



December 2, 2024

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

**Re: Draft Guidance for Industry: Voluntary Sodium Reduction Goals (Edition 2) (Docket Number: FDA-2014-D-0055)**

Dear Deputy Commissioner Jones:

Trust for America's Health (TFAH) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) guidance to provide measurable voluntary goals to reduce excess population sodium intake in commercially processed, packaged, and prepared foods. TFAH is a nonprofit, non-partisan public health policy, research, and advocacy organization that promotes optimal health for all individuals and communities and makes the prevention of illness and injury a national priority. TFAH has long championed evidence-based policies that support equitable access to healthy foods and improve the overall nutritional health of Americans. We support the FDA's efforts to reduce sodium in the food supply as a critical public health intervention.

Over 70% of sodium consumed in the United States comes from foods prepared, packaged, or processed outside of the home,<sup>1,2,3</sup> making federal level policy changes in this area highly impactful for reducing the population's sodium intake. Research shows that consumers generally

---

<sup>1</sup> U.S. Food & Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress. August 15, 2024. <https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=The%20majority%20of%20sodium%20people,how%20much%20sodium%20we%20consume>. Accessed September 25, 2024.

<sup>2</sup> American Heart Association. How much sodium should I eat per day? January 5, 2024. <https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/sodium/how-much-sodium-should-i-eat-per-day#:~:text=Because%20the%20average%20American%20eats,an%20overall%20healthy%20eating%20pattern>. Accessed September 25, 2024.

<sup>3</sup> Trumbo PR, Kirkpatrick KM, Roberts J, Smith P, Zecca P. Perspective: Challenges and Strategies to Reduce the Sodium Content of Foods by the Food Service Industry. *Adv Nutr*. 2023;14(4):592-598. doi:10.1016/j.advnut.2023.04.013



do not notice a reduction of 10% in sodium.<sup>4,5</sup> In Phase I, the FDA recommended lowering the average daily sodium intake to 3,000 milligrams (mg) per day, with Phase II targeting a further reduction to 2,750 mg per day.<sup>6</sup>

The FDA's stepwise approach to help reduce sodium gradually is effective in helping lower sodium intake without compromising the consumer experience. Reducing sodium in processed and packaged foods has the potential to significantly improve health outcomes, particularly for communities disproportionately affected by sodium-related diseases, such as hypertension, obesity, heart disease, stroke, and stomach cancer.<sup>7,8</sup>

### **Support for the Phase I Voluntary Sodium Reduction Targets**

TFAH supported the FDA's Phase I voluntary sodium reduction targets and recognizes the promising evidence of their effectiveness. Prior to 2021, the average daily consumer intake of sodium was 3,400 mg/day. According to the Dietary Guidelines for Americans, the recommendation for sodium intake for individuals older than 14 years old is 2,300 mg/day.<sup>9,10</sup> To address this, the FDA released guidance in October 2021 outlining Phase I voluntary sodium targets.<sup>11</sup> Early data from Phase I has shown that the voluntary targets led to a reduction in sodium levels, particularly in the packaged and restaurant food categories, reinforcing the importance of continuing this effort. Compared to 2010, the baseline year for Phase I evaluations, over 60% of packaged foods and 35% of restaurant menu items reduced sodium

---

<sup>4</sup> U.S. Food & Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress. August 15, 2024. <https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=The%20majority%20of%20sodium%20people.how%20much%20sodium%20we%20consume>. Accessed September 25, 2024.

<sup>5</sup> Jachimowicz-Rogowska K, Winiarska-Mieczan A. Initiatives to Reduce the Content of Sodium in Food Products and Meals and Improve the Population's Health. *Nutrients*. 2023;15(10):2393. Published 2023 May 19. doi:10.3390/nu15102393

<sup>6</sup> U.S. Food & Drug Administration. Sodium Reduction in the Food Supply. September 3, 2024. [https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=Data%20from%202022%20show%20that,tar%20get%20s%20\(through%20April%202024\)](https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=Data%20from%202022%20show%20that,tar%20get%20s%20(through%20April%202024)). Accessed September 25, 2024.

<sup>7</sup> Lucarini M, Durazzo A, Sette S, Lombardi-Boccia G, Santini A, Strazzullo P. Sodium Intake and Related Diseases. *Int J Mol Sci*. 2021;22(14):7608. Published 2021 Jul 16. doi:10.3390/ijms22147608

<sup>8</sup> Jachimowicz-Rogowska K, Winiarska-Mieczan A. Initiatives to Reduce the Content of Sodium in Food Products and Meals and Improve the Population's Health. *Nutrients*. 2023;15(10):2393. Published 2023 May 19. doi:10.3390/nu15102393

<sup>9</sup> U.S. Food & Drug Administration. FDA Announces Milestone in Sodium Reduction Efforts, Issues Draft Guidance with Lower Target Levels for Certain Foods. August 15, 2024. <https://www.fda.gov/news-events/press-announcements/fda-announces-milestone-sodium-reduction-efforts-issues-draft-guidance-lower-target-levels-certain#:~:text=Today%2C%20the%20U.S.%20Food%20and,health%20initiatives%20in%20a%20generation>. Accessed September 25, 2024.

