American Heart Association | American Stroke Association
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December 2, 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 Association (AHA), including the American Stroke Association (ASA) and more than 30 million volunteers and supporters, we appreciate the additional opportunity to provide comments on the draft guidance "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods."

First and foremost, AHA reaffirms our strong support for the Food and Drug Administration's (FDA) efforts to reduce sodium consumption through the development of voluntary sodium targets. If adopted by the food and restaurant industry, the proposed targets could lead to measurable reductions of sodium in the food supply, helping Americans lower their sodium intake. As described in detail in our October 17, 2016 letter,[1] the evidence overwhelmingly shows that reducing sodium consumption can have significant health benefits and lower medical costs.

AHA is pleased that many members of the food and restaurant industry have publicly expressed support for voluntary sodium reduction targets, and are already working to reduce sodium in their products and meals. We are hopeful that the FDA targets will encourage other food manufacturers and restaurants to make similar commitments and make sodium reduction a priority. A coordinated, widespread industry effort is needed to make significant sodium reductions across the entire food supply.

[1] AHA Comments to the FDA on Short-Term Voluntary Sodium Reduction Goals. October 17, 2016. http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_489008.pdf.

Reducing the amount of sodium in the food supply is key to helping Americans achieve an appropriate sodium intake. We cannot emphasize this point enough. Because sodium is ubiquitous in the food supply, consumers have limited ability to control the amount of sodium they eat. While we can – and should – educate consumers about the health consequences of consuming too much sodium, decades of public education campaigns have proven that knowledge alone is not enough. To help consumers lower their sodium intake, the amount of sodium in the food supply must be decreased. That is why we support the FDA's voluntary sodium targets, and why we will continue to encourage the food and restaurant industry to lower the sodium content of their foods.

FDA Draft Guidance Document

Proposed Target Means and Upper Bounds

As we have previously expressed to the Agency, AHA appreciates the tremendous amount of work that went into the development of the proposed target means and upper bounds. We recognize that it was a complicated task that required the Agency to consider salt's functional and technical roles, food safety concerns, and the availability of sodium reduction technologies.

Target Feasibility

While it is not within AHA's area of expertise to determine if the proposed target values for a specific food category are feasible from a food technology and food safety perspective, we are pleased that the long-term targets call for an overall reduction in sodium content of between 30 and 40%. Although 30 to 40% may seem ambitious, we believe it is a reasonable goal given that the average American currently consumes 3,400 mg of sodium per day, or almost 48% more sodium than the 2,300 mg recommended by the Dietary Guidelines for Americans.

And, because the FDA has proposed phasing in sodium reductions over time, the food and restaurant industry would not be expected to lower sodium content by 30 to 40% all at once. Instead, food companies and restaurants would first be encouraged to meet more modest short-term targets that decrease sodium content by an average of 15%. Companies would then work toward the long-term targets for a total reduction of 30 to 40%. Thus, for companies that achieve the short-term targets first (as we understand many foods already do), the move from the short to the long-term targets would be less abrupt, as illustrated by the examples below.

Food Category	Short-Term Target Mean	Long-Term Target Mean	% Reduction
3. Processed Cheese/ Cheese Food (Semi-Soft)	1,210 mg	1,000 mg	17% or 210 mg
19. Canned Vegetables	290 mg	250 mg	13% or 40 mg
34. Canned, Ready-to-Eat Soup	230 mg	200 mg	13% or 30 mg
59. Wheat and Mixed Grain Bread	420 mg	300 mg	28% or 120 mg
83. Deli Meats – Turkey/ Chicken	900 mg	780 mg	13% or 120 mg

We also note that because the upper bound for some of the long-term targets is very close to the 2010 baseline, some products would only require a minimal or modest decrease in sodium content to fall under the upper bound.

Food Category	2010 Baseline	Long-Term Upper Bound	% Lower Than Baseline
3. Processed Cheese/ Cheese Food (Semi-Soft)	1,358 mg	1,310 mg	3% or 48 mg
32. Nut/Seed Butters and Pastes	447 mg (P) 436 mg (R)	430 mg	4% or 17 mg 1% or 6 mg
34. Canned, Ready-to-Eat Soup	265 mg	260 mg	2% or 5 mg
59. Wheat and Mixed Grain Bread	471 mg	410 mg	13% or 61 mg
121. Deli Meat-Based Sandwiches	589 mg	510 mg	13% or 79 mg

P = Packaged foods
R = Restaurant foods

While in other cases, the upper bound is *higher* than the 2010 baseline, which means that some products may not require *any* sodium reduction to fall underneath it.

