January 26, 2012

Division of Dockets Management
HFA-305
Food & Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Docket Clerk
U.S. Department of Agriculture
Food Safety & Inspection Service
1400 Independence Avenue, SW
Washington, DC 20250

RE: FDA-2011-N-0400 and FSIS-2011-0014

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to provide comments on approaches to reducing sodium consumption.

AHA applauds the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) for soliciting public comment on this important topic. Excess sodium consumption is a significant public health issue and we are extremely pleased that the agencies are examining ways to promote a reduction in sodium intake over time. We cannot overemphasize the need for the FDA, FSIS, and others within the federal government to work together to achieve this goal.

The need for action by FDA and FSIS is clear. We have long known that high levels of sodium can have a detrimental effect on health, particularly blood pressure. We know that Americans consume sodium in amounts that far exceed the recommended daily limits. And we know that the majority (77%) of the sodium we consume comes from salt *added* to processed foods, beverages, and restaurant foods; thereby severely limiting consumers' ability to control the amount of sodium they consume. And while there have been some voluntary efforts by industry to reduce the sodium content in foods, these efforts – while laudatory – are woefully insufficient. Americans continue to consume excess amounts of sodium and continue to suffer the health-related consequences.

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Reversing this trend will require action by the FDA and FSIS. **We urge you to make reducing the sodium content in the food supply a priority.** To do so, the agencies should:

- Implement the recommendations in the Institute of Medicine's (IOM) report "Strategies to Reduce Sodium Intake in the United States."
- Set mandatory national standards for the sodium content of foods.
- Base the Daily Value for sodium on Adequate Intake (1,500mg).
- Update and continue to promote the federal government's procurement standards, including strong criteria for sodium limits.
- Develop evidence-based nutrition standards for competitive foods in schools that include sodium limits that are in line with the Dietary Guidelines for Americans; and work with the food industry and schools to implement the new sodium limits for the National School Lunch and School Breakfast Programs as expeditiously as possible.
- Submit to Congress the robust, evidence-based principles that were developed by the Interagency Work Group on Food Marketed to Children that include limits on sodium.
- Collaborate to enhance and upgrade the accuracy and timeliness of the U.S. food database to capture the current nutrition profile, especially the sodium content, of foods in the marketplace in order to improve our surveillance of existing sodium content and our ability to track changes over time.
- Improve the monitoring of sodium intake, ideally through 24 hour urine collections in national surveys.
- Develop a comprehensive, proven effective and user-friendly consumer education campaign on the need for and how to reduce sodium intake.

We expand upon these recommendations and respond to the topic areas proposed by the agencies in the *Federal Register* notice below. Please note we have also provided a copy of *AHA's Presidential Advisory: The Importance of Population-Wide Sodium Reduction as a Means to Prevent Cardiovascular Disease and Stroke: A Call to Action from the American Heart Association* as an additional resource for the agencies in Attachment A.

The Science Behind Sodium

As noted above, excess sodium consumption has been linked to high blood pressure. A substantial number of studies show a direct relationship between salt intake and blood pressure. The studies found that on average, as dietary salt intake rises, so does blood pressure. Evidence includes results from animal studies, epidemiological studies, clinical trials, and meta-analyses of trials. Over 50 randomized trials examining the effects of salt 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.[1]

Unfortunately elevated blood pressure is extraordinarily common. It has been estimated that 76 million – nearly one in three U.S. adults – has high blood pressure or hypertension, an additional 30% of the adult population age 20 and older has pre-hypertension, and the prevalence of hypertension in

[1] Lawrence Appel, et al. Dietary Approaches to Prevent and Treat Hypertension: A Scientific Statement from the American Heart Association. 2006.

the U.S. continues to rise.[2] An estimated nine in ten Americans will develop high blood pressure during their lifetime.[3]

Individuals with hypertension are at increased risk for stroke, heart failure, kidney failure, stomach cancer, and osteoporosis.[4] Sadly these risks extend to children and adolescents as well. Children are at risk of developing heart disease and elevated blood pressure at an earlier age, because an estimated 97% of them currently consume too much sodium.[5]

The good news is that lowering sodium consumption can have significant health benefits. Studies have shown that a reduced sodium intake can prevent hypertension in non-hypertensive individuals, can lower blood pressure in the setting of antihypertensive medication, and can facilitate hypertension control. A reduced sodium intake is also associated with a blunted age-related rise in systolic blood pressure and a reduced risk of atherosclerotic cardiovascular events and congestive heart failure.[6]

We are aware, however, that despite the abundance of studies showing the benefits of lowering sodium consumption, there are some who question the science and argue that sodium reductions will hurt rather than improve health. The salt industry has, for example, claimed that "there may indeed be very negative consequences if the diet limits sodium to the range of 1,500 - 2,300mg Na/day as recommended in the Dietary Guidelines"[7] and that "there are more medical studies that caution against population-wide salt reduction than support it… and could result in mass illnesses"[8]. We strongly disagree with these statements – they are not supported by the science. We also question studies that the salt industry has used to show that reductions in salt intake do not result in improved cardiovascular outcomes. One such study reported that reducing salt consumption did not affect the likelihood of dying or experiencing cardiovascular disease.[9] Yet when the study data were reexamined by outside researchers, they found that a small reduction in salt intake <u>does</u> result in a significant reduction (20%) in cardiovascular events and a non-significant reduction in all-cause mortality (5-7%).[10] Research studies with paradoxical findings are often observational studies with methodological limitations, particularly suboptimal measurement of habitual sodium intake and the potential for reverse causality.[11]

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. This evidence supports the need to make population-wide reductions in the amount of sodium in the food supply.

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[2] Heart Disease and Stroke Statistics 2011 Update: A Report from the American Heart Association.
[3] Vasn RS. Beiser A., et al. Residual Lifetime Risk for Developing Hypertension in Middle-Aged Women and Men: The Framingham Study. JAMA. 20202; 287:1003-1010.
[4] He FJ, MacGregor GA. A Comprehensive Review on Salt and Health and Current Experience of Worldwide Salt Reduction Programmes. J Hum Hypertens 2008.
[5] Institute of Medicine. Dietary Reference Intakes for Water Potassium, Sodium Chloride, and Sulfate. 2004.
[6] Alice Lichtenstein, et al. Diet and Lifestyle Recommendations Revision 2006: A Scientific Statement from the American Heart Association Nutrition Committee. 2006.
[7] Correspondence. Salt Institute letter to Secretary Vilsack and Secretary Sebelius. September 30, 2011.
[8] Salt Health. 5 Sample Comments You Can Use. http://www.facebook.com/SaltHealth?sk=app_208412272531040. Accessed October 28, 2011.
[9] Taylor RS, et al. Reduced Dietary Salt for the Prevention of Cardiovascular Disease. Cochrane Database Syst Rev 2011, Issue 7. Art. No.: CD009217.
[10] FJ He, G MacGregor. Salt Reduction Lowers Cardiovascular Risk: Meta-Analysis of Outcome Trials. The Lancet. Vol 378. July 30, 2011.
[11] FJ He, et al. Does Reducing Salt Intake Increase Cardiovascular Mortality? JAMA 2011;305:1777-1785.

Current Consumption Levels
As the agencies are aware, Americans currently consume sodium in levels that far exceed the recommended amounts. Intake data show that Americans consume an average of 3,400mg of sodium daily with some populations, particularly males between the ages of 12 and 49, consuming over 4,000mg of sodium per day.[12] This means that 98.6% of individuals who are advised by the 2010 Dietary Guidelines for Americans to consume less than 1,500mg of sodium per day – and 88.2% of the individuals advised to eat less than 2,300mg per day – are missing those goals by a large margin.[13]

Unfortunately, these numbers show no sign of decreasing. As the IOM's Committee on Strategies to Reduce Sodium Intake found, intake data reveal persistently high sodium consumption since the early 1970s.[14] These data indicate that existing sodium reduction efforts have been unsuccessful.

Consumer Understanding and Consumption Practices
According to the *Federal Register* notice, the FDA and FSIS are interested in learning if consumers understand the role of sodium in hypertension and other chronic illnesses, and if so, whether this awareness changes their consumption practices.

Before starting its National Salt Reduction Initiative (NSRI), the New York City Department of Health and Mental Hygiene commissioned a qualitative research study that examined these questions. That study found that consumers frequently associate salt intake with high blood pressure and heart disease, and that study participants with a diagnosis or family history of a diet-related disease such as hypertension, diabetes, or heart disease, were more aware of the amount of salt they consumed, more aware of the effects of an unhealthy diet, and more likely to take preventive action. Yet, study participants who were concerned about eating a healthy diet were more concerned with calories, cholesterol, or fat than with sodium.[15]

AHA recently conducted an online survey of 1,000 adults and found similar results. As with the NSRI study, we found that the majority of respondents (85%) associated excess salt/sodium consumption with high blood pressure. Respondents also accurately associated sodium consumption with other health outcomes, but in lower numbers. For example, only 16% recognized an association between sodium consumption and osteoporosis and just 9% recognized an association with stomach cancer. However, respondents also associated sodium with unrelated conditions such as tooth decay (13%).

Respondents were also asked to compare excess salt consumption with a range of other health issues. The majority of respondents (75% and 64%, respectively) view smoking and obesity as more or much more serious than consuming too much salt. Forty-five percent are more or much more concerned with eating too much fat and 29% with too much sugar. And 24% find having tooth decay to be more serious than eating too much salt.

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[12] 2010 Dietary Guidelines for Americans. Figure 3-1: Estimated Mean Daily Sodium Intake, by Age-Gender Group, NHANES 2005-2006.
[13] Centers for Disease Control and Prevention. Usual Sodium Intakes Compared with Current Dietary Guidelines: United States, 2005-2008. MMWR. October 21, 2011: 60(41);1413-1417.
[14] Institute of Medicine. Strategies to Reduce Sodium Intake in the United States. 2010.
[15] Marco International, Inc. A Qualitative Research Study: Illustrations and Message Testing – Sodium Awareness and Consumers. Prepared for New York City Department of Health and Mental Hygiene. July 2007.

The survey also examined whether respondents try to reduce their salt intake, and if so, why. Forty-one percent indicated that they always or regularly make choices to reduce the salt in their diet; however, disappointingly, 28% indicated that they rarely or never do. Of those that attempt to reduce their salt consumption, the majority (65%) stated that health reasons such as improving their blood pressure are a driving factor. Other high scoring reasons include because a doctor, friend, or family member suggested that they lower their salt intake (21%), and/or because they do not want added ingredients in their food (21%). [Note that respondents were allowed to give multiple responses]. (See Attachment B).

Lastly, 38% of respondents stated that they would definitely or probably buy a food product if it claimed it had 25% less sodium.

Both the NSRI and AHA surveys show that consumers are largely aware of the link between sodium and blood pressure, although they are less certain about other potential health effects, and they may not recognize how serious excess sodium consumption can be. The studies also show that many would like to reduce their sodium consumption, but as discussed above, sodium intake continues to trend upwards.

