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1150 Connecticut Ave., NW | Suite 300 | Washington, DC 20036

P 202-785-7900 | F 202-785-7950 | www.heart.org

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(ASA) and more than 30 million volunteers and supporters, we appreciate the opportunity to provide comments on the draft guidance "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods."

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. 1991. Relative contributions of dietary sodium sources. *Journal of the American College of Nutrition* 10(4):383-393.

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 of years, as recommended by the National Academy of Medicine in 2010. This will provide the food and restaurant industries with time to reformulate, and will allow consumers to adapt their taste sensitivities to the lower sodium content of foods.² And most importantly, reducing the sodium content in the food supply is expected to result in significant health benefits and reduced medical costs.

We expand upon our support for the targets, offer a number of suggestions to improve the guidance document and the proposed target values, and address the specific issues raised by the FDA below.

The Science Behind Sodium Reduction

As the Agency is well aware, excess sodium consumption has been linked to high blood pressure. A substantial number of studies show a direct relationship between sodium intake and blood pressure. The studies found that on average, as dietary sodium intake rises, so does blood pressure. Evidence includes results from animal studies, epidemiological studies, clinical trials, and meta-analyses of these data. More than 50 randomized trials examining the effects of sodium on blood pressure have been conducted, including a number of rigorously controlled, dose-response trials. The evidence is persuasive – there is a statistically significant, clinically relevant, progressive dose-response relationship between sodium intake and blood pressure.³

Unfortunately, elevated blood pressure is extraordinarily common. It has been estimated that 80 million U.S. adults have high blood pressure or hypertension, an additional 36% of the adult population has pre-hypertension, and the prevalence of hypertension in the U.S. continues to rise.⁴ About 77% of those with diagnosed high blood pressure are using anti-hypertensive medication, but only 54% of those have their condition controlled.⁵ It is important to note that these numbers may worsen as modeling predicts that an estimated 41.4% of U.S. adults will have hypertension by 2030,⁶ and nine in ten American adults are expected to develop high blood pressure in their lifetime.⁷

Individuals with hypertension are at increased risk for coronary heart disease, stroke, heart failure, kidney failure, gastric cancer, and osteoporosis. Worldwide, 54% of strokes and 47% of heart disease events are attributed to elevated blood pressure.⁸

² National Academy of Medicine. 2010. Strategies to Reduce Sodium Intake in the United States. Washington, DC.

³ Whelton et al. Sodium, blood pressure, and cardiovascular disease: Further evidence supporting the American Heart Association sodium reduction recommendations. *Circulation*. 2012;126:2880-2889.

⁴ National Health and Nutrition Examination Survey (2009–2012)

⁵ Ibid.

⁶ AHA Statistical Update: Heart Disease and Stroke Statistics – 2016 Update. A Report from the American Heart Association. *Circulation*. 2015;132:000-000. DOI: 10.1161/CIR.0000000000000350.)

⁷ Vasan RS, et al. Residual Lifetime Risk for Developing Hypertension in Middle-Aged Women and Men: The Framingham Study. *JAMA*. 2002; 287:1003-1010.

⁸ Lawes CM, et al. Global Burden of Blood Pressure-Related Disease, 2001. *Lancet*. 2008 May 3;371(9623):1513-8. doi: 10.1016/S0140-6736(08)60655-8.

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 Available data are sufficiently robust to recommend a lower sodium intake beginning early in life as an effective, and well-tolerated approach to minimize the risk of children developing elevated blood pressure, a condition that extends into adulthood.¹¹

The good news is that reducing sodium consumption can have significant health benefits and reduce medical costs. Studies have shown that a reduced sodium intake can prevent hypertension in non-hypertensive individuals, can lower blood pressure, and can facilitate hypertension control. A reduced sodium intake is also associated with a blunted age-related rise in systolic blood pressure and a lower risk of atherosclerotic cardiovascular events, congestive heart failure, and stroke.¹² A long-term study published in 2014 documented a direct relationship between sodium intake and cardiovascular disease; lowering sodium intake lowered cardiovascular risk without any evidence of harm.¹³

One study, for example, projected that reducing sodium intake by 1,200mg daily could result in 60,000 to 120,000 fewer coronary heart disease cases, 32,000 to 66,000 fewer strokes, 54,000 to 99,000 fewer myocardial infarctions, and 44,000 to 92,000 fewer deaths from any cause, as well as save \$10 to \$24 billion in health care costs each year.¹⁴ Another study suggested that if Americans moved to an average intake of 2,300mg a day, it could result in 11 million fewer cases of hypertension and \$18 billion in health care savings annually.¹⁵ While another study projected that gradually reducing sodium intake by 40% would reduce deaths from cardiovascular disease by 280,000 to 500,000 over the next 10 years.¹⁶

The benefits of sodium reduction have also been demonstrated in the United Kingdom, which launched a sodium reduction program in 2003. Between 2003 and 2011, the average population salt intake fell by 15% due to a gradual reduction in the sodium content of processed foods. During the same time period, the average population blood pressure also fell (3 mm Hg systolic / 1.4 mm Hg diastolic) and deaths from heart disease and stroke decreased 40% and 42%, respectively. The authors of the study suggested that the reduction in blood pressure and

⁹ CDC. Prevalence of Excess Sodium Intake in the United States – NHANES, 2009-2012. *MMWR*. Vol. 64, January 8, 2016.