Food Category	2010 Baseline	Long-Term Upper Bound	% Higher Than Baseline
9. Feta Cheese (Soft)	1,174 mg	1,220 mg	4% or 46 mg
13. Parmesan and Other Hard Cheese	1,554 mg	1,690 mg	9% or 136 mg
19. Canned Vegetables	307 mg	320 mg	4% or 13 mg
83. Deli Meats – Turkey/ Chicken	990 mg	1030 mg	4% or 40 mg
91. Bone-In, Non-Breaded Non-Battered Poultry	367 mg (P)	430 mg	17% or 63 mg

P = Packaged foods

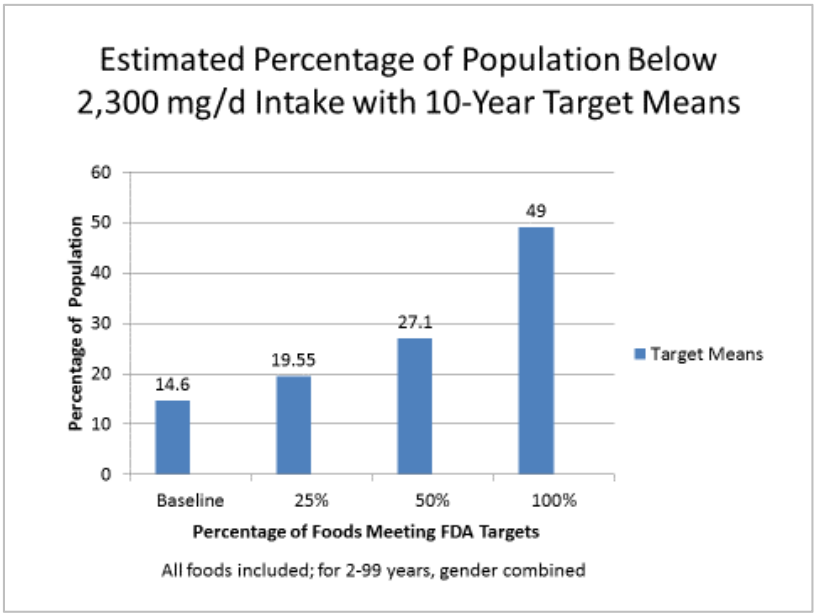
In addition, because the baseline calculations are based on data from 2010, the baseline numbers do not reflect changes in sodium content that occurred between 2010 and 2016. A number of major food manufacturers, food service providers and restaurants, such as Aramark, General Mills, Kraft Heinz, Mars Food, Nestle, Panera, PepsiCo, Subway, Tyson, and Unilever, have launched or expanded sodium reduction initiatives during that time. Therefore, the baseline numbers may not reflect the current state of the food supply; the baseline numbers for specific food categories may actually be lower than indicated. Thus the amount of sodium reduction required to meet the FDA targets may be overstated.

Furthermore, we are aware that some foods already meet the long-term targets. And, as noted in our previous comment letter, examining sodium concentrations in foods sold outside of the United States show that more substantial sodium reductions are possible.

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 modeling study that used 2013-2014 NHANES data to determine how sodium intake would change if foods meet the new FDA long-term targets.[2] The study examined the target means and upper bounds separately, and conducted three different scenarios in which 25, 50, and 100% of all available foods meet the FDA target values.[3] We shared some of the study's results with the Agency in our October 17th letter. For the Agency's convenience, we repeat and expand upon that data below.

As described in our previous letter, our study found that the long-term targets could lead to measurable reductions of sodium in the food supply. If the 10-year targets were universally adopted, 49% of Americans would consume less than 2,300 mg of sodium per day. This would be over a three-fold increase – from 14.6% to 49% – in the number of Americans who meet the 2,300 mg recommended by the Dietary Guidelines for Americans. This is a significant step in the right direction.

