



September 30, 2011

The Honorable Tom Vilsack
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, DC 20250

The Honorable Kathleen Sebelius
Secretary of the Department of Health and
Human Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Requests for Withdrawal of Sodium Dietary Guideline Provisions, Transparent Rulemaking and Freedom of Information Act Request

Dear Secretary Vilsack and Secretary Sebelius:

As demonstrated below, the provisions of the *Dietary Guidelines for Americans, 2010* (“*2010 Dietary Guidelines*”) related to sodium (“sodium provisions”), violate the National Nutrition Monitoring and Related Research Act, 7 U.S.C. §5301, et seq. As a result, we respectfully request the withdrawal of the sodium provisions, and the initiation of an open and transparent rulemaking procedure, with public hearings, to establish sodium provisions supported by current and reliable scientific and medical evidence.

In addition, pursuant to the Freedom of Information Act (“FOIA”), we request that you provide us and the public with all of the documents related to the *2010 Dietary Guidelines*, the sodium provisions, and of the proposed National School Lunch and School Breakfast Programs Rules related to sodium, as the term “documents” is defined by the Federal Rules of Evidence, including but not limited to the documents related to the Dietary Guidelines Advisory Committee and its formation. We will pay the appropriate charges for responding to this FOIA request, but ask that you contact us in advance should the charges be estimated to exceed \$5,000.00. We note that we would consider the placement of all of these documents on the Departments’ web site, in an indexed and searchable manner, to be in compliance with this request and with the President’s Executive Order mandating transparency in agency proceedings.

The sodium provisions, jointly issued as part of the *Dietary Guidelines* on January 31, 2011, by the U.S. Department of Agriculture (“USDA”) and the Department of Health and Human Services (“HHS”), are based on inadequate medical and scientific evidence, as admitted by their original author, the Institute of Medicine (“IOM”). IOM published “Dietary Recommended Intakes (“DRIs”) in 2004, that were adopted as the *2010 Dietary Guidelines*, regardless of the IOM conclusion that: “[b]ecause of insufficient data from

dose-response trials, an Estimated Average Requirement could not be established and thus a Recommended Dietary Allowance could not be derived.”¹

Regardless of this scientific conclusion, IOM’s arbitrary, outdated, non-governmental guidelines, issued without adequate protections against bias and conflicts of interest, and without the protections of transparent rulemaking under the Administrative Procedures Act, were adopted by *Dietary Guidelines*,² improperly delegating the statutory role of the Departments and the Executive Branch, to an outside party, without regard to the statutory duties imposed on the Departments.

Your intervention is sought to assure both compliance with law and sound policy created by transparent rulemaking procedures that rely on current scientific and medical evidence, evaluated by the Departments.

The National Nutrition Monitoring and Related Research Act, 7 U.S.C. §5301 et seq., requires USDA and HHS to publish “nutritional and dietary information and guidelines for the general public” and to base the *Dietary Guidelines* on “the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.” 7 U.S.C. § 5341(a). The *Dietary Guidelines* are inconsistent with the statutory mandate because its sodium provisions are arbitrary and capricious.

Alone, the flawed sodium provisions in the *Dietary Guidelines* cause significant harm to the public and the salt producers that we represent, by distributing scientifically unsupportable information disparaging sodium, a mineral essential to human health, under the banner of the United States, and thereby adversely impacting the market for dietary salt, and causing concern for inappropriate regulatory and litigation initiatives.

Increasing the harm to the public and the salt producers are the corresponding sodium provisions of the recently proposed Nutritional Standards in the National School Lunch and School Breakfast Programs Rule.³ If adopted, this proposed rule will be arbitrary and capricious due to its reliance on, and adoption of, the scientifically and medically unsupported sodium provisions contained in the *Dietary Guidelines*.

Below, we explain further why the proposed sodium provisions in the *Dietary Guidelines* and the Nutritional Standards in the National School Lunch and School Breakfast

¹ Institute of Medicine, *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*, 269-423 (2004).

² Both the *Dietary Guidelines* and the *2005 Dietary Guidelines* contain the same sodium limit range of 1500-2300 mg/day. Because a Recommended Daily Allowance could not be determined, the IOM set DRIs that are the basis for the sodium limits in both the *2010 Dietary Guidelines* and the *2005 Dietary Guidelines*. See IOM, *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride, and Sulfate* (2004).

³ *Nutritional Standards in the National School Lunch and School Breakfast Programs*, 76 Fed. Reg. 2494 (proposed January 13, 2011).

Programs Rule should be withdrawn and we provide an assessment of current available scientific and medical evidence that was not adequately considered by the Departments. We trust that you will find this assessment helpful as you fulfill your duties to enhance the public health and welfare with sound dietary policies and standards consistent with medical and scientific evidence.

I. The Sodium Provisions of the *Dietary Guidelines* Violate the Statutory Mandate, Are Contradicted by the Latest, Sound Scientific Evidence and Must be Withdrawn

The *2010 Dietary Guidelines* are a joint product of USDA and HHS. The *Dietary Guidelines* are reviewed, updated (if necessary), and published every five years. 7 U.S.C. § 5341(a)(1) (“At least every five years the Secretaries shall publish a report entitled ‘Dietary Guidelines for Americans’ [which]... shall contain nutritional and dietary information and guidelines for the general public, and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program”) (alteration in the original).

The *2010 Dietary Guidelines* must contain nutritional and dietary information for the general public and must be “based on the preponderance of the scientific and medical knowledge which is current at the time the report is prepared.” 7 U.S.C. § 5341(a)(2).

The process of generating each edition of the *Dietary Guidelines* is a joint effort of the USDA and HHS and has evolved to include at least three publicly disclosed stages. In the first stage, an external scientific Dietary Guidelines Advisory Committee (“DGAC”) is appointed. During the second stage, the Agencies develop the *Dietary Guidelines* and consider comments provided in response to the DGAC’s report. Finally, the two Agencies develop messages and material communicating the *Dietary Guidelines* to the general public.

