American Heart Association. | American Stroke Association.
life is why
Advocacy Department
Chairm
1150 Connecticut A
P 202-785-7900 | F 202-785-795

October 17, 2016

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-D-0055

Dear Sir or Madam:

On behalf of the American Heart Associat¾ E HE meme bEged, foS m and Prepared Foods."

AHA applauds the Food and Drug Administration (FDA) for its efforts to reduce sodium consumption. Excess sodium consumption is an important, and unfortunately, longstanding, public health issue. For years, consumers have been warned about the link between excess sodium in the diet and high blood pressure and advised to eat less salt. This recommendation appeared in the first edition of the Dietary Guidelines for Americans, released in 1980, and continues to be a key recommendation in the eighth edition released just last year. But Americans continue to consume sodium in amounts that far exceed the recommended daily limits, in large part because the amount of sodium in the food supply remains high, and consumers are often unaware of the foods that contribute the most sodium in the American diet. With more than 75% of the sodium we eat coming from salt (sodium chloride) added to foods *before* they are sold,

[1] consumers have little control over the amount of sodium they eat.

[1] Mattes, R. D., and D. Donnelly

That is why AHA supports the FDA's voluntary sodium targets. If adopted by the food industry, the proposed targets will gradually reduce the amount of sodium in the overall food supply, helping Americans lower their sodium intake. We also appreciate that the FDA's proposal uses a two-step process that lowers the sodium targets over a period

Children may also be at risk of developing elevated blood pressure at an early age, because nine out of ten kids consume sodium in excess of current recommendations.[9] Children who have high sodium diets are about 40% more likely to have elevated blood pressure than kids who have lower sodium diets.[10]

the resulting decrease in mortality are likely due, at least in part, to the lower sodium consumption across the population.[17]

We understand, however, that there is some research that questions whether sodium reduction is necessary, or if significant reductions could in fact be harmful. These questions are the result of observational studies that often have methodological problems, including unreliable measures of long-term sodium intake (systematic error), reverse causality and lack of adjustment for total kilocalorie intake or other nutrients that influence blood pressure, residual confounding, and inadequate follow-up.[18] These methodological issues severely limit the usefulness of these studies in guiding nutrition policy, much l

AHA also operates a sodium reduction campaign for consumers with more than 100,000 supporters. Thus far in 2016, campaign members have written to 10 food companies asking for a continued focus on sodium reduction, and even more have expressed support for sodium reduction in the food supply on various social media platforms.

Food and Restaurant Industry Efforts

There are many examples of major food manufacturers, food service providers and restaurants, such as Aramark, General Mills, Mars Food, Nestle, PepsiCo, Kraft-Heinz, Tysons, Subway, Panera and Unilever that are already working to reduce sodium in their products and meals. In addition, the National Salt Reduction Initiative (NSRI), which launched in 2009, secured lower sodium commitments from nearly 30 companies, including snack manufacturers, restaurants, and fast food dining.

AHA is encouraged that a number of food companies have been working to reduce sodium, and we applaud and support their efforts. But we are concerned that other food manufacturers and restaurants have not yet made sodium reduction a priority. To achieve a significant public health benefit from sodium reductions, a coordinated widespread industry effort is needed.

Consider, for example, the impact that existing sodium reduction efforts have had in recent years. A survey by the Center for Science in the Public Interest (CSPI) measured the change in sodium content of 451 packaged and restaurant products between 2005 and 2015.[20] The survey found that sodium decreased in 55% of products, *increased* in 30% of products, and did not change in 15% of products. Among the products that experienced an increase, 30 products experienced an increase of 30% or more. According to the survey results, "On average, the products had only about 4% less sodium in 2015 than in 2005, with an average decrease of 41 milligrams per 100 grams of product" (emphasis added).[21]

The NSRI generated similarly modest, yet impactful results. Between 2009 and the beginning of 2015, sodium in a sample of top-selling packaged products fell by 6.8%, while sodium in restaurant foods decreased by 1.5%.[22]

The CPSI survey and the NSRI results show that sodium reduction is possible, but illustrates that more must be done to achieve significant sodium reductions across the entire food supply and lower sodium consumption to healthier levels. We are hopeful that the FDA's voluntary sodium reduction targets will serve as the catalyst for an industry-wide, concerted sodium reduction effort. By encouraging food manufacturers and restaurants to meet new sodium reduction targets, the Agency is sending a clear message that excess sodium consumption is a public health concern and the food industry must be a part of the solution.

