



July 29, 2016

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

ALAMEDA COUNTY (OAKLAND)  
BALTIMORE CITY  
BOSTON  
CHICAGO  
CLEVELAND  
DALLAS COUNTY  
DENVER  
DETROIT  
FULTON COUNTY (ATLANTA)  
HOUSTON  
KANSAS CITY  
LONG BEACH  
LOS ANGELES COUNTY  
MARICOPA COUNTY (PHOENIX)  
MIAMI-DADE COUNTY (MIAMI)  
MINNEAPOLIS  
MULTNOMAH COUNTY (PORTLAND)  
NEW YORK CITY  
PHILADELPHIA  
SACRAMENTO  
SAN ANTONIO  
SAN DIEGO COUNTY  
SAN FRANCISCO  
SANTA CLARA COUNTY (SAN JOSE)  
SEATTLE - KING COUNTY  
SOUTHERN NV (LAS VEGAS)  
TARRANT COUNTY (FORT WORTH)  
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 Dr. Califf:

On behalf of the 28 member jurisdictions that comprise the Big Cities Health Coalition (BCHC), I write to oppose any extension of the comment period for the two-year targets for the Food and Drug Administration's (FDA) draft Voluntary Guidance to Industry for Sodium-Reduction Targets. 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.

The 90-day comment period, set to end August 31, 2016, provides sufficient time for all stakeholders to review the draft guidance and provide informed comments. Moreover, given the critical public health importance of sodium reduction, any delay in allowing the FDA to move forward toward finalizing the two-year targets continues to put tens of thousands of Americans at increased risk for hypertension and death or disability from heart attacks and strokes.

The June 1, 2016, issuance of the draft guidance should not have come as a surprise to any stakeholder. There was ample time to prepare and think about the guidance before its release. Former FDA Commissioner Margaret A. Hamburg told the Associated Press in June 2014 the agency was working on the draft guidance.<sup>1</sup> In fact, in 2011 the FDA established a docket for soliciting public comment on sodium reduction and received comments from stakeholders across industry and the public health community.<sup>2</sup> The likely shape and direction of the draft guidance was also well known, given the sodium-reduction initiatives of Canada, the United Kingdom and New York City.<sup>3,4,5</sup> Indeed, the FDA points to each of those initiatives as guiding its thinking and formulation of the draft categories and targets.<sup>6</sup> Finally, sodium reduction efforts are well underway across the food industry and have been for several years now, demonstrating industry readiness for, and the technical feasibility of, reformulation.<sup>7</sup>

The public health need for timely action is well established. It is time for national guidelines to catch up with both the research and policy innovation underway across the nation. A few examples are below.

- In April 2010, the then Institute of Medicine issued its landmark report calling for *mandatory* sodium reduction in packaged and restaurant foods the United States.<sup>8</sup> The report cited analysis that population-wide sodium reduction could prevent as many as 100,000 deaths a year.<sup>9</sup>
- A consensus statement of scientists released by the New York City Department of Health and Mental Hygiene in June 2014 affirmed the reduction of population sodium intake as a key strategy for reducing the burden of cardiovascular disease.<sup>10</sup>
- The Philadelphia Department of Health has partnered with local Chinese restaurants to reduce the amount of sodium used in their food preparation.<sup>11</sup>
- In 2010, the Los Angeles County Department of Public Health started an initiative to reduce sodium intake in schools and government offices.<sup>12</sup>
- Finally, in October 2014 and December 2015, more than 30 local and state public health departments and organizations called for the FDA to release the draft guidance.<sup>13,14</sup>

This FDA action is an important step forward and moving ahead on the proposed achievable two-year targets, which are *voluntary*, should not be delayed. Given the body of research and on the ground experience from our cities, the BCHC urges FDA not to extend the comment period for the two-year targets for the FDA's draft Voluntary Guidance to Industry for Sodium-Reduction Targets. Action is needed now to enable Americans to make healthier choices every day.

Sincerely,



Chrissie Juliano, MPP  
Director, Big Cities Health Coalition

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<sup>1</sup> American Heart Association. (2014). Government to Issue Guidelines for Lowering Sodium in Foods.

<http://news.heart.org/government-to-issue-guidelines-for-lowering-sodium-in-foods/>

<sup>2</sup> Voluntary Sodium Reduction Goals: Target Mean and Recommended Maximum Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods, 81 Fed. Reg. 35363 (proposed 2016, June 2).

<sup>3</sup> Health Canada. (2010). Sodium Reduction Strategy for Canada. <http://www.hc-sc.gc.ca/fn-an/nutrition/sodium/related-info-connexes/strateg/reduct-strat-eng.php>

<sup>4</sup> Food Standards Scotland. (2015). 2017 Salt Targets. <http://www.foodstandards.gov.scot/2017-salt-targets>

<sup>5</sup> City of New York Health. (2016). Sodium Initiative. <https://www1.nyc.gov/site/doh/health/health-topics/national-salt-reduction-initiative.page>

<sup>6</sup> U.S. Food and Drug Administration. (2016). Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm494732.htm>

<sup>7</sup> Center for Science in the Public Interest. (2013). Sampling of Company Announcements of Reduced/Lowered Sodium Foods. [https://cspinet.org/new/pdf/company-announcements-of-lower-sodium\\_foods-june-2013.pdf](https://cspinet.org/new/pdf/company-announcements-of-lower-sodium_foods-june-2013.pdf)

<sup>8</sup> Institute of Medicine of the National Academies. (2010). Strategies to Reduce Sodium Intake in the United States.

<http://www.nap.edu/catalog/12818/strategies-to-reduce-sodium-intake-in-the-united-states>

<sup>9</sup> Danaei G, et al. The preventable causes of death in the United States: comparative risk assessment of dietary, lifestyle, and metabolic risk factors. PLoS Med. 2009 Apr 28;6(4):e1000058.

<sup>10</sup> City of New York. Consensus Statement on Sodium.

<https://www1.nyc.gov/assets/doh/downloads/pdf/cardio/consensus-statement.pdf>

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<sup>11</sup> Philadelphia Department of Health. (2015). Data Brief – The Healthy Chinese Take-Out Initiative, 2012-2014: <http://www.phila.gov/health/pdfs/DataBriefHealthyChineseTakeOutInitiative2012to2014.pdf>

<sup>12</sup> Centers for Disease Control and Prevention. Reducing Sodium in Los Angeles County: [https://www.cdc.gov/dhdsp/docs/success\\_story\\_la.pdf](https://www.cdc.gov/dhdsp/docs/success_story_la.pdf)

<sup>13</sup> New York City Department of Health and Mental Hygiene Commissioner. (2014, October 8). Letter to Sylvia Burwell, Secretary of the United States Department of Health & Human Services. <https://www1.nyc.gov/assets/doh/downloads/pdf/cardio/sodium-ltr.pdf>

<sup>14</sup> New York City Department of Health and Mental Hygiene Commissioner. (2015, December 9). Letter to Stephen Ostroff, Acting Commissioner of the United States Food and Drug Administration.