For the *2010 Dietary Guidelines*, the DGAC consisted of 13 nutrition and health experts who were appointed to conduct an analysis of scientific information on diet and health and to prepare a report summarizing its findings.⁴ It is at this stage where the problems with the *2010 Dietary Guidelines* first arise. Rather than independently assessing all of the scientific and medical data currently available, the DGAC merely adopted the conclusions of the DGAC that prepared the *2005 Dietary Guidelines* and apparently considered “subsequent evidence, especially regarding diet and blood pressure in

⁴ See *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*, ii (originally submitted June 14, 2010) (“In the initial charge to this panel, we were asked to ‘provide science-based advice for Americans, in order to promote health and reduce the risk of major chronic diseases through diet and physical activity.’ More specifically, this involved, among other tasks, that we base our Report upon ‘the preponderance of the most current scientific and medical knowledge, and determine what issues for change need to be addressed,’ with a ‘primary focus on the review of scientific evidence published since the last DGAC deliberations’ and place ‘primary emphasis on the development of food-based recommendations.’”)

children.” *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*, D6-2 (originally submitted June 14, 2010).

The DGAC in 2005 derived its sodium consumption recommendations by simply adopting the Dietary Recommended Intakes (“DRIs”), published in 2004 by the Institute of Medicine (“IOM”).⁵ This document clearly stated that for sodium, “[b]ecause of insufficient data from dose-response trials, an Estimated Average Requirement could not be established and thus a Recommended Dietary Allowance could not be derived.” Despite acknowledging a lack of evidence, the document went on to make arbitrary recommendations that are followed to this day.⁶ One common thread links the decision to adopt flawed recommendations in the first instance, and then base two separate sets of *Dietary Guidelines* on the flawed DRIs -- the chair of the 2010 DGAC’s subcommittee on electrolytes served in the same capacity when the *2005 Dietary Guidelines* were developed, and was the chair of the *Panel on Dietary Reference Intakes for Electrolytes and Water*, which was responsible for developing the DRI’s. A rigorous analytical process cannot feature one individual piloting the creation of standards and then being charged with evaluating his own recommendations, and then five years later, being tasked once again to evaluate his prior evaluation.

The *2010 Dietary Guidelines* purport “to summarize and synthesize knowledge about individual nutrients and food components into an interrelated set of recommendations for healthy eating that can be adopted by the public[.]” The *Dietary Guidelines* also are relied upon by “policymakers in designing and carrying out nutrition-related programs, including Federal food, nutrition education, and information programs.” See *2010 Dietary Guidelines* at ix. In fact, the *2010 Dietary Guidelines* “establish the scientific and policy basis for all Federal nutrition programs.” See U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, *2010 Dietary Guidelines for Americans – Backgrounder: History and Progress*, 2.⁷

Rather than thoroughly assessing the current scientific and medical knowledge, the Agencies reached a conclusion in 2005 based on insufficient evidence and then repeated the error in 2010.⁸ To cure this defect, the Agencies should withdraw the flawed sodium provisions and subject the topic of appropriate sodium limits to rulemaking under the Administrative Procedures Act to ensure that all interested parties are permitted to

⁵ Institute of Medicine, *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*, v.-xiii (2004).

⁶ Both the *Dietary Guidelines* and the *2005 Dietary Guidelines* contain the same sodium limit range of 1500-2300 mg/day. Because a Recommended Daily Allowance could not be determined, the IOM set DRIs that are the basis for the sodium limits in both the *2010 Dietary Guidelines* and the *2005 Dietary Guidelines*. See IOM, *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride, and Sulfate* (2004).

⁷ Available at:

<http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/Backgrounder.pdf>

⁸ See *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2010*, D6-2 (originally submitted June 14, 2010)

participate in a public forum and that decision making is supported by sound and current scientific evidence.

As we described in numerous prior public comments,⁹ USDA and HHS repeatedly failed to consider and account for strong, evidence-based data that contradicts their preconceived hypotheses related to sodium intake. Moreover, the latest and best scientific evidence contradicts the sodium provisions in the *2010 Dietary Guidelines*, emphasizes the critical role of sodium in health protection, and supports far higher levels of sodium intake than adopted by the Guidelines. See Section III of this letter.

II. The Proposed Nutritional Standards in the National School Lunch and School Breakfast Programs Rule Demonstrate the Harm Caused by the *Dietary Guidelines* and Must be Withdrawn

The failure of USDA and HHS to issue *Dietary Guidelines* that comply with their statutory mandate invalidate efforts to propose binding agency rules that are based on the *Dietary Guidelines* and cause grave concerns about the impact of adopting the sodium provisions of the *Dietary Guidelines* in school meal programs.

The Richard B. Russell National School Lunch Act, 42 U.S.C. §1751 et seq., requires schools participating in the national school lunch program (“NSLP”) to meet minimum nutritional standards “prescribed by the Secretary on the basis of tested nutritional research.” 42 U.S.C. § 1758(a)(1)(A). Pursuant to the statute, schools participating in the program must serve lunches and breakfasts that are “consistent with the goals of the most recent *Dietary Guidelines for Americans* published under Section 5341 of Title 7.” 42 U.S.C. § 1758(f)(1)(A) (emphasis added). The statute authorizing the School Breakfast Program (“SBP”) includes a similar mandate requiring schools to provide meals under SBP that “meet the minimum nutritional requirements prescribed by the Secretary on the basis of tested nutritional research... under the same terms and conditions as section 1758” of the NSLP. 42 U.S.C. § 1773(e)(1)(A) (referring to 42 U.S.C. § 1758(a)(1)(A), which requires NSLP consistency with the *Dietary Guidelines*).

