NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Michelle Morse, MD, MPH
Acting Health Commissioner

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via electronic submission: [https.www.regulations.gov]

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Acting Health Commissioner

Gotham Center
42-09 28th St.
Long Island City, NY 11101

Re: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Edition 2): Guidance for Industry. [FDA-2014-D-0055]

The New York City (NYC) Health Department is pleased to submit a comment regarding the Food and Drug Administration's guidance for voluntary Phase II (3-year) sodium reduction goals in commercially processed, packaged, and prepared foods. The NYC Health Department has been at the forefront of sodium reduction efforts in the United States, and we are happy to see continued efforts at the federal level.

Consistent with national data, sodium consumption in NYC is higher than the recommended limit. Heart disease has been the number one leading cause of death among New Yorkers for over twenty years and a persistent indicator of health inequity. In 2021, premature death (defined as death before the age of 65) from heart disease was the number one cause of death among non-Hispanic Black New Yorkers.[1] In Fall 2023, NYC announced HealthyNYC, a campaign to increase life expectancy among New Yorkers by 2030, which decreased significantly since 2019. A goal of the campaign is to reduce rates of chronic and diet-related conditions like heart disease and stroke and address the inequities we see in rates of these conditions by race and ethnicity in NYC.

NYC has a long history of addressing high rates of sodium consumption. In 2008, NYC was the first major city in the country to set nutrition standards for all foods and meals purchased and served by the City. The Food Standards apply to over 192 million meals served each year and include sodium limits on meals served and foods purchased. In the restaurant setting, NYC was the first city in the nation to pass a sodium warning policy. The policy, codified in rulemaking enacted by the New York City Board of Health in 2015, requires chain restaurants to post a warning icon next to menu items that contain at least 2,300 mg of salt, the daily recommended limit for an adult.

[1] Li W, Onyebeke C, Castro A, Gurung S, Maduro G, Sun Y, Seil K, and Van Wye G. Summary of Vital Statistics, 2021. New York, NY: Bureau of Vital Statistics, New York City Departmentof Health and Mental Hygiene.

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National Salt Reduction Initiative (NSRI): As the FDA referenced in its draft guidance, in 2009, the NYC Health Department convened the National Salt Reduction Initiative (NSRI), now the National Salt and Sugar Reduction Initiative (NSSRI). The goal of the NSRI was to reduce sodium in packaged and restaurant food, reduce population sodium intake, and ultimately reduce risk of hypertension, heart disease, and stroke. A partnership of organizations from across the country called on the food industry to voluntarily commit to sodium reduction in their products. Through a robust engagement process with the industry, the NSRI set sodium reduction targets for 62 packaged food categories and 25 restaurant categories for 2012 and 2014. As noted by the FDA, the NSRI informed the development of both the Phase I and Phase II sodium reduction goals.

The NSRI tracked sodium in the food supply over time by creating and updating databases with the most recent nutrition information for packaged and restaurant food. We conducted analyses of the progress of companies that committed to NSRI targets and tracked industry progress as a whole and by category (including companies that did not publicly commit). We found that from 2009 to 2018, sodium density declined significantly in almost half of all packaged food categories. Overall, sodium density in U.S. packaged foods declined significantly by 8.5%.[2] The greatest decline occurred between 2009-2012 (5.1%) with smaller declines between 2012-2014 and 2014-2018.[3] In an internal analysis, using 2018 NSSRI data, we assessed the sodium content of the packaged foods that were the highest selling items (by volume) in each of the FDA packaged food categories. In the categories analyzed, we found that 18% of highest selling items already met the 2021 FDA sodium targets in 2018 and 63% of products were within 20% of the targets (Appendix).[4] Looking at the highest selling items is important because it reflects the drivers of population sodium intake. Together these results show the importance of:

1) consecutive sets of targets of short-, medium-, and long-term time frames to ensure food and beverage companies are continuing to decrease sodium after initial targets are met, without incremental targets, momentum wanes and progress stalls.
2) setting ambitious goals for industry as so many of the highest selling products were already at or near the first set of FDA targets.
3) transparency about which products are contributing the most to sodium intake (i.e highest selling items) and whether those products in particular are decreasing in sodium content as a result of targets.

The NYC Health Department is supportive of national sodium reduction targets, and we urge the FDA to consider additional action to strengthen the targets and accelerate sodium reduction in the food supply.