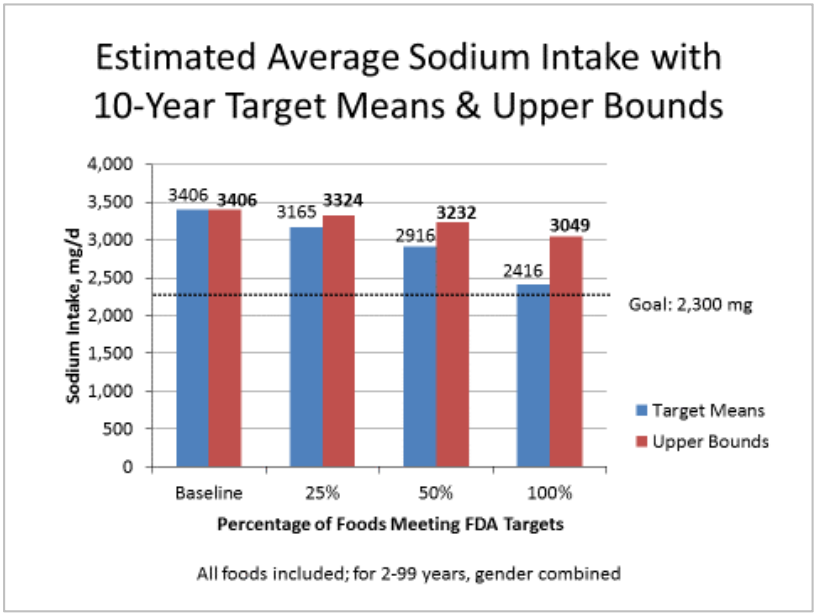


[2] Study conducted by Victor Fulgoni, III of Nutrition Impact, LLC. The study used the FNDDS mapping file provided by the FDA, which shows how the FDA mapped the FNDDS food codes to the draft sodium reduction categories, and then used 2013-2014 NHANES data to determine how sodium intake would change if foods meet the new FDA targets.

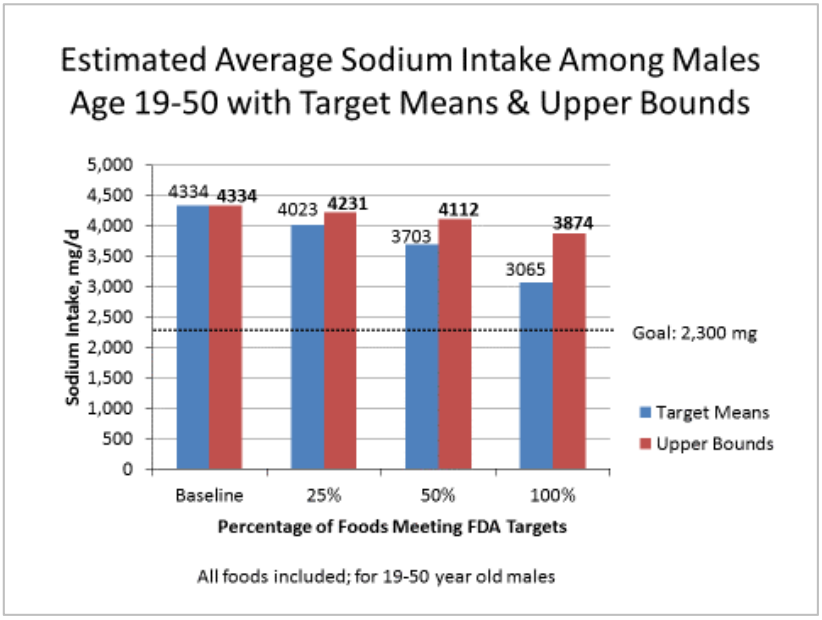
[3] Foods that fall outside of the 150 categories identified by FDA, because they do not contribute meaningfully to overall sodium intake, were included in the study's calculations of overall intake.

However, we must reiterate our concern that half of all Americans will continue to consume sodium at levels greater than 2,300 mg per day.

Even with universal adoption of the long-term targets, average sodium consumption would still exceed the recommended amount of 2,300 mg a day. Our study estimated that the average daily sodium intake would be 2,416 mg if 100% of all foods meet the proposed target means, or 3,049 mg if 100% of all foods complied with the upper bounds.