<sup>10</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. December 2020. [https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary\\_Guidelines\\_for\\_Americans\\_2020-2025.pdf](https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf). Accessed September 25, 2024.

<sup>11</sup> U.S. Food & Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress. August 15, 2024. <https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=The%20majority%20of%20sodium%20people.how%20much%20sodium%20we%20consume>. Accessed September 25, 2024.

content by 2022.<sup>12</sup> Overall, nearly 40% of target sodium levels for Phase I have already been met or are within 10% of the goal.<sup>13</sup> These results demonstrate the feasibility of the FDA's phased approach to gradually reduce the daily sodium intake.

### **Support for Phase II of the Voluntary Sodium Reduction Targets**

TFAH supports the FDA's Phase II voluntary guidance to further reduce average sodium intake by gradually reducing sodium in commercially processed, packaged, and prepared foods to 2,750 mg/day over 3 years. While this target remains higher than the recommended sodium limit of 2,300 mg/day, the gradual approach minimizes the impact on consumer taste preferences while still generating public health benefits.<sup>14</sup> Continuously analyzing the effectiveness of the reduction targets will provide critical public health data to understand the impact on human health. Studies show that voluntary sodium reduction is effective in reducing sodium intake, and even modest reductions can improve health outcomes, as seen in global sodium reduction initiatives.

For example, the United Kingdom (UK) and Canada have successfully implemented voluntary sodium reduction programs. In the UK, the Food Standards Agency achieved a 16% reduction in salt intake over 4 years.<sup>15</sup> Health Canada's sodium reduction evaluation showed that 52% of targeted food categories met Phase I, II, or III goals for sodium reduction.<sup>16</sup> The UK, Finland, and Poland have observed improved health outcomes linked to sodium reduction. Between 2003 to 2011, the UK's sodium intake decreased from 3,800 mg/day to 3,240 mg/day, leading researchers to conclude that the reductions in blood pressure during this time was associated with the reduction in sodium intake.<sup>17</sup> Similarly, in Finland and Poland, salt reductions efforts led to a 10.1% and 23.1% decrease in stroke prevalence, respectively.<sup>18</sup> As these countries have

---

<sup>12</sup> U.S. Food & Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress. August 15, 2024. <https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=The%20majority%20of%20sodium%20people,how%20much%20sodium%20we%20consume>. Accessed September 25, 2024.

<sup>13</sup> U.S. Food & Drug Administration. Sodium Reduction in the Food Supply. September 3, 2024. [https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=Data%20from%202022%20show%20that,tar%20get%20s%20\(through%20April%202024\)](https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply#:~:text=Data%20from%202022%20show%20that,tar%20get%20s%20(through%20April%202024)). Accessed September 25, 2024.

<sup>14</sup> U.S. Food & Drug Administration. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Edition 2): Guidance for Industry. August 2024. <https://www.fda.gov/media/180784/download?attachment>. September 25, 2024.

<sup>15</sup> Nurmilah S, Cahyana Y, Utama GL, Ait-Kaddour A. Strategies to Reduce Salt Content and Its Effect on Food Characteristics and Acceptance: A Review. *Foods*. 2022;11(19):3120. Published 2022 Oct 7. doi:10.3390/foods11193120

<sup>16</sup> Health Canada. Sodium Reduction in Processed Foods in Canada: An evaluation of Progress toward Voluntary Targets from 2012 to 2016. January 2018. <https://www.canada.ca/content/dam/hc-sc/documents/services/food-nutrition/legislation-guidelines/guidance-documents/guidance-food-industry-reducing-sodium-processed-foods-progress-report-2017/pub1-eng.pdf>. Accessed September 25, 2024.

<sup>17</sup> U.S. Food & Drug Administration. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Edition 2): Guidance for Industry. August 2024. <https://www.fda.gov/media/180784/download?attachment>. September 25, 2024.

<sup>18</sup> Nurmilah S, Cahyana Y, Utama GL, Ait-Kaddour A. Strategies to Reduce Salt Content and Its Effect on Food Characteristics and Acceptance: A Review. *Foods*. 2022;11(19):3120. Published 2022 Oct 7. doi:10.3390/foods11193120

demonstrated, reducing sodium improves population health, and voluntary sodium reduction programs are effective in lowering sodium levels in the food supply.

