

January 13, 2025

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

#### Re: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry (Edition 2); Availability (Docket No. FDA-2014-D-0055)

Dear Dockets Management Staff:

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the U.S. Food and Drug Administration's (FDA's) draft guidance for industry on Phase II voluntary sodium reduction targets for commercially processed, packaged, and prepared foods. CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. CSPI has an extensive history of advocating for policies related to sodium reduction through food labeling, menu labeling, restaurant nutrition standards, school meals and competitive foods nutrition standards, and federal dietary guidance. CSPI publishes *Nutrition Action* (NA) and is supported by its member-subscribers to NA, individual donors, and foundation grants. CSPI is an independent organization that does not accept any corporate donations.

In this comment, we provide feedback on both FDA's draft Phase II sodium reduction targets, and on the agency's preliminary assessment of its Phase I sodium reduction targets,<sup>1</sup> which FDA leadership characterized as "showing encouraging progress."<sup>2</sup> As we describe in more detail below (see point 2), we re-analyzed FDA's data, and did not find evidence that Phase I is showing encouraging progress. Although FDA's preliminary assessment found that 52% of food categories decreased in sodium and only 34% increased from 2010-2022,<sup>3</sup> our analysis found that the magnitude of change in food categories' sodium content was typically very small during that period (median: -3% change; interquartile range: -8% to 6%), with worse results for restaurant foods (median: +2% change; interquartile range: -5% to 11%).

To ensure successful sodium reduction across the food supply, we offer the following feedback on FDA's sodium reduction efforts:

- 1. FDA action to spur industry-wide sodium reduction is crucial for Americans' health, and we generally support the agency's efforts.
- 2. Contrary to FDA's preliminary assessment of the effectiveness of its Phase I sodium targets, a CSPI reanalysis does not provide evidence of encouraging industry progress.
- 3. Lessons from other sodium reduction initiatives show that FDA must be more aggressive with its sodium reduction efforts.

- a. FDA must set more aggressive Phase II targets with additional per-serving maxima to reduce population sodium consumption lower than the 2,750-mg/day goal in the Proposed Guidance.
- b. FDA's monitoring and evaluation of Phase I and II targets must be timely, transparent, and methodologically rigorous.
- c. FDA should more actively and transparently engage with the food industry and should urge companies to publicly commit to sodium reduction targets.
- d. FDA should strongly consider setting mandatory sodium reduction targets if Phase II voluntary targets are not met.

Our comments are as follows:

1. FDA action to spur industry-wide sodium reduction is crucial for Americans' health, and we generally support the agency's efforts.

We concur with former FDA Commissioner Scott Gottlieb's assertion that "there remains no single more effective public health action related to nutrition than the reduction of sodium in the diet."<sup>4</sup>

Americans consume an average of about 3,100 mg of sodium per day,<sup>5</sup> roughly 35 percent more than the 2,300 mg limit recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM)<sup>6</sup> and the Dietary Guidelines for Americans (DGA).<sup>7</sup> Overconsumption of sodium is a serious threat to Americans' health, because it increases blood pressure and the risk of cardiovascular disease.<sup>8</sup> Nearly half of all U.S. adults suffer from high blood pressure,<sup>9</sup> and cardiovascular disease is a leading cause of death in the U.S.<sup>10</sup> In 2010, a reduction in daily sodium consumption of 1,200 mg/day (about what was needed at the time to reach the federally recommended limit) was estimated to save between 44,000 and 92,000 lives and \$10–24 billion per year.<sup>11</sup>

The majority of sodium in the U.S. diet comes from commercially processed, packaged, and prepared foods (including restaurant foods), with only limited sodium coming from home cooking or addition at the table.<sup>12</sup> This means that sodium consumption is largely out of consumers' control, necessitating federal action to spur industry-wide reduction.

CSPI has been urging FDA to reduce sodium in the food supply for nearly 50 years.<sup>13</sup> We were heartened when FDA took steps towards addressing this crisis in 2016; partly in response to a 2015 lawsuit that CSPI filed against FDA seeking action on an earlier petition.<sup>14</sup> FDA issued a draft 2016 guidance with both short- (2-year) and long-term (10-year) targets.<sup>15</sup> In October 2021, five years after the original targets were drafted, the agency finalized part of the guidance, establishing "Phase I" short-term (2.5-year) voluntary targets that, if met, would reduce average daily sodium intake to 3,000 mg/day.<sup>16</sup> CSPI again petitioned FDA in 2023 calling for the agency to finalize long-term targets, establish intermediate targets, monitor industry compliance, and maintain a public database of products that contribute the most to U.S. sodium intake.<sup>17</sup>

We are pleased to see that FDA has now proposed an updated set of 3-year ("Phase II") targets for industry across 163 food categories that approximate in time the interim targets our petition called for, with full compliance bringing Americans' sodium consumption to safer levels.<sup>18</sup> We support FDA in continuing its work to reduce average sodium consumption to 2,300 mg/day, and we look forward to seeing FDA's full evaluation of Phase I targets.

### 2. Contrary to FDA's preliminary assessment of the effectiveness of its Phase I sodium targets, a CSPI reanalysis does not provide evidence of encouraging industry progress.

