

February 10, 2006

Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
300 12th Street, SW  
Room 102 – Cotton Annex  
Washington, DC 20250

Re: Docket No. 05-033IF; FDMS Docket Number FSIS-2005-0038

Dear Sir or Madam:

The Salt Institute submits these comments to the Food Safety and Inspection Service's ("FSIS") proposed rule to drop the "second tier" from USDA's sodium labeling scheme. We support both the ConAgra petition and USDA/FSIS's response, although we continue to feel that the entire policy of applying a "healthy" decision based on sodium content to be deeply flawed and unsupported by scientific evidence. If a low-sodium food is considered more "healthy," we believe there should be scientific studies of the health outcomes of consuming such foods (or, at least, consuming a low-sodium diet). Only ten studies, all observational, none controlled trials, have studied the health outcomes of persons based on consuming diets with salt content similar to that consumed in this country (and none have studied diets that employ low-sodium foods). None of these ten studies has identified a population benefit in terms of reduced cardiovascular events or lowered morbidity/mortality. So, on what basis is this "healthy"?

That your docket closes February 10 is a coincident irony since earlier this week the *Journal of the American Medical Association (JAMA)* published an important – and cautionary – article shredding the popular notion that low-fat diets convey health benefits.<sup>1</sup> We feel a similar trial is needed to determine whether advocacy of low-salt diets is, likewise, another unsupported myth.

The Salt Institute is the trade association representing virtually all United States food salt producers. The Salt Institute has, for many years, closely monitored the scientific literature concerning the alleged relationship between sodium, hypertension, and adverse health outcomes and participated in funding research and symposia concerning this alleged relationship. The relationship between sodium intake, and cardiovascular health has become increasingly complex and unclear over the last two decades. Notwithstanding this increasing scientific complexity, however, FSIS (like FDA) has continued to advocate a now-simplistic and -incomplete sodium/hypertension message, which has been shown to be unrelated to positive cardiovascular health outcomes. The Salt Institute therefore strongly recommends for the reasons discussed below that FSIS recognize this current scientific uncertainty, and avoid worsening any problems with its current rule defining sodium for use of the term “healthy.”

The Salt Institute believes that FSIS should go further and rescind the current rule in recognition of recent Supreme Court decisions that clarify that speech that contains elements of commercial and non-commercial (public-issue-oriented) speech, such as nutrition labels, should be afforded the highest level of speech protection possible. That is not the present proposal, but

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<sup>1</sup> Susan, you have my hard copy; I'll insert the citation.

evidence suggests that moving further in the wrong direction such as implementing the “second tier,” would compound the error. The Salt Institute objects to the entire “healthy” labeling scheme because it violates the First Amendment protection for commercial speech by improperly restricting the use of the nutrient content claim “healthy” on foods containing more than 360 mg. of sodium per serving. The agency has not demonstrated through scientific or other evidence that it is either appropriate or necessary to further its public health goals to reduce the amount of sodium that can be present to use the term healthy, which thereby would further restrict the number of products that can use this claim. In fact, based on recent current science on the sodium-health relationship, FSIS instead should delete sodium as a criterion for use of the term “healthy.” But that is a question for another rulemaking.

Finally, the Salt Institute believes that FSIS has improperly relied on dietary recommendations and studies from NIH and been misled by FDA’s labeling decisions which, we believe, do not meet the requirements of the Data Quality Act. Last week, the 4th U.S. Circuit Court of Appeals heard oral arguments in *Salt Institute v. Leavitt* wherein the Salt Institute and the U.S. Chamber of Commerce challenge NIH’s refusal to release data relating to the DASH-sodium study in view of its pronouncements on the findings of the study. To the extent that FSIS is relying on NIH’s findings and recommendations to substantiate its “healthy” definition for sodium, FSIS is further vulnerable to challenge.

The effort to reduce sodium consumption by the general population has been encouraged under the assumption that it will provide positive cardiovascular profile benefits. However, there is no evidence that restricting sodium consumption results in improved cardiovascular health outcomes. In fact, the rulemaking in which FSIS decided what makes a food healthy with respect to dietary

sodium intake was completed before the first published “health outcomes” study in 1995 examined the question of whether low-sodium diets reduce cardiovascular risk.