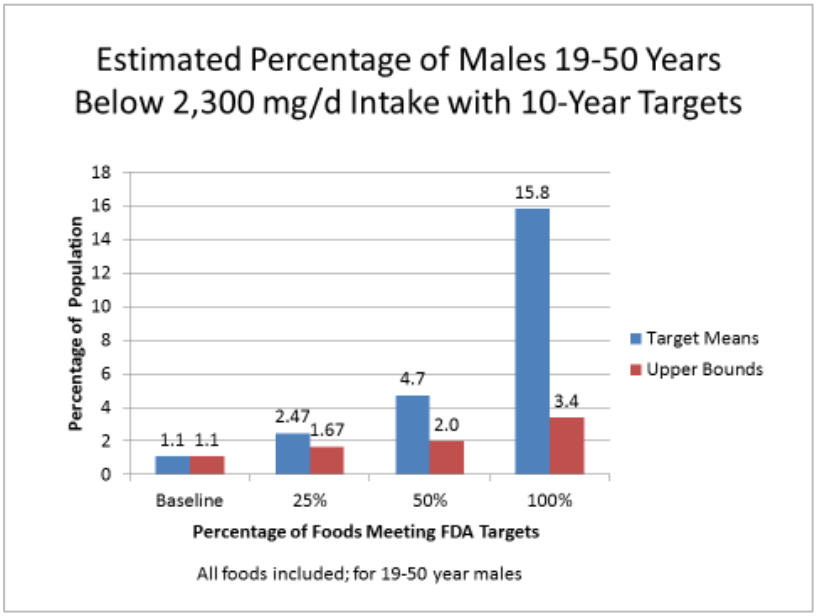


However, it is important to note that these numbers represent the average consumption amount when looking at the entire population between two and 99 years of age and both genders combined. Certain segments of the population will still have sodium intakes that *significantly* exceed the 2,300 mg recommended by the Dietary Guidelines for Americans.



For example, males between the ages of 19 and 50 will have an average intake of 3,065 mg even if 100% of foods meet the 10-year target means, or 3,874 mg with the upper bounds.

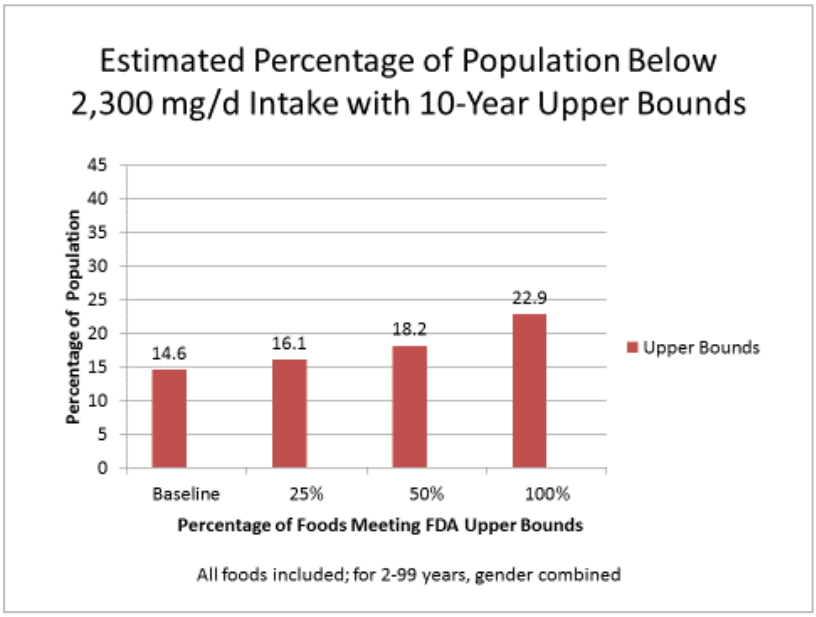
In that scenario, only 15.8% of males in the 19 to 50 age group will achieve a sodium intake of 2,300 mg per day. That number falls even further to 3.4% if foods meet the upper bounds instead of the target means.



These data show that more must be done to get the entire population down to recommended levels. To get a greater percentage of the population down to 2,300 mg within 10 years as the FDA intends, more aggressive targets may be necessary.

Our study also shows the importance of uniform adherence and implementation. As stated above, 49% of Americans will lower their sodium intake to 2,300 mg in 10 years, but only if 100% of the foods for which voluntary sodium targets are established meet the new sodium target means. If fewer companies adopt the targets, those numbers decrease. For example, if only 50% of foods meet the long-term target means, the estimated percentage of the population consuming below 2,300 mg drops from 49% to 27%.

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. 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.

We also encourage the Agency to lower the upper bound for any food category where the upper bound is *higher* than the 2010 baseline. See chart on page three for examples.

Need for Upper Bounds

We are aware that several organizations have called on the FDA to remove the upper bounds from the guidance document. The requests argue that the FDA does not have the legal authority to set maximum limits on the amount of salt a product can contain. We respectfully disagree.

Although salt is currently considered Generally Recognized as Safe (GRAS), the FDA has the authority – in fact, the responsibility – to alter an ingredient's GRAS status when concerns are raised about the ingredient's safety; and as we've communicated previously to the Agency, concerns about salt's safety have been raised for many years. Hence, the FDA could modify salt's GRAS status, either affirming salt as GRAS in certain conditions or at certain levels, or revoking its GRAS status altogether and requiring manufacturers to utilize the food additive process. Either option would result in the FDA legally setting maximum limits on the use of salt.

