



October 17, 2016

Dr. Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20093

Re: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Docket No. FDA-2014-D-0055

Dear Commissioner Califf:

On behalf of Trust for America's Health, an organization dedicated to promoting better health and preventing chronic conditions, we are pleased to support the Food and Drug Administration's (FDA) proposal to set voluntary sodium-reduction targets and upper bound concentrations for commercially processed, packaged, and prepared foods. Trust for America's Health (TFAH) is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community. We applaud the FDA for moving forward with this important proposal.

Given the preponderance of scientific evidence linking excess sodium intake to hypertension and increased risk of heart attack, stroke, and kidney disease, as well as the voluntary nature of the targets, TFAH strongly urges the FDA to finalize this guidance in an expeditious manner.

In summary, given the variation in sodium concentration within similar types of foods, TFAH strongly believes the sodium-reduction targets are feasible and should be strengthened. The two-year sodium-reduction targets should be finalized by the end of 2016 given the urgent need to start reducing the harm from excessive sodium in foods. Additionally, the upper bounds for categories should be maintained because they are the one element of the FDA proposal that provides specific guidance on individual products and because they 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.

Finally, we urge the Secretary of Health and Human Services to seek funding for a national, comprehensive public education campaign that includes all stakeholders and especially focuses on the communities most at risk from consuming excessive sodium. This also should include funding for 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—as many as 44,000 to 92,000 deaths from heart attacks and strokes

could be prevented each year and potential health-care-cost savings range from \$10 billion to \$24 billion annually.¹

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

I. Sodium Intake and Health Consequences

Since nearly 80 percent of the sodium in the average American's diet comes from processed and restaurant foods,² sodium intake is largely out of the consumer's control.

The 2015–2020 Dietary Guidelines for Americans recommends that healthy adults limit sodium consumption to no more than 2,300 milligrams (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 notes 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.³ However the 2011–2012 National Health and Nutrition Examination Survey (NHANES) showed that the average American consumes more than 3,400 mg of sodium per day.⁴ A recent pilot study by the Centers for Disease Control and Prevention (CDC) found average estimates of sodium intakes of between 3,657 mg and 3,773 mg per day.⁵ 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 current dangerously high levels of sodium consumption. The goal of 3,000 mg per day with the 2-year targets is most 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.⁶ Fortunately, cutting sodium intake helps lower blood pressure, and blood pressure responds with greater decreases at increasingly lower levels of dietary sodium intake.⁷ Researchers estimate that reducing current sodium intakes 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.⁸ Reducing sodium intake to 2,300 mg per day would save an estimated \$10 billion to \$24 billion in health-care costs annually.⁹

II. Representativeness of Sodium Concentration in the Food Supply

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

Approximately 50 percent of chain restaurants were excluded from FDA's baseline and target calculations due to missing serving-size weights. Those omissions are critical, especially because restaurant foods largely make up the top three contributors (Sandwiches, Mixed Ingredient

Dishes, and Other Combination Foods) to sodium intake. Therefore, TFAH 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.

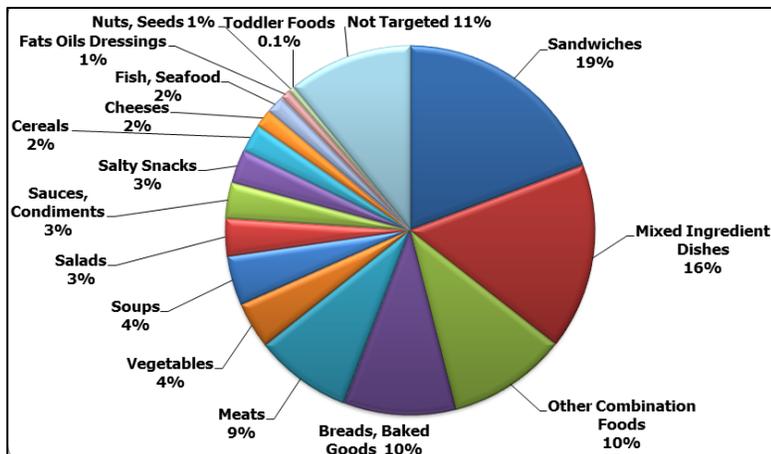
A. TFAH proposes maximum sodium levels *per serving* of food for Sandwiches, Mixed Ingredient Dishes, and Other Combination Foods.

To encourage sodium reductions in restaurant foods, TFAH recommends that FDA set voluntary long-term maximum sodium levels *per serving* for foods that fall 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.

TFAH encourages the 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.¹⁰

As documented in FDA’s June 21, 2016 webinar, Sandwiches, Mixed Ingredient Dishes, and Other Combination Foods contribute a total of 45 percent of U.S. sodium intake (Figure 2).¹¹ 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.