## Equity Considerations

TFAH encourages the FDA to recognize and address the impact of high sodium intake on population groups disproportionately impacted by nutrition-related diseases.<sup>19</sup> Scientific evidence has shown that targeted interventions, such as lowering sodium intake levels, can reduce morbidity and mortality by lowering the risk for chronic diseases.<sup>20</sup> Since underserved communities, including people from some racial and ethnic groups and people experiencing poverty, develop elevated rates of high blood pressure compared to the national average, reducing sodium in the food supply could help reduce disease-related disparities and advance health equity in these communities.<sup>21</sup>

Research shows that people from some racial and ethnic groups are 1.5 to 2 times more likely than white individuals to have chronic diseases.<sup>22</sup> Meanwhile, populations with low-incomes are at a heightened risk for these diseases due to higher consumption of ultra-processed foods, which are typically high in sodium.<sup>23,24</sup> Ultra-processed foods (UPF) are often more affordable, widely available, and have longer shelf lives, making them a convenient and more accessible option for households with lower incomes.<sup>25</sup> In part due to the higher level of UPF consumption, these population groups are at higher risk for intaking higher amounts of sodium, leading to higher rates of diet-related chronic health conditions.<sup>26</sup>

---

<sup>19</sup> Dhillon J, Jacobs AG, Ortiz S, Diaz Rios LK. A Systematic Review of Literature on the Representation of Racial and Ethnic Minority Groups in Clinical Nutrition Interventions. *Adv Nutr.* 2022;13(5):1505-1528. doi:10.1093/advances/nmac002

<sup>20</sup> U.S. Food & Drug Administration. FDA Announces Milestone in Sodium Reduction Efforts, Issues Draft Guidance with Lower Target Levels for Certain Foods. August 15, 2024. <https://www.fda.gov/news-events/press-announcements/fda-announces-milestone-sodium-reduction-efforts-issues-draft-guidance-lower-target-levels-certain#:~:text=Too%20much%20sodium%20can%20raise,diet%2Drelated%20diseases%20by%202030>. Accessed September 26, 2024.

<sup>21</sup> U.S. Food & Drug Administration. FDA Announces Milestone in Sodium Reduction Efforts, Issues Draft Guidance with Lower Target Levels for Certain Foods. August 15, 2024. <https://www.fda.gov/news-events/press-announcements/fda-announces-milestone-sodium-reduction-efforts-issues-draft-guidance-lower-target-levels-certain#:~:text=Too%20much%20sodium%20can%20raise,diet%2Drelated%20diseases%20by%202030>. Accessed September 26, 2024.

<sup>22</sup> Price JH, Khubchandani J, McKinney M, Braun R. Racial/ethnic disparities in chronic diseases of youths and access to health care in the United States. *Biomed Res Int.* 2013;2013:787616. doi:10.1155/2013/787616

<sup>23</sup> Matthews ED, Kurnat-Thoma EL. U.S. food policy to address diet-related chronic disease. *Front Public Health.* 2024;12:1339859. Published 2024 May 16. doi:10.3389/fpubh.2024.1339859

<sup>24</sup> National Health Service. Processed Foods. June 12, 2023. <https://www.nhs.uk/live-well/eat-well/how-to-eat-a-balanced-diet/what-are-processed-foods/#:~:text=Not%20all%20processed%20foods%20are,Food%20labels%20on%20processed%20foods>. Accessed September 26, 2024.

<sup>25</sup> Matthews ED, Kurnat-Thoma EL. U.S. food policy to address diet-related chronic disease. *Front Public Health.* 2024;12:1339859. Published 2024 May 16. doi:10.3389/fpubh.2024.1339859

<sup>26</sup> Price JH, Khubchandani J, McKinney M, Braun R. Racial/ethnic disparities in chronic diseases of youths and access to health care in the United States. *Biomed Res Int.* 2013;2013:787616. doi:10.1155/2013/787616

The FDA's guidance focuses on foods that make up to 80% of sales volume in each category.<sup>27</sup> TFAH requests that the FDA begin to assess any racial or ethnic differences in the consumption of targeted foods. This would ensure that if certain foods, currently not included in the top 80% of sales, are consumed more regularly by specific populations, their impact on sodium intake can be evaluated. By doing this, the FDA can better tailor sodium reduction strategies to address the dietary habits and health needs of all communities, ensuring a more comprehensive approach to reducing sodium-related chronic health conditions.

### **Conclusion**

TFAH appreciates the opportunity to comment on strategies to prevent chronic diseases. We look forward to further discussions about how to best advance policies that protect the health and security of our country. Please contact Madison West, Government Relations Manager, at [mwest@tfah.org](mailto:mwest@tfah.org) with any questions or for additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Nadine Gracia". The signature is fluid and cursive, with a large initial "J" and "G".

J. Nadine Gracia, MD, MSCE  
President and CEO  
Trust for America's Health

---

<sup>27</sup> U.S. Food & Drug Administration. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Edition 2): Guidance for Industry. August 2024. <https://www.fda.gov/media/180784/download?attachment>. September 25, 2024.