Although FDA cannot fully assess progress against the Phase I targets until relevant data from the 2.5year period ending April 2024 are available, the agency conducted a preliminary assessment to understand changes in sodium in the food supply thus far.<sup>19</sup> The agency's analysis found that from 2010 (well before the Phase I targets went into effect) to 2022 (somewhat before the Phase I targets would be implemented), 34% of food categories increased in sodium (52% decreased and 14% remained unchanged), and nearly half of restaurant categories increased in sodium.<sup>20</sup> While this assessment is interesting, it tells us little about the magnitude of changes over time, which are crucial to inform whether the targets are having their intended effect. FDA described these findings as "encouraging,"<sup>21</sup> but without these magnitudes, it remains possible that there has been little change in the amount of sodium in the food supply or even that the food supply now contains more sodium.

To measure the magnitude of change in sodium in the food supply from 2010 to 2022, we reanalyzed the data that FDA published alongside its analysis; these data contained sales-weighted mean sodium content (mg/100g) by food subcategory in 2010<sup>22</sup> and 2022.<sup>23</sup> Ideally, these data would contain more timepoints than just 2010 and 2022, so that we could understand how sodium content changed each year and whether the average rate of change in sodium was different before vs. after the Phase I targets were published in 2021. Because these data only contain two timepoints, however, we could not use them to evaluate more granular trends over time or swings in sodium content within the overall assessment period.

However, we used these data to measure the magnitude of change from 2010 to 2022 by calculating the percent change in sales-weighted mean sodium content (mg/100 mg) by subcategory (see **Appendix Exhibit 1** for detailed methodology). We also calculated descriptive summary measures (e.g., median) for the percent change across subcategories overall, for packaged and restaurant categories, and for each food category (**Appendix Table 1**). We recognize that summary measures are imperfect to inform progress, because they are not weighted by each subcategory's contribution to overall sodium in the U.S. diet, but we were limited in our analyses to FDA's publicly released data, which did not include subcategory weights.

We found that the magnitude of change in the sales-weighted mean sodium content (mg/100g) of food subcategories was very small overall (median: -3% change, interquartile range (IQR): -8% to 6%) and especially across restaurant subcategories (median: +2%, IQR: -5% to 11%), although packaged subcategory results showed slightly larger reductions (median: -4%, IQR -9% to -1%) (**Figure 1**). However, it is of particular concern that eleven food subcategories increased in sales-weighted mean sodium content by 25% or more, and many of these were restaurant subcategories (**Appendix Table 2**). Conversely, only seven food subcategories decreased by 25% or more. For example, the sales-weighted mean sodium content of mixed seafood-based dishes (not breaded) at restaurants increased by 99%, from 365mg/100g in 2010 to 728mg/100g in 2022.

Overall, these results do not provide evidence of substantial industry progress in reducing sodium from 2010-2022. Our findings do suggest that restaurants appear to have increased sodium in their foods overall.

Despite limited evidence of progress in sodium reduction in the U.S. food supply from 2010-2022, population-wide sodium consumption (another way of measuring progress on sodium reduction) appears to have gone down during that period. FDA's Phase I targets were set based on 2009-2010 U.S. consumption data from the What We Eat in America survey,<sup>24</sup> which showed average sodium consumption for people aged 2 years and older to be 3,463mg/day.<sup>25</sup> When the targets were finalized in 2021, the most recent population data were from 2017-March 2020 (pre-pandemic), and showed average sodium consumption to be 3,346mg/day.<sup>26</sup> Since then, updated consumption data from 2021-2023 shows average sodium consumption to be 3,113mg/day.<sup>27</sup> While this decrease is a positive sign, the role played by FDA's sodium targets is unclear, because changes in sodium consumption could also result from reduced food intake overall or from movement away from food categories that contribute more sodium to the American diet.

# 3. Lessons from other sodium reduction initiatives show that FDA must be more aggressive with its sodium reduction efforts.

FDA's sodium reduction target model was informed by the United Kingdom's (UK's) Salt Reduction Campaign and the New York City Department of Health and Mental Hygiene's (NYC DOHMH's) National Salt Reduction Initiative (NSRI),<sup>28</sup> and the evaluations of those initiatives provide important lessons. The UK launched voluntary sodium reduction targets for 85 packaged and restaurant food categories in 2003.<sup>29</sup> From 2003 to 2011, salt in many UK food categories decreased by 20-50%, and population sodium intake decreased by 15%.<sup>30</sup> An evaluation of the initiative found that key components for success included: timely and rigorous monitoring of both sodium in the food supply and population sodium intake; close engagement with the food industry to secure public commitments to the targets, along with public praising of companies that made progress and shaming those that did not take action; and maintaining the threat of mandatory targets should industry fail to act voluntarily.<sup>31</sup> Progress stalled thereafter, however, after a new administration adopted a more industry-friendly posture and reduced or eliminated all three components.<sup>32</sup>

In 2009, the NYC DOHMH used the UK's earlier efforts as a model to launch the NSRI,<sup>33</sup> a partnership with state and local health authorities and national health organizations.<sup>34</sup> This initiative also aimed to encourage food manufacturers and restaurants to voluntarily reduce sodium in their products. An evaluation of the NSRI from 2009 to 2014 found a 6.8% reduction in sales-weighted mean sodium density in foods, which was far below the 25% reduction target.<sup>35</sup> A more extended evaluation from 2009 to 2018 found that food manufacturers reduced sodium in the earliest years of the NSRI (2009 to 2012), but progress slowed thereafter.<sup>36</sup> The researchers posited that this early industry action was largely driven by widespread media attention with the launch of the NSRI, the broader political attention on sodium reduction, and industry's resulting anticipation of regulatory oversight.<sup>37</sup>

These experiences illustrate that, for FDA's voluntary initiative to succeed, the agency must maintain pressure on the food industry by: a) setting more aggressive Phase II targets; b) monitoring and evaluating targets in a timely, transparent, and methodologically rigorous manner; c) engaging more

actively and publicly with the food industry; and d) setting mandatory sodium reduction targets if Phase II voluntary targets are not met.