Instead, FDA has relied on studies that have examined the relationship between intermediate variables, such as salt intake and blood pressure, rather than focusing on the relationship between intake levels of dietary sodium and improved cardiovascular health outcomes. Since 1995, nine different studies have now examined the health outcomes of reducing dietary sodium. As briefly summarized below, none of them show a benefit to the general population in terms of health outcomes such as reduced incidence of heart attacks or strokes. In fact, as noted, some of the studies found that low sodium diets actually cause adverse health outcomes (*i.e.*, greater incidence of heart attacks). They are the following:

- H. Tunstall-Pedoe *et al.*, 1997. Comparison of the Prediction by 27 Different Factors of Coronary Heart Disease and Death in Men and Women of the Scottish Heart Health Study: Cohort Study. *BMJ* 315:722-729. (This ten-year follow-up study to the Scottish Heart Health Study found no improved health outcomes for those on low-salt diets, and specifically, no association between sodium intake and cardiovascular or all-cause mortality).
- An analysis of the MRFIT database by Dr. J. Cohen examined data over fourteen years and suggested that there was no improved health benefit from low-sodium diets. The author noted that there is “no relationship observed between dietary sodium and mortality.” [Cohen, J.D. presentation to NHLBI Workshop on Sodium and Blood Pressure, January 28, 1999, Bethesda, MD (unpublished)].

- An analysis by Dr. J. Cutler of the National Institutes of Health, National Heart Lung and Blood Institute, of the first six years' data from the MRFIT database documented no health outcomes benefits of lower-sodium diets. (1997). [Cutler, J.R., Presented May 30, 1997, at American Society of Hypertension annual meeting, San Francisco, CA. (unpublished)].
- M. Alderman *et al.* 1998. Dietary Sodium Intake and Mortality: the National Health and Nutrition Examination Survey (NHANES I). *Lancet* 351:781-785. (An analysis of the health outcomes over twenty years from those in the NHANES I documented a 20% greater incidence of heart attacks among those on low-salt diets compared to normal-salt diets).
- M. Alderman *et al.*, 1995. Low Urinary Sodium Is Associated With Greater Risk of Myocardial Infarction Among Treated Hypertensive Men. *Hypertension* 25:1144-1152. (An eight-year study of a New York City hypertensive population stratified for sodium intake levels finding that patients on low-salt diets had more than four times as many heart attacks as those on normal-sodium diets).
- A health outcomes study in Finland, reported to the American Heart Association that no health benefits could be identified and concluded "...our results do not support the recommendations for entire populations to reduce dietary sodium intake to prevent coronary heart disease." [Valkonen, V-P. "Sodium and potassium excretion and the risk of acute myocardial infarction" Presented October 15, 1998 to the American Heart Association Scientific Sessions, Dallas, TX (unpublished)].

- He, J. et al. 1999. "Dietary sodium intake and subsequent risk of cardiovascular disease in overweight adults." *Journal of the American Medical Association*, 282:2027-2034. (A study of Americans found that less sodium-dense diets did reduce the cardiovascular mortality of one population sub-set, overweight men, but not the general population. The article reporting the findings did not explain why this obese group actually consumed less sodium than normal-weight individuals in the study).
- Tuomilehto J. et al. 2001. "Urinary sodium excretion and cardiovascular mortality in Finland: a prospective study." *Lancet* 357:848-51. (This Finnish study reported an increase in cardiovascular events for obese men, but not women or normal-weight individuals of either gender. The article, however, failed to adjust for potassium intake levels which many researchers consider a key associated variable).
- Hooper, L. et al. 2002. "Systematic review of long term effects of advice to reduce dietary salt in adults." *British Medical Journal* 325:628-636. (This study by the prestigious Cochrane Collaboration is the latest and highest-quality meta-analysis of clinical trials. It confirmed earlier meta-analyses' conclusions that significant salt reduction would lead to very small blood pressure changes in sensitive populations and no health benefits).

Because these studies represent updated and state-of-the-art research regarding the relationship of sodium intake and cardiovascular health outcomes, not only must FSIS evaluate these studies in determining what amount of sodium is healthy for an individual serving of food, but FSIS will also find that these studies confirm that there is no basis on which to conclude that there is a need for any

further restriction on sodium content in order to consider a food item healthy. In fact, these studies will demonstrate that the sodium content of foods contained in a normal American diet is irrelevant to cardiovascular health outcomes of healthy Americans and thus foods with 500, 700 or 900 mg. sodium per serving are just as healthy as foods with 480 mg. sodium per serving.

Moreover, the courts have made it clear that FSIS should not ignore studies that examine the relationship of salt intake to health outcomes, and should not give undue emphasis to studies which address health issues that are not relevant to the general population. Importantly, although the case is an FDA matter, the precedent is appropriate, in *Whitaker v. Thompson*, the court noted that approximately one-third of the more than 150 intervention and observational studies considered by FDA actually supported the antioxidant vitamin/cancer relationship.<sup>2</sup> Of the antioxidant vitamin/cancer studies reviewed by FDA: a) five of seventeen intervention studies supported the relationship, and one study produced mixed reports both for and against the relationship; b) two of the six post-hoc intervention studies supported the relationship; and c) sixty-five of 191 observational studies supported the relationship as did the one observational meta-analysis reviewed by FDA. However, FDA discounted many of the studies supporting the relationship for study errors or design limitations.<sup>3</sup> The *Whitaker* court found that, contrary to its own protocols, FDA gave undue emphasis to many intervention studies that did not focus on the general population, but rather focused on specific populations that were at a higher risk for cancer (i.e., smokers at risk for lung cancer). FDA banned the plaintiff's antioxidant claim by concluding that the evidence in support of it was

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<sup>2</sup> See *Whitaker v. Thompson*, 248 F. Supp. 2d at 11 (D.D.C. 2002).