¹⁰ Rosner B, Cook NR, Daniels S, Falkner B. Childhood blood pressure trends and risk factors for high blood pressure: The NHANES experience 1988-2008. *Hypertension*. 2013;62:247-254.

¹¹ Appel LJ, et al. Reducing Sodium Intake in Children: A Public Health Investment. *The Journal of Clinical Hypertension*. September 2015. 17(9):657-662.

¹² Lichtenstein A, et al. Diet and Lifestyle Recommendations Revision 2006: A Scientific Statement from the American Heart Association Nutrition Committee. 2006.

¹³ Cook NR, et al. Lowers levels of sodium intake and reduced cardiovascular risk. *Circulation*. 2014;129(9):981-9.

¹⁴ Bibbins-Domingo K, et al. Projected effect of dietary salt reductions on future cardiovascular disease. *New England Journal of Medicine* 2010, vol. 362, pp. 590-599.

¹⁵ Palar K, Sturm R. Potential societal savings from reduced sodium consumption in the U.S. Adult population. *American Journal of Health Promotion*. 2009;24:49-57.

¹⁶ Coxson P, et al. Mortality benefits from US population-wide reduction in sodium consumption: projections from three modeling approaches." *Hypertension* 2013, vol. 61, pp. 564-570.

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 less revising longstanding recommendations to lower sodium consumption. Instead, policy recommendations, such as the FDA's voluntary sodium reduction targets, must be based on the high quality investigations and the robust body of evidence linking sodium with elevated blood pressure.

The overwhelming evidence shows that reductions in sodium consumption are linked to improvements in blood pressure and a reduced risk for a number of chronic diseases. That is why AHA and many other well-respected scientific and professional health organizations, including the American Academy of Pediatrics, the Academy of Nutrition and Dietetics, the American College of Cardiology, the American Medical Association, the American Public Health Association, and the American Society of Hypertension all recommend reductions in sodium consumption. Sodium reduction is also a key message in the 2015-2020 Dietary Guidelines for Americans, a Healthy People 2020 objective, and the focus of global recommendations from the World Health Organization.

The evidence is strong and it clearly supports the benefits of reducing the amount of sodium in the food supply.

Consumers Want More Control over Sodium

In addition to the public health authorities mentioned above, many consumers have expressed an interest in sodium reduction across the food supply. An AHA commissioned survey of 1,003 adults, conducted between May 25 and June 10, 2016, found that 60% – or 3 out of 5 – want more choice or control over how much sodium is in their food. 74% of respondents indicated that they would prefer less sodium in processed foods, and 72% want restaurants to reduce the amount of sodium in their offerings.¹⁹

The AHA survey also found support among consumers for public policies, like the FDA's proposed sodium targets, to help reduce the amount of sodium in the food supply. According to the survey, a majority of respondents (62%) believe the government should play a role in setting limits, with 27% indicating that the government should establish voluntary sodium limits, such as the ones the FDA has proposed, and 35% preferring mandatory standards.

¹⁷ He FJ, et al. Salt reduction in England from 2003 to 2011: its relationship to blood pressure, stroke and ischemic heart disease mortality. *BMJ Open*. 2014;4:e004549. doi:10.1136/bmjopen-2013-004549.

¹⁸ Cobb LK, et al. Methodological issues in cohort studies that relate sodium intake to cardiovascular disease outcomes: A science advisory from the American Heart Association. *Circulation*. 2014.

¹⁹ Understanding Sodium Consumption Attitudes and Behaviors. IPSOS. Survey conducted May 25-June 10 2016. Margin of error: 3.09.

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

FDA Draft Guidance Document

In this section of our letter, we shift from discussing *why* sodium reduction targets are needed, to offering comments on the content of the draft guidance document released by FDA. Our comments address the process used to identify food categories and determine the baseline sodium values, the target values themselves, and the implementation timeline.

Identification of Food Categories

AHA strongly supports the FDA's proposal to create sodium reduction targets by food category. This is the same approach used by both the NSRI and AHA's Heart-Check Food Certification Program. Establishing sodium targets by food category allows the FDA to evaluate each food type independently and take into account factors such as the role of sodium in food processing and food safety, the range of sodium for products in the market today, and the food's contribution to overall sodium intake.