A number of factors likely contribute to this problem. For example, many consumers – 79% according to a recent HealthFocus International Study – do not know the daily recommended intake for sodium.[16] Consumers also have misconceptions about the best way to reduce their sodium consumption. One study found that 46% of adults believe that table salt is the primary source of sodium in American diets[17] and 55% reduce the amount of table salt they use even though it is only a small contributor to their total sodium intake.[18]

The main reason people continue to consume too much sodium is because there is too much salt added to the food supply. This along with increased calorie consumption constitutes a major public health problem that could be avoided. As the agencies are aware, 77% of sodium in the diet comes from salt added to processed foods, beverages, and restaurant foods.[19] Even fresh meats are being injected with sodium to add weight and moisture.[20] This makes it difficult for consumers to meet the recommended level of intake without preparing foods from scratch and carefully reading food labels. In other words, the high level of sodium in the food supply leaves Americans with little control over the amount of sodium they consume. And as we learned in our recent survey, 60% of consumers want more choice or control over the amount of sodium in their food.

The present lack of control explains why the IOM found that 40 plus years of efforts to reduce the sodium intake of Americans have not been successful. Simply educating consumers about the need to select lower sodium foods and ad hoc efforts by the food and restaurant industries to lower the sodium content of certain food products are not enough. To give consumers the ability to readily control their sodium intake, we need an overall reduction in the amount of sodium in the food supply.

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[16] HealthFocus International study.
[17] American Heart Association. Blood Pressure Awareness Survey. March 2011.
[18] HealthFocus International study.
[19] Mattes RD, et al. Relative Contributions of Dietary Sodium Source. Journal of the American College of Nutrition. 1991; 10(4): 383-93.
[20] USDA. Agricultural Research Service. Nutrient Comparison Between Enhanced and Natural Fresh Pork. 2007.

Existing Sodium Reduction Efforts

As the agencies are aware, a number of voluntary sodium reduction efforts are currently underway. Some of these efforts are led by members of the food and restaurant industries. A number of companies have chosen voluntarily to decrease the sodium content of their foods. The extent of the sodium reductions vary by company. Some have focused on a limited number of products, while others are focused on an entire product line. The amount of sodium removed from products also varies. AHA appreciates the industry's efforts to lower the sodium content of foods, but greater reductions are needed.

We know greater reductions in sodium content are possible. For example, there is often less sodium in food and restaurant products that are sold outside of the United States. Companies sell the same product with the same brand name, but with different sodium content. This shows that the food and restaurant industries are capable of producing and selling foods with lower sodium content.

Sodium content is likely lower outside of the U.S. because the food industry has been responding to international initiatives to reduce sodium consumption. We do not describe those initiatives here since they are detailed in the IOM report, but we do note that these government-led programs have demonstrated success in reducing sodium consumption. For example, in the first five years (2003 to 2008) after the start of the United Kingdom's Consensus Action on Salt and Health (CASH) strategy, sodium consumption, dropped 10%.[21] And Finland saw sodium consumption decrease from 5,600mg a day in 1972 to 3,200mg a day in 2002 and experienced a significant drop in diastolic blood pressure and stroke mortality.[22]

Because there is currently no government-led program encouraging or requiring industry to reduce sodium content of foods in the U.S., we must rely on incentives to encourage voluntary reductions. AHA has seen the power of incentives through our Heart-Check food certification program. A number of companies have reformulated their products in order to qualify for certification, and in some cases, companies have contacted AHA to inquire about qualifying criteria when formulating new products and have specifically designed those products to meet the program criteria. Thus, the Heart-Check program – while voluntary – acts as an incentive for sodium reductions. Companies must meet the program's sodium targets if they want to participate and display the Heart-Check Mark on their product's packaging.

The National Salt Reduction Initiative (NSRI) is another example of a voluntary initiative that contains a form of incentive. Companies that participate in the initiative will be publicly recognized. Participating companies must commit to meeting sodium reduction targets in one or more of 62 packaged food categories or 25 restaurant categories.

AHA is a proud supporter of the NSRI and we recommend that the FDA and FSIS examine this program and determine what elements could be expanded further. For example, a federal sodium reduction initiative could build off of the NSRI's sodium reduction targets. As noted above, the sodium targets vary by food category. A federal initiative could also follow the NSRI's example and establish targets that allow for a step-wise reduction in sodium content over time. One change, however, we would recommend regards the allowance for target "ranges" in the NSRI. Under the

[21] GA MacGregor. Global Salt Initiatives: From Evidence to Worldwide Implementation. worldactiononsalt.com.
[22] Institute of Medicine. Strategies to Reduce Sodium Intake in the United States. 2010.

NSRI, participating companies can meet the sodium reduction targets by averaging a product line across a food category. This allows companies to claim they meet the sodium target even if one or more of their products exceed the target level. While we understand that this target flexibility increases the likelihood that companies will voluntarily choose to participate in the program, AHA believes individual food products should be required to meet specific, absolute values. If a federal sodium reduction initiative is developed, the use of averaging or ranges should not be allowed.

Finally, all of the voluntarily sodium reduction programs in the U.S. have one element in common – whether it is the Heart-Check, NSRI, or the Sodium Reduction in Communities Program being funded by the Centers for Disease Control and Prevention (CDC) – they all lead to some degree of sodium reduction. But the programs are limited in scope and do not have the ability to require sodium reductions in the entire food supply. To achieve widespread sodium reductions, a mandatory nationwide standard will be required.

Mandatory Nationwide Standards for Sodium Content

AHA strongly supports the IOM recommendation calling for the establishment of mandatory national standards for the sodium content of foods. As discussed in the IOM report, voluntary sodium reduction initiatives, nutrition labeling, and consumer education have not resulted in significant changes in sodium consumption. Mandatory limits on sodium content, which were found to be 20 times more effective than voluntary efforts,[23] are necessary to achieve significant sodium reductions in the food supply. We urge the FDA to implement these limits as expeditiously as possible. The sodium limits should be:

- Implemented by food category
- Based on a recommended daily intake of no more than 1,500mg
- Designed to allow for gradual reductions in sodium content over time

As noted above, we recommend that the FDA implement sodium limits by food category. For example, the FDA could set one sodium limit for cold breakfast cereals, another limit for breads, another limit for canned vegetables, and so on. This is the approach taken by both the NSRI and the AHA Heart-Check program. AHA recently made a number of changes to the nutritional criteria for the Heart-Check program, including lowering the sodium limit for many products and setting those limits by food category. To determine the limit for a food category, each category was evaluated independently taking the following factors into account: does the category include foods and nutrients of public health concern; what is the role of sodium in food processing; and what is the current sodium range for products in the market today. Based on these factors, each category was then assigned one of four sodium levels: 140mg, 240mg, 360mg, or 480mg.[24] The levels were designed to help consumers reach a daily sodium consumption of no more than 1,500mg.

We suggest the FDA proceed in a similar manner – establishing sodium limits based on a recommended daily intake of less than 1,500mg. 1,500mg is the Adequate Intake (AI) amount recommended by the IOM Report on Dietary Reference Intakes: Water, Potassium, Sodium Chloride, and Sulfate.[25] 1,500mg has also been identified as the appropriate target for at-risk individuals, and

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[23] Linda Cobiac, et al. Mandatory Sodium Reduction 20 Times More Effective, Finds Study. Food Navigator-USA.com. November 2, 2010.

[24] Participating products must meet these revised sodium limits no later than January 2014.

[25] Institute of Medicine. *Dietary Reference Intakes: Water, Potassium, Sodium Chloride, and Sulfate*. 1st ed. Washington, DC: National Academy Press; 2004.

two CDC analyses found that one-half to as much as 70% of the entire U.S. population fall into these at risk groups.[26,27] Basing sodium limits on the AI will help people achieve this recommendation, as would revising the Daily Value (DV) to reflect this amount.

We recognize it will be difficult for food companies and restaurants to meet sodium limits based on an overall intake of 1,500mg. Thus, we recommend that the FDA use a step-wise process to reduce sodium content over time. Setting a series of sodium limits that decrease over a period of years will provide the food and restaurant industries with time to reformulate their products, and will allow consumers to adapt their taste sensitivities to the lower sodium content in foods. For example, the FDA could establish intermediate sodium limits designed to reduce overall sodium consumption to 2,300mg by 2015. Final limits reducing sodium consumption to 1,500mg could take effect in 2020.

GRAS Status for Salt

We understand that establishing mandatory sodium limits will be challenging. The FDA will have to make changes to the Generally Recognized as Safe (GRAS) status for salt. Current regulations allow food manufacturers to add salt to foods as a GRAS substance and do not limit or require a specific level. AHA supports modifying the GRAS status for salt. We would also like to see the overall GRAS process strengthened.

Strengthen the GRAS Process

AHA is concerned that the current process allows food manufacturers to make their own GRAS determinations. Under the GRAS regulations, a substance's GRAS status may be determined by food manufacturers or by the FDA. If a manufacturer determines that a use of a substance is GRAS as set forth in the FDA regulations, it does not need to seek premarket approval from the FDA to use the substance in that way.[28] This means that manufacturers are responsible for establishing the GRAS use of substances they wish to add to foods.[29]

We are further concerned that manufacturers may choose – but are not required – to notify the FDA of their GRAS determination. If manufacturers choose not to submit notifications to the Agency, the FDA will, in general, have no information about those GRAS determinations. Thus, the FDA cannot ensure the sufficiency of all new GRAS determinations because it only reviews the ones that are sent to it.[30] Furthermore, a company does not have to wait for a response from the Agency before marketing the substance or foods containing the substance.

Another weakness in the GRAS process is that there is no mechanism for systematically ensuring the independence and sufficiency of the expert determinations that companies may rely on for their GRAS determinations. To show that there is a consensus among qualified experts about the safety of a GRAS substance, companies may assemble scientific review articles, convene a panel of experts, or

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[26] Centers for Disease Control and Prevention. Press Release. Americans Consume Too Much Salt: Lower Sodium Reduction Applies to Almost 70% of American Adults. March 26, 2009.
Presentation at the Institute of Medicine Committee on Strategies to Reduce Sodium Intake. January 13, 2009.

[27] Centers for Disease Control and Prevention. Usual Sodium Intakes Compared with Current Dietary Guidelines: United States, 2005-2008. MMWR. October 21, 2011: 60(41);1413-1417.

[28] Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,939.

[29] See 21 CFR §§ 170.30(i) and 184.1(b)(1). See also *U.S. v. An Article of Food*, 752 F.2d 11, 15 (1st Cir. 1985).