Figure 2. Contribution to U.S. Sodium Intake by Foods Targeted in FDA’s Sodium Guidance



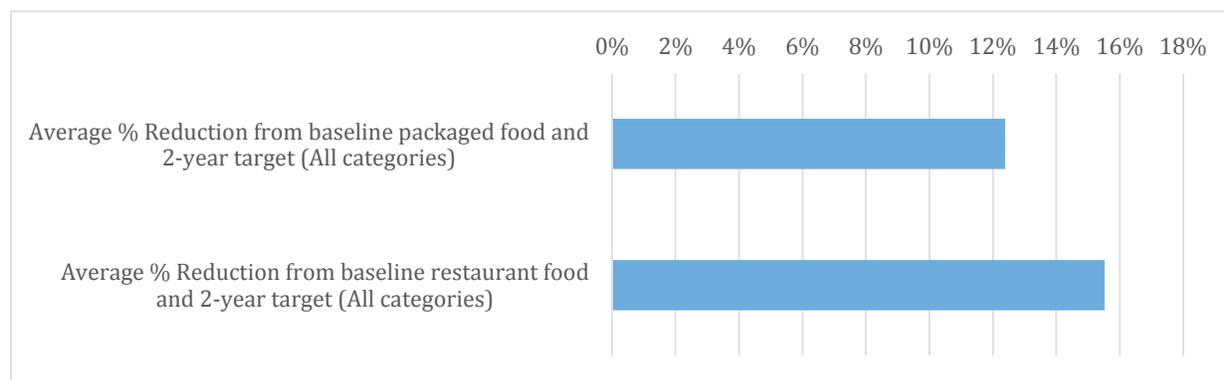
Setting a maximum sodium level *per serving* might also discourage the growing portion sizes—and sodium content—of restaurant foods and meals.¹² Portion sizes have grown since the 1970s, and some table-service and fast-food restaurant menu items are now two to five times larger than similar foods were two decades ago.¹³ The average entrée in non-chain restaurants has roughly 1,300 calories.¹⁴ FDA’s current targets might lead to sodium concentrations that met the targets per 100g of food, but failed to meet the public health goals of reducing sodium intake.

III. Feasibility of Reduction Targets

TFAH 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 appear to represent reasonable reduction efforts from the packaged food and restaurant industries.

As seen in Figure 3, 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).

Figure 3. Average sodium reductions from baseline to 2-year sales-weighted-average targets for all categories.



IV. Monitoring Sodium Intake

TFAH recognizes the FDA’s commitment to monitoring the impact of the voluntary guidance by collaborating with other agencies to measure changes in sodium consumption. HHS should ensure that NHANES continues to collect nationally representative 24-hour urine samples. Without such data, FDA and the public would not know the extent to which companies were lowering sodium. The FDA also should periodically assess the distribution of sodium levels in various categories of food to know where progress has been adequate and where companies need help in lowering sodium or where the targets, especially the longer-term targets, warranted 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 campaign¹⁵ and the successful educational effort in the United Kingdom (U.K.),¹⁶ the Secretary of Health and Human Services should seek sufficient funding for a comprehensive, long-term, national public-education campaign that involves all stakeholders and especially focuses on the communities most at risk from excessive sodium in the food supply.

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 cutting down on sodium 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.

It is important to note that the consumer education campaign was just one component of the Food Standards Agency's sodium-reduction initiative, which also included the development of voluntary sodium targets to encourage reformulation, as the FDA is currently doing, and strongly and sometimes publicly encouraging companies to meet those targets.

A recent consumer survey indicates that 59 percent of Americans are "not concerned" about their sodium intake.²⁰ And 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.²¹ The fact that labeling a product as "reduced sodium" sometimes turns off consumers and reduces product sales signals a critical gap in public awareness of and concern over health risks.

A sodium-reduction education campaign should encourage *consumers* to read labels and understand the sodium content of potential food products. That would encourage consumers to help themselves, and also indirectly encourage companies to lower sodium levels.

VI. Conclusion

TFAH strongly supports the 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 two-year targets, as quickly as possible so that companies have predictable expectations regarding voluntary industry standards and can start or continue their sodium-reduction efforts, and, most importantly, so that the public can begin to realize health benefits stemming from less sodium in their foods.

Thank you for the opportunity to provide these comments on this proposal. If you have any questions, please do not hesitate to contact Jack Rayburn, Senior Government Relations Manager, Trust for America's Health (202-223-9870, x 28 or jrayburn@tfah.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Hamburg". The signature is fluid and cursive, with a prominent initial "R" and a long, sweeping tail.

Richard Hamburg
Interim President and CEO
Trust for America's Health

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- ¹ Bibbins-Domingo K, Chertow GM, Coxson PG, et al. (2010). Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease. *The New England Journal of Medicine*, 362(7): 590-599.
- ² Mattes RD, Donnelly D. (1991). Relative contributions of dietary sodium sources. *Journal of the American College of Nutrition*, 10(4), 383-393.
- ³ 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/>.
- ⁴ 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.
- ⁵ 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.
- ⁶ 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.
- ⁷ 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.
- ⁸ Bibbins-Domingo, Chertow, Coxson, op cit.
- ⁹ Bibbins-Domingo, Chertow, Coxson, op cit.
- ¹⁰ 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>
- ¹¹ 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>
- ¹² 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.
- ¹³ Ibid.
- ¹⁴ 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.
- ¹⁵ Taylor CL, Henry JE. (Eds.). (2010). Strategies to reduce sodium intake in the United States. National Academies Press.
- ¹⁶ 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.
- ¹⁷ Op Cit. Food Standards Agency.
- ¹⁸ Ibid.
- ¹⁹ Ibid.
- ²⁰ 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.
- ²¹ 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.