We have five recommendations for FDA to strengthen their guidance:

1. Include additional data points as part of the forthcoming Phase I evaluation:
   When FDA conducts its final evaluation of progress toward the Phase I targets, we suggest including additional time points for analysis. This will provide additional granularity as to when industry changed sodium content in their

[2] Moran AJ, Wang J, Sharkey AL, Dowling EA, Curtis CJ, Kessler KA. US Food Industry Progress Toward Salt Reduction, 2009-2018. Am J Public Health. 2022 Feb;112(2):325-333. doi: 10.2105/AJPH.2021.306571. PMID: 35080946; PMCID: PMC8802589.

[3] Moran AJ, Wang J, Sharkey AL, Dowling EA, Curtis CJ, Kessler KA. US Food Industry Progress Toward Salt Reduction, 2009-2018. Am J Public Health. 2022 Feb;112(2):325-333. doi: 10.2105/AJPH.2021.306571. PMID: 35080946; PMCID: PMC8802589.

[4] Sodium Levels in US Packaged Foods in 2018. National Salt and Sugar Reduction Initiative. December 2024. National Salt and Sugar Reduction Initiative (NSSRI) - NYC Health

products, as well as assess progress during the specific time period of the Phase I targets, October 2021-April 2024. FDA's preliminary analysis looking at 2010 baseline data compared to 2022 data is a large time frame to be able to clearly understand how industry responded to FDA action of the Phase I targets. We recommend that FDA consider assessing the following time periods: 2010-2016 (beginning with the Phase I baseline year), 2016-2021 (beginning with the release of preliminary targets were released) and 2021-2024 (the Phase I target period). This would provide a more comprehensive look at the impact of preliminary and final Phase I targets by category and help inform future target setting.

2. Establish short and long-term targets to be released together to facilitate industry compliance:

   The NYC Health Department encourages FDA to release ambitious short, medium, and long-term targets simultaneously. This would maintain momentum in sodium reduction efforts and facilitate gradual, incremental sodium reduction in foods over time. A lack of long-range targets makes it likely that progress will stall once targets expire, as occurred following NSRI 2014 targets.

   A set timeline of sodium reduction targets may be most helpful for companies in planning long-term product development and reformulations. Some products, including vegetable juice and butter, increased in sodium content in FDA's preliminary analysis and now have Phase II targets that are higher than the original Phase I targets. If short-term and long-term targets are released together, then all food categories would have incremental sodium decreases over time, rather than changes in targets depending on the baseline year. We also encourage FDA to revisit those food products with Phase II targets that are higher than Phase I targets and consider lowering the target.

3. Establish a public database to monitor nutrition content in packaged and restaurant foods over time:

   The database could track category level data in addition to including product level nutrient information. A public database would allow for the tracking of progress made towards sodium targets while also providing transparency for levels of other nutrients of concern such as added sugars and saturated fats. It would also ensure public accountability that could incentivize food companies to meet the voluntary targets. A database could also be used by researchers to publish important analyses on our food supply. As an example, MenuStat has made accessible the nutrient content of menu items for the top chain restaurants in the U.S. and has been an invaluable resource to researchers interested in tracking how the nutrient content of these items have changed over time.[5]

4. Invest in research on population sodium intake:

   We are eager to see the results of the FDA's evaluation of the Phase I targets and their effect on the amount of sodium in the food supply. Beyond that, the FDA should consider 1) modelling studies to estimate the potential impact of the

[5] Publications - MenuStat

targets on subsequent health outcomes and 2) investigating the impact of the targets on actual U.S. population sodium intake using NHANES data.

Recent research has demonstrated that while the sodium content of packaged foods may be decreasing, Americans are consuming more ultra-processed items,[6] highlighting the importance of continued surveillance of both sodium consumption and sodium in the food supply.

5. Consider setting mandatory sodium reduction targets if industry progress stalls: Establishing mandatory sodium reduction targets would ensure that food companies must comply. Research shows that if the targets set by the NSRI were fully met, the proportion of U.S. adults who consume greater than 2,300 mg of sodium per day would decline from 88% to 71%.[7] Even modest reductions in sodium consumption are associated with fewer cardiovascular disease (CVD) cases and deaths. A modeling study found that if sodium consumption declined to 2,974 mg per day, even higher than FDA's Phase II goal of 2,750 mg per day, 120,000 CVD cases could be prevented or postponed and approximately $9.7 billion in total net healthcare costs could be saved.[8]

Finally, we ask that the FDA finalize these targets in a timely manner to continue the momentum on sodium reduction. We are eager to see the final Phase II targets and urge FDA to expeditiously publish the final guidance.

Thank you for the opportunity to comment on this important issue.