---

[20] Salt Assault: Brand-Name Comparisons of Processed Foods. Center for Science in the Public Interest. 4th Edition. 2016.

[21] Ibid, page 5.

[22] Christine J. Curtis, et al. US Food Industry Progress During the National Salt Reduction Initiative: 2009–2014. American Journal of Public Health: October 2016, Vol. 106, No. 10, pp. 1815-1819. doi: 10.2105/AJPH.2016.303397

We recommend that the Agency update the 2010 baseline calculations to include no-, low-, and reduced-sodium products. If this is not possible, the FDA should include no-, low-, and reduced-sodium products in the baseline calculations, as well as the calculation of sales-weighted averages for individual companies and restaurants, moving forward.

We are also concerned that the data used to calculate the baseline sodium concentration values for restaurants were rather limi

And, because the upper bound for the short-term targets is, in the majority of cases, *higher* than the 2010 baseline, many products would likely not require *any* sodium reduction to fall under the upper bound.

Food Category	2010 Baseline	Short-Term Upper Bound	% Higher Than Baseline
19. Canned Vegetables	307 mg	360 mg	17.2%
34. Canned Ready-to-Eat Soup	265 mg	310 mg	16.9%
59. Wheat & Mixed Grain Bread	471 mg	540 mg	14.6%
83. Deli Meats – Turkey/Chicken	990 mg	1160 mg	17.1%

In addition, many foods already meet the initial targets, demonstrating that existing food technology can reduce sodium content to the short-term levels. For example, as the New York City Department of Health and Mental Hygiene describes in its comments to FDA, "Using the NSRI Packaged Food Database, a total of 2,442 foods in 78 FDA categories already meet the FDA's two-year targets. Using MenuStat restaurant food data, 2,809 foods in 80 FDA categories already meet the FDA's two-year targets."[24]

AHA's experience with our own Heart-Check Food Certification program further demonstrates that the proposed short-term targets are achievable. The Heart-Check program requires foods to meet sodium standards that are more stringent than the two-year targets proposed by FDA in many of the food categories in which AHA certifies products. A number of examples follow below.

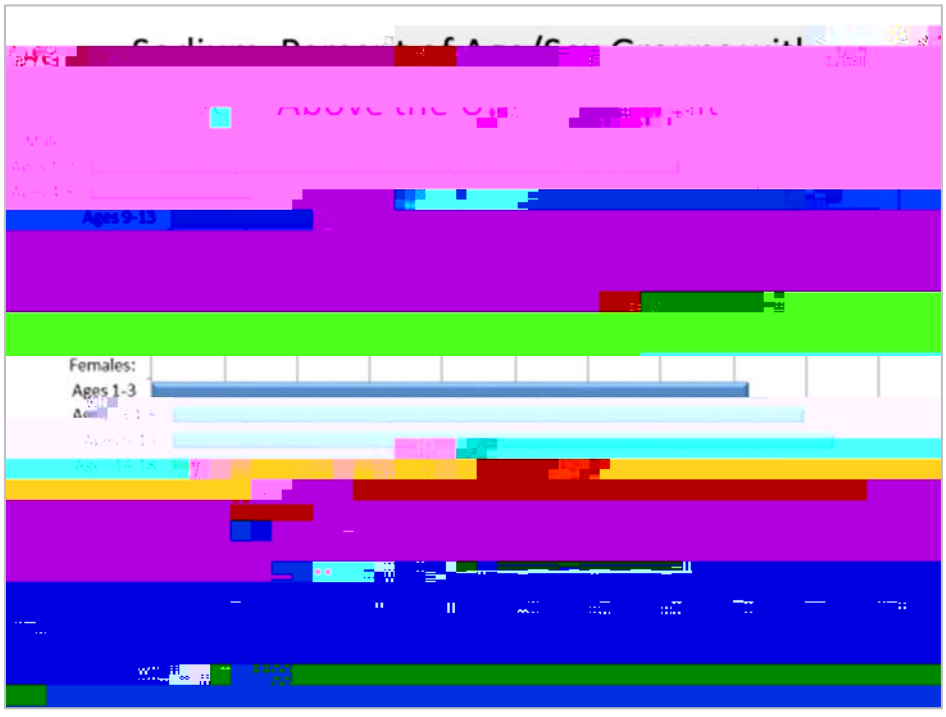
Food Category	FDA 2-Year Goal	FDA 2-Year Upper Bound	Heart-Check Sodium Limit*
3. Processed Cheese	1210	1510	800
9. Feta Cheese	1120	1340	436
10. Cottage and Other Soft Cheese	340	430	218
19. Canned Vegetables	290	360	88 – 277
26. Fried Potatoes without Toppings	310	490	165 – 200
34. Canned, Ready-to-Eat Soup	230	310	196
45. Cream-Based Sauce	400	590	288
67a. Frozen Biscuits	820	1010	436
78a. Breakfast Bakery Products	420	580	218 – 282
81. Deli Meats – Ham	1020	1300	873

