.¹¹ The average entrée in non-chain restaurants has roughly 1,300 calories.¹² FDA’s current targets might lead to sodium concentrations that meet the targets per 100 grams of food, but fail to meet the public health goals of reducing sodium intake.

Setting a maximum sodium level *per serving* could also increase the ability of industry to comply with the targets by effectively including all restaurant meals regardless of whether the restaurants supply gram weights. The hypothetical model, described by FDA in Section 5.5 Estimated Impact of the Supplementary Memo, in which all members of the food industry choose to adopt the sodium reduction targets, could not be achieved if 50 percent of chain restaurants did not have the necessary data.

III. Feasibility of reduction targets

APHA strongly supports the proposed short-term sodium reduction targets. We recognize the various factors that impact the feasibility of each reduction target, including taste preference, technological requirements, reformulation and food safety. In general, the targets would be reasonable reduction efforts from the packaged food and restaurant industries. The 2-year targets offer modest sodium reduction below the 2010 baseline – an average of 12 percent reduction for packaged foods and 15 percent for restaurant foods. However, recognizing that this view is based on generalized information and data, APHA also encourages the industry to provide FDA with category-specific data and additional detailed evidence regarding purported barriers to sodium reduction so that the agency could revise particular targets if necessary.

IV. Monitoring sodium intake

FDA’s commitment to monitoring the impact of the voluntary guidance by collaborating with other agencies to measure changes in sodium consumption is important. FDA should ensure that NHANES continues to collect nationally representative 24-hour urine samples. How this data is collected and evaluated is important. Multiple 24-hour urine samples should be taken to ensure accurate approximations of sodium intake are consistent and not significantly influenced by the chance that an individual consumed more sodium on one day. Study participants on diuretics, those with renal disease, those with a diagnosis of hypertension and potentially others may need to be excluded due to situational impact on sodium excretion. If possible, when making decisions on future sodium standards, the information from the urine samples should be used in conjunction with other assessments of sodium intake, sodium content in the food supply and impact on health outcomes of target groups and at-risk populations. Additionally, FDA, in collaboration with the United States Department of Agriculture Food Composition Databases, should periodically assess the distribution of sodium levels in various categories of food, and by brand name where possible, to know where progress has been adequate and where companies need help in lowering sodium or where the targets, especially the longer-term targets, warrant adjustment.

V. Education campaign

Given the FDA's voluntary approach to reducing sodium, as well as the 2010 recommendation by the Institute of Medicine for a national public education campaign¹³ and the successful educational effort in the U.K.,¹⁴ the Secretary of HHS, should seek sufficient funding for a comprehensive, long-term, national public education campaign that involves all stakeholders, including USDA and health organizations, and focuses on the communities most at risk of excessive sodium in the food supply.

A recent consumer survey indicates that 59 percent of Americans are not concerned about their sodium intake.¹⁵ Even after significant publicity that processed and restaurant foods are by far the greatest sources of dietary sodium, 46 percent of adults believe that table salt is the main source of sodium in American diets.¹⁶ The fact that labeling a product as "reduced sodium" sometimes turns consumers off and reduces product sales signals a critical gap in public awareness of the health risks.

A sodium reduction education campaign should encourage consumers to read labels and choose lower-sodium products. This effort would enable consumers to help themselves, and also indirectly encourage companies to lower sodium levels. A campaign should encourage consumers to eat fewer high-sodium foods and to prepare more meals from scratch.

FDA should also launch a sodium reduction campaign that publicly encourages companies to lower sodium levels. The voluntary nature of FDA's sodium reduction targets might make it unrealistic to reach the hypothetical scenario in which all manufacturers and restaurants voluntarily adopt the targets (see Section 5.5 Estimated Impact).