# a. FDA must set more aggressive Phase II targets with additional per-serving maxima to reduce population sodium consumption lower than the 2,750 mg/day goal in the Proposed Guidance.

While we support FDA in its sodium reduction efforts, full industry compliance with FDA's new draft guidance would only reduce average sodium intake to 2,750 mg/day,<sup>38</sup> which is still far from the 2,300 mg recommended daily limit. Given the life-saving potential of sodium reduction, FDA must set more aggressive Phase II targets to more quickly reduce consumption to recommended levels. FDA's Phase I targets represented a 12% reduction in sodium, from 3,400 to 3,000 mg/day, over 2.5 years; the proposed Phase II targets represent a smaller reduction in sodium (8%, 3,000 to 2,750mg/day) over a longer period (3 years). Larger reductions over a shorter timeframe are needed.

We urge FDA to be more aggressive with its Phase II targets, aiming to reduce overall sodium intake to at least 2,640 mg/day, which is another 12% reduction in keeping with Phase I, and is also roughly halfway between the 2024 target of 3,000 mg and the ultimate goal of 2,300 mg. This is especially important because it is likely that industry will not fully comply with these voluntary targets. We recognize that FDA's proposed Phase II targets align with the Healthy People 2030 goal of reducing average U.S. sodium intake to approximately 2,750 mg/day by 2030,<sup>39,40</sup> and we appreciate coordination of sodium reduction efforts across the U.S. government. However, we believe that more aggressive FDA targets would only help the U.S. population meet the Healthy People 2030 goals.

It is disheartening to see that FDA adjusted several Phase II targets to be higher than Phase I targets, which we understand was informed by "the distribution of sodium concentrations [FDA] found in products within that category [in 2022]."<sup>41</sup> In other words, these adjustments appear to have been made due to a lack of industry progress on Phase I targets. Instead of accommodating industry's lack of progress, FDA must follow its charge of protecting public health by following the strategies below to hold food manufacturers accountable to reasonable, stepwise sodium reduction.

In addition to setting more aggressive targets, we urge FDA to add an additional set of targets to ensure individual products do not contain exorbitant levels of sodium. FDA's Phase II draft guidance currently contains category-specific targets for sales-weighted mean sodium content across all products within each food category, as well as product-specific upper-bound (maximum) targets for all products within a category. These maximum targets are the only ones that apply to individual products, and thus the only ones particular food companies can be held directly accountable for. The targets are designed to decrease overall sodium density (mg sodium/100g of food), which is important to adequately reduce sodium across the food supply. However, there are currently no maximum targets for how much sodium a single serving of a product should contain, which allows products to meet these targets while still containing exorbitant levels of sodium depending on their portion size. For example, the proposed Phase II upper-bound target for restaurant soups is 420mg/100g.<sup>42</sup> With no per-serving limit, a 12-oz bowl of chicken noodle soup served in a restaurant could meet the Phase II proposed upper-bound target while still containing 1,543mg of sodium per serving (67% of the daily limit).<sup>43</sup> No single product should provide 2/3 of a person's daily sodium intake. FDA should fix this by adding upper-bound per-serving sodium targets (e.g., no more than 20% of the daily value per serving) in addition to the upper-bound sodium density targets.

## b. FDA's monitoring and evaluation of Phase I and II targets must be timely, transparent, and methodologically rigorous.

For these voluntary targets to have any teeth, FDA must conduct methodologically rigorous, timely, and transparent monitoring and evaluation for both Phase I and Phase II targets. FDA's evaluation plan should identify the specific data sources FDA will use and its exact methodology for analyzing the data. Any datasets assembled by FDA or otherwise in the public realm should be made available to the public in raw form. In its evaluations, FDA should evaluate the magnitude of change in sales-weighted mean sodium in the food supply over time overall (weighting food categories by their contribution to sodium consumption in the American diet) and by food category and subcategory. To isolate the specific effects of Phase I and Phase II targets to understand whether or not they are working, the agency must also evaluate more granular (e.g., annual) trends over time. FDA should also track category-specific progress towards sales-weighted mean sodium targets and product-specific progress towards upper-bound targets by the largest packaged and restaurant food manufacturers. FDA should also use population-wide sodium consumption data to understand how changes in the food supply are associated with overall changes in consumption. In addition to tracking sodium content and consumption, FDA should evaluate how the food industry is reformulating packaged and restaurant foods in response to the sodium reduction targets. This includes potential changes in other nutrients like added sugar and saturated fat, and in additives like potassium chloride.

FDA should publish and publicize its findings in reports with aggregated data on its website for all the food categories covered in its guidance. In addition to these technical progress reports, FDA should publish corresponding summary reports that are written for a general audience. These reports should indicate how industry is faring compared to the established target means and product upper bounds in each category at the end of each Phase. FDA should publicly praise companies that are meeting the upper-bound targets, and name and shame companies that are lagging behind.

