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Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue, SW
Patriots Plaza 3, Mailstop 3782, Room 163A
Washington, D.C. 20250-3700

Dear Sir or Madam:

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on approaches to reducing sodium consumption [Docket No. FDA-2011-N-0400 and Docket No. FSIS-2011-0014]. We urge the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) to make sodium reduction a top public health priority. The FDA and FSIS can accomplish that by supporting strong, but realistic, mandatory regulations to reduce sodium levels in packaged and restaurant foods. Those regulations are necessary to curb one of the single greatest causes of cardiovascular disease.

FDA action to lower sodium consumption is long overdue. Over 30 years ago, CSPI first petitioned the FDA to reduce sodium levels in packaged and restaurant foods, in part, by revoking the “generally recognized as safe” (GRAS) status of salt and regulating salt as a food additive. That petition documented the scientific consensus on the relationship between diets high in sodium and cardiovascular disease. Since then, the evidence has gotten much stronger, including the publication of the DASH-sodium study, which confirmed the effect of lowering sodium levels on blood pressure.¹ More recently, a long-term follow-up of the “trials of hypertension prevention” (TOHP) found that lower-sodium intervention groups had a 30 percent lower risk of a cardiovascular event than the control groups.²

In 1979, the year after CSPI's petition, the FDA's GRAS review panel concluded that the evidence was *not* sufficient to consider salt to be GRAS. Then in 1980, the Health and Human Services (HHS) and Department of Agriculture (DOA) Dietary Guidelines for Americans report advised Americans to consume less salt³...and every subsequent edition of that key report has retained the same recommendation. Over the next quarter-century, numerous other health organizations, including the American Medical Association and the National Heart, Lung, and Blood Institute (NHLBI), have echoed that same recommendation: *cut the salt*. Doing so would both protect consumers' health and reduce health-care costs. Clearly, sodium, at the levels commonly consumed by the vast majority of Americans, should be considered "generally recognized as *dangerous*," not safe.

The U.S. government's 2010 Dietary Guidelines for Americans also addressed the issue, recommending that people with hypertension, those who are middle-aged or older, and African Americans should consume no more than 1,500 milligrams (mg) of sodium daily.⁴ Although almost half of the U.S. adult population⁵ (and close to 70 percent of the adult population over 40 plus African Americans and those at high risk)⁶ falls into those categories, current average daily consumption for all adults is at least 3,400 mg and probably closer to 4,000 mg when one considers underestimations of dietary intake and salt added in cooking and at the table.⁷

Reducing sodium consumption would save billions of dollars annually. A 2008 RAND Corporation study estimated that reducing sodium by 1,100 mg per day, from 3,400 mg to 2,300 mg, would reduce direct medical costs by \$18 billion per year and improve quality of life by \$32 billion per year. That study also estimated that reducing sodium to 1,500 mg per day would reduce medical costs by \$28 billion per year.⁸

In 2004, the former director of the National Heart, Lung, and Blood Institute and other experts estimated that at least 150,000 lives could be saved annually in the United States if sodium levels in packaged and restaurant foods were cut in half.⁹ *There is probably nothing else that the FDA and FSIS could do with regard to America's food supply that would provide a greater benefit to public health.*

Set forth below are responses to the questions raised by the FDA and FSIS:

Voluntary Efforts by the Food Industry

Over the last several years, some companies have voluntarily pledged to reduce sodium in their products, including, but not limited to, Walmart, Con Agra, and Darden Restaurants.

According to the 2010 Institute of Medicine (IOM) report, "Voluntary reductions in the sodium content of food supply have had limited success. Reports suggest that during the past 20 years some food companies have accomplished a 10–20 percent reduction in sodium for some products, with a few reportedly achieving reductions closer to 40–50

percent. While this is encouraging, the committee found the general picture to reveal little success for the industry as a whole.”¹⁰

To examine the industry’s voluntary efforts, in 2005, CSPI began monitoring the sodium content of foods in various food categories. Our report, *Salt Assault*, compares different brands of similar products and compares the amount of sodium in milligrams per 100-gram quantities of food to adjust for different serving sizes. The report includes dozens of product categories. The initial value of *Salt Assault* was to demonstrate that some brands in a given category contained two or even three times as much sodium as other brands. That demonstrates that many companies could dramatically lower sodium and still have marketable products. The report has also served as a barometer of changes that companies have been making to packaged foods and restaurant meals in subsequent years.