Congress amended the NSLP in 2004 via Section 103 of the Child Nutrition and WIC Reauthorization Act of 2004. The Act requires the Secretary of Agriculture to promulgate rules based on the most recent *Dietary Guidelines* reflecting specific serving recommendations “for increased consumption of foods and food ingredients offered in

⁹ *Dietary Guidelines for Americans, 2010 – Written Public Comments –* (Posted Oct. 17, 2008 – July 30, 2010), Salt Institute, No. 00010 *Comments to Dietary Guidelines Committee*, (Oct. 21, 2008); No. 000248 *Statement 2: Comments to Dietary Guidelines Advisory Committee*, (Jan. 28, 2009); No. 000447 *Salt Institute Letter to the Dietary Guideline Advisory Committee* (Mar. 16, 2009); No. 000494 *Salt Institute Letter to the Dietary Guidelines Advisory Committee* (May 8, 2008); No. 000566, *Salt Institute Letter to the Dietary Guidelines Advisory Committee* (July 20, 2009); No. 000743 *Salt Institute Letter to the Dietary Guidelines Advisory Committee* (Oct. 28, 2009); No. 000744 *The Mediterranean Diet*, 4 (3) Salt & Health for Nutrition Policy Makers (2009); No. 000752, *Salt Institute Letter to the Dietary Guidelines Advisory Committee* (Nov. 5, 2009).

school nutrition programs,” including both the School Lunch Program and the School Breakfast Program. See Public Law 108-265, Section 9(a)(4), *codified at* 42 U.S.C. 1758(a)(4)(B).

The USDA issues, and periodically updates, regulations implementing the NSLP and the SBP.¹⁰ In an effort to meet its obligation to revise meal patterns and nutrition requirements for the NSLP and the SBP to align them with current *Dietary Guidelines*, USDA recently proposed the National Standards in the National School Lunch and School Breakfast Programs Rule. 76 Fed. Reg. 2494 (proposed January 13, 2011).

However, the failure of USDA and HHS to follow their statutory mandate led to the issuance of flawed *Dietary Guidelines*¹¹ that contain arbitrary and capricious findings. As a result, USDA’s recently proposed rule is equally flawed.¹² When promulgating rules addressing meal patterns and nutrition requirements for the NSLP and the SBP, the USDA is required to promulgate rules revising nutrition standards, based on the most recent *Dietary Guidelines*, that reflect specific recommendations, expressed in serving recommendations, for increased consumption of foods and food ingredients offered in school nutrition programs.¹³ Schools participating in the program must serve lunches and breakfasts that are consistent with the goals of the most recent *Dietary Guidelines*.¹⁴ Because the basis for the proposed sodium standards in the proposed rule comes directly from the fatally flawed *Dietary Guidelines*, the proposed rule as currently written is arbitrary and capricious.

III. Both the Process Used to Derive the *Dietary Guidelines* and the Assessment of the Scientific and Medical Evidence Were Fundamentally Flawed

The process used by USDA and HHS to develop the *2010 Dietary Guidelines* was systemically flawed. Rather than assessing all of the available scientific and medical evidence and using this analysis to draw valid conclusions, the DGAC began with a conclusion based on bias, and then justified its conclusion with selected evidence. By predetermining its conclusion, the DGAC was forced to undertake analytically suspect methods to justify its conclusion, including failing to consider the negative health impacts

¹⁰ See 7 C.F.R. pt. 210 (NSLP) and 7 C.F.R. pt. 220 (SBP).

¹¹ Both the *2010 Dietary Guidelines* and the *2005 Dietary Guidelines* contain the same sodium limit range of 1500-2300 mg/day. Because a Recommended Daily Allowance could not be determined, the Institute of Medicine (“IOM”) set Dietary Recommended Intakes that are the basis for the sodium limits in both the *2010 Dietary Guidelines* and the *2005 Dietary Guidelines*. See IOM, *Dietary Reference Intakes: Water, Potassium, Sodium, Chloride, and Sulfate* (2004).

¹² *Nutritional Standards in the National School Lunch and School Breakfast Programs*, 76 Fed. Reg. 2494 (proposed Jan. 13, 2011). Although the proposed rule cautions that the *2010 Dietary Guidelines* were not available at the time the proposed rule was published, and therefore seeks comment on how to incorporate them, this distinction is immaterial to our issues because both sets of *Dietary Guidelines* contain the same standards for sodium.

¹³ 42 U.S.C. § 1758(a)(4)(B).

¹⁴ 42 U.S.C. § 1758(f)(1)(A).

of sodium reduction in diets, failing to address the reality that there is a physiological sodium appetite, and failing to address conflicting and inconsistent evidence related to the impact of sodium on blood pressure and obesity.

A. Key Members of the DGAC Appear to Have Injected Personal Bias into Process

As we explained in Section I of this letter, we are concerned that the entire process that led to the development of the *2010 Dietary Guidelines* was flawed. First, it appears that the DGAC began with a conclusion and then worked to justify its conclusion.¹⁵ This is counter to its mandate to perform a rational and independent assessment of all currently available scientific and medical knowledge in order to arrive at its recommendations. In addition to being analytically unsound, an approach with a foregone conclusion evidences the biases of the members of the DGAC.

As we pointed out in our comments to the Agencies, at the first meeting of the 2010 DGAC, when invited to make an opening statement, the chair of the DGAC's subcommittee on electrolytes chose to use the platform to espouse his personal beliefs regarding the evidence. Rather than focusing the discussion on an assessment of all currently available scientific and medical evidence related to sodium, he revealed significant aspects of his own personal philosophy surrounding the issue of sodium intake and health, citing only the literature that supported his personal view.¹⁶

This was not aberrational behavior on the part of the subcommittee chair. During the second meeting of the DGAC, the transcript¹⁷ notes that when a Committee member observed that a very recent randomized controlled trial on congestive heart failure outcomes carried out in Italy^{18, 19} demonstrated that patients placed on low salt diets died or were re-admitted in much greater numbers than those placed on a regular salt diet, the subcommittee chair squelched debate and immediately dismissed this study. He stated

¹⁵ We also question whether the DGAC was constituted and operated in compliance with the Federal Advisory Committee Act. Public Law 92-463 (5 U.S.C. Appendix 2, the Federal Advisory Committee Act of 1972), as amended.