As part of the agency's ongoing monitoring of the food supply, FDA should—on its own or in collaboration with other government agencies—launch and maintain a publicly accessible database with regularly updated nutrition information for branded packaged and restaurant foods that allows the public to understand which companies are failing to meet the upper-bound product targets. Agency decisions must be transparent to allow for meaningful democratic engagement, so if FDA is relying on proprietary sources for its evaluation, it should, as far as possible, enter only into agreements that allow the data to be shared with the public. There is already a precedent for this type of public-private data partnership for packaged foods, as the USDA currently maintains the publicly accessible Global Branded Food Products Database, which sources food-company-uploaded nutrition and ingredient data from private data providers.<sup>44</sup> In cases in which FDA is relying on public sources—which it has indicated it will do for restaurant data<sup>45</sup>—FDA should also share these consolidated data via a publicly accessible database.

These activities will allow FDA, other government agencies, industry, advocacy groups, researchers, and the public to: 1) identify which food and beverage target categories and specific products are/are not on track to meeting the sodium reduction goals; 2) understand which food companies are most successful at sodium reduction and which need additional technical assistance to meet the targets; and 3) catch unintended changes to the food supply resulting from sodium reduction efforts that may make it more dangerous to consumers (e.g., increasing amounts of added sugar). FDA should adjust its strategy and coordinate with relevant stakeholders based on its findings.

### c. FDA should more actively and transparently engage with the food industry and should urge companies to publicly commit to sodium reduction targets.

As mentioned above, we believe that sodium reduction efforts in the UK and New York City have illustrated the importance of active engagement with the food industry in ensuring compliance with voluntary targets. We urge FDA to engage with the food industry to understand barriers and facilitators to successful sodium reduction; connect industry stakeholders to one another so that those who are lagging can learn from those who are leading; and be as transparent as possible with the public about these engagements and what the agency ultimately gleans from them. We also urge FDA to increase industry accountability by pushing packaged and restaurant food companies to make public commitments to meet FDA's sodium reduction targets, as has been done in New York City's sodium reduction efforts.<sup>46</sup>

As a starting point, we recommend focusing engagement with food industry players who manufacture foods that contribute the largest amount of sodium to the U.S. diet, as their commitments present the greatest potential for impact on sodium intake reduction. A recent analysis of dietary data from the combined National Health and Nutrition Examination Survey, What We Eat in America, 2009–2018 found that the food subgroups contributing the most sodium to the U.S. diet include store-bought lunchmeat sandwiches and hot dogs, restaurant-prepared burgers, store-bought and restaurant-prepared tacos/burritos, restaurant-prepared pizza with meat, and store-bought white/wheat bread.<sup>47</sup> We thus urge FDA to engage most closely with the packaged and restaurant food manufacturers who produce those foods to reduce their sodium content.

We also recommend FDA conduct outreach with chain restaurants that continue to offer items that are very high in sodium. FDA should have these data from its preliminary assessment of restaurant progress, and we encourage the agency to also review a recent study published by CSPI-affiliated authors that assessed the sodium content of menu items in 91 of the highest-grossing chain restaurants in the U.S.<sup>48</sup> This study found that at limited and full-service chain restaurants, respectively, 3% and 11% of single-serve menu items exceeded the daily recommended sodium limit for U.S. adults, and 17% and 33% of menu items across all restaurant chains from each food category, and we encourage FDA to use these data (in addition to the article's restaurant-chain-level data) to identify restaurants to prioritize. The study used data from 2019, the most recent year available from a national database (MenuStat) at the time of analysis, but updated 2024 sodium information affirms that restaurant chain menu items still have astronomically high levels of sodium—including a bowl of chicken noodle soup from Frisch's Big Boy with 10,320 mg of sodium (449% of the sodium Daily Value, DV), and a turkey muffaletta sandwich from Jason's Deli with 8,520 mg of sodium (370% DV).<sup>50</sup>

## d. FDA should strongly consider setting mandatory sodium reduction targets if Phase II voluntary targets are not met.

If FDA's evaluation of Phase II voluntary reduction targets finds little to no industry progress, FDA must modify its approach to protect Americans' health by strongly considering setting mandatory sodium reduction targets (e.g., making product-specific upper-bound targets mandatory). While the process of setting mandatory targets through regulation (or legislation) may take substantial time and effort, we believe it is the clear next step if industry continually fails to meet FDA's voluntary targets. The U.S. could

follow the lead of the 19 other countries that already have mandatory sodium reduction targets in place.<sup>51</sup> The mere threat of mandatory targets is useful for voluntary industry compliance.

In conclusion, FDA has an obligation to protect Americans' health by ensuring that industry reduces sodium across the food supply. We encourage the agency to hold industry accountable by setting aggressive reduction targets, implementing a strong and transparent monitoring and evaluation plan, and working actively and publicly with packaged and restaurant food companies to achieve sodium reduction. We urge the FDA to act quickly on these recommendations to ensure a safer U.S. food supply.