We also agree with the Agency's decision to focus on food categories that contribute significantly to overall sodium intake, and we are pleased that the top 50 sources of sodium in the American diet (as determined by the National Health and Nutrition Examination Survey or NHANES) are largely represented in the sodium categories identified by the FDA.

We understand, however, that new NHANES data was released at the end of September and that a number of the top sources of sodium changed. We encourage the FDA to review the new NHANES data and make sure that the top sources of sodium continue to be adequately addressed by the voluntary sodium targets.

Baseline Sodium Concentration Values

As noted above, one of the factors the FDA considered when identifying food categories and establishing sodium targets was the range of sodium for products in the marketplace today. To determine the "state of the market," the Agency examined the food labels and menus for a large array of packaged and restaurant foods on the market in 2010. A baseline value for each category was then calculated based on a sales-weighted average of sodium concentrations. Products labeled as no-sodium added, low-sodium, and reduced-sodium were not included in the baseline calculations.

AHA questions the Agency's decision to exclude no-sodium added, low-sodium, and reduced-sodium products from the baseline calculations. We do not understand how the baseline values represent an "average" sodium concentration when products with a lower sodium content were not included in the calculations. Excluding no-, low-, or reduced-sodium products may have artificially inflated or pushed the "average" baseline to a higher number.

This concerns us for a number of reasons. First, the baseline values serve as the foundation for establishing the proposed sodium reduction targets; thus they should be an accurate representation of the sodium content for the *entire range* of products in a given food category. Second, including no-, low-, and reduced-sodium products in the baseline better illustrates the level of sodium reduction achievable in a particular food category. And third, artificially inflating the 2010 baseline values may make it difficult to accurately monitor changes in sodium concentrations in food categories over time.

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 limited. It is our understanding that the FDA had to exclude approximately 50% of chain restaurants from the calculations due to missing serving size weights. These omissions are unacceptable, especially since food prepared away from home “plays an increasingly large role in the American diet,” increasing from 25.9% of all food spending in 1970 to 43.1% in 2012.²³ In addition, restaurant foods make up some of the top contributors (pizza, sandwiches, mixed ingredient dishes, and other combination foods) to sodium intake. The Agency should encourage restaurants to publish the weight (in grams) of dishes. The FDA should also consider establishing maximum sodium levels per serving, as well as per 100 g, to better represent the current state of the restaurant-food supply.

Proposed Target Means and Upper Bounds

AHA appreciates the tremendous amount of work the Agency put 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 many different factors, including salt’s varied functional and technical roles, food safety concerns, and the availability of sodium reduction technologies.

Target Feasibility

We believe that the target values proposed by the FDA can be achieved within the two-year timeframe, especially since the reductions are relatively modest in nature, as illustrated by the examples below.

Food Category	2010 Baseline	Short-Term Target Goal	% Reduction
19. Canned Vegetables	307 mg	290 mg	5.5% or 17 mg
34. Canned Ready-to-Eat Soup	265 mg	230 mg	13% or 35 mg
59. Wheat & Mixed Grain Bread	471 mg	420 mg	10.8% or 51 mg
83. Deli Meats – Turkey/Chicken	990 mg	900 mg	9% or 90 mg

²³ USDA Economic Research Service. Food-Away-From-Home. <http://www.ers.usda.gov/topics/food-choices-health/food-consumption-demand/food-away-from-home.aspx>

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.

Food Category	FDA 2-Year Goal	FDA 2-Year Upper Bound	Heart-Check Sodium Limit*
86. Uncooked Sausage	590	740	480
96. Canned/Smoked Pork, Can. Bacon	970	1220	873
105. Non-Breaded Fish & Other Seafood	380	550	327
121. Deli Meat-Based Sandwiches	480	660	185 – 257
127. Hamburgers with Cheese	480	630	185 – 257
138. Lettuce/Green Salads w/Additions	280	400	240
145a. Pizza w/Meat, Poultry or Seafood	480	640	185 – 257
147. Tacos, Burritos, and Enchiladas	390	560	185 – 257

* The Heart-Check program applies sodium limits by serving size/RACC. The Heart-Check sodium limits were converted to a mg per 100g basis to allow for comparison with the FDA’s targets.

Sodium concentrations in foods sold outside of the United States provide additional evidence in support of the feasibility of the FDA’s proposed targets. There is often less sodium in food and restaurant products that are sold in other countries. Companies sell the same product with the same brand name, but with a lower sodium content. This validates that the food and restaurant industries are capable of producing and selling foods with a lower sodium content, and that these products are met with consumer acceptance.