[30] U.S. Gov't Accountability Office, Food Safety: The FDA Should Strengthen its Oversight of Food Ingredients Determined to be Generally Recognized as Safe (GRAS) 11 (2010) at 8-9.

use reports from authoritative bodies, or some combination of these methods.[31] According to FDA staff, about half of the GRAS determination notices the Agency receives include expert panel reports, most of which have not been published in peer-reviewed journals.[32] However, the FDA has not issued any guidance about conflicts of interest for these experts, nor does it require companies to provide information or assurances about the independence or potential conflicts of interest of these expert panelists.[33] Additionally, because companies may make GRAS determinations without notifying the FDA (and hence, the public), there is no way to ensure independent review of such GRAS determinations. [34]

Another major concern, which was identified in the Government Accountability Office's report "Food Safety: FDA Should Strengthen its Oversight of Food Ingredients Determined to be Generally Recognized as Safe" is that the FDA does not "systematically ensure the continued safety of current GRAS substances."[35] The GAO noted that despite the fact that FDA regulations specifically contemplate that a substance's GRAS status can change "and must be reconsidered as new information comes to light or new methods of evaluating its safety arise," the FDA has no process in place for such a systematic review. And, when new evidence and/or concerns have been raised about a GRAS substance, the Agency has been slow to take action.

AHA hopes that the FDA is able to address these weaknesses in the GRAS process. The current process relinquishes too much of the Agency's authority to food manufacturers and does not do enough to ensure the safety of substances that are added to foods. We believe the FDA should have greater involvement in GRAS determinations, should increase its level of enforcement, and should implement a process to periodically review the science supporting a GRAS claim. Ideally, these changes should be made before or in tandem with revising the GRAS status of salt.

<u>The Need to Modify Salt's Status</u>
As noted above, FDA regulations allow for a substance's GRAS status to change, particularly when concerns are raised about a substance's safety – and concerns with salt have been raised for many years.

Consider, for example, that salt/sodium chloride was one of the GRAS substances identified for review by the FDA during a review process that started in 1969. Upon concluding that review, the Select Committee on GRAS Substances (SCOGS) stated: "It is the prevalent judgment of the scientific community that the [U.S.] consumption of sodium chloride in the aggregate should be lowered," and went on to conclude that the evidence of harm due to salt intake that it had reviewed was "insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in a manner now practiced".[36] Yet the FDA took no action to affirm or revoke salt's GRAS status in response to the SCOGS report.

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[31]Substances Generally Recognized as Safe, 62 Fed. Reg. at 18,942-43.
[32] Substances that Are Generally Recognized as Safe (GRAS); Experience with GRAS Notices (memo from Linda S. Kahl, Ph.D., Office of Regulations, Policy and Social Sciences (HFS-024), Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA)), Nov. 4, 2010, at 5.
[33] GAO Report on FDA Oversight of GRAS at 15.
[34] GAO Report on FDA Oversight of GRAS at 24.
[35] GAO Report on FDA Oversight of GRAS at 20.
[36] *Database of Select Committee on GRAS Substances (SCOGS) Reviews: Sodium Chloride*, U.S. FOOD & DRUG ADMIN. (Oct. 31, 2006)

Then, in response to a 1978 citizens petition filed by the Center for Science in the Public Interest asking the FDA to revoke sodium's GRAS status and regulate it as a food additive, the Agency announced it would defer action on salt's GRAS status until after the impact of sodium labeling regulations being proposed at the time, and industry's voluntary sodium reduction efforts, could be assessed.[37] The FDA explained this decision stating that salt added to processed foods constituted about one-third to one-half of Americans' sodium intake; that consumers control the amount of salt added at the table; and that by providing labeling information on sodium, consumers could allocate their sodium intake as they chose. But the FDA also noted that if the sodium content of processed foods was not "substantially reduced", it would consider taking additional action such as changing salt's GRAS status.[38] Clearly, the situation has not improved – Americans now obtain 77% of their sodium from processed foods; the high level of sodium in the food supply leaves individuals with little control over the amount of sodium they consume; and we have not seen substantial reductions in the food supply – but salt's GRAS status remains the same.

We request that the FDA act now and modify salt's GRAS status.

To be considered GRAS, salt must be "generally recognized" by scientific experts or scientific procedures "to be safe under the conditions of its intended use".[39] Salt does not meet the FDA's definition for a "general recognition" of safety. General recognition requires reasonable scientific certainty that the substance is harmless when used as intended.[40] A consensus of scientific opinion is sufficient – unanimity is not required.[41] However, "a severe conflict among experts precludes a finding of general recognition."[42] For a consensus to exist, information about the substance's safety typically will be publicly available, to show that there is "common knowledge" about the substance's safety throughout the relevant scientific community.[43] As stated above, salt does not meet this definition; there is no general consensus among the scientific community that salt is harmless.

In fact, the general consensus among the scientific community – including the experts appointed to the 2010 Dietary Guidelines Advisory Committee – is that sodium is not safe and has negative health consequences. Thus, salt also does not meet the "safe" requirement. Safety is defined as requiring "a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use."[44] To determine safety, the FDA must consider how much salt is used and in what food categories and the "relation of its probable human intake to the level at which adverse effects are observed in toxicological studies."[45] The FDA must consider not only the amount of salt in a particular food product, but an individual's likely *cumulative* intake, which as we discussed previously, far exceeds the recommended daily amounts.

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http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=291.

[37] GRAS Safety Review of Sodium Chloride; Policy Notice; Solicitation of Views, 47 Fed. Reg. 26,590 (June 18, 1982) at 26,592.

[38] Ibid at 26,593.

[39] 21 U.S.C. §321(s) (2010).

[40] 21 C.F.R. § 170.3(i) (2010).

[41] Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938 (proposed Apr. 17, 1997) at 18,941

[42] *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d. 166, 177 (D.D.C. 2000).

[43] 21 C.F.R. § 170.30(a) (2010).

[44] 21 C.F.R. § 170.3(i) (2010).

[45] Ctr for Food Safety & Applied Nutrition. *Guidance for Industry: Frequently Asked Questions About GRAS*, Food & Drug Admin. (Dec. 2004).

Finally, GRAS substances must be used in accordance with "good manufacturing practices" which require that the quantity of the substance added to food must not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect,[46] and that any amounts that may become part of the food through manufacture, processing, or packaging also be reduced as much as reasonably possible.[47] Therefore, any use of salt that is not related to food safety, binding, thickening, or another technical effect should be "reduced as much as reasonably possible". We suspect many uses of salt do not meet this requirement.

Because salt does not meet the requirements for GRAS as illustrated above, the FDA should modify salt's GRAS status.

<u>Options for Modifying Salt's GRAS Status</u>
We strongly believe that the FDA should modify the GRAS status of salt.

Using the GRAS process to reduce sodium content over time, however, will not be easy. The IOM's recommendation to use the GRAS process to reduce sodium content in a stepwise manner would require the FDA to establish sodium limits that decrease over time. Each of these levels would likely have to qualify as GRAS, and it may be difficult for the FDA to simultaneously declare two or more levels of salt (both the initial higher amount and the final lower amount) as GRAS. While we believe the FDA should be allowed to approve varying levels of salt as GRAS in order to achieve a reduction in sodium content over time, we understand some could question the FDA's authority to do so. Therefore, we present three alternatives the FDA could consider to implement the IOM's recommendation.

For your convenience, we have summarized the three alternatives and highlighted their strengths and weaknesses in Attachment C and Attachment D.

Option 1: Safe Harbor Approach – Affirm Salt as GRAS with Limited Conditions; Other Uses May or May Not be GRAS
Under the first option, <u>some</u> uses and use levels of salt would be affirmed as GRAS. The uses or use levels would be established by food category, technical effect, and/or specific food types. Food manufacturers who adhere to the established GRAS uses would be covered by a "safe harbor" and would be assured of compliance with the Food Drug and Cosmetic Act.

This option, however, <u>would not establish all</u> of the GRAS uses or levels of use for salt. Other uses or use levels may be allowed if the manufacturer can determine that the proposed use would also qualify as GRAS. For example, if a food manufacturer wished to use a higher level of salt in a food product, it would be responsible for making its own determination that the use qualifies as GRAS. If the manufacturer could not establish that the use was GRAS, it would be required to seek a food additive regulation for the use. In this situation, the manufacturer would still have to show that the proposed use is safe, but it could rely on proprietary information to do so.

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[46] A list of physical or technical effects for which substances may be added to food can be found at 21 C.F.R. § 170.3 (o).
[47] 21 C.F.R. § 182.1(b) (2010); *see also* 21 C.F.R. § 110.5 (2010) (defining "current good manufacturing practice" for food manufacturing, packaging, or storing for the purposes of determining whether food has been adulterated).

We believe that this option may represent a step in the right direction. It would set conditions for the use of salt, which currently do not exist (other than general good manufacturing practices). It could also bolster incentives for product reformulation by providing a clear GRAS benchmark for salt content in food products, because, as noted in the IOM report, some purchasers of food ingredients prefer or require proof that the ingredients have been determined to qualify for GRAS status. In addition, the salt benchmark could be incorporated into food procurement policies.

There is, however, one drawback to this approach that must be considered. This option would continue to allow manufacturers – not the FDA – to make their own GRAS determinations for uses that do not fall under the safe harbor. And as noted above, manufacturers are currently not required to notify the FDA of their GRAS determinations. Unless the FDA strengthens the GRAS process, requiring manufacturers to submit their GRAS determinations and establishing a system to review the GRAS determinations it receives, this approach may suffer from the same weaknesses that are inherent to the current GRAS process. As described above, these weaknesses are not insignificant. For this reason, option one is our least preferred option of the three.

Option 2: All GRAS Salt Uses Would be Determined; Other Uses Would Require a Food Additive Regulation or be Prohibited

Under the second option, the FDA would determine and establish all of the uses and use levels of salt that are GRAS. In general, any non-GRAS use of salt would be prohibited. The only exception would be for manufacturers who successfully petition the FDA for a food additive regulation or some other form of exemption.

The advantage of this option over the "safe harbor" approach is that it would define all of the GRAS uses, and it would require any other use to either be covered by a food additive or be prohibited. Thus, this option would clearly delineate between GRAS and non-GRAS uses. This option would also ensure that the FDA has complete knowledge of what salt uses are GRAS, because the uses would be established through a public rulemaking as opposed to allowing manufacturers to make these determinations on their own.

We do recognize that determining and establishing all of the GRAS uses of salt will require extensive time and resources, both for the FDA and for food manufacturers. And the food additive regulatory process would require additional rulemakings, increasing the Agency's burden. But there is precedent for this type of approach; there is at least one substance (calcium silicate) for which certain uses have been approved as GRAS and additional uses have been approved under a food additive regulation.[48]

Both option one and option two could incorporate stepwise reductions designed to reduce sodium content over a period of time.

Option 3: Some Salt Uses Could be Established as GRAS; Others Could be Permitted Under Interim Food Additive Regulations

The third option uses a combination of GRAS and interim food additive regulations. Under this option, the FDA could designate some uses and use levels of salt as GRAS. The uses or use levels would be established by food category and related technical effect. The GRAS limits would represent

[48] See 21 C.F.R. §172.410 (food additive regulation for calcium silicate); and 21 C.F.R. §182.2227 (GRAS regulation for calcium silicate).

the final target levels for salt that manufacturers would eventually be expected to meet. Other uses of salt, such as the interim targets, could be established as interim food additive regulations. The interim targets would allow manufacturers to temporarily use higher levels of salt, without putting the companies at risk for violating the law,[49] as they move toward the final target limits.