¹⁶ Transcript of First Dietary Guidelines Advisory Committee Meeting, 197-203 (Oct. 30, 2008). Available at: <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/Meeting1/DGACMtg1-Day1transcript.pdf>

¹⁷ Transcript of Second Dietary Guidelines Advisory Committee Meeting, 368-370 (Jan. 29, 2009). Available at: <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/Meeting2/transcript-meeting2-day1.pdf>

¹⁸ S. Paterna, P. Gaspare, S. Fasullo, F.M. Sarullo, P. Di Pasquale, *Normal-Sodium Diet Compared With Low-Sodium Diet in Compensated Congestive Heart Failure: Is Sodium an Old Enemy or a New Friend?*, 114 *Clinical Sci.* 221-30 (London) (2008) (ISSN: 1470-8736).

¹⁹ S. Paterna, et al., *Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients With Recently Compensated Heart Failure*, 103 *Am. J. Cardiology* 93-102 (2009).

that it was carried out in another country using different diuretics than used in the US. It is very troubling that the first high quality, randomized controlled trial on the impact of dietary salt on health outcomes (not simply blood pressure) was dismissed without analysis. This failure to consider evidence that does not support a predetermined outcome undermines the credibility of the entire *Dietary Guidelines* review process.

Further, as we described in Section I of this letter, the DGAC subcommittee chair was also the chair of the *Panel on Dietary Reference Intakes for Electrolytes and Water* – the group tasked with developing the flawed DRIs²⁰ upon which both the *2005 and 2010 Dietary Guidelines* are based. Rather than engaging in a fresh and objective analysis of all the scientific and medical evidence available to craft the *Dietary Guidelines*, the process that appears to have occurred was to put the same individual who oversaw the development of the flawed DRIs in the position of evaluating his own recommendations for the creation of the *2005 Dietary Guidelines*, and again for the creation of the *2010 Dietary Guidelines*. Rather than appearing neutral and unbiased, taken together with the DGAC's failure to consider contrary evidence, the process used strongly suggests that the DGAC relied heavily on the predisposition of its subcommittee chair when drafting its recommendations.

The behavior of the subcommittee chair did not occur in a vacuum. On the second day of the first DGAC meeting, the Chairperson of the DGAC repeated what the electrolytes subcommittee chair had previously stated, making reference only to those recent papers that support sodium reduction in the diet and ignoring all others that caution a prudent review of all the health outcomes associated with such a strategy.²¹ Again, this statement was made at the outset of the review process and was prejudicial to a neutral review. It is difficult to see how an objective review can be carried out when both the Chairperson of the DGAC, and of the subcommittee, abandoned an evidence-based approach in favor of their preordained biased views.

²⁰ Institute of Medicine, *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*, ix (2004) (“The group responsible for developing this report, the *Panel on Dietary Reference Intakes for Electrolytes and Water*, under the oversight and assistance of the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes (the DRI Committee), has analyzed the evidence on risks and beneficial effects of nutrients included in this review.”)

²¹ Transcript of First Dietary Guidelines Advisory Committee Meeting, 4-6 (Oct. 31, 2008). Available at: <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/Meeting1/DGACMtg1-Day2transcript.pdf>

B. The DGAC Failed to Consider Evidence Related to Negative Impacts of Sodium Reduction

By committing immediately to the DRIs developed in 2004, the DGAC failed to properly consider evidence related to the impact of salt consumption on the production of plasma renin. The Renin-Angiotensin System (“RAS”) is the physiological mechanism to make up for inadequate salt (sodium chloride) consumption. When any one of our body’s sensory mechanisms detects that we’re not consuming sufficient salt, the RAS is activated to signal the kidney conserve sodium and reabsorb it back into the circulatory system.²² This complex neuro-hormonal chain reaction, perfected through biological evolution, is critical for maintaining balance in our circulatory system.

Unfortunately, although the RAS helps us make up for too little salt consumption, it does so at a heavy cost to our health. Elevated RAS levels cause metabolic syndrome²³, insulin resistance²⁴, cardiovascular disease²⁵, and a host of other serious conditions.^{26, 27, 28} There is no longer any doubt whatsoever that an elevated RAS is a very serious risk factor for overall health.

As can be seen from the diagram taken from Alderman²⁹, as our sodium intake is reduced, the plasma renin increases dramatically – it is the body’s natural response to salt reduction. The blue arrow shows that, once our sodium intake falls below 150 mmol sodium/day (3,450 mg), the body reacts by producing high levels of renin to activate the RAS chain reaction to conserve the available sodium. It is nature’s way to make up for an inadequate salt consumption.

²² J.A. Schafer, H. Valtin, *Renal Function: Mechanisms Preserving Fluid and Solute Balance in Health*, (3d ed. 1995).

²³ C.H. Wang, F. Li, N. Takahashi, *The Renin Angiotensin System and the Metabolic Syndrome*. *Open Hypertension*. J. 2010;3:1-13.

²⁴ Z. Liu, *The Renin-Angiotensin System and Insulin Resistance*, 7 (1) *Curr. Diab. Rep.* 34-42 (Feb. 7, 2007).

²⁵ S. Verma, M. Gupta, D.T. Holmes, et al., *Plasma Renin Activity Predicts Cardiovascular Mortality in the Heart Outcomes Prevention Evaluation (HOPE) Study*. *Eur. Heart J.* (2011), (first published online Mar. 17, 2011, doi:10.1093/eurheartj/ehr066).

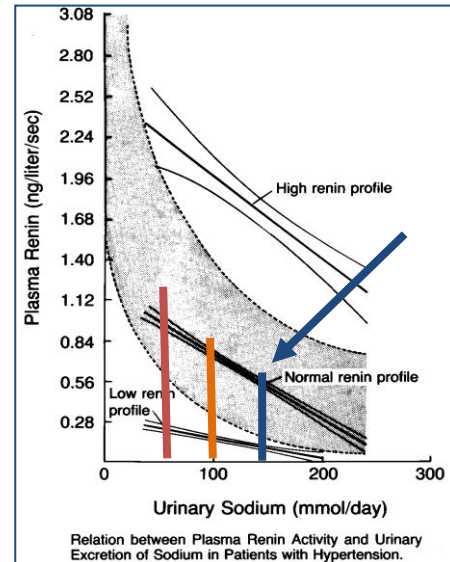
²⁶ J. Peti-Peterdi, J.J. Kang, I. Toma, *Activation of the Renal Renin–Angiotensin System in Diabetes—New Concepts*, 23(10) *Nephrol. Dial. Transplant* 3047-49 (2008).