However, we note that the FDA is not attempting to modify salt's GRAS status or set any sort of regulatory requirement. The guidance document is very clear; the sodium reduction targets are voluntary. Food companies and restaurants will not be required to lower sodium content to the recommended target means or upper bounds. Instead, the guidance document is intended to encourage food reformulations. The FDA is explicit in saying that the guidance contains "recommendations" and "do(es) not establish legally enforceable responsibilities."[4] Since the Agency does not establish mandatory restrictions on the amount of sodium a food product can contain or require the food industry to make *any* sodium reductions, the argument that the FDA does not have the appropriate legal authority to set maximum levels is moot.

Another concern has been raised that including upper bounds in the guidance document will weaken the Agency's goal to "promote a level playing field among the industry sectors" as some companies work toward the target means, while others focus on the upper bounds. There is concern that this will perpetuate an uneven playing field and place companies and restaurants working toward the target means at a disadvantage. We understand this concern and we believe all food companies and restaurants should work toward achieving the target means rather than the upper bounds. However, we would not support removing the upper bounds from the guidance document.

[4] Food and Drug Administration. Voluntary Sodium Reduction Goals: Target Means and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry. Draft Guidance. June 2016.

The upper bounds should be maintained because they are the one element of the FDA's proposal that provides specific guidance on individual products and because they ensure that foods do not contain unsafe levels of sodium. The maximums also enable consumers and health officials to identify foods with excessive sodium and to determine whether companies are participating in the Agency's sodium reduction initiative.

Timeline for Target Implementation

Under the proposed timeline, food companies and restaurants would be encouraged to meet the short-term sodium reduction targets within two years and the long-term targets in 10. AHA strongly supports this stepwise approach and we believe that the proposed timeframes are reasonable for both the short- and long-term targets.

We understand, however, that many members of the food and restaurant industry have asked the FDA to extend the timeline for the short-term targets from two to four years, with an additional (fifth) year for the products to gain full distribution in the marketplace before the FDA begins to measure the targets' impact. We strongly oppose requests to extend the timeline. Two years is a reasonable amount of time to achieve the modest reductions called for by the short-term targets. The food industry has been aware of the need to reduce sodium content for several years, and many members of the industry have already started. In addition, many foods currently meet the initial targets, demonstrating that existing food technology can reduce sodium content to the short-term levels. The timeline for the short-term targets should remain at two years.

We expect the FDA will receive similar requests to extend the timeline for the long-term targets as well. One industry association has already suggested that the Agency "wait until the results of the short-term targets have been assessed" *before issuing* the long-term goals (emphasis added). That proposal, combined with the recommendation that the FDA wait five years before assessing the short-term targets' impact, would delay the release of the long-term targets by at least five years. Others have called on the FDA to wait until the Dietary Reference Intake (DRI) for sodium is updated. While we support updating the DRI, there is no need to wait for an updated DRI before moving forward with the sodium reduction targets.

We discourage the Agency from extending the timeframe for the long-term targets. Reducing the amount of sodium in the food supply is a public health imperative and should be implemented as expeditiously as possible.

Similarly, we are concerned by suggestions that the FDA revise and reissue the guidance document and provide another comment opportunity. While we encourage the FDA to continue to work with the food and restaurant industry to refine the guidance document as needed, we caution the Agency from taking any action that would further delay the implementation of the targets.

Closing

In closing, AHA strongly supports the FDA's efforts to reduce the amount of sodium in the food supply. Reducing the amount of sodium in commercially processed, packaged, and prepared foods is key to helping Americans lower their sodium intake to healthier levels.

As the FDA works to finalize the guidance document, we recommend that the Agency consider how it can encourage the food and restaurant industry to adopt and implement the final targets. As our sodium modeling found, uniform adoption and adherence to the target means by the food and restaurant industry will have the most dramatic impact on sodium consumption.

We also recommend that the Agency develop more aggressive targets to help a greater percentage of the population achieve an appropriate intake. Again, our sodium modeling found that certain population groups will continue to exceed their recommended daily intake even if 100% of foods meet the proposed target means.

In addition, we urge the FDA to resist any calls to extend the implementation timeline for the short or long-term targets. The timeline for the short-term targets should remain at two years and the long-term targets should be no longer than 10.

Finally, if it would be helpful to the Agency, AHA would be happy to convene a meeting of industry members, public health organizations, and consumer groups to discuss the guidance document and any of the issues that have been raised by stakeholders. We are committed to working with the FDA and members of the food and restaurant industry to successfully reduce the amount of sodium in the food supply. The health benefit to the American public would be significant.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop of AHA staff at (202) 785-7908 or susan.k.bishop@heart.org.

Thank you for your consideration of our comments.

Sincerely,

Steven R. Houser, PhD
President
American Heart Association