For example, a group of researchers examined fast foods in different countries to determine whether companies should be able to reduce sodium among their menu items.²⁵ This study examined the top fast-food chains, including Burger King, Domino’s Pizza, Kentucky Fried Chicken, McDonald’s, Pizza Hut, and Subway, in Australia, Canada, France, New Zealand, the U.K., and the U.S.²⁶ Seven categories of fast food covering 2,124 menu items were analyzed across these countries. The results demonstrated significant variability between countries. For instance, savory breakfast items in the U.S. had significantly higher sodium content (per 100 g) compared to Australia, New Zealand, and the U.K. Chicken products also contained significantly more sodium in the U.S. (720 mg per 100 g) than in the U.K. (440 mg per 100 g). Most notably, there were significant variations in the sodium content of a single company’s products in different countries. McDonald’s Chicken McNuggets sold in the U.S. contained two and a half times more sodium than those sold in the U.K. (640 mg vs. 240 mg per 100 g), and the amount of sodium in U.K. McNuggets falls under the two- and 10-year upper bounds for chicken nuggets.

The sizeable variability in sodium by category of food, and by company and country in which the food is sold, demonstrates the feasibility of reformulating foods to meet the short-term targets.

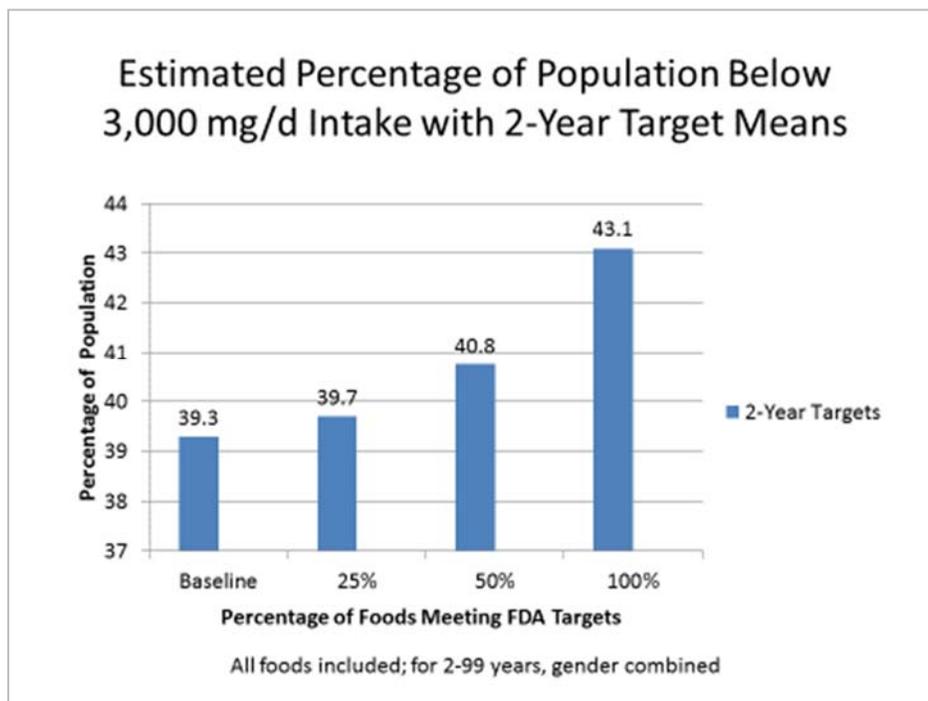
²⁵ Dunford E, et al. (2012). The variability of reported salt levels in fast foods across six countries: opportunities for salt reduction. *Canadian Medical Association Journal*. 184(9), 1023-1028.

²⁶ Ibid.

Appropriateness of Targets

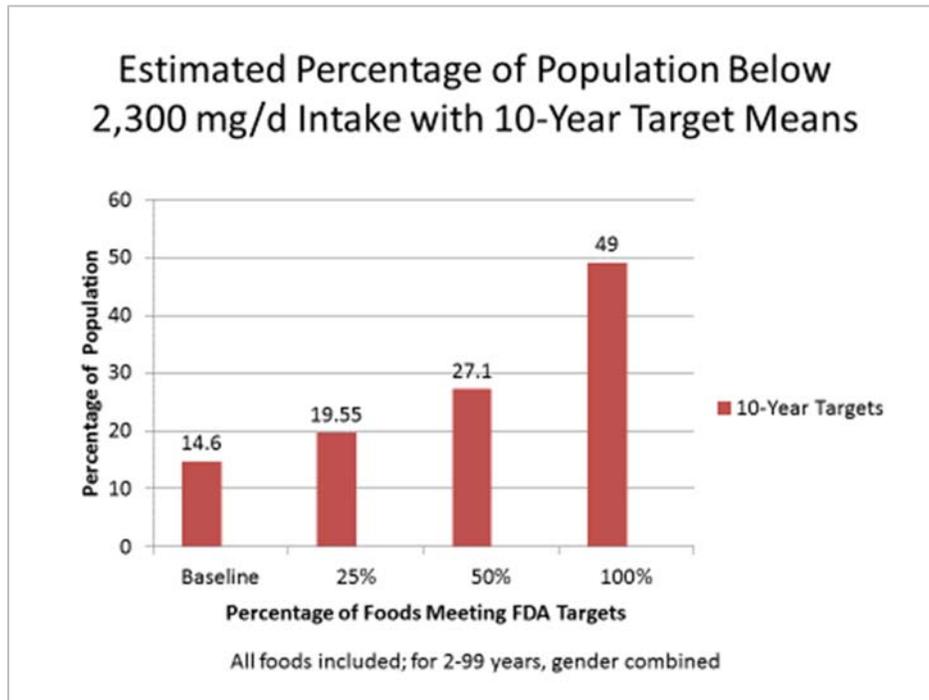
In addition to considering the feasibility of the targets, AHA also examined whether the target values would lead to sufficient reductions in overall sodium consumption across the population. To do this, AHA commissioned a food modelling study by Victor Fulgoni, III of Nutrition Impact, LLC. The study used the Food and Nutrient Database for Dietary Studies (FNDDS) mapping file provided by the FDA,²⁷ 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. The study examined both the short- and long-term targets; looked at 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.²⁸