²⁷ S. Inaba, M. Iwai, M. Furuno, et al., *Continuous Activation of Renin-Angiotensin System Impairs Cognitive Function in Renin/Angiotensinogen Transgenic Mice*, 52(2) *Hypertension* 356-62 (Feb. 2009). *Epub* 2008 Dec. 1.

²⁸ N. Takahashi, F.Li, K. Hua, et al., *Increased Energy Expenditure, Dietary Fat Wasting and Resistance to Diet-Induced Obesity in Mice Lacking Renin*, 6(6) *Cell Metab.* 506-12 (Dec. 2007).

²⁹ M.H. Alderman, S. Madhavan, W.L. Ooi, H. Cohen, J.E. Sealey, J.H. Laragh, *Association of the Renin-Sodium Profile With the Risk of Myocardial Infarction in Patients With Hypertension*, 324 *N. Engl. J. Med.* 1098–1104 (1991).

The level of 3,450 mg sodium per day comes to approximately 9 grams of salt, which is close to the average American consumption.³⁰ This is an example of the ‘wisdom of the body,’³¹ the view that our body’s physiology is the best authority on determining our personal needs. As we discuss later in this section of the letter, this concept is supported by scientific evidence. This average level of salt consumption is sufficient to prevent any spike in RAS activity. However, the *2010 Dietary Guidelines* recommend that we drop our consumption well below this, down to 2,300 mg sodium (100 mmol)/day. At this level, the orange line, the renin begins to rise rapidly. It is also abundantly clear that moving to the 1,500 mg sodium (65 mmol)/ day level suggested in the *2010 Dietary Guidelines* for more than half the American population significantly increases the impact. At this red line level, renin levels spike up dramatically. Nature’s response to reduced sodium has been deliberately downplayed and ultimately ignored to support the sodium provisions of the *Dietary Guidelines*.³²



While few would question the benefits of reduced blood pressure per se, salt reduction, the *Dietary Guidelines*’ primary strategy to achieve this, is a very poor and dangerous choice. Other more effective lifestyle strategies to reduce blood pressure, such as more physical exercise or the adoption of a Mediterranean-type diet, have no negative side effects. But reducing salt to lower the risk of blood pressure in the general population will stimulate elevated RAS and increases the risk of other diseases.

In fact, a recent issue of *American Heart Journal*³³ makes it clear that the most important strategies to control cardiovascular disease involve blocking excess levels of renin and aldosterone, the principle components of the RAS. If blocking elevated RAS levels is so critical, then it’s clear that consuming enough salt to prevent elevated RAS in the first place is essential to good health.

³⁰ A.M. Bernstein, W.C. Willett, *Trends in 24-h Urinary Sodium Excretion in the United States, 1957–2003: A Systematic Review*, 92 Am. J. Clin. Nutr. 1172-80 (2011).

³¹ W.B Cannon, *The Wisdom of the Body* (1932).

³² IOM, *Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate*, 282 (2004).

³³ G.C. Fonarow, C.W. Yancy, A.F. Hernandez, et al., *Potential impact of optimal implementation of evidence-based heart failure therapies on mortality*, 161 Am. Heart. J. 1024-30 (2011)

There have also been a string of recent meta-reviews making it clear that population-wide salt reduction will not provide any significant health benefits and may possibly result in harm to consumers. Three Cochrane Collaboration reviews^{34 35 36} and a German Institute for Quality and Efficiency in Health Care meta-review³⁷ all conclude that there is insufficient evidence to warrant population-wide salt reduction.

There is also a significant body of scientific and medical evidence that illustrates other serious negative consequences of a low-salt diet. For example, a very recent study from Harvard Medical School demonstrated that when healthy people were placed on a low-salt diet, they developed insulin resistance within 7 days.³⁸ Other recently derived evidence showing the grave negative consequences of a low-salt diet also does not appear to have been seriously considered in developing the *Dietary Guidelines*, including:

- a) insulin resistance³⁹
 - i. This study, carried out at the University of São Paulo, demonstrates the insulin resistance induced by chronic dietary salt restriction.
- b) metabolic syndrome⁴⁰
 - i. This study demonstrated that low-salt diets induced alterations in the plasma lipoproteins and in inflammatory markers that are common features of the metabolic syndrome (precursor to heart attack, stroke and diabetes) in healthy adults.
- c) congestive heart failure⁴¹

³⁴ L. Hooper, C. Bartlett, G. Davey Smith, S. Ebrahim, *Reduced Dietary Salt for Prevention of Cardiovascular Disease*, The Cochrane Library (2003), Issue 1.

³⁵ Jurgens G, Graudal NA. Effects of low sodium diet versus high sodium diet on blood pressure, renin, aldosterone, catecholamines, cholesterols, and triglycerides. *Cochrane Database Syst Rev* 2004; (1):CD004022.

³⁶ Taylor RS, Ashton KE, Moxham T, Hooper L, Ebrahim S. Reduced dietary salt for the prevention of cardiovascular disease. *Cochrane Database Syst Rev* 2011, Issue 7. Art. No.: CD009217. DOI: 10.1002/14651858.CD009217

³⁷ Institute for Quality and Efficiency in Health Care. Executive Summary of Report A05-21B, Benefit Assessment of Non-drug Treatment Strategies in Patients with Essential Hypertension: Reduction in Salt Intake (Nutzenbewertung Nichtmedikament? Ser Behandlungsstrategien Bei Patienten Mit Essenzieller Hypertonie: Kochsalzreduktion). Cologne, Germany 2009.: Executive summary in English can be accessed at, http://www.iqwig.de/download/A05-21B_Executive_Summary_Nondrug_treatment_strategies_for_hypertension-reduction_in_salt_intake.pdf.

