



October 17, 2016

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

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WASHINGTON, D.C.

**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 the 28 member jurisdictions that comprise the Big Cities Health Coalition (BCHC), I write to strongly 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. BCHC is a forum for the leaders of America's largest metropolitan health departments to exchange strategies and jointly address issues to promote and protect the health and safety of the 54 million people they serve.

High sodium intake increases blood pressure and the risk of heart disease and stroke. Salt intake remains a major public health problem in America. Salt intake and its resulting cardiovascular diseases, including heart disease and stroke, continue to be a costly problem for big cities in America and the nation as a whole. Nearly 800,000 Americans die each year from heart disease, stroke, and other cardiovascular diseases accounting for one in every three deaths.<sup>1</sup> Given the preponderance of scientific evidence linking excess sodium intake to hypertension, and the scope of the problem, as well as the voluntary nature of the targets, BCHC strongly urges the FDA to finalize this guidance in an expeditious manner. Industry adherence to the targets would save tens of thousands lives annually.

BCHC has long supported efforts aimed at bringing about new policies and organizational practices that improve the nutrition content of prepared and processed foods. Thus, we would like to highlight the following major points:

- Given successful population-wide sodium-reduction efforts in several other countries and the variation in sodium concentration within similar types of foods, we strongly believe the sodium-reduction targets are feasible and should even be strengthened.
- The modest 2-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.
- 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.

- Many restaurant meals contain one or even several *days'* worth of sodium, though the amount of sodium per 100 grams might meet FDA's targets. 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. The FDA should also urge restaurants to publish the weight (in grams) of their dishes.
- The Secretary of Health and Human Services (HHS) should 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.
- The HHS Secretary should establish comprehensive surveillance activities, including biennial nationally representative 24-hour urinary sodium tests, to monitor sodium intake. Moreover, the surveillance should provide the ability 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.<sup>ii</sup>

*We respectfully submit the following comments to address questions in FDA's June 2, 2016 FR notice.*

## **I. Sodium Intake and Health Consequences**

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.<sup>iii</sup> Despite those and previous similar recommendations, 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 (which does not account for underreporting).<sup>iv</sup> Furthermore, 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.<sup>v</sup> 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.

A quarter-century-old report found that almost 80 percent of the sodium in the average American's diet comes from processed or restaurant food.<sup>vi</sup> Excess sodium boosts blood pressure, and high blood pressure (hypertension) is a leading cause of cardiovascular disease, accounting for two-thirds of all strokes and half of all cases of heart disease.<sup>vii</sup> Fortunately, cutting sodium intake helps lower blood pressure, and it responds with greater decreases at increasingly lower levels of dietary sodium intake.<sup>viii</sup> 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.<sup>ix</sup> Reducing sodium intake to 2,300 mg per day would save an estimated \$10 billion to \$24 billion in health-care costs annually.<sup>x</sup>

## II. Representativeness of Sodium Concentration in the Food Supply

While FDA did not include no-, low-, or reduced-sodium products in its baseline calculations, BCHC 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, we strongly recommend 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. BCHC proposes maximum sodium levels *per serving* of food for Sandwiches, Mixed Ingredient Dishes, and Other Combination Foods.

To encourage sodium reductions in restaurant foods, BCHC recommends that FDA set 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. A large sandwich, burger, individual pizza, burrito, or serving of fried rice, pad Thai, spaghetti & meatballs, enchiladas, and many other mixed dishes may contain an unhealthy level sodium even if the sodium content per 100 grams of food is within the proposed targets.

BCHC 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.<sup>xi</sup>

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).<sup>xii</sup> 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.<sup>xiii</sup> 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.<sup>xiv</sup> The average entrée in non-chain restaurants has roughly 1,300 calories.<sup>xv</sup> 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.

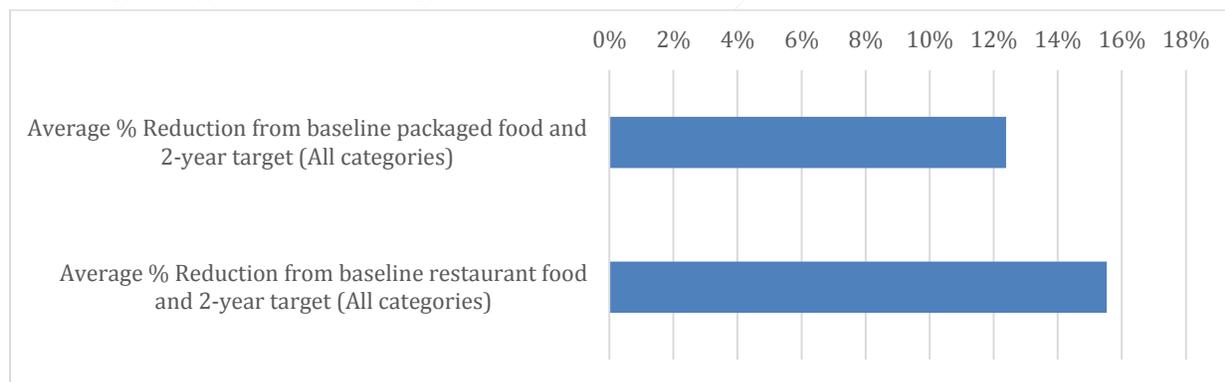
Setting a maximum sodium level *per serving* could also increase the ability of industry to comply with the targets by effectively including all restaurant meals regardless of whether the restaurants supply gram weights. The hypothetical model, described by FDA in Section 5.5 Estimated Impact of the 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

BCHC 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. However, recognizing that this view is based on generalized information and data, we also encourage 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.