Sincerely,

Aviva Musicus, ScD Science Director Center for Science in the Public Interest

#### Peter Lurie, MD, MPH

President and Executive Director Center for Science in the Public Interest













<sup>a</sup> Frequencies are shown in 5% change increments, with each increment including the higher value. For example, in Figure 1A, there were 45 total subcategories that had a percent change in sales-weighted

mean sodium content (mg/100g) from 2010 to 2022 that was greater than -5% and less than or equal to 0%.

<sup>b</sup> There are more than 163 food subcategories because some are split into separate categories for restaurant and packaged versions. Packaged and restaurant subcategories do not add up to 190 because there are an additional 69 combined food categories that encompass both packaged and restaurant foods (see Appendix Exhibit 1).

#### Appendix Exhibit 1. Data analysis methodology

We merged data that FDA publicly released in 2021<sup>52</sup> (2010 mean sodium content and Phase I targets) and 2024<sup>53</sup> (2022 mean sodium content and Phase II targets) by food (sub)category ID. FDA frames its targets as spanning 163 food categories, but these "categories" are actually subcategories of 16 broader food categories (e.g., Dairy). While many of the subcategories encompass both restaurant and packaged foods ("combined" subcategories), others are split into additional subcategories for restaurant ("-R" subcategories) and packaged ("-P" subcategories) foods. Between 2010 and 2022, FDA added or removed some subcategories because of available data.<sup>54</sup> Because of this, the 2010 data contained 220 subcategories and the 2022 data contained 222 subcategories. Upon merging by subcategory ID, 190 subcategories matched (exact same subcategory ID, e.g., "122-R"), while 62 did not (30 in 2010 data and 32 in 2022 data). FDA's preliminary analysis does not provide detailed methodology, but it does say that "only comparable subcategories were analyzed,"<sup>55</sup> so to approximate FDA's methodology, we excluded the 62 incomparable entries. We then classified any subcategory with an ID in 2010 and 2022 that included "-P" as "packaged" and ("-R") as "restaurant." Our final merged dataset contained 190 subcategories, including 47 packaged, 74 restaurant, and 69 combined (no designation of "P" or "R" in either 2010 or 2022) food subcategories.

Using this dataset, we calculated the percent change in "baseline" sales-weighted mean sodium content (mg/100 mg) by subcategory from 2010 to 2022. We then calculated the mean, standard deviation, standard error, median, first quartile, third quartile, minimum, and maximum percent change across all subcategories overall; across combined, packaged, and restaurant subcategories; and across each food category. We recognize that these summary measures are not perfect to inform progress, because they are not weighted by each subcategory's contribution to overall sodium in the U.S. diet, but we were limited in our analyses to FDA's publicly released data, which did not include subcategory weights.

Appendix Table 1. Magnitude of percent change in mean sales-weighted sodium (mg/100g) from 2010 to 2022 overall; by combined, packaged, and restaurant subcategories; and by category

		Percent change in mean sales-weighted sodium (mg/100g) from 2010 to 2022								
	n subcategories	Mean	SD	SE	Median	p25	p75	Min	Max	
All subcategories	190	0%	15%	1%	-3%	-8%	6%	-34%	99%	
Combined subcategories	69	-2%	13%	2%	-4%	-9%	5%	-34%	33%	
Packaged subcategories	47	-4%	8%	1%	-4%	-9%	-1%	-27%	19%	
Restaurant subcategories	74	4%	19%	2%	2%	-5%	11%	-28%	99%	
Breakdown by FDA Category										
Bakery	34	-2%	10%	2%	-4%	-7%	5%	-28%	17%	
Cereals	2	-5%	0%	0%	-5%	-5%	-5%	-5%	-5%	
Dairy	8	-6%	12%	4%	-6%	-11%	-3%	-23%	19%	
Fats, Oils, and Dressings	4	3%	23%	11%	-5%	-10%	17%	-13%	37%	
Fish and Other Seafood	4	6%	13%	6%	1%	-2%	13%	-4%	25%	
Fruits, Vegetables, and Legumes	19	6%	12%	3%	2%	-2%	12%	-11%	33%	
Meat and Poultry	22	0%	12%	3%	-4%	-7%	11%	-19%	26%	
Mixed Ingredient Dishes	16	5%	29%	7%	3%	-9%	7%	-25%	99%	
Nuts and Seeds	4	-4%	5%	3%	-3%	-7%	-1%	-11%	0%	
Other Combination Foods	9	-2%	9%	3%	-1%	-4%	3%	-19%	12%	
Salads	4	3%	10%	5%	-1%	-3%	9%	-3%	18%	
Sandwiches	14	1%	12%	3%	0%	-9%	6%	-14%	27%	
Sauces, Gravies, Dips, Condiments, and Seasonings	30	1%	19%	3%	-3%	-8%	9%	-28%	75%	
Snacks	10	-3%	10%	3%	-6%	-9%	1%	-15%	17%	
Soups	7	-1%	8%	3%	-3%	-9%	8%	-10%	9%	
Toddler/Baby Foods	3	-31%	3%	2%	-30%	-34%	-28%	-34%	-28%	

Abbreviations: SD = standard deviation; SE = standard error of the mean; p25 = first quartile, 25<sup>th</sup> percentile; p75 = third quartile, 75<sup>th</sup> percentile; min = minimum value; max = maximum value