The study found that the FDA targets could lead to measurable reductions of sodium in the food supply. If the two-year targets were universally adopted by the food and restaurant industry, the study found that approximately 43% of Americans would consume less than 3,000 mg of sodium a day. If the 10-year targets were universally adopted, 49% of Americans would consume less than 2,300 mg of sodium per day. For the long-term targets, 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.

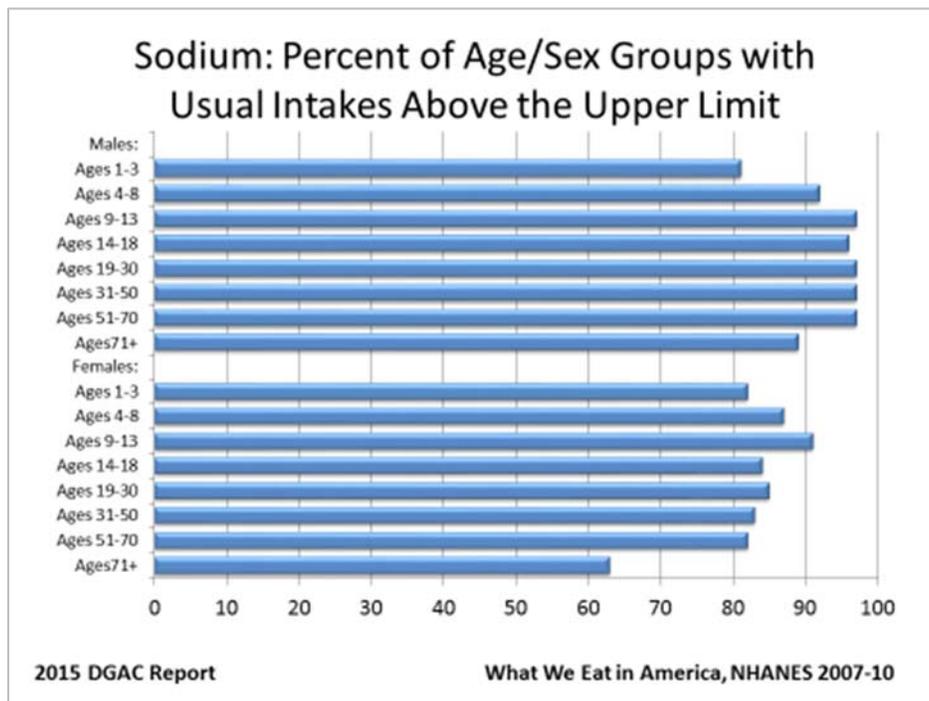


²⁷ See <https://www.regulations.gov/document?D=FDA-2014-D-0055-0410>.