Interim food additive regulations may be used "when new information raises a substantial question about the safety or functionality of the substance but there is reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time" while further studies are conducted.[50] Because this approach is premised on an assumption that there is some uncertainty about whether certain levels of salt use in food are harmful to public health, and what those levels may be,[51] this approach seems to be an appropriate fit.

The FDA may propose interim food additive regulations on its own initiative. Studies "adequate and appropriate" to resolve the questions about the substance's safety must be undertaken within 60 days of the regulation's effective date, either by interested parties or the FDA, although the FDA can grant extensions "if necessary to review and act on proposed protocols." If studies are not undertaken and no commitment to undertake them is made, the interim food additive regulation must be revoked. Additionally, the FDA is responsible for monitoring the progress of these studies, by reviewing semiannual reports.

In 1982, the FDA considered a somewhat similar option – the Agency considered revoking salt's GRAS status, and instead regulating its use through interim food additive regulations to allow for its continued use in food while studies were conducted about its health effects. The FDA rejected this option at that time for several reasons. The Agency stated that "many uses of salt are prior sanctioned and therefore not subject to control under an interim food additive regulation."[52] Additionally, the FDA expressed concern about the fact that it would have to define what studies were needed and monitor their progress, and expressed doubt about whether an appropriate study could even be designed. The Agency asserted that what was needed was a "general advance in scientific knowledge" about the relationship between salt consumption and hypertension.[53] It concluded that interim food additive regulations thus were not appropriate because specific studies could not be promptly undertaken to resolve concerns about salt's safety.

Regarding the Agency's concerns, as noted previously, the extent of prior-sanctioned uses of salt is unclear, and FDA regulations include mechanisms for discovering and addressing these uses. Regarding the concern about the state of scientific knowledge – arguably, the intervening three decades have seen the necessary advance in knowledge, as demonstrated by the IOM Report. Finally, regarding the concern about whether safety studies could be undertaken promptly, while the FDA's rationale has merit based on the language of the regulations, it should be noted that at least two interim food additive regulations appear to have been on the books for over 30 years: that for mannitol and saccharin.[54] Thus, it appears that the Agency's concern about the ability of "definitive" studies being

[49] 21 C.F.R. §170.38 (2010).
[50] 21 C.F.R. §180.1(a) (2010).
[51] *See* 21 C.F.R. §180.1(b) (2010).
[52] GRAS Safety Review of Sodium Chloride; Policy Notice; Solicitation of Views, 47 Fed. Reg. at 26,594
[53] Ibid.
[54] *See* 21 C.F.R. §§180.25, 180.37 (2010) (respectively).

promptly undertaken has not necessarily prevented other substances from being regulated through interim food additive regulations. Therefore, we believe that interim food additive regulations could be a useful mechanism for establishing temporary limits that are higher than the final GRAS limits.

Based on our review of the GRAS process, we agree with the IOM that modification of salt's GRAS status is the most appropriate regulatory tool the FDA has to lower sodium consumption, but we acknowledge that GRAS modification is not an ideal or perfect tool. Of the three alternative options described above, AHA favors option two or option three. Options two and three could have a significant impact on reducing sodium intake in the United States. While option one should result in reduced sodium consumption, it seems less likely to achieve salt reductions as quickly as options two and three; and, as described above, option one relies on voluntary manufacturer reporting of GRAS determinations, which is a significant concern.

We encourage the FDA to consider these options as you move forward. We welcome the opportunity to further discuss these options with you and offer our assistance to the Agency.

Additional Approaches to Reduce Sodium Consumption

In addition to creating mandatory national standards for sodium and modifying salt's GRAS status, we recommend that the agencies take the following steps to further reduce sodium consumption.

The FDA should decrease the Daily Value (DV) for sodium to 1,500mg per day, which is the Adequate Intake amount. Lowering the DV to 1,500mg will reinforce the need for food manufacturers to lower the sodium content of their foods. No manufacturer wants their food product's label to reflect an extremely high percentage of the DV for sodium, a scenario that would be increasingly more likely if the DV is lowered; thereby, encouraging reformulation. Lowering the DV to 1,500mg also complements AHA's recommendation that the FDA establish new sodium limits for foods based on an overall daily intake of no more than 1,500mg. As with that recommendation, the FDA could lower the DV over time.

The USDA should develop and implement strong sodium limits for competitive foods in schools, and work with schools to implement the new sodium limits for the National School Lunch and School Breakfast Programs. To help schools reach the new sodium targets, the Agency will have to encourage the food industry to reduce the sodium content of their products as expeditiously as possible. The Agency must also ensure that any products supplied to schools through the commodities program are low in sodium; the USDA commodities program should set the example for schools.

We also encourage both agencies to work with your partners at the CDC and the Federal Trade Commission and submit to Congress the robust, evidence-based principles that were developed by the Interagency Working Group on Food Marketed to Children. We strongly support the proposed nutrition principles and we were pleased the original proposal included very strict standards for sodium. We hope to see the principles finalized and sent to Congress as soon as possible to bolster voluntary efforts by industry under the Children's Food and Beverage Advertising Initiative.

And finally, the agencies should continue to update and promote the federal government's guidance and standards for food and beverage procurement. These standards will cover thousands of government workers across the country and they will serve as a model for other private and public employers.

We believe these actions will help reduce the amount of sodium in the overall food supply.

Potential Barriers and Concerns
AHA acknowledges that efforts to reduce the sodium content of the food supply may raise several concerns, but they do not represent insurmountable barriers.

Food Safety
The agencies have questioned if efforts to reduce sodium could have unintended consequences for food safety, nutrition, or food manufacturing technologies. Safety of the food supply is a legitimate concern; salt is used as a preservative to increase the shelf life in foods. However, we agree with the IOM that reducing the sodium content of many foods should not create any food safety or spoilage concerns. For those products that may present a concern, "product reformulation, changes in processing, and changes in handling may be required."[55]

We believe food manufacturers should be able to easily determine if a reduction in sodium would present a safety concern for their products. Food manufacturers know how much salt, if any, has to be added to a product to prevent microbial growth. Food manufacturers should share this information with the FDA as the Agency works to develop sodium limits for foods. This would allow the FDA to set appropriate levels for each food category, recognizing categories where the addition of salt serves a legitimate food safety role. In addition, the FDA should work with food manufacturers to make this information – the amount of salt required for food safety – more transparent.

Food Technology
Food manufacturers may have to explore new food technologies that will facilitate sodium reductions. A number of useful technologies already exist and new technologies will likely be developed in the future. For example, Soda-Lo salt reduction technology is reported to change the structure of salt, reducing the size of the particles and creating a more intense salt taste with a smaller amount. The technology is said to substantially lower the sodium content of bread and bakery products, as well as cheeses, soups, pizza bases, and baked snacks. This technology is scheduled for a global rollout in 2012.[56]

We are concerned, however, that sodium reduction technologies are often proprietary and may be used exclusively by the company that made the initial technology investment. This prevents other companies from making use of sodium reduction technologies. Since reducing the sodium content of the food supply is a public health imperative, we encourage companies to share the technology and make it more widely available in the marketplace.

Nutrient Adequacy
We are aware of some concerns that reducing sodium consumption may inadvertently lead to reductions in other desirable nutrients. For example, some have argued that adding salt to vegetables will increase the palatability of these foods, leading to an increased consumption of beneficial nutrients,[57] or that higher sodium limits for canned vegetables should be allowed. We agree that the

[55] Institute of Medicine. Strategies to Reduce Sodium Intake in the United States. 2010.
[56] Nathan Gray. Tate & Lyle Signs Agreement for Salt Reduction Technology. Food Navigator-USA.com. October 31, 2011. http://www.foodnavigator-usa.com/Business/Tate-Lyle-signs-agreement-for-salt-reduction-technology.
[57] The Salt Institute. Food salt essential to life, health. http://www.saltinstitute.org/1-Page-Fact-Sheets/Food-Salt.

agencies should be mindful of foods and nutrients of public health concern when evaluating approaches to reduce sodium consumption. AHA recommends that the FDA consider nutrients of concern when establishing mandatory sodium levels and allow some flexibility when setting limits for desirable foods that are currently under-consumed.

We also recommend that the agencies consider ways to promote consumption of foods that contain potassium. As the agencies are aware, potassium can lower blood pressure by blunting the adverse effects of sodium. Unfortunately very few people consume enough potassium to meet the daily AI of 4,700mg, and a recent evaluation of dietary intake data found that only nine out of 20,000 people surveyed met the Adequate Intakes for both potassium and sodium.[58] Because potassium can help blunt the negative effects of excess sodium consumption, Americans should be encouraged to increase their potassium consumption, and consume a wide variety of fruits and vegetables as recommended by the Dietary Guidelines for Americans. Some foods, however, present a challenge with this recommendation. For example, canned tomatoes are high in potassium, yet are also high in sodium.[59] This further illustrates why the sodium content in foods must be reduced.

Although obvious, AHA also notes that there is no concern that Americans are not consuming enough sodium. While sodium is an essential nutrient, very little sodium is needed to meet biologic requirements. Under conditions of maximal adaptation and without sweating, the minimum amount of sodium required to replace losses is estimated to be no more than 180mg per day, which is roughly 5% of current intake. However, because a diet providing this level of sodium is unlikely to meet dietary requirements for other nutrients, healthy adults generally need about 1,500mg to ensure nutrient adequacy and replace sweat losses[60] – far less than what the average American currently consumes.

Finally, the agencies should conduct food modeling to evaluate the relationship of consuming foods that meet the proposed sodium limits to overall diet quality and physiological parameters. This will be an important step in minimizing unintended consequences.

Consumer Preferences

Another concern – particularly for the food industry – is that consumers are accustomed to products with a high salt flavor and may not purchase products that contain less salt. While we understand the food industry's concern, research has shown that salt preference is malleable and adjusts over time. "As salt intake falls, the salt receptors in the mouth adapt and become more sensitive to lower concentrations of salt within months. Once salt intake is reduced, people prefer the taste of food with less salt."[61] This indicates that consumers will adapt to lower sodium food products if the changes are made gradually over a period of time. And, as previously discussed, there is evidence that many consumers respond positively to lower sodium products; almost 40% of consumers in an AHA survey responded that they would definitely or probably buy a food product if it had 25% less sodium.

[58] Elaine Watson. Potassium and Sodium Targets are Incompatible Warns Academic. Food Navigator-USA.com. September 27, 2011.
[59] Ibid.
[60] Institute of Medicine. *Dietary Reference Intakes: Water, Potassium, Sodium Chloride, and Sulfate.* 1st ed. Washington, DC: National Academy Press; 2004.
[61] FP Cappuccio. Policy Options to Reduce Population Salt Intake. *BMJ* 2011;343:d4995.