Sincerely,

[redacted]

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New York City Department of
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[6] Juul F, Parekh N, Martinez-Steele E, Monteiro CA, Chang VW. Ultra-processed food consumption among US adults from 2001 to 2018. Am J Clin Nutr. 2022 Jan 11;115(1):211-221. doi: 10.1093/ajcn/nqab305. PMID: 34647997.

[7] Cogswell ME, Patel SM, Yuan K, Gillespie C, Juan W, Curtis CJ, Vigneault M, Clapp J, Roach P, Moshfegh A, Ahuja J, Pehrsson P, Brookmire L, Merritt R. Modeled changes in US sodium intake from reducing sodium concentrations of commercially processed and prepared foods to meet voluntary standards established in North America: NHANES. Am J Clin Nutr. 2017 Aug;106(2):530-540. doi: 10.3945/ajcn.116.145623. Epub 2017 Jul 12. PMID: 28701299.

[8] Pearson-Stuttard J, Kypridemos C, Collins B, Mozaffarian D, Huang Y, Bandosz P, Capewell S, Whitsel L, Wilde P, O'Flaherty M, Micha R. Estimating the health and economic effects of the proposed US Food and Drug Administration voluntary sodium reformulation: Microsimulation cost-effectiveness analysis. PLoS Med. 2018 Apr 10;15(4):e1002551. doi: 10.1371/journal.pmed.1002551. PMID: 29634725; PMCID: PMC5892867.

Sodium Levels in U.S. Packaged Foods in 2018

Summary: High sodium intake contributes to cardiovascular disease, the leading cause of death in the U.S. Setting sodium targets for packaged foods can help reduce a key source of dietary sodium.

This report uses national packaged food information from 2018, incorporating both sodium content and food category sales data, to assess progress toward the first set of U.S. Food and Drug Administration sodium targets.

In 2021, the U.S. Food and Drug Administration (FDA) announced voluntary short-term sodium targets for 2024 for 136 packaged and 84 restaurant food categories (Phase I), with the promise of further targets.[1] In 2024, the FDA announced draft voluntary targets for 2027 (Phase II).[2] The Phase I targets were the first of their kind from the FDA for any nutrient and provide an opportunity to support sodium reduction if appropriately monitored and lowered over subsequent phases. The FDA set two kinds of targets: a sales-weighted mean (SWM) target for each food category and an upper bound target for any product in that category, using baseline data from 2010.[1]

The NYC Department of Health and Mental Hygiene (Health Department) assessed progress toward the Phase I FDA targets among top-selling products based on a national database of U.S. packaged foods from 2018.

How did we use the data? The NYC Health Department created a Popular Packaged Food dataset to assess the sodium concentration of the highest-selling packaged foods, categorized according to FDA food categories using data the Health Department had access to as part of building the National Salt Reduction Initiative (NSRI) database. The NSRI database, described in detail in previous research,[3] includes Nielsen sales data from 2017 linked by Universal Product Code to nutrition data from Label Insight and manufacturer websites in 2018 for 62 NSRI packaged food categories.[4]

Of the 136 packaged food categories included in Phase I, 93 had enough overlap with the categories included in the NSRI database to identify the top 10 highest-selling products within those categories by units sold, referred to here as "popular products." Ten categories were excluded from the analysis because nutrition information for two or more of the 10 most popular products in the category was either missing or collected before 2016. For the 83 remaining categories, the SWM sodium concentration was calculated and products were assessed for proximity to the upper bound.

What did we find?

Sales-Weighted Mean Target Analysis: Of the categories analyzed, the SWM sodium concentration of popular products in 15 categories (18%) already met the Phase I FDA SWM target, the SWMs of 52 categories (63%) were within 20% of the FDA target, and the remaining 16 categories (19%) had a SWM that was more than 20% higher than the FDA target (Figure 1). Overall, 74 categories (89%) contained at least one popular product that already met the FDA SWM 2024 target.

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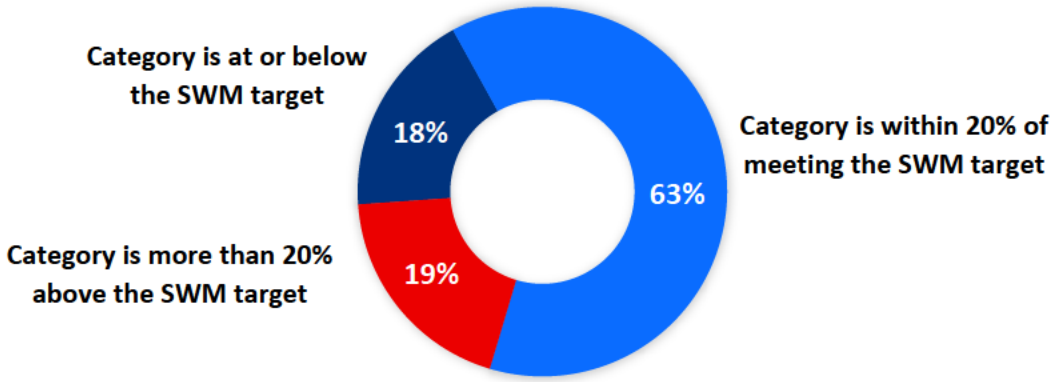
[1] U.S. FDA. Guidance for industry: voluntary sodium reduction goals. October 2021. Accessed June 9, 2022. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals