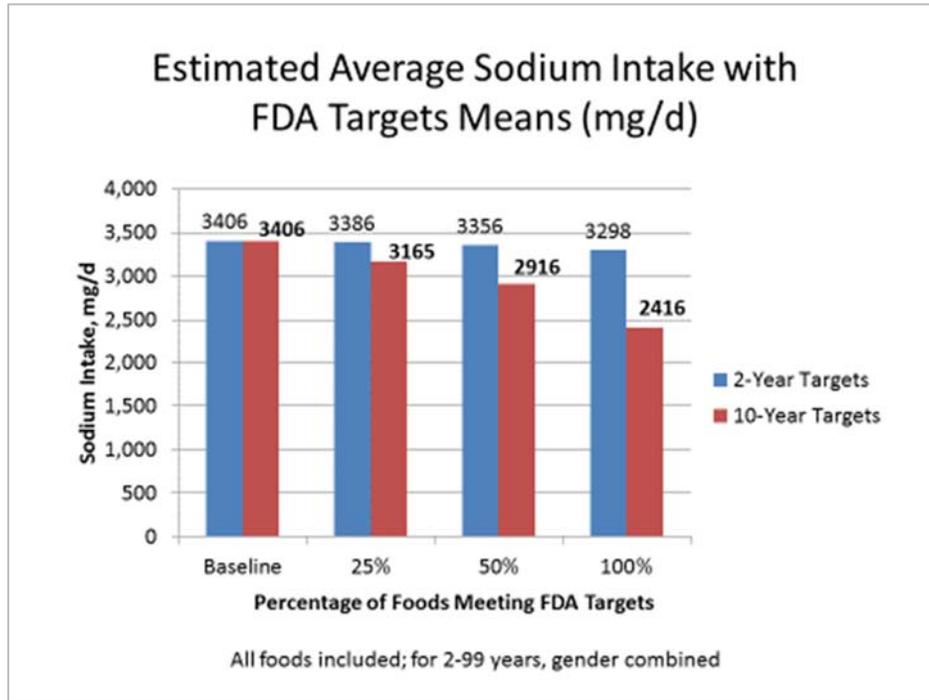
²⁸ Foods that fall outside of the 150 categories identified by FDA, because they do not contribute meaningfully to overall sodium intake, were included in the study's calculations of overall sodium intake.



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.

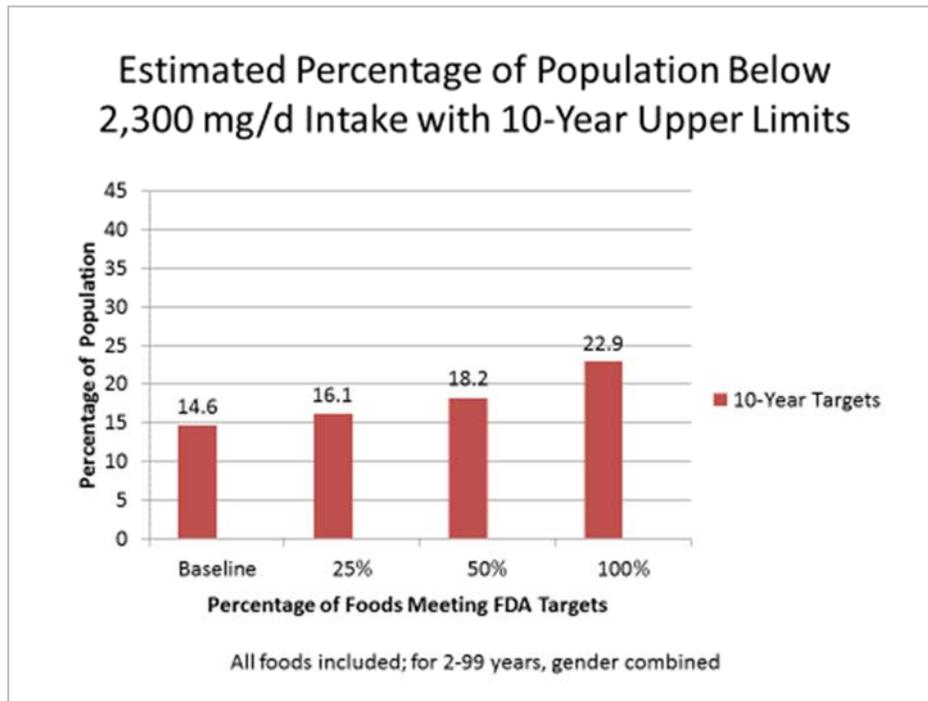


However, it is important to note that these numbers represent the average consumption amount when looking at the entire population between two and 99 years of age and both genders combined. Certain segments of the population will still have sodium intakes that *significantly* exceed the 2,300 mg recommended by the Dietary Guidelines for Americans. For example, males between the ages of 19 and 50 will have an average sodium intake of 4,181 mg even if 100% of foods meet the two-year targets. Males in this same age group will have an average intake of 3,065 mg even if 100% of foods meet the 10-year targets.

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 3,000 mg in two years and 2,300 mg within 10 as the FDA intends, more aggressive targets may be necessary.

In addition, our study shows the importance of uniform adherence and implementation. As stated above, 43% and 49% of Americans, respectively, will lower their sodium intake to 3,000 mg in two years and 2,300 mg in 10, but only if 100% of the foods they eat meet the new sodium target means. If fewer companies adopt the targets, those numbers decrease. For example, if only 50% of foods meet the short-term target means, the estimated percentage of the population consuming below 3,000 mg drops from 43% to 40%. For the long-term targets, the decrease is more dramatic, going from 49% to only 27% of the population lowering their sodium intake to 2,300 mg per day.