<u>Consumer Response to Sodium Reductions</u>

The agencies are interested in learning more about the impact of sodium reduction initiatives on consumer food choices. For example, will consumers add salt back to foods that have been reformulated to contain less sodium? We agree this is an important question to consider. Unfortunately there is not much data in this area. AHA recommends that the agencies conduct research to examine if consumers add salt during preparation or at the table to food products with reduced sodium content. The agencies may want to focus on foods that consumers expect to have a salty flavor. The agencies should also consider some of the possible techniques industry can use with herbs and other seasonings to maintain flavor while reducing sodium.

Monitoring the Sodium Content of the Food Supply

The sodium reduction initiatives recommended by the IOM and supported by AHA in this letter should lead to significant reductions in the level of sodium in the food supply. It will be important, however, to periodically evaluate the impact of these initiatives and modify them if necessary. This evaluation should include measuring the sodium content of specific food products, as well as updating dietary intake survey data to determine overall sodium consumption. Data on the population-based impact of these initiatives will be particularly important. To collect this data, we encourage the agencies to continue to develop surveillance programs at both the state and national level. The FDA and FSIS should also encourage the National Center for Health Statistics to collect 24 hour urine samples in a subset of National Health and Nutrition Examination Survey (NHANES) participants.

We also request that the FDA, USDA, and CDC collaborate to improve the accuracy and timeliness of the U.S. food database. A robust food database that captures the nutrition profile of foods in the marketplace will improve our ability to measure sodium in the food supply and track changes over time. It will also allow us to hold the food industry accountable for their actions, or lack thereof, to reduce sodium content in their food products. The database should include information on packaged and prepared foods, as well as information about restaurant foods; measurements for restaurant foods are not currently available.

Consumer Education

To maximize the effectiveness of the FDA's and FSIS's efforts to reduce sodium consumption, we urge the agencies to collaborate with the CDC, HHS, 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 to reduce sodium intake

We suggest these four 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. The majority of consumers are also unaware of how much sodium they can safely consume, and they tend to underestimate how much sodium food products contain. For example, one study reported that 86% of respondents were surprised to learn that one serving of fresh chicken, which was injected with a saltwater solution, could have as much sodium as a large order of fast food french fries.[62] But perhaps the biggest challenge will be determining how to overcome consumer behavior. We know that even when consumers are able to identify foods as high in sodium, only one-third are likely to actively avoid them.[63]

To learn how to communicate effectively with consumers and change behavior, AHA recommends that the agencies examine other sodium reduction initiatives, such as the NSRI and those underway with the Food Standards Agency in the United Kingdom, Canada, Finland, and other countries.

In addition, the agencies 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 into practical terms, encourages personal choice, and underscores a nutrient-dense and calorie-balanced energy pattern, which should lead to a healthier diet overall. We also encourage the agencies 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.

Economic Impact on the Health Care System

Finally, we understand the agencies are interested in the economic impact of sodium reduction initiatives, especially since cardiovascular disease costs more than $444 billion each year and high blood pressure is a primary driver of these costs.

We are pleased to report that a number of studies have shown that reducing sodium intake will lead to substantial costs savings for the health care system. A population drop in sodium consumption to 1,500mg per day would result in a 25.6% overall decrease in blood pressure and an estimated $26.2 billion in health care savings.[64] A national effort that reduces sodium intake by 1,200mg per day should result in 60,000 to 120,000 fewer coronary heart disease events, 32,000 to 66,000 fewer strokes, 54,000 to 99,000 fewer heart attacks, and 44,000 to 92,000 fewer deaths, and save 194,000 to 392,000 quality-adjusted life-years and $10 to $24 billion in healthcare costs annually.[65] According to one study, this represents a $6 to $12 return on investment for each dollar the agencies would spend on regulating salt content.[66]

These studies are clear – a population-wide decrease in sodium consumption would have a positive economic impact. But we also recommend that the agencies consider the costs of not acting to reduce sodium consumption. If sodium consumption is not reduced, it will result in more cardiovascular events, more lives lost, and more health care costs. Simply put, the price of inaction is too high to pay.

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[62] Foster Farms Survey of 1,000 consumers. April 2010. http://www.fosterfarms.com/about/press/press_release.asp?press_release_id=118
[63] HealthFocus International 2010 Study.
[64] Potential Health Benefits and Medical Costs Savings from Calorie, Sodium, and Saturated Fat Reductions in the American Diet. American Journal of Health Promotion. July/Aug 2009 (23) 16:412.
[65] Bibbins-Domingo K, et al. Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease. N Engl J Med. 2010;362:590-599.
[66] FP Cappuccio. Policy Options to Reduce Population Salt Intake. *BMJ* 2011;343:d4995.

Conclusion

In closing, AHA reiterates our appreciation of the FDA's and FSIS's decision to begin exploring approaches to reduce sodium consumption. The amount of sodium Americans consume is a major public health issue and AHA is committed to helping consumers lower their sodium intake, thereby lowering their risk of blood pressure-related diseases and improving their overall health. But as discussed above, we can no longer rely on voluntary efforts alone. The sodium content in the food supply is too high and provides consumers with little control over their sodium consumption.

To achieve substantial reductions of sodium in the food supply, the FDA and FSIS must take action and implement the recommendations in the IOM report. Specifically, the FDA should modify salt's GRAS status, set mandatory national standards for the sodium content of foods, and revise the Daily Value for sodium to 1,500mg based on the AI. The FSIS/USDA should implement strong sodium targets for competitive foods in schools, and help schools implement the new sodium limits for the National School Lunch and School Breakfast Programs. And both agencies should work together to promote strong procurement standards, implement the Interagency Work Group's nutrition standards for foods marketed to children, and develop a robust food database to track changes in the sodium content of foods. In addition, the agencies should 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 agencies on a sodium reduction 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 at (202) 785-7908 or susan.k.bishop@heart.org.

Thank you for your consideration of our comments.

Sincerely,

Gordon F. Tomaselli, MD, FAHA
President
American Heart Association

Attachment A

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

The Importance of Population-Wide Sodium Reduction as a Means to Prevent Cardiovascular Disease and Stroke : A Call to Action From the American Heart Association

Lawrence J. Appel, Edward D. Frohlich, John E. Hall, Thomas A. Pearson, Ralph L. Sacco, Douglas R. Seals, Frank M. Sacks, Sidney C. Smith, Jr, Dorothea K. Vafiadis and Linda V. Van Horn

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The Importance of Population-Wide Sodium Reduction as a Means to Prevent Cardiovascular Disease and Stroke

A Call to Action From the American Heart Association

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Blood pressure (BP)-related diseases, specifically, stroke, coronary heart disease, heart failure, and kidney disease, are leading causes of morbidity and mortality in the United States and throughout the world. In the United States, coronary heart disease and stroke are the leading causes of mortality, whereas heart failure is the leading cause of hospitalizations.[1] Concurrently, the prevalence of chronic kidney disease remains high and is escalating.[2,3] The direct and indirect costs of these conditions are staggering, over $400 billion just for cardiovascular disease (CVD) in 2009.[1,4] The human consequences are likewise enormous.

The relation between BP and adverse health outcomes is direct and progressive with no evidence of a threshold, that is, the risk of CVD, stroke, and end-stage kidney disease increases progressively throughout the range of usual BP starting at a level of ≈115/75 mm Hg.[5–7] Overall, elevated BP is the second leading modifiable cause of death, accounting for an estimated 395 000 preventable deaths in the United States in 2005.[8] Worldwide, elevated BP accounts for 54% of stroke and 47% of coronary heart disease events; importantly, about half of these events occur in persons without hypertension.[9]

The 2020 goal of the American Heart Association (AHA) is to improve the cardiovascular heath of all Americans by 20% while continuing to reduce deaths from CVD and stroke by 20%.[4] Two of the key metrics for ideal cardiovascular health are a BP of <120/80 mm Hg and sodium consumption of <1500 mg/d. The purpose of this advisory is 2-fold: first is to highlight the impressive body of evidence that links sodium intake with elevated BP and other adverse outcomes, and second, to serve as a call to action on behalf of the AHA for individuals, healthcare providers, professional organizations, governments, and industry to address this major public health issue. See Table for key points.

The Evidence

Excess intake of salt (sodium chloride) has a major role in the pathogenesis of elevated BP. Excess sodium intake also has BP-independent effects, promoting left ventricular hypertrophy as well as fibrosis in the heart, kidneys, and arteries.[10] Evidence on the adverse health effects of excess sodium intake includes results from animal studies, epidemiological studies, clinical trials, and meta-analyses of trials.[11] To date, >50 randomized trials have tested the effects of sodium reduction on BP in adults. A meta-analysis[12] of these trials documented that a median reduction in urinary sodium of ≈1800 mg/d lowered systolic/diastolic BP by 2.0/1.0 mm Hg in nonhypertensive individuals and by 5.0/2.7 mm Hg in hypertensive individuals. In a subsequent meta-analysis of trials in children, a reduced sodium intake lowered mean systolic/diastolic BP by 1.2/1.3 mm Hg in children and adolescents and lowered systolic BP by 2.5 mm Hg in infants.[13] The benefits of sodium reduction in persons with poorly controlled BP are striking. In a recent trial of patients with resistant hypertension, reducing sodium intake by 4600 mg/d lowered systolic/diastolic BP by 22.7/9.1 mm Hg.[14]

Some of the most persuasive evidence on the effects of sodium on BP comes from rigorously controlled, dose-response trials.[15–17] Each of these trials tested at least 3 sodium levels, and each documented statistically significant, direct, progressive, dose-response relations. The lowest level of sodium intake in

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This statement was approved by the American Heart Association Science Advisory and Coordinating Committee on January 7, 2011.