Subcategory	Subcategory ID	Subcategory Type	Category	Mean sales- weighted sodium (mg/100g)		Change in mean sales-weighted sodium (mg/100g), 2012 to 2022		Targets	
				2010	2022	Absolute	Percent	Phase 1	Phase 2
Seafood-based Dishes - Not Breaded	144-R	Restaurant	Mixed Ingredient Dishes	365	728	change 363	change 99%	Target 310	Target 450
Mustard and Worcestershire	59-R	Restaurant	Sauces, Gravies, Dips, Condiments, and Seasonings	699	1226	527	75%	650	980
Butter	16-R	Restaurant	Fats, Oils, and Dressings	639	874	235	37%	590	620
Vegetable Juice	33	Combined	Fruits, Vegetables, and Legumes	180	240	60	33%	160	180
Meat/Poultry-based Dishes	143-R	Restaurant	Mixed Ingredient Dishes	404	520	116	29%	340	280
Dry Seasoning and Dry Sauce Mixes	61	Combined	Sauces, Gravies, Dips, Condiments, and Seasonings	10378	13321	2943	28%	8800	7190
Vegetarian Sandwiches with Cheese	126-R	Restaurant	Sandwiches	625	792	167	27%	550	470
Vegetables - Breaded	21-R	Restaurant	Fruits, Vegetables, and Legumes	558	703	145	26%	480	380
Poultry - Not Breaded	97-R	Restaurant	Meat and Poultry	460	579	119	26%	430	400
Fish and Other Seafood - Not Breaded	107	Combined	Fish and Other Seafood	377	471	94	25%	350	320
Vegetables - Not Breaded	20	Combined	Fruits, Vegetables, and Legumes	254	317	63	25%	190	190

Appendix Table 2. Subcategories with the highest percent increase in mean sales-weighted sodium (mg/100g) from 2010 to 2022

#### References

<sup>1</sup> U.S. Food and Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress, August 2024. https://www.fda.gov/food/nutrition-food-labeling-and-criticalfoods/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress. Accessed October 15, 2024. <sup>2</sup> Califf RM, Warraich HJ, Jones J. FDA commissioner: We need action and higher-quality research on ultraprocessed foods. STAT, November 15, 2024. Available at: https://www.statnews.com/2024/11/15/ultra-processedfoods-fda-califf-research-diet-related-disease <sup>3</sup> U.S. Food and Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress, August 2024. https://www.fda.gov/food/nutrition-food-labeling-and-criticalfoods/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress. Accessed October 15, 2024. <sup>4</sup> Gottlieb S. Reducing the Burden of Chronic Disease. Remarks presented at the National Food Policy Conference, Washington DC. March 29, 2018. https://www.fda.gov/news-events/speeches-fda-officials/reducing-burdenchronic-disease-03292018. Accessed October 15, 2024. <sup>5</sup> U.S. Agricultural Research Service, USDA. Table 1. Nutrient Intakes from Food: Mean Amounts Consumed per Individual, by Gender and Age, in the United States, 2021-2023. What We Eat in America, NHANES 2021-2023. https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/foodsurveys-research-group/docs/wweia-data-tables/ <sup>6</sup> National Academies of Sciences, Engineering, and Medicine. 2019. *Dietary Reference Intakes for Sodium and* Potassium. Washington, DC: The National Academies Press. https://doi.org/10.17226/25353. <sup>7</sup> U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. DietaryGuidelines.gov. (accessed October 15, 2024). <sup>8</sup> National Academies of Sciences, Engineering, and Medicine. 2019. Dietary Reference Intakes for Sodium and Potassium. Washington, DC: The National Academies Press. https://doi.org/10.17226/25353. <sup>9</sup> Centers for Disease Control and Prevention. Hypertension cascade: hypertension prevalence, treatment and control estimates among US adults aged 18 years and older applying the criteria from the American College of Cardiology and American Heart Association's 2017 Hypertension Guideline—NHANES 2017–March 2020. Published 2023. Accessed October 15, 2024. https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html <sup>10</sup> Centers for Disease Control and Prevention. High Blood Pressure Facts. https://www.cdc.gov/high-blood-

pressure/data-research/facts-stats/. Accessed October 15, 2024.

<sup>11</sup> Bibbins-Domingo K, Chertow GM, Coxson PG, et al. Projected effect of dietary salt reductions on future cardiovascular disease. N Engl J Med. 2010;362(7):590-599.

<sup>12</sup> Harnack LJ, Cogswell ME, Shikany JM, Gardner CD, Gillespie C, Loria CM, Zhou X, Yuan K, Steffen LM. Sources of sodium in US adults from 3 geographic regions. Circulation. 2017 May 9;135(19):1775-83.

<sup>13</sup> Center for Science in the Public Interest. Petition to revoke the GRAS status of salt, to set ceilings on the amount of sodium in processed foods, to require a health warning on packaged salt, and to reduce the daily value for sodium. November 8, 2005.

https://www.cspinet.org/sites/default/files/media/documents/resource/fda\_salt\_petition.pdf. Accessed October 15, 2024.

<sup>14</sup> Center for Science in the Public Interest. FDA issues voluntary sodium reduction targets. June 1, 2016. <u>https://www.cspinet.org/news/fda-issues-voluntary-sodium-reduction-targets-20160601</u> Accessed October 15, 2024.

<sup>15</sup> U.S. Food and Drug Administration. Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods, June 2016.

<sup>16</sup> U.S. Food and Drug Administration. Guidance for Industry: Voluntary Sodium Reduction Goals; Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods, October 2021. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals</u>. Accessed October 15, 2024.