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 stepwise approach. Setting a series of sodium targets that decrease over a period of years will provide the food and restaurant industries with time to reformulate their products, making use of new technology and acceptable salt substitutes, if needed, as they become more prevalent. A two-step phased reduction will also allow consumers to adapt their taste sensitivities to foods with less sodium. This phased-in approach is also consistent with the 2010 National Academy of Medicine report which recommended reducing sodium content in a stepwise manner.²⁹

²⁹ IOM. 2010. Strategies to Reduce Sodium Intake in the United States. Washington, DC.

We believe that two years is a reasonable timeframe for the short-term targets. In addition to the targets being relatively modest in nature, the food industry has been aware of the need to reduce sodium content for several years; the National Academy of Medicine first recommended that the FDA establish sodium limits in 2010, the FDA and U.S. Department of Agriculture solicited comments on approaches to reduce sodium in 2011, and the FDA publicly stated that it was working on voluntary sodium targets as early as 2013 if not sooner. And, as the FDA states in the Federal Register notice, “as many as half of all products may already have achieved these interim results.”³⁰

For these reasons, we urge the Agency to resist any calls to extend the implementation timeline for the short-term targets beyond two years.

We also encourage the FDA to consider whether 10 years is an appropriate timeframe for the long-term targets. AHA will address this in more detail in separate comments on the long-term targets, but we question if 10 years is too long of a timeline. If the targets are finalized next year, there will already be a seven-year lag between the time the 2010 baseline data was collected and the creation of the final sodium targets. Providing companies 10 years to meet the targets means that there will be a *17-year gap* between the collection of the baseline data and the long-term target deadline. Because many companies are already working on sodium reduction, they may be able – and should be encouraged – to meet the long-term targets sooner.

Ongoing Monitoring

AHA is pleased that the FDA intends to monitor the impact of the voluntary sodium targets. According to the supplementary memorandum, the Agency will measure the sodium content of foods, track estimated sodium intake, follow NHANES measures of urinary sodium analysis, and examine data on public health outcomes, including blood pressure, cardiovascular disease events and overall mortality.³¹ The plan appears robust, however, other than stating that the monitoring will occur “over time,” the documents do not indicate how frequently the monitoring will occur. We request that the FDA clarify how often it intends to evaluate the impact of the program and to what degree the impact will be measured.

We also recommend that the Agency specify that 24-hour urine samples will be obtained from a subset of NHANES participants to provide a more accurate measure of sodium intake.

In addition, we understand that the FDA plans to monitor for unintended consequences, such as companies replacing sodium with sugar or solid fats in reformulated foods. We agree that assessing these general nutritional issues is important, and we encourage the Agency to examine how the sodium reduction targets impact consumption of both positive (e.g., potassium, fiber) and negative (e.g., added sugars, solid fats) nutrients as well as total caloric intake.

³⁰ 81 FR at 35,365.

³¹ Division of Biotechnology and GRAS Notice Review (HFS-255) Sodium Team. FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance. June 1, 2016.

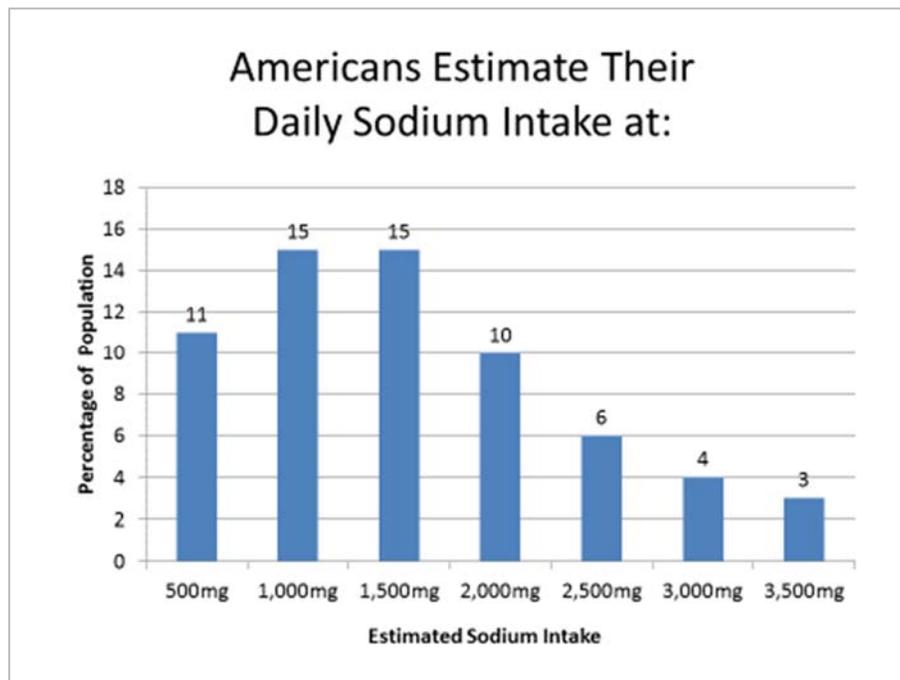
Consumer Education Campaign

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
- Healthy dietary patterns

We suggest these five areas because consumer research has shown that while many consumers are aware of at least some of the negative health effects of excess sodium consumption, gaps in knowledge remain. For example, the consumer survey commissioned by AHA found that 77% of respondents accurately associated sodium consumption with high blood pressure, but fewer people were aware of the association with other health outcomes such as heart disease (56%), stroke (39%), and kidney failure (36%).³²