[2] U.S. FDA. Guidance for industry: voluntary sodium reduction goals. August 2024. Accessed September 12, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-sodium-reduction-goals-edition-2

[3] Moran AJ, Wang J, Sharkey AL, Dowling EA, Curtis CJ, Kessler KA. US food industry progress toward salt reduction, 2009-2018. *Am J Public Health*. 2022;112(2):325-333. doi:10.2105/AJPH.2021.306571; PMID:35080946; PMCID:PMC8802589

[4] NYC Health Department. National Salt Reduction Initiative packaged food categories and targets. https://www.nyc.gov/assets/doh/downloads/pdf/cardio/packaged-food-targets.pdf

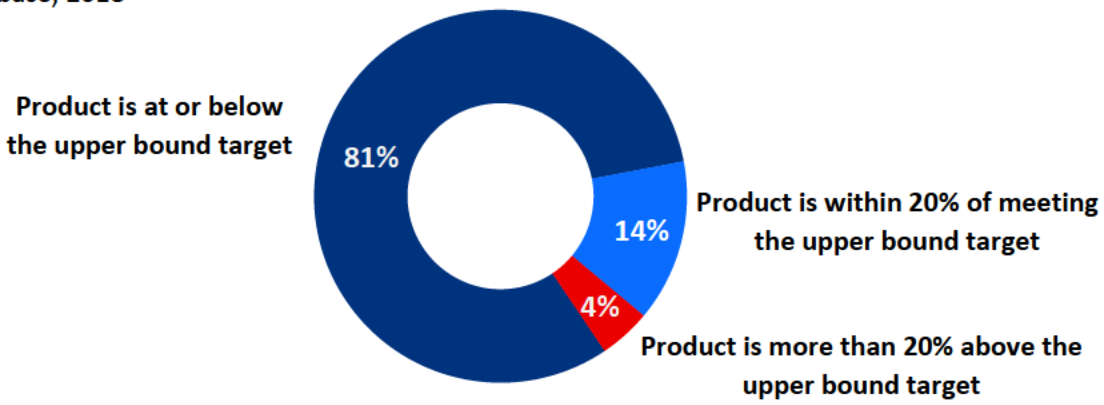
Figure 1. Percent of Categories (N = 83) Meeting the FDA Sales-Weighted Mean (SWM) Sodium Target[a] Based on Sodium Content of Popular Products[b] in Each Category From the National Salt Reduction Initiative Packaged Food Database, 2018



[a] FDA sales-weighted mean (SWM) sodium target is the sodium concentration (milligrams of sodium per 100 grams of food) weighted by the sales volume of individual products in the category.
[b] Popular products are defined as the top 10 highest-selling products in each category by units sold.

Upper Bound Target Analysis: There were 803 popular products with nutrition information available included in the 83 analyzed categories. A total of 654 products (81%) had a sodium concentration value that met the FDA 2024 upper bound target for their category, while 113 products (14%) were within 20% of the upper bound target and 36 (4%) were more than 20% higher (Figure 2).

Figure 2. Percent of Popular Products[a] Meeting the FDA Upper Bound Sodium Target[b] for Their Category (N = 803) Based on Product Sodium Content From the National Salt Reduction Initiative Packaged Food Database, 2018



[a] Popular products are defined as the top 10 highest-selling products in each category by units sold.
[b] The upper bound sodium target is for the sodium concentration of an individual food product included in a category.
Note: Percentages do not add to 100 due to rounding.

Conclusions: This analysis found that for many categories the SWM of popular products already met or was close to the Phase I FDA targets as of 2018. Further, the sodium concentration of most popular products was already below the upper bound target. As the FDA works to finalize Phase II, we encourage them to set aggressive targets in the future and look forward to their continued reporting of industry progress toward both Phase I and Phase II targets as part of a transparent, public process to lower the sodium content of the food supply.