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Table. Key Points

● Elevated blood pressure (BP) is a leading, preventable cause of mortality and morbidity in the United States and throughout the world.
● The relation of BP and adverse health outcomes is direct, progressive, consistent, continuous, independent, and etiologically relevant throughout the range of usual BP starting at a level of approximately 115/75 mm Hg.
● A diverse body of evidence has implicated excess sodium intake in the pathogenesis of elevated BP.
● Independent of its effects on BP, excess sodium intake adversely affects the heart, kidneys, and blood vessels.
● Current intake of sodium greatly exceeds 1500 mg/d, the upper level of intake recommended by the American Heart Association and the 2010 Dietary Guidelines Scientific Advisory Committee.
● The potential public health benefits of sodium reduction are enormous and extend to virtually all Americans.

each trial was ≈1500 mg/d, the level currently recommended by the AHA.[4] Importantly, the BP response to sodium reduction, while direct and progressive, was nonlinear. Specifically, decreasing sodium intake by ≈900 mg/d caused a greater reduction in BP when the starting sodium intake was ≈2300 mg/d than when it was ≈3500 mg/d. The DASH (Dietary Approaches to Stop Hypertension)-Sodium trial, the largest of the 3 major dose-response trials,[18,19] also documented that reduced sodium intake significantly lowered BP in each of the major subgroups studied (ie, nonhypertensive individuals, hypertensive individuals, men, women, African Americans, non–African Americans). The benefits of sodium reduction in non-hypertensive individuals were recently corroborated in the GenSalt feeding study, which documented that lowering sodium intake to ~1500 mg/d reduced BP in ~2,000 Asian adults with mean systolic/diastolic BP <120/80 mm Hg.[20]

Sodium reduction also blunts the age-related rise in BP. Because BP rises with age, about 90% of adults eventually become hypertensive.[21] The DASH-Sodium trial demonstrated that sodium reduction to a level of ≈1500 mg/d lowers BP more in older adults than younger adults.[19] Systolic BP decreased by 8.1 mm Hg in those aged 55 to 76 years, compared with 4.8 mm Hg for adults aged 23 to 41 years. In persons without hypertension, BP decreased by 7.0 mm Hg in those >45 years of age compared with 3.7 mm Hg in those ≤45 years of age. These results demonstrated that sodium reduction can lessen the rise in BP with age[22] and also confirmed the well-documented observation of a reduced age-related rise in BP in isolated populations with low sodium intake.[23] Consistent with this evidence, a major trial in the United States documented that a reduced sodium intake can prevent hypertension by ≈20%.[24]

Evidence supporting a direct relation of sodium intake and CVD is also accumulating. In a recent meta-analysis of observational studies, a higher sodium intake was associated with an increased risk of stroke and likely CVD.[25] To date, 3 trials conducted in general populations have reported the effects of reduced sodium interventions on CVD outcomes. Two of these trials tested lifestyle interventions that focused on reducing sodium intake, and 1 trial tested the effects of a reduced sodium/high potassium salt. In each instance, there was a 21% to 41% reduction in clinical CVD events in those who received a reduced sodium intervention (significant reduction in 2 trials[26,27] and a nonsignificant trend in the third[28]). Hence, direct evidence from trials, albeit limited, is consistent with indirect evidence on the health benefits of sodium reduction.

Independent of its effects on BP, an increased sodium intake has other adverse effects. These include subclinical CVD (ie, left ventricular hypertrophy, ventricular fibrosis, diastolic dysfunction), kidney damage, gastric cancer, and disordered mineral metabolism (ie, increased urinary calcium excretion, potentially leading to osteoporosis).[11] It is well-established that sodium loading suppresses the systemic renin-angiotensin-aldosterone system by inhibiting renin release from the renal juxtaglomerular apparatus. Less well appreciated are findings that sodium loading increases oxidative stress and endothelial dysfunction and promotes mitogenic responses (fibrosis in heart, kidneys, and arteries) resulting in cardiac and vascular remodeling.[10,29–33]

With regard to arterial dysfunction, higher sodium intake is associated with greater increases in large elastic artery stiffness with aging,[34,35] and reducing sodium intake from moderate levels by ≈50% to less than ≈1500 mg/d reduces large elastic artery stiffness in otherwise healthy middle-aged and older adults with elevated systolic BP.[36,37] An acute increase in sodium intake has been shown to impair vascular endothelial function in young adults with normal BP.[38] Among middle-aged and older adults with elevated systolic BP, lower sodium intake is associated with enhanced vascular endothelial function, independent of BP or other risk factors.[39] A low sodium diet of ≈1200 mg/d improves endothelial function in overweight and obese adults with normal BP.[40] These findings have important clinical implications given that stiffening of the large elastic arteries, independent of BP, is a major independent risk factor for CVD and incident cardiovascular events,[41,42] whereas vascular endothelial dysfunction is associated with increased cardiovascular events and CVD mortality.[43,44]

Sodium-induced increases in BP may directly induce renal injury or accelerate kidney disease caused by other conditions such as diabetes mellitus or glomerulonephritis. However, excess sodium intake also has deleterious effects on the kidneys independent of increased BP. Studies in experimental animals and in human beings have shown, for example, that high sodium intake can cause glomerular hyperfiltration and increased albumin excretion, renal oxidative stress, and renal fibrosis independent of BP.[45–47] A direct association between sodium intake and urinary albumin excretion, independent of BP, has been observed in epidemiological studies.[47] In a trial of whites, blacks, and Asians with elevated BP, decreasing sodium intake from an average of ≈3800 mg/d to ≈2500 mg/d significantly reduced 24-hour urinary albumin excretion, an early marker of renal injury.[48] A retrospective analysis of patients with chronic kidney disease, with an average observation period of 3 years, showed that in patients with a sodium intake >4600 mg/d, the rate of decline in creatinine clearance and increase in proteinuria were greater compared with patients with a sodium intake <2300 mg/d, despite similar BP control.[49] Excess sodium intake also attenuates the beneficial effects of many antihypertensive drugs, especially the antiproteinuric effect of blocking the renin-angiotensin system.[50] Thus, there is considerable evidence linking increased sodium intake with kidney injury not only through increased BP but also by effects that appear to be at least partly independent of BP.[51]

Some sodium intake is required. An Institute of Medicine Committee set 1500 mg of sodium per day as an adequate intake level, primarily to assure nutrient adequacy.[52] Based on the DASH-Sodium trial, it is apparent that Western type diets can provide this level of sodium intake and that such a diet also can provide adequate levels of other nutrients.[53] In 2005, the US Dietary Guidelines for Americans recommended a sodium intake of $<$2300 mg/d for the general adult population and stated that hypertensive individuals, blacks, and middle-aged and older adults would benefit from reducing their sodium intake even further to 1500 mg/d.[53] Because these latter groups comprise at least 50% of adults and perhaps as high as 70%,[54] and because $\approx$90% of US adults will develop hypertension over their lifetime, the goal should be 1500 mg/d, as recommended by the scientific advisory of the 2010 Dietary Guidelines Committee.[55] The health benefits apply to Americans in all groups, and there is no compelling evidence to exempt special populations from this public health recommendation. Although clinical research has identified groups that experience greater or lesser BP effects from sodium reduction, there is no practical clinical test to assess sodium sensitivity in individuals. Hence, it is not feasible, from a public health perspective, to classify individuals as sodium-sensitive or not.

A Call to Action

The projected benefits of sodium reduction are substantial. Several studies have estimated the societal benefits of population-wide sodium reduction.[56–58] In the most recent and comprehensive set of projections, Bibbins-Domingo and colleagues[58] quantified the effects of 400 mg/d to 1200 mg/d reductions in sodium intake on a variety of relevant outcomes. A national effort that reduces sodium intake by 1200 mg/d should result in 60 000 to 120 000 fewer coronary heart disease events, 32 000 to 66 000 fewer strokes, 54 000 to 99 000 fewer myocardial infarctions, and 44 000 to 92 000 fewer deaths, and save 194 000 to 392 000 quality-adjusted life-years and $10 to $24 billion in healthcare costs annually. Even if average sodium intake is reduced by just 400 mg/d, the benefits would still be substantial and warrant implementation.

Accomplishing population-wide sodium reduction is similar to achieving other lifestyle modifications, in that a substantial public health approach will be required to facilitate environmental changes that support changes in individual behavior. Indeed, the need for an effective public health approach is even greater for sodium reduction than other lifestyle modifications. For example, in contrast to cigarette smoking, where usage is evident and deliberate by the consumer, the sodium content of our diets is not readily apparent.

More than 75% of consumed sodium comes from processed foods.[59] Even those who read labels are often left without realistic alternatives to high-sodium foods, and those who eat out, a behavior that has increased more than 200% from 1977 to 1995, are subjected to excessive sodium intakes from routinely served, processed foods.[55] Some food items are extremely high in sodium. However, from a public health perspective, the problem of excess sodium intake largely reflects the cumulative intake of common foods that are only moderately high in sodium. Hence, any meaningful strategy to reduce sodium intake population-wide must involve the efforts of food manufacturers, food processors, and restaurant industries, a strategy that is being successfully implemented in other countries. For example, the United Kingdom has a vigorous salt reduction campaign, which has resulted in an estimated population-wide reduction in sodium intake of $\approx$10%.[60] Ongoing surveillance is necessary to evaluate the progress of such strategies.

Some scientists still question the evidence supporting population-wide sodium reduction. Common arguments include the absence of a major trial with hard clinical outcomes. It is well-known, however, that such trials are not feasible because of logistic, financial, and often ethical considerations. In fact, there is no trial of weight reduction or increased physical activity on hard clinical outcomes, and only 1 definitive trial of smoking cessation therapy on lung cancer.[61] It also has been argued that sodium reduction might be harmful.[62] However, the evidence for harm is unpersuasive, based largely on inferences from cohort studies with major methodological limitations, particularly, incomplete assessment of sodium intake and the potential for reverse causality.[63]

In 2010, the Institute of Medicine issued a report that provides a roadmap for lowering Americans' intake of sodium.[64] It was noted that for $>$40 years, efforts to reduce sodium intake of the US population have been unsuccessful. This absence of tangible progress reflects the lack of a substantive, multidimensional, environmentally focused strategic plan with measurable outcomes, joint-ownership, and accountability among the many stakeholders. Specifically, given the ubiquity of sodium in the food supply, the prior focus on encouraging individuals to select reduced-sodium products has been insufficient to meaningfully reduce sodium intake and achieve levels consistent with the Dietary Guidelines for Americans. Such efforts must be accompanied by an overall reduction of the level of sodium in the food supply. The Institute of Medicine made a series of recommendations, many of which involved regulatory actions (eg, setting mandatory national standards for the sodium content of foods). Such a strategy extends the voluntary approaches implemented in New York City.[65]

Conclusion

A compelling and still increasing body of evidence supports the imperative for population-wide sodium reduction as an integral component of public health efforts to prevent CVD, stroke, and kidney disease. The potential public health benefits are enormous and extend to virtually all Americans. The AHA is committed to improving cardiovascular health of the whole population, as recently articulated in its 2020 strategic goals.[4] Successful sodium reduction requires action and partnership at all levels—individuals, healthcare providers, professional organizations, public health agencies, governments, and industry. The AHA urges a renewed and intensive focus on this critically important public health issue and looks forward to partnering with public and private organizations to achieve our shared goal of population-wide reduction in sodium intake.

Disclosures

Writing Group Disclosures

Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/ Advisory Board	Other
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*Significant.

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KEY WORDS: AHA Scientific Statements ■ sodium ■ salt ■ blood pressure ■ hypertension ■ cardiovascular disease ■ stroke ■ kidney disease

American Heart Association
Learn and Live

Salt/Sodium
Awareness and Attitudes
October 2011

Background:
AHA wishes to respond to the IOM report adding to the body of knowledge regarding perception and attitudes of salt/sodium. A series of questions were identified where consumer insight is limited.

Methods:
A national online survey was administered to 1000 adults age 18+, Oct 17 - Oct 20, 2011 through Synovate, Inc.'s eNation Consumer Opinion Panel. Results are representative of the U.S. population within a margin of error +/- 3%.