The majority of consumers are also unaware of how much sodium they can safely consume, and they tend to underestimate how much sodium products contain. When asked how much sodium they consume on an average day, respondents to AHA's survey overwhelmingly underestimated their sodium intake at levels far below the actual average of 3,400 mg per day:



³² Understanding Sodium Consumption Attitudes and Behaviors. IPSOS. Survey conducted May 25-June 10 2016. Margin of error: 3.09.

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 reduce sodium content, the Food Service Agency launched an awareness campaign with a series of advertisements. The public awareness campaign included three stages: 1) educate consumers about the health consequences associated with excess sodium intake, 2) inform adults of the daily recommended sodium intake, and 3) encourage consumers to check package labels to compare sodium levels in different brands when they are shopping.³³ “Within a year, public awareness of recommended salt intake limits increased from 3% to 34% and within three years, salt content of processed foods sold in supermarkets was reduced by 20%-30%... [and] the FSA reported a 10% reduction in actual salt intake.”³⁴

The National Academy of Medicine also described the importance of consumer education in its 2010 report. According to the NAM:

[C]hanges in the food supply must also be accompanied by informed food choices on the part of individual consumers. Consumers have an important role to play and education and skill building efforts can help to motivate consumers and provide them with skills and tools to reduce sodium intake. Even with reductions of sodium in the food supply, consumers will still need to take actions to reduce their intake of sodium and to lower their preference for the taste and flavor of salty foods... Implementation of the strategies related to consumers and behavior change must rest on a foundation of acceptance regarding the importance of reducing sodium intake. This can take the form of efforts to enhance consumer awareness of the importance of sodium reduction, as well as engaging consumers to be supportive of efforts to reduce sodium in the food supply.³⁵

In addition, the Agency should continue to educate consumers about the need for an overall healthy eating pattern. The message to limit consumption of sodium, added sugars, and solid fats and increase consumption of whole grains and fruits and vegetables, will reinforce the need to reduce sodium intake. Focusing on the total diet concept also puts dietary recommendations

³³ Food Standards Agency. (2011). U.K. salt reduction initiatives.

<http://www.food.gov.uk/sites/default/files/multimedia/pdfs/saltreductioninitiatives.pdf>

³⁴ European Food Information Council. UK salt campaign may have successfully reduced salt intake, but what are the next steps? <http://www.eufic.org/page/en/show/latest-science-news/fftid/UK-salt-campaign-may-have-successfully-reduced-salt-intake-but-what-are-the-next-steps/>

³⁵ Institute of Medicine. Strategies to Reduce Sodium Intake in the United States. April 20, 2010. Pg. 309.

into practical terms, encourages personal choice and control, and underscores a nutrient-dense and calorie-balanced energy patterns, which should lead to a healthier diet overall. We also encourage the FDA to educate consumers about serving sizes, and work with food manufacturers and restaurants to develop smaller portion sizes. If serving size and portion size are reduced, sodium intake will also go down.

Closing

In closing, AHA is extremely pleased that the FDA has developed voluntary sodium-reduction targets for commercially processed, packaged, and prepared foods. Sodium is ubiquitous in the food supply making it very difficult for consumers to reduce sodium intake on their own. A public policy and population-based approach like the FDA targets is urgently needed.

To strengthen the guidance document – and increase the likelihood that it will lead to meaningful sodium reduction – we recommend that the FDA:

- Update the food categories based on the new NHANES data
- Include no-, low-, and reduced-sodium products in the baseline concentrations
- Work with the restaurant industry to develop more robust baseline concentrations
- Encourage companies to work toward the target means, not the upper bound limits
- Develop more aggressive targets to help a greater percentage of the population achieve an appropriate intake
- Maintain the two-year timeframe for the short-term targets
- Consider shortening the timeframe for the long-term targets

In addition, the FDA should implement an ongoing monitoring program that includes 24-hour urine monitoring, as well as assess how the targets impact consumption of other nutrients.

Finally, we urge the Agency to work with other government partners and public health organizations, like AHA, to develop and promote a comprehensive consumer education campaign. We are eager to work with the FDA on this initiative and offer any assistance you may require.

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