³⁸ Garg R., Williams G.H., Hurwitz S., Brown N.J., Hopkins P.N., Adler G.K., *Low-Salt Diet Increases Insulin Resistance in Healthy Subjects*, 60(7) *Metabolism* 965-68 (July 2010). Epub 2010 Oct 30.

³⁹ G.F. Ruivo, S.M. Leandro, C.A. do Nascimento, et al., *Insulin Resistance Due to Chronic Salt Restriction is Corrected by α and β Blockade and by l-arginineI*, 88(4-5) *Physiology and Behavior* 364-70 (2006).

⁴⁰ E/R/ Nakandakare, A.M. Charf, F.C.Santos, et al., *Dietary Salt Restriction Increases Plasma Lipoprotein and Inflammatory Marker Concentrations in Hypertensive Patients.*, 200(2) *Atherosclerosis* 410-16 (2008).

- i. This randomized, controlled, double blind study demonstrated that low-salt diets result in much higher rates of mortality and hospital readmissions in patients with congestive heart failure compared to similar patients on a regular salt diet.
- d) diabetes 2 (all cause mortality)⁴²
 - i. In this Australian study with type 2 diabetes patients, lower sodium was associated with increased all-cause and cardiovascular mortality.
- e) cardiovascular events⁴³
 - i. This study was the third in a long series of NHANES-based analyses which showed higher mortality associated with lower sodium intake.
- f) iodine deficiency diseases⁴⁴
 - i. This recent study demonstrated that more and more of the population is experiencing the potential for iodine deficiency diseases since the call for reduces salt consumption.
- g) cognition loss⁴⁵
 - i. This study demonstrated that mild, chronic hyponatremia in the elderly resulting from low-salt diets induce a high incidence of falls, possibly as the result of marked gait and attention impairments.
- h) death⁴⁶
 - i. This multi-year study on a very large cohort concluded that lower salt intakes resulted in higher morbidity and mortality.

As we have explained in prior comments, the evidence of the health outcomes of diets reduced in sodium show no benefit in terms of reduced mortality⁴⁷ and we now remind

⁴¹ S. Paterna, G. Parrinello, S. Cannizzaro, et al., *Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients With Recently Compensated Heart Failure*, 103(1) Am. J. of Cardiology 93-102 (2009).

⁴² E.I. Ekinici, S. Clarke, M.C. Thomas, et al., *Dietary Salt Intake and Mortality in Patients With Type 2 Diabetes*, 34 Diabetes Care 703-09 (2011).

⁴³ H.W. Cohen, S.M. Hailpern, M.H. Alderman, *Sodium Intake and Mortality Follow-Up in the Third National Health and Nutrition Examination Survey (NHANES III)*. 23 (9) J. Gen. Intern. Med. 1297-302 (Sep. 2008). Epub 2008 May 9.

⁴⁴ M.P.J. Vanderpump, J.H. Lazarus, P.P. Smyth, et al., *Iodine Status of UK Schoolgirls: A Cross-Sectional Survey*, 377 (9782) Lancet 2007-12 (June 11, 2011).

⁴⁵ B. Renneboog, W. Musch, X. Vandemergel, M.U. Manto, *Mild Chronic Hyponatremia is Associated with Falls, Unsteadiness, and Attention Deficits*, 119 Am. J. of Med. 71.e1-71.e8 (2006).

⁴⁶ K. Stolarz-Skrzypek, T. Kuznetsova, L. Thijs, et al., *Fatal and Nonfatal Outcomes, Incidence of Hypertension, and Blood Pressure Changes in Relation to Urinary Sodium Excretion*, 305(17) JAMA. 1777-85 (May 4, 2011).

⁴⁷ M.H. Alderman, et al., *Dietary Sodium Intake and Mortality: The National Health and Nutrition Examination Survey (NHANES I)*, 351 Lancet 781-85 (1998); H. Cohen, et al., *Sodium Intake and Mortality in the NHANES II Follow-Up Study* 119 Am. J. of Med. 275 (2006); H.W. Cohen, S.M. Hailpern, and M.H. Alderman, *Sodium Intake and Mortality Follow-Up in the Third National Health and Nutrition*

you that the single controlled trial of this hypothesis found that subjects in the salt-reduced group of the cohort had a considerably greater incidence of mortality and more frequent re-hospitalization.⁴⁸

Because of the mistaken understanding that a reduction in salt intake will reduce blood pressure, which will in turn reduce cardiovascular events, the gold standard for dietary interventions for post-heart failure patients is a low sodium diet. However, the most recent evidence indicates that post-heart failure patients placed on low-sodium diets tend to die or are readmitted to hospital in far greater numbers than those that have not been placed on low-sodium diets.^{49 50 51} Further, recent research indicates that there may indeed be very negative consequences if the diet limits sodium to the range of 1500 – 2300 mg Na/day as recommended in the *Dietary Guidelines*.^{52, 53}

In addition to the compelling evidence related to the RAS and other negative impacts of a low-salt diet, the DGAC failed to address other studies that linked lowered salt intakes to a variety of health problems, including low-birth weights⁵⁴ and cognitive impairment⁵⁵ in

Examination Survey (NHANES III), J. Gen. Intern. Med., (2008); DOI: 10.1007/s11606-008-0645-6 and Michael H. Alderman, *Presidential Address: 21st Scientific Meeting of the International Society of Hypertension: Dietary Sodium and Cardiovascular Disease: the 'J'-Shaped Relation*, 25(5) J. of Hypertension 903-907 (2007)

⁴⁸ S. Paterna; P. Gaspare; S. Fasullo; F.M. Sarullo; P. Di Pasquale, *Normal-sodium diet compared with low-sodium diet in compensated congestive heart failure: is sodium an old enemy or a new friend?*, 114 Clinical Science 221-30 (London) (2008) (ISSN: 1470-8736); S. Paterna, et al., *Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients With Recently Compensated Heart Failure*, Am. J. Cardiology 93–102 (2009).