Highlights:

- 85% of American adults think eating too much salt/sodium can cause high blood pressure.
    - Women and the oldest adults think this slightly more than others.

- 75% of American adults think smoking is more serious than eating too much salt/sodium.
    - Sugar seems to be a more serious concern for the oldest adults compared to younger adults.

- Only one in ten (14%) American adults always make choices to reduce salt/sodium in their diet. About 30% never or rarely make this choice.
    - Women, more so than men, are likely to make these choices.
    - Adults age 45+ are more likely than younger adults to make these choices.

- Health reasons drive motivation to reduce salt/sodium, 65%. Surprisingly, only 20% are motivated by someone telling them to reduce their intake. That includes a doctor, family or friend.
    - Motivation tends to differ by gender
        - Health is a stronger driver for women.
        - Suggestion from a doctor, friend or family is a stronger motivator for men.
    - Motivation differs by age
        - Health reasons are a stronger motivator for 55+ compared to all younger groups.
        - Suggestion from another is a stronger motivator for those over age 45 compared to those under 34.

    - Not wanting added ingredients in their food is a stronger motivator for under age 34 compared to 55-64 and stronger for 45-54 compared to both 35-44 and 55-64.
    - Appearance is a stronger motivator for those under 44 compared to those over 55.
    - Saving the environment is a stronger motivator for those 25-34 compared to 55-64.

- 60% of American adults would like more choice/control over the amount of salt/sodium in their food.
  - Those ages 45+ are more likely to feel strongly about wanting more control than younger adults.

- Nearly four in ten (38%) would you buy a food product if a company claimed that it has 25% less sodium.
  - Oldest adults (65+) are directionally more likely to buy a food product that claims 25% less sodium.

Details:
Q1. Can eating too much salt/sodium cause any of the following problems?

YES
85% High blood pressure (8% not sure); Women 88%, adults 65+ 91%
35% Kidney stones
16% Bone problems, for example, osteoporosis
13% A cavity in your tooth
9% Stomach cancer

Q2. How serious is eating too much salt/sodium compared to other health issues? Is each of the following health issues more serious, less serious or about the same as eating too much salt/sodium?

<u>Top-2 box</u>
75% Smoking is more/much more serious than eating too much salt
64% Obesity is more/much more serious than eating too much salt
45% Eating too much fat is more/much more serious than eating too much salt
29% Eating too much sugar is more/much more serious than eating too much salt

- 38% of adults age 65+ think eating too much sugar is more/much more serious than eating too much salt, compared to adults under age 45 ~ 25%.

24% A cavity in your tooth is more/much more serious than eating too much salt

	Much less serious than eating too much salt/sodium	Less serious than eating too much salt/sodium	About the same	More serious than eating too much salt/sodium Much more serious than eating too much salt/sodium	Much more serious than eating too much salt/sodium	Not sure
Obesity is	2%	2%	27%	26%	38%	5%
Eating too much sugar	2%	7%	55%	18%	11%	8%
A cavity in your tooth	8%	24%	32%	16%	8%	12%
Eating too much fat is	2%	5%	42%	26%	19%	7%
Smoking is	3%	1%	16%	19%	56%	5%

Q3. How often, if at all, do you make choices to reduce the salt/sodium in your diet?

	Total	Men	Women
Top-3 box (always, regularly, sometimes)	72%	66%	78%*
Top-2 box (always, regularly)	41%	38%	45%*
Bottom-2 box (rarely, never)	28%	34%	22%
Always	14%	12%	15%
Regularly	28%	26%	30%
Sometimes	31%	28%	33%
Rarely	19%	22%*	16%
Never	9%	13%*	6%

	18-24	25-34	35-44	45-54	55-64	65+
Top-2 box (always, regularly)	25%	30%	30%	45%*	55%*	62%*

*Significant difference at 95% confidence level.

Adults age 45+ are more likely than all younger adults to make these choices. 65+ more so than 45-54 also.

Q4. What, if anything, motivates you to reduce the salt/sodium in your diet? Please select all that apply.

	Total	Men	Women
Health reasons (improve blood pressure, good for my heart, family history, etc.)	65%	61%	69%*
My doctor/family/friend suggests I lower my sodium intake	21%	25%*	16%
I don't want added ingredients in my food	21%	15%	26%*
For my appearance	14%	11%	16%*
I want to help save the environment	2%	2%	2%
Other	4%	5%	4%
Nothing	18%	22%*	14%

	18-24	25-34	35-44	45-54	55-64	65+
Health reasons (improve blood pressure, good for my heart, family history, etc.)	55%	56%	63%	64%	75%*	79%*
My doctor/family/friend suggests I lower my sodium intake	13%	14%	19%	23%*	27%*	28%*
I don't want added ingredients in my food	22%*	26%*	18%	28%*	12%	18%
For my appearance	22%*	22%*	17%*	10%	5%	7%
I want to help save the environment	1%	4%*	2%	1%	-	2%

*Significant difference at 95% confidence level.

Health reasons are a stronger motivator for 55+ compared to all younger groups.
Suggestion from another is a stronger motivator for those over age 45 compared to those under 34.
Not wanting added ingredients in their food is a stronger motivator for under age 34 compared to 55-64 and stronger for 45-54 compared to both 35-44 and 55-64.
Appearance is a stronger motivator for those under 44 compared to those over 55.
Saving the environment is a stronger motivator for those 25-34 compared to 55-64.

Q5. Please rate how strongly you agree or disagree with the following statement:

++"I would like more choice or control over the amount of salt/sodium in my food."++

60% (top-2 box) agree they would like more choice/control over the amount of salt/sodium in their food.

26% Strongly agree
34% Somewhat agree
30% Neither disagree nor agree
6% Somewhat disagree
5% Strongly disagree

	18-24	25-34	35-44	45-54	55-64	65+
Strongly agree (top-box)	19%	18%	18%	29%*	37%*	32%*

*Significant difference at 95% confidence level.

Those ages 45+ are more likely to feel strongly about wanting more control than younger adults. (Adults age 45-54 more so then 25-44, 55+ more so than <44,)

Q6. Would you buy a food product if a company claimed that it has 25% less sodium?

91% Top-3 box (definitely, probably, maybe)
38% Top-2 box (definitely, probably)
9% Bottom-2 box

9% Definitely
29% Probably
53% Maybe
8% Probably not
1% Definitely not

	18-24	25-34	35-44	45-54	55-64	65+
Top-2 box (definitely/probably)	35%	39%	39%	36%	33%	49%*

Oldest adults (65+) are directionally more likely to buy a food product that claims 25% less sodium. (Adults age 65+ significantly more likely than 55-64 to buy a low sodium product.)

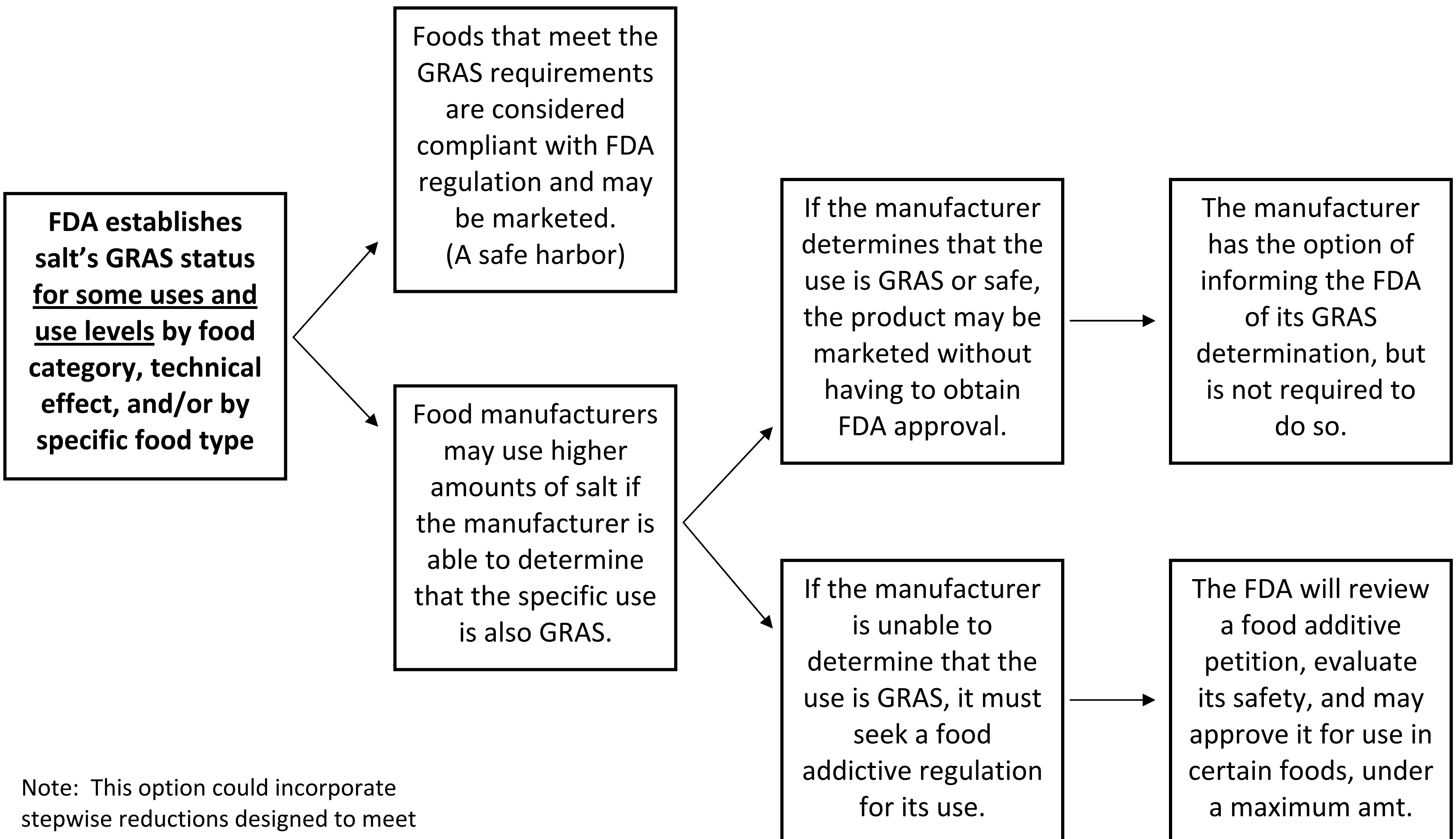
Source: American Heart Association Salt/Sodium Awareness and Attitude Survey, October 2011 (unpublished). A recent survey conducted by the American Heart Association with Synovate, Inc., a global marketing research firm.