<sup>17</sup> Center for Science in the Public Interest. Citizen Petition Requesting that the U.S. Food and Drug Administration Finalize its 10-Year Sodium Reduction Goals and Take Other Actions to Reduce Sodium Consumption. April 6, 2023. https://www.cspinet.org/sites/default/files/2023-04/CSPI%20Sodium%20Petition%2004-06-2023.pdf. Accessed October 15, 2024.

<sup>18</sup> U.S. Food and Drug Administration. Draft Guidance for Industry: Voluntary Sodium Reduction Goals (Edition 2), August 2024. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-sodium-reduction-goals-edition-2</u>. Accessed October 15, 2024.

<sup>19</sup> U.S. Food and Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress, August 2024. <u>https://www.fda.gov/food/nutrition-food-labeling-and-critical-</u>

foods/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress. Accessed October 15, 2024. <sup>20</sup> U.S. Food and Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress, August 2024. <u>https://www.fda.gov/food/nutrition-food-labeling-and-critical-</u>

foods/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress. Accessed October 15, 2024. <sup>21</sup> U.S. Food and Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress, August 2024. <u>https://www.fda.gov/food/nutrition-food-labeling-and-critical-</u>

<u>foods/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress</u>. Accessed October 15, 2024. <sup>22</sup> U.S. Food and Drug Administration. FDA Guidance for Industry: Voluntary Sodium Reduction Goals. Table 1.

Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods. <u>https://www.fda.gov/media/98277/download?attachment</u>. Accessed October 15, 2024.

<sup>23</sup> U.S. Food and Drug Administration. <u>Appendix Table 1 - Voluntary Sodium Reduction Goals: Phase II Target Mean</u> and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared

Foods. https://www.fda.gov/media/183284/download?attachment.. Accessed December 16, 2024.

<sup>24</sup> U.S. Food and Drug Administration. Guidance for Industry: Voluntary Sodium Reduction Goals; Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods, October 2021. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals</u>. Accessed October 15, 2024.

<sup>25</sup> U.S. Agricultural Research Service, USDA. Table 1. Nutrient Intakes from Food: Mean Amounts Consumed per Individual, by Gender and Age, in the United States, 2009-2010. What We Eat in America, NHANES 2009-2010. <u>https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweia-data-tables/</u>

<sup>26</sup> U.S. Agricultural Research Service, USDA. Table 1. Nutrient Intakes from Food: Mean Amounts Consumed per Individual, by Gender and Age, in the United States, 2017-March 2020 Prepandemic. What We Eat in America, NHANES 2017-March 2020 Prepandemic. <u>https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsvillehuman-nutrition-research-center/food-surveys-research-group/docs/wweia-data-tables/</u>

<sup>27</sup> U.S. Agricultural Research Service, USDA. Table 1. Nutrient Intakes from Food: Mean Amounts Consumed per Individual, by Gender and Age, in the United States, 2021-2023. What We Eat in America, NHANES 2021-2023. <u>https://www.ars.usda.gov/northeast-area/beltsville-md-bhnrc/beltsville-human-nutrition-research-center/food-surveys-research-group/docs/wweia-data-tables/</u>

<sup>28</sup> U.S. Food and Drug Administration. Guidance for Industry: Voluntary Sodium Reduction Goals; Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods, October 2021. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals</u>. Accessed October 15, 2024.

<sup>29</sup> He FJ, Brinsden HC, Macgregor GA. 2014. Salt reduction in the United Kingdom: a successful experiment in public health. J. Hum. Hypertens. 28(6):345–52 50.

<sup>30</sup> He FJ, Brown M, Tan M, MacGregor GA. 2019. Reducing population salt intake—an update on latest evidence and global action. J. Clin. Hypertens. 21(10):1596–601.

<sup>31</sup> He FJ, Brinsden HC, Macgregor GA. 2014. Salt reduction in the United Kingdom: a successful experiment in public health. J. Hum. Hypertens. 28(6):345–52 50.

<sup>32</sup> MacGregor, G. A., He, F. J., & Pombo-Rodrigues, S. (2015). Food and the responsibility deal: how the salt reduction strategy was derailed. *BMJ (Online)*, *350*(apr28 19), h1936–h1936.

<sup>33</sup> Institute of Medicine (US) Committee on Strategies to Reduce Sodium Intake; Henney JE, Taylor CL, Boon CS, editors. Strategies to Reduce Sodium Intake in the United States. Washington (DC): National Academies Press (US);
2010. Appendix G, National Salt Reduction Initiative Coordinated by the New York City Health

Department. Available from: <u>https://www.ncbi.nlm.nih.gov/sites/books/NBK50950/</u>. Accessed October 21, 2024. <sup>34</sup> NYC Health. National Salt Reduction Initiative: Packaged and Restaurant Food. 2024.

<u>https://www.nyc.gov/site/doh/health/health-topics/national-salt-reduction-initiative-packaged-food.page</u>. Accessed October 21, 2024.

<sup>35</sup> Curtis CJ, Clapp J, Niederman SA, Ng SW, Angell SY. 2016. US food industry progress during the National Salt Reduction Initiative: 2009–2014. Am. J. Public Health 106(10):1815–19.