⁴⁹ H.W. Cohen, S.M. Hailpern, and M.H. Alderman, *Sodium Intake and Mortality Follow-Up in the Third National Health and Nutrition Examination Survey (NHANES III)*, J. Gen. Intern. Med., DOI: 10.1007/s11606-008-0645-6, (May 18, 2008).

⁵⁰ S. Paterna, P. Gaspare, S. Fasullo, F.M. Sarullo, P. Di Pasquale, *Normal-Sodium Diet Compared With Low-Sodium Diet in Compensated Congestive Heart Failure: Is Sodium an Old Enemy or a New Friend?*, 114 Clinical Sci. 221-30 (London) (2008).

⁵¹ S. Paterna, G. Parrinello, S. Cannizzaro, S. Fasullo, D. Torres, F.M. Sarullo, and P. Di Pasquale, *Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients With Recently Compensated Heart Failure*, 103 Am. J. Cardiology 93-102 (2009).

⁵² Y. Shapiro, M. Boaz, Z. Matas, A. Fux, and M. Shargorodsky, *The Association Between the Renin-Angiotensin-Aldosterone System and Arterial Stiffness in Young Healthy Subjects*, 68(4) Clinical Endocrinology 510-12 (Apr. 2008).

⁵³ Edna R. Nakandakarea, Ana M. Charfa1, Flávia C. Santosa1, Valéria S. Nunesa, Katia Ortegab, Ana M.P. Lottenberga, Décio Mion Jr.b, Takamitsu Nakanoc, Katsuyuki Nakajimac, Elbio A. D'Amicod, Sergio Catanozia, Marisa Passarellia, Eder C.R. Quintãoa, *Dietary Salt Restriction Increases Plasma Lipoprotein and Inflammatory Marker Concentrations in Hypertensive Patients*, 200(2) Atherosclerosis 410-16 (Oct. 2008).

⁵⁴ A. Shirazki, Z. Weintraub, D. Reich, E. Gershon, M. Leshem, *Lowest Neonatal Serum Sodium Predicts Sodium Intake in Low Birth Weight Children*, 292(4) Am. J. Physiol. Regul. Integr. Comp. Physiol. R1683-89 (Apr. 2007). Epub 2006 Dec 14.

children. Also ignored were peer-reviewed studies that demonstrated increased rate of falls⁵⁶ and fractures among the elderly⁵⁷, another nutritionally susceptible segment of society. In assisted living facilities, where all residents are given low-salt diets, the rate of falls and fractures are three times as great as in the normal home environment⁵⁸. We are left to surmise that the DGAC failed to consider this evidence because it did not fit within its justification for its predetermined conclusions.

Since the publication of the *2010 Dietary Guidelines*, additional scientifically-derived clinical evidence continues to be published. In a recent study, published in the May 4, 2011 edition of the *Journal of the American Medical Association*, researchers studying 4,000 patients over 8 years found that lower sodium consumption was associated with an increased risk of cardiovascular mortality, while higher sodium consumption did not correspond with increased risk of hypertension or cardiovascular disease complications.⁵⁹

C. The DGAC Failed to Consider Evidence Related to the Reality that there is a Physiological Sodium Appetite

In furtherance of its salt reduction program, dating back to the first set of *Dietary Guidelines*, Americans have been cautioned, then warned, about alleged dangers in high salt intakes.⁶⁰ Americans have been convinced that salt intake should be minimized. Polls show that public education campaigns have been successful. Food companies have developed thousands of reduced-sodium foods to cater to this demand and those foods are consumed today in amounts far greater than in 1980. The “sodium density” of the American diet has been steadily decreasing resulting in less sodium intake per calorie. The result, however, has been an unchanged level of sodium intake and an increase in caloric intake.

Although certainly not a primary cause, the continued promotion of salt reduction found in the recommendations in the *Dietary Guidelines* will likely worsen, not improve, the ongoing obesity crisis because people will consume more calories just to satisfy their

⁵⁵ J. Al-Dahhan, L. Jannoun, G.B. Haycock, *Effects of Salt Supplementation of Newborn Premature Infants on Neurodevelopmental Outcome at 10–13Years of Age*, 86 Arch. Dis. Child Fetal Neonatal Ed. 120–123 (2002).

⁵⁶ B. Renneboog, W. Musch, X. Vandemergel, M.U. Manto, G. Decaux, *Mild Chronic Hyponatremia is Associated With Falls, Unsteadiness, and Attention Deficits*, 119(1) Am. J. Med. 71.e1 – 71.e18 (Jan. 2006).

⁵⁷ F. Gankam Kengne, C. Andres, L. Sattar, C. Melot, G. Decaux, *Mild Hyponatremia and Risk of Fracture in the Ambulatory Elderly*, 101(7) QJMed. 583-88 (2008).

⁵⁸ H.K. Kamel, *Preventing Falls in the Nursing Home*. *Annals of Long Term Care*, (Sept. 5, 2008). Available at: <http://www.annalsoflongtermcare.com/article/6319?page=0.0>

⁵⁹ K. Stolarz-Skrzypek, T. Kuznetsova, L. Thijs, et al., *Fatal and Nonfatal Outcomes, Incidence of Hypertension, and Blood Pressure Changes in Relation to Urinary Sodium Excretion*, 305(7) JAMA. 177-85 (May 4, 2011); See *supra* note 35

⁶⁰ Americans’ salt intakes are exactly average in the world.

innate salt appetite. Decades of animal feeding experience serve as a foundation for this statement. In addition, the most recent UK Food Standards Agency⁶¹ survey demonstrated that despite the food industry reducing salt significantly (10-25%) in their processed food formulations, people still consume the same amount of salt, indicating they are voluntarily adding more with the shaker or are simply eating more food (and calories) to satisfy their need for sodium.