<sup>3</sup> *Id.* at 12 n. 12.

weaker than evidence against it. The *Whitaker* court noted that it was clear that *more than 60 recent studies* reviewed by FDA supported the claim. The court noted that this number “hardly constitutes the ‘one or two old studies’ that the Court of Appeals contemplated might support a total ban.”<sup>4</sup>

Here, the most recent credible science has shown that it is irrelevant to focus on the sodium/hypertension relationship; rather, it is only appropriate to focus on the sodium/health relationship and determine if reducing sodium reduces the number of heart attacks and strokes. If it does not, as the recent studies show, then there is no basis for restricting sodium consumption at all. In any event, there is no credible medical basis whatsoever to further reduce sodium levels in an effort to produce health outcomes which have not been shown to exist.

Moreover, the public interest will not be served by further restricting salt content in individual healthy foods as would have occurred had the “second tier” been implemented. As noted in the above-cited scientific studies, dietary sodium restriction for most adults does not affect health outcomes. Although dietary sodium restriction is associated with some decrease in blood pressure (an intermediate variable), recent studies indicate that the effect that sodium intake has on blood pressure is related to deficiencies of minerals and other key nutrients. Moreover, although it is well accepted that a substantial variation in dietary salt intake (75 to 100 mmol/day) can produce measurable but modest changes in blood pressure, this effect is heterogeneous. For example, the amount of sodium intake effect on blood pressure appears to be more substantial in older and

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<sup>4</sup> *Id.* at 13.



hypertensive subjects.<sup>5</sup> Thus, certain subjects can be classified as salt-sensitive and salt-resistant, indicating their blood pressure response to dietary sodium.

In addition, several studies have suggested that reducing dietary sodium produces other effects that may negatively affect health outcomes. The Alderman studies suggest that many hypertensive persons on reduced sodium diets actually experience a greater increase in heart attacks. Similarly, mandating reduced sodium content in healthy foods may cause consumers to reduce their intake of foods with high levels of calcium, potassium and magnesium, minerals which are now known to be critical in maintaining cardiovascular health. Consequently, the use of a more restrictive “healthy” claim may result in consumers making dietary choices adverse to their health (e.g., not eating low fat dairy products) based on the misperception that even low levels of dietary sodium should be avoided.

There is no evidence that FSIS’s existing rule has adversely affected public health. Likewise, there is no evidence that it is more important or effective to restrict sodium in individual food sources than in meals and main dish products. Consumers typically have a wide variety of food choices available to them and do not necessarily make a distinction regarding individual food sources and main dish choices.

Further, neither maintaining FSIS’s existing sodium criteria for individual foods nor removing sodium completely as a determinant of “healthy” foods would prevent FSIS from achieving its goal of allowing consumers to make informed choices concerning their daily sodium intake.

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<sup>5</sup> See M. Alderman, *et al.*, “Salt, Blood Pressure, and Human Health,” *Hypertension* (2000): Vol. 36, 890-893.

Moreover, a more expansive interpretation of “healthy” foods would be consistent with the Federal Trade Commission (“FTC”) position that there are a spectrum of food choices that in the aggregate can help a consumer eat a healthy diet.<sup>6</sup> This view is more reflective of the recent science that there are a myriad of foods from which informed consumers can properly choose to balance their diet in order to achieve health.

For the reasons stated above, the Salt Institute requests FSIS to maintain, loosen or jettison the use of sodium content as a factor in determining whether a product can be labeled “healthy.” As noted in the above scientific studies, current nutritional science confirms that reducing dietary sodium consumption in the general population does not result in beneficial health outcomes such as reduced cardiovascular events. Therefore, it is misleading to consumers in the general population to suggest that a food, or an entire diet, with reduced sodium content is healthier than a comparable food or diet with higher sodium content. Not only are such conclusions not substantiated, but they are refuted by current science.

## **CONCLUSION**

The Salt Institute submits that there exists no well-documented scientific data supporting any clear relationship between dietary sodium and cardiovascular health outcomes applicable to the general population. Further, recent scientific evidence shows that a reduced sodium diet does not reduce the risk of hypertension in healthy individuals, and may, in fact, contribute to serious health

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<sup>6</sup> See FTC Comments to FDA Docket No. 02N-0209, (Sept. 13, 2002).

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outcomes such as heart disease and additional health risks. Consequently, FSIS should conclude that restriction of sodium levels to tighten the definition of “healthy” is unwarranted.

The Salt Institute appreciates the opportunity to submit these comments.

Sincerely,

Richard L. Hanneman  
President

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