<sup>36</sup> Moran, A. J., Wang, J., Sharkey, A. L., Dowling, E. A., Curtis, C. J., & Kessler, K. A. (2022). US Food Industry Progress Toward Salt Reduction, 2009-2018. *American Journal of Public Health*, *112*(2), 325–333.

<sup>37</sup> Moran, A. J., Wang, J., Sharkey, A. L., Dowling, E. A., Curtis, C. J., & Kessler, K. A. (2022). US Food Industry Progress Toward Salt Reduction, 2009-2018. *American Journal of Public Health*, 112(2), 325–333.

<sup>38</sup> U.S. Food and Drug Administration. Draft Guidance for Industry: Voluntary Sodium Reduction Goals (Edition 2), August 2024. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-sodium-reduction-goals-edition-2</u>. Accessed October 15, 2024.

<sup>39</sup> U.S. Food and Drug Administration. Draft Guidance for Industry: Voluntary Sodium Reduction Goals (Edition 2), August 2024. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-sodium-reduction-goals-edition-2</u>. Accessed October 15, 2024.

<sup>40</sup> U.S. Department of Health and Human Services. Reduce consumption of sodium by people aged 2 years and over
— NWS-12. Healthy People 2030. <u>https://odphp.health.gov/healthypeople/objectives-and-data/browse-</u>

objectives/nutrition-and-healthy-eating/reduce-consumption-sodium-people-aged-2-years-and-over-nws-12/datamethodology. Accessed October 21, 2024.

<sup>41</sup> U.S. Food and Drug Administration. Draft Guidance for Industry: Voluntary Sodium Reduction Goals (Edition 2), August 2024. <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-voluntary-sodium-reduction-goals-edition-2</u>. Accessed October 15, 2024.

<sup>42</sup> U.S. Food and Drug Administration. <u>Appendix Table 1 - Voluntary Sodium Reduction Goals: Phase II Target Mean</u> and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared

<u>Foods</u>. https://www.fda.gov/media/183284/download?attachment. Accessed December 16, 2024. <sup>43</sup> USDA ARS. FoodData Central Food Details: Soup, chicken noodle. <u>https://fdc.nal.usda.gov/food-details/2709149/nutrients</u>.

<sup>44</sup> U.S. Department of Agriculture (USDA), Agricultural Research Service. FoodData Central: USDA Global Branded Food Products Database. Version Current: April 2024. Internet: fdc.nal.usda.gov/about-us.

<sup>45</sup> U.S. Food and Drug Administration. FDA's Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance. June 1, 2016. Accessible at <u>https://www.regulations.gov/document/FDA-2014-D-0055-0011</u>. Accessed October 21, 2024.

<sup>46</sup> NYC Health. National Salt Reduction Initiative: Packaged and Restaurant Food. 2024.

https://www.nyc.gov/site/doh/health/health-topics/national-salt-reduction-initiative-packaged-food.page. Accessed October 21, 2024.

<sup>47</sup> Keast DR, Guenther PM. Sodium Content and Sodium Intake Contributions of Store-Bought and Restaurant-Prepared Foods in Their As-Eaten Form: National Health and Nutrition Examination Survey, 2009-2018. Curr Dev Nutr. 2024 Sep 2;8(10):104455.

<sup>48</sup> Hill A, Nara D, Sorscher S, Musicus AA, Lurie P. How Salty Is Too Salty? Designing Sodium Warning Label Policies to Identify High-Sodium Items on Restaurant Menus in the United States. *Nutrients*. 2024; 16(12):1797.

<sup>49</sup> Hill A, Nara D, Sorscher S, Musicus AA, Lurie P. How Salty Is Too Salty? Designing Sodium Warning Label Policies to Identify High-Sodium Items on Restaurant Menus in the United States. *Nutrients*. 2024; 16(12):1797.

<sup>50</sup> Goldstein, ZM. How salty is too salty? A look at high-sodium menu items. CSPI News.

https://www.cspinet.org/cspi-news/how-salty-too-salty-look-high-sodium-menu-items. Accessed October 21, 2024.

<sup>51</sup> Santos JA, Tekle D, Rosewarne E, Flexner N, Cobb L, Al-Jawaldeh A, Kim WJ, Breda J, Whiting S, Campbell N, Neal B. A systematic review of salt reduction initiatives around the world: a midterm evaluation of progress towards the 2025 global non-communicable diseases salt reduction target. Advances in Nutrition. 2021 Sep 1;12(5):1768-80.
<sup>52</sup> U.S. Food and Drug Administration. FDA Guidance for Industry: Voluntary Sodium Reduction Goals. Table 1.
Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods. <u>https://www.fda.gov/media/98277/download?attachment</u>. Accessed October 15, 2024.

<sup>53</sup> U.S. Food and Drug Administration. <u>Appendix Table 1 - Voluntary Sodium Reduction Goals: Phase II Target Mean</u> and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared

Foods. https://www.fda.gov/media/183284/download?attachment. Accessed December 16, 2024.

<sup>54</sup> U.S. Food and Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress, August 2024. <u>https://www.fda.gov/food/nutrition-food-labeling-and-critical-</u>

foods/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress. Accessed October 15, 2024.

<sup>55</sup> U.S. Food and Drug Administration. Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress, August 2024. <u>https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/sodium-reduction-us-food-supply-2010-2022-preliminary-assessment-progress</u>. Accessed October 15, 2024.