As we have reported in our comments, there is scientific evidence of a non-behavioral, neurally-mediated “salt appetite.”⁶² Nowhere in the record created in support of the *Dietary Guidelines* were we able to find any serious consideration of this scientific evidence even though we shared it with the DGAC. Other recent studies support findings that there is a non-behavioral, neurally-mediated “salt appetite,” including a recent study in *The Clinical Journal of the American Society of Nephrology* that indicates that physiology, not public policy, will determine a human’s daily sodium intake. This research should have been considered by the DGAC because it undercuts the hypothesis that salt intake can be controlled by regulators rather than by nature. The study, *Can Dietary Sodium Intake be Modified by Public Policy?*,⁶³ analyzed existing research to determine whether sodium or salt intake follows a pattern consistent with a range set by the brain to protect normal functions of organs such as the heart and kidney. The analysis is based upon 19,151 subjects studies in 62 previously-published surveys and reflects the differing “food environments” of 33 countries. The data reported documents that humans have a habitual sodium intake in the range of 2800 to 4600 mg/day -- with an average intake of 3600 mg/day. Currently, the U.S. citizens consume an average of about 3,500 mg/day of salt.⁶⁴

Taken in combination, these two studies strongly suggest that salt/sodium intake is a neurally-determined salt appetite signaled unconsciously from the brain and not the product of taste, labeling, consumer education, nor of the availability of low-sodium alternative products. A needs-based salt appetite suggests that whatever the *Dietary Guidelines* may say about salt intake, physiology will prevail over the opinions of policy makers.

⁶¹ Salt intakes remain static in Scotland - June 22, 2011 accessible at:

<http://www.food.gov.uk/news/newsarchive/2011/june/salt>

⁶² J.C. Geerling, and A.D. Loewy, *Central Regulation of Sodium Appetite*, 93(2) Exp. Physiol. 177-209 (Feb 2008).

⁶³ David A. McCarron, Joel C. Geerling, Alexandra G. Kazaks, and Judith S. Stern, *Can Dietary Sodium Intake be Modified by Public Policy?*, 4 Clinical J. of the Am. Soc’y of Nephrology 18788-82 (2009). Available at: <http://cjasn.asnjournals.org/cgi/reprint/CJN.04660709v1>

⁶⁴ This is consistent with the conclusion of renowned Swedish researcher, Björn Fokow, who described a “hygienic safety range” for sodium of 2,300 mg/day to 4,600 mg/day – recognizing that it could be as high as 5,750 mg/day. See Bjorn Folkow, *News in Physiological Sciences* (1990).

D. The DGAC Failed to Address Conflicting and Inconsistent Evidence Related to the Impact of Sodium Intake on Blood Pressure

As we have previously explained to the DGAC, some recent research carried out on the issue of salt and health casts a significant shadow over the DGAC's predetermined conclusion that reducing salt intake to the degree prescribed necessarily leads to significant reductions in blood pressure. While we are in full agreement with the potential health benefits of reducing blood pressure for those in our population that require it, the means of doing so should have its intended consequence and not provoke the development of negative biomarkers or cause harm of any kind.

Reduction of sodium intake to the 1500-2300 mg/day level does not conform to those needs. In the first instance, the intended impact on the target population is not highly significant as stated in the 2003 Cochrane review⁶⁵ and restated once again in 2008.⁶⁶ While salt reduction may result in a minor reduction in blood pressure for some portion of the population, a reduction in salt intake increases the blood pressure of another significant portion of the population.^{67, 68, 69} In light of these findings, if such a recommendation were to be made, surely the proviso must be given that a particular segment of the population will experience an increase in blood pressure. However, as with much of the other scientific and medical evidence provided in both our submitted comments and in this letter, it appears that no attention has been given to these studies by the DGAC in its dogged efforts to justify its predetermined conclusions.

IV. Conclusion

It is troubling that the Agencies have, to this point, adopted a mentality of continuous justification of a preordained conclusion rather than doing their statutory duty and setting standards based upon a rigorous assessment of all available scientific and medical evidence. However, we encourage you to change this practice and abandon the sodium provisions in the *Dietary Guidelines* in favor of an open, transparent rulemaking proceeding. Continuing to build policy and regulation on a fatally flawed foundation is both bad government and does nothing to protect our citizenry.

⁶⁵ L. Hooper, C. Bartlett, G. Davey Smith, S. Ebrahim, *Reduced Dietary Salt for Prevention of Cardiovascular Disease*, The Cochrane Library (2003), Issue 1

⁶⁶ L. Hooper, C. Bartlett, G. Davey Smith, S. Ebrahim., "Advice to Reduce Dietary Salt for Prevention of Cardiovascular Disease (Review)," The Cochrane Library (2008), Issue 4

⁶⁷ F.C. Luft, L.I. Rankin, R. Block R, et al., *Cardiovascular and Humoral Responses to Extremes of Sodium Intake in Normal Black and White Men*, 60 *Circulation* 697-706 (1979).

⁶⁸ J.Z. Miller, M.H. Weinberger, S.A. Daugherty, et al., *Heterogeneity of Blood Pressure Responses to Dietary Sodium Restriction in Normotensive Adults*, 40 *J. Chronic. Dis.* 245-50 (1987).

⁶⁹ F.C. Luft, D.A. McCarron, *Heterogeneity of Hypertension: The Diverse Role of Electrolyte Intake*, 42 *Annu. Rev. Med.* 347-55 (1991).

We hope that you will agree that the portions of the *2010 Dietary Guidelines* that pertain to sodium are fatally flawed and should be withdrawn because they are not based on a preponderance of the scientific and medical evidence. The Agencies must withdraw those portions of the *2010 Dietary Guidelines* in order to meet their statutory mandate. We also suggest that the USDA withdraw its recently proposed sodium provisions contained in the Nutritional Standards in the National School Lunch and School Breakfast Programs Rule. Failure to take this action would be arbitrary and capricious given the admissions made regarding the flawed foundation of the sodium provisions of the *Dietary Guidelines*, the impropriety of the process used by the DGAC in justifying the sodium provisions in the *Dietary Guidelines*, and the lack of consideration of the current science and medical evidence, including the evidence of harm that will be caused by the sodium provisions in the *Dietary Guidelines*.

Thank you for your attention and consideration.

Sincerely,

Lori Roman
President, Salt Institute