[24] Mary T. Bassestt, Commissioner, New York City Department of Health and Mental Hygiene. Comments to FDA on Docket No. FDA-2014-D-0055. September 12, 2016.

Appropriateness of Targets

In addition to considering the feasibility of the targets, AHA also examined whether the target values would lead to sufficient reductions in overall sodium consumption across the population. To do this, AHA commissioned a food modelling study by Victor Fulgoni, III of Nutrition Impact, LLC. The study used the Food and Nutrient Database for Dietary Studies (FNDDS) mapping file provided by the FDA,[27]

However, we are concerned that half of all Americans will continue to consume sodium at levels greater than the 2,300 mg a day recommended by the Dietary Guidelines. This is especially concerning considering that every population group, regardless of age or gender, currently consumes more sodium than recommended.



Even with universal adoption of the FDA targets, average sodium consumption would still exceed the recommended amount of 2,300 mg a day. Our study estimated that the average sodium intake with the two-year targets would be 3,298 mg (a decrease of approximately 108 mg from current consumption levels), and 2,416 mg with the 10-year targets.

However, it is important to note that these numbers represent the average consumption amount when looking at the entire population between two and 99 yed o p ∓ n o p A d o

Likewise, if the sodium content of foods is decreased to achieve the upper bound limits rather than the target means, fewer Americans will meet the recommended daily limits. This effect was most noticeable when examining the 10-year FDA targets where the percentage of Americans meeting the 2,300 mg recommendation dropped from 49% with the target means to 22.9% with the upper bounds, which is less than a 10% increase from baseline.

Again, we believe that these data illustrate the need for FDA to encourage the entire food industry to adopt the targets; recommend that companies aim for the target means, not the upper bound limits; and consider more aggressive targets overall to help a greater percentage of the population achieve an appropriate sodium intake.

Timeline for Target Implementation

Under the FDA's proposal, food companies and restaurants would be encouraged to meet the initial short-term sodium reduction targets within two years. Companies would have a longer amount of time (10 years) to make more substantial sodium reductions.

AHA strongly supports this step

Consumer Education Campaign

To maximize the effectiveness of the voluntary sodium targets, we encourage the Agency to collaborate with the Centers for Disease Control and Prevention, Department of Health and Human Services, the U.S. Department of Agriculture and other federal agencies as well as public health organizations and consumer groups to develop and launch a nationwide consumer education campaign. The campaign should focus on:

The health effects of excess sodium consumption
The recommended daily limit for sodium
Major sources of sodium in processed and restaurant foods
Strategies and practical tips to reduce sodium intake, including recipes

While the remaining 36% of respondents stated that they are unable to estimate their daily sodium intake at all.

And perhaps most importantly, consumers are also unsure how to best control their sodium intake. When asked what actions they take to reduce their sodium consumption, the top two responses were (1) using less salt when cooking (68%) and (2) using less salt at the table (67%), even though these sources contribute relatively small amounts to the diet when compared to processed and restaurant foods.

Consumer education has been a component of effective sodium reduction campaigns. The U.K. Food Standard Agency, for example, used a two-pronged approach to reducing sodium consumption. In addition to encouraging food companies to redu