Attachment C

Possible Approaches for Implementing the IOM's Recommendation

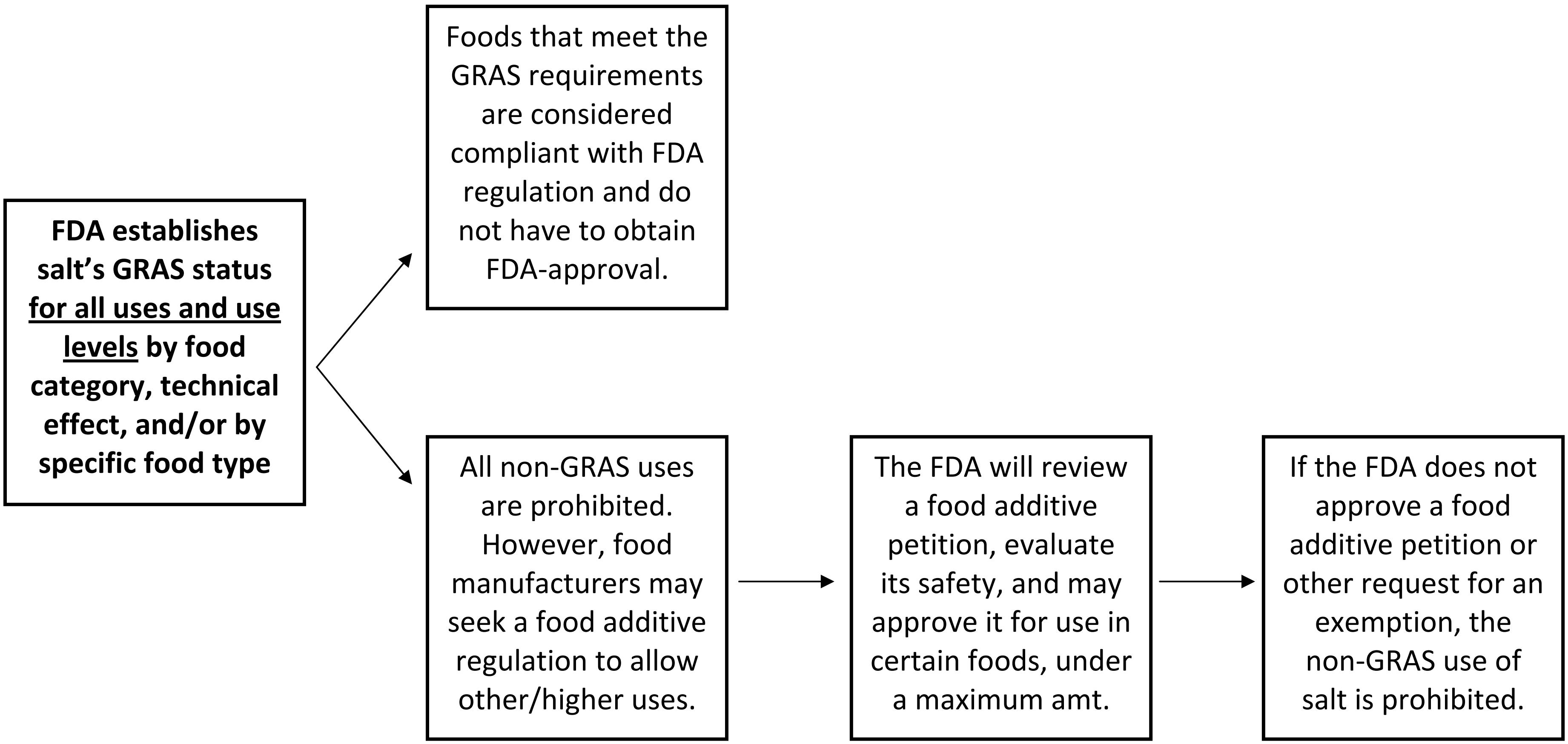
Approaches	Strengths	Weaknesses
Option1 **A "safe harbor" approach: salt would be affirmed as GRAS with limited conditions, and other uses may or may not be GRAS.**	• Salt would be affirmed as GRAS for specific uses and use levels. Manufacturers who conform to these conditions would be assured of compliance with the FDCA. • Would establish conditions for the use of salt, which do not exist currently (other than general good manufacturing practice), such as food category, technical effects; functional uses; and levels of use. • Manufacturers would have the flexibility to use higher levels of salt, but only if they can establish and document that such uses are GRAS. Non-GRAS uses would require a food additive regulation. • Could encourage faster product reformulation by providing clear GRAS benchmarks for salt content levels in food products that similarly could be incorporated into food procurement policies. • Could promote awareness that some uses may not be GRAS.	• The FDA would need to establish the GRAS uses, a task about which it has expressed concerns in the past. • Tied to the inherent weaknesses of the GRAS process, *i.e.*, the FDA will not necessarily receive information about companies' additional GRAS determinations, nor is there a system in place for the FDA to systematically review or assess these determinations.
Option 2 **All GRAS salt uses would be determined; other uses would require a food additive regulation or be prohibited.**	• Salt would be affirmed as GRAS *only* as used at specific levels, by food category, for specified uses. Any use beyond the specified limitations would require a food additive regulation, or some other kind of exemption. • All GRAS uses would be defined, so that uses that are GRAS or not GRAS would be clearly delineated. • Would ensure that the FDA has complete knowledge of what salt uses are GRAS, because these uses would be established through a public rulemaking (as opposed to determinations being made through internal company processes). • Likely to result in faster attainment of sodium reduction goals than the "safe harbor" alternative.	• Establishing all of the GRAS uses of salt would require extensive time and resources, both for the FDA and for food companies. • Whether sufficient scientific evidence currently exists to permit all necessary GRAS determinations to be made would need to be determined. • The food additive regulatory process would require additional rulemakings, increasing the FDA's regulatory burden.
Option 3 **Some salt uses could be established as GRAS; others could be permitted under interim food additive regulations.**	• Levels of salt for food categories (and related technical effects) would be designated as GRAS. Other (higher) uses of salt could be established as interim food additive regulations so that their safety could be assessed while at the same time, they still could be used without putting companies at risk for violating the law. • There is precedent – the FDA has regulated other substances (mannitol and saccharin) though interim food additive regulations. • Interim food additive regulation for some salt uses could be a useful mechanism for establishing temporary limits. • Likely to result in faster attainment of sodium reduction goals than the "safe harbor" alternative.	• Would only be appropriate to the extent that there is uncertainty about whether certain levels of salt use in food are harmful to public health, and what those levels are. • FDA has previously rejected this option, citing concerns such as: many uses of salt are already sanctioned and therefore not subject to control under an interim food additive regulation, and the agency would have to define what studies were needed and monitor their progress. Several years ago, the FDA asserted there was a need for a general advance in scientific knowledge about the relationship between salt consumption and hypertension.

Option 1:
Safe Harbor Approach – Affirm Salt as GRAS with Limited Conditions; Other Uses May or May Not be GRAS



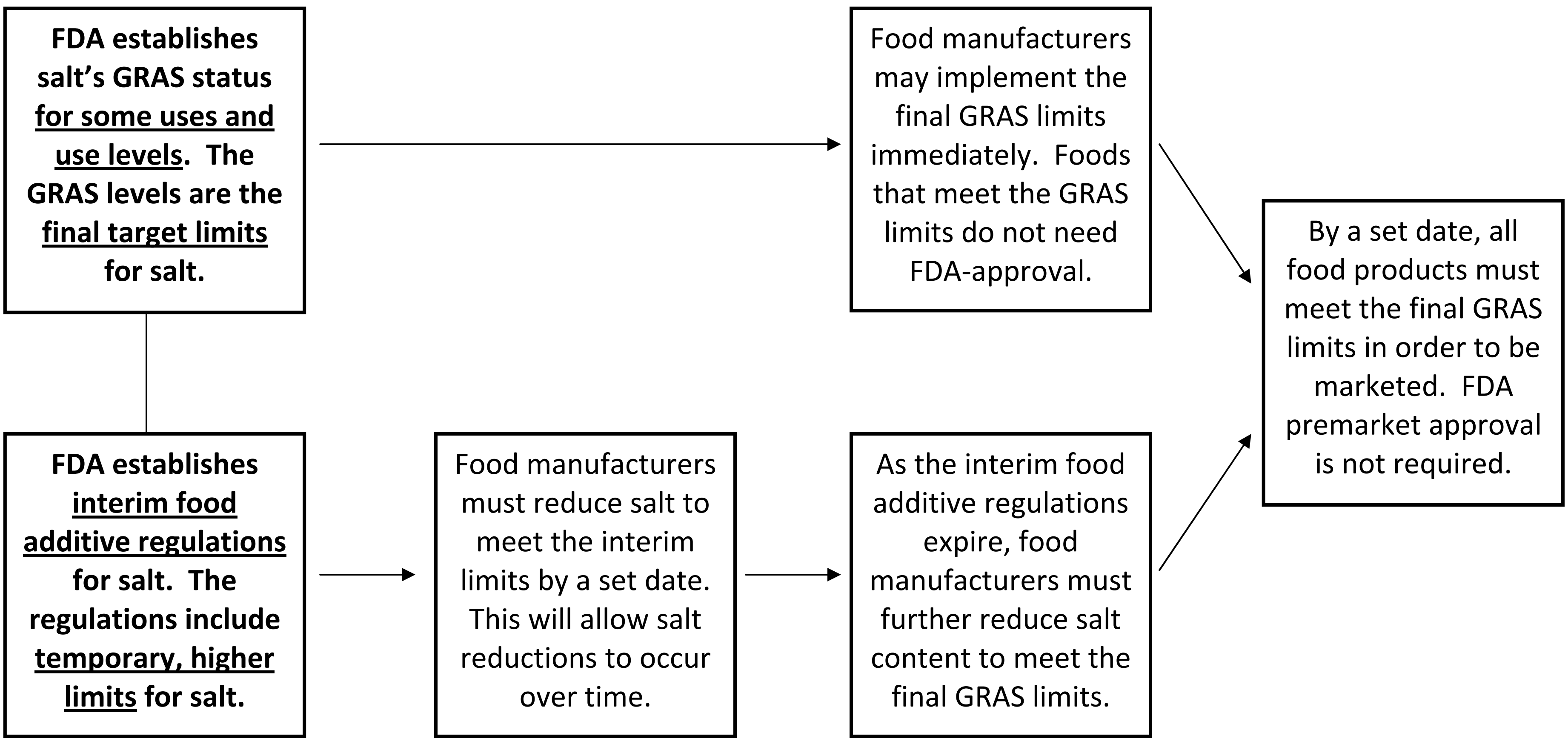
Note: This option could incorporate stepwise reductions designed to meet a final GRAS target.

Option 2:
All GRAS Salt Uses Would be Determined; Other Uses Would Require a Food Additive Regulation or be Prohibited



Note: This option could incorporate stepwise reductions designed to meet a final GRAS target.

Option 3:
Some Salt Uses Could be Established as GRAS; Others Could be Permitted Under Interim Food Additive Regulations



Note: Under the requirements for interim food additive regulations, studies to resolve questions about salt's safety should be undertaken within 60 days or the regulations must be revoked. However, as noted elsewhere, there are at least two examples of interim food additive regulations remaining in place for approximately 30 years. Thus, the study requirement has not prevented the use of interim regulations.