The three-stage approach to educating consumers implemented by the U.K. through Consensus Action on Salt and Health, a non-governmental organization, and the Food Standards Agency, the equivalent of FDA, provides a framework for success.¹⁷ The public awareness campaign included three stages: 1) educate consumers about health consequences associated with excess sodium intake; 2) inform adults of the daily recommended sodium intake; and 3) encourage consumers to check package labels to compare sodium levels in different brands when they are shopping.¹⁸ Surveying consumer knowledge after the U.K. campaign demonstrated that the number of individuals reducing sodium intake increased by 26 percent, the number of adults checking labels increased by 72 percent and the number of people aware of the daily recommended limit increased ten-fold.¹⁹ The U.K. campaign, largely cited as a principal contributor to sodium reductions, demonstrated the importance of engaging consumers. The Food Standards Agency's sodium reduction initiative also included the development of voluntary sodium targets to encourage reformulation, and strongly encouraging companies to meet those targets.

Conclusion

APHA strongly supports FDA's proposal to set voluntary sodium reduction targets for commercially processed, packaged and prepared foods. We urge the agency to finalize the proposed targets, especially the 2-year targets, as quickly as possible so that companies know

what is expected of them and can start or continue their sodium reduction efforts, and, most importantly, so that the public can benefit from less sodium in their foods. Enhancing the framework with our recommendations for FDA to urge restaurants to provide the weights of all offerings and to set maximum sodium levels per serving, coupled with efficient monitoring and an effective education campaign would enable the American public to eat a healthier, lower-sodium diet.

Sincerely,



Georges C. Benjamin, MD
Executive Director

¹ U.S. Department of Health and Human Services and U.S. Department of Agriculture. (2015). 2015 – 2020 Dietary Guidelines for Americans. 8th Edition. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.

² NHANES. (2011–2012). What We Eat in America. USDA ARS. Available at http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/1112/Table_1_NIN_GEN_11.pdf.

³ Terry AL, Cogswell ME, Wang C, et al. (2016). Feasibility of collecting 24-hour urine to monitor sodium intake in the National Health and Nutrition Examination Survey. *American Journal of Clinical Nutrition*, ajcn121954.

⁴ He FJ, MacGregor GA. (2009). A comprehensive review on salt and health and current experience of worldwide salt reduction programmes. *Journal of Human Hypertension*, 23(6), 363-384.

⁵ Sacks FM, Svetkey LP, Vollmer WM, et al. (2001). Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. *New England journal of medicine*, 344(1), 3-10.

⁶ Bibbins-Domingo, Chertow, Coxson, op cit.

⁷ Bibbins-Domingo, Chertow, Coxson, op cit.

⁸ Food and Drug Administration. (2016). Sodium in the U.S. Food Supply for Products in 2010. Docket number: FDA-2014-D-0055-0351. Available at <https://www.regulations.gov/document?D=FDA-2014-D-0055-0351>

⁹ Food and Drug Administration. (2016). Sodium Reduction: FDA's Voluntary Initiative. Docket number: FDA-2014-D-0055-0001. Available at <http://www.fda.gov/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM507537.pptx>

¹⁰ Young, LR, Nestle M. (2002). The contribution of expanding portion sizes to the US obesity epidemic. *American journal of public health*, 92(2), 246-249.

¹¹ Ibid.

¹² Urban LE, Lichtenstein AH, Gary CE, et al. (2013). The energy content of restaurant foods without stated calorie information. *JAMA Intern Med.* 173(14):1292-9. doi:

10.1001/jamainternmed.2013.6163.

¹³ Taylor CL, Henry JE. (Eds.). (2010). Strategies to reduce sodium intake in the United States. National Academies Press.

¹⁴ Food Standards Agency. (2011). U.K. salt reduction initiatives. Available at

<http://www.food.gov.U.K./multimedia/pdfs/saltreductioninitiatives.pdf>. Accessed July 8, 2016.

¹⁵ International Food Information Council. (2011). Assessing The Sodium Situation: The Consumer's Perspective. Available at <http://www.foodinsight.org/newsletters/assessing-sodium-situation-consumers-perspective> Accessed August 5, 2016.

¹⁶ American Heart Association. (2011). Most Americans don't understand the health effects of wine and sea salt, survey finds. Available at <http://newsroom.heart.org/pr/aha/1316.aspx>. Accessed July 8, 2016.

¹⁷ Op Cit. Food Standards Agency.

¹⁸ Ibid.

¹⁹ Ibid.