As seen in Figure 1, 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 1. Average sodium reductions from baseline to 2-year sales-weighted-average targets for all categories.**



### IV. Monitoring Sodium Intake

BCHC recognizes the FDA's commitment to monitoring the impact of the voluntary guidance by collaborating with other agencies to measure changes in sodium consumption. FDA 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 campaign<sup>xvi</sup> and the successful educational effort in the U.K.,<sup>xvii</sup> the HHS Secretary 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.

A recent consumer survey indicates that 59 percent of Americans are “not concerned” about their sodium intake.<sup>xviii</sup> 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.<sup>xix</sup> 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 choose lower-sodium products. That would encourage 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.

The FDA also should launch a sodium-reduction campaign that publicly encourages *companies* to lower sodium levels. After all, the voluntary nature of the FDA's sodium-reduction targets might make it unrealistic to reach the “hypothetical scenario” in which all manufacturers and restaurants voluntarily adopted the targets. The FDA should not shy away from applauding companies that have made major sodium reductions (or met the targets without needing to reduce sodium), nor should it shy away from naming companies that have *not* made significant reductions.

## VI. Additional Recommendation – Monitoring and Reporting

In order to facilitate widespread adoption of the sodium targets and upper bounds by the food industry, BCHC recommends that the FDA develop a comprehensive monitoring plan to accompany the final guidance on the targets. A monitoring plan should ideally include the use of nutrition databases that are public, breaded, time-stamped, and comprehensive to ensure that monitoring efforts are robust, accurate, and transparent. We also recommend that FDA produce a bi-annual report that updates baseline sodium concentrations in each category and provides an appendix of data sources. As part of this process, we recommend FDA issue a template for companies to voluntarily submit updated nutrition information for their products.

## VII. Conclusion

BCHC 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 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.

Given that restaurant targets are based on information from only about half of all chain restaurants, we recommend that the FDA urge restaurants to provide the weights of all their offerings. Whether or not those restaurants comply, it is indisputable that many restaurant meals are enormous, with some providing one or more days' worth of sodium, even though their sodium content per 100 grams may not be excessive. Therefore, we urge the FDA to set maximum sodium levels per serving, not just per 100 grams, for three key categories (Sandwiches, Mixed Ingredient Dishes, and Other Combination Foods).

BCHC strongly supports the FDA targets. Enhancing the framework with these recommendations, coupled with efficient monitoring and effective education campaign, would enable Americans to eat a healthier, lower-sodium diet.

If you have any questions, please contact me at [cjuliano@naccho.org](mailto:cjuliano@naccho.org) or at 202-783-3627.

Sincerely,

A handwritten signature in black ink that reads "Chrissie Juliano". The signature is written in a cursive, flowing style.

Chrissie Juliano, MPP  
Director, Big Cities Health Coalition

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- <sup>i</sup> <http://www.cdcfoundation.org/pr/2015/heart-disease-and-stroke-cost-america-nearly-1-billion-day-medical-costs-lost-productivity>
- <sup>ii</sup> 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.
- <sup>iii</sup> 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/>.
- <sup>iv</sup> 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](http://www.ars.usda.gov/SP2UserFiles/Place/80400530/pdf/1112/Table_1_NIN_GEN_11.pdf).
- <sup>v</sup> 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.
- <sup>vi</sup> Mattes RD, Donnelly D. (1991). Relative contributions of dietary sodium sources. *Journal of the American College of Nutrition*, 10(4), 383-393.
- <sup>vii</sup> 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.
- <sup>viii</sup> 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.
- <sup>ix</sup> Bibbins-Domingo, Chertow, Coxson, op cit.
- <sup>x</sup> Bibbins-Domingo, Chertow, Coxson, op cit.
- <sup>xi</sup> 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>
- <sup>xii</sup> 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>
- <sup>xiii</sup> 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.
- <sup>xiv</sup> Ibid.
- <sup>xv</sup> 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.
- <sup>xvi</sup> Taylor CL, Henry JE. (Eds.). (2010). Strategies to reduce sodium intake in the United States. National Academies Press.
- <sup>xvii</sup> 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.
- <sup>xviii</sup> 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.
- <sup>xix</sup> 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.