In 2011 we resurveyed the 500 foods included in *Salt Assault*. Of the 500 products surveyed, compared to 2008 levels, 152 had *less* sodium; 232 products were unchanged; and 116 products had *more* sodium. Over the last three years, we’ve seen only a 1.2 percent decrease in average sodium levels of the products surveyed and over the last six years only a 2 percent decrease. There has been enormous publicity on the dangers of sodium over the last several years, and we would have expected greater reductions in sodium in response to increased consumer and industry awareness. Unfortunately, many food manufacturers and restaurants, when acting voluntarily, have failed to reduce sodium content to acceptable levels.

Some in the food industry still maintain that voluntary actions should suffice to lower sodium to safe levels, and that no further governmental action is appropriate or necessary. However, as the Institute of Medicine’s 2010 landmark report on sodium reduction concluded, voluntary efforts by industry over the last 40 years to reduce sodium levels had failed.¹¹

Also, voluntary reductions are not always permanent. For example in 2010, Campbell Soup Co. garnered much favorable publicity for lowering the sodium content of dozens of canned soups, but last year the company announced that it was raising sodium levels in all of its *Select Harvest* soups to 650 milligrams from 480 milligrams a serving.¹²

Importantly, mandatory change would create a level playing field for manufacturers. Currently, some manufacturers won’t make changes because they fear that a less desirable taste would result in lower sales and profits—and their competitors won’t lower sodium levels. The IOM report cites a Unilever press release that states “...consumers will be more likely to adapt their taste preference to lower levels of salt if the food industry as a whole reduces salt levels.”¹³

Recently the American Public Health Association (APHA) passed a resolution that calls on the FDA to begin regulating sodium in the food supply within one year and to establish a timetable for gradually reducing sodium in the food supply by 75 percent within 10 years.

The APHA's ambitious goal, supported by CSPI, as well as the recommendations in the Dietary Guidelines for Americans, will be impossible to reach if sodium reduction efforts remain voluntary. The United States has a health crisis on its hands – one that has significant implications for the U.S. budget and government-sponsored health care – and history suggests that we need more certain and more permanent measures to regulate sodium in foods to ensure meaningful improvements in public health and attendant decreases in health care expenditures.

Consumer Understanding of the Role of Sodium

According to the 2010 IOM sodium-reduction report, past initiatives to reduce sodium reduction placed the principal burden on consumers to reduce sodium consumption. Unfortunately, consumer education and awareness programs to reduce sodium consumption have not been successful and sodium consumption levels are still far too high.¹⁴

A recent consumer survey indicates that 59 percent of Americans are “not concerned” about their sodium intake, and 70 percent of Americans did not know the dietary guidelines for sodium.¹⁵ In addition, more than half of all Americans don't know how much sodium they consume per day.¹⁶ And shockingly, even after extensive publicity that processed and restaurant foods are by far the greatest sources of dietary sodium, 46 percent of adults believe that table salt is the main source of sodium in American diets.¹⁷

Even more troubling, a recent CDC report showed that more than 98 percent of people with a recommended sodium intake level of 1,500 mg sodium/day actually exceed that level, and 88 percent of people with a recommended sodium intake of 2,300 mg/day exceed that amount.¹⁸

Even in the face of overwhelming evidence demonstrating that excess sodium consumption poses a major risk to health, public education, which inevitably is poorly funded, sporadic, and dull, has failed to reform the dietary habits of most Americans. Voluntary action by the food industry has also failed miserably to reduce average daily sodium consumption for most Americans. As the IOM committee recommended, FDA and USDA should adopt regulations that gradually lower sodium levels in the next decade.

A recent survey commissioned by CSPI found strong public support for government and industry action to reduce the sodium content of their foods. In a January 2012 national telephone survey conducted for CSPI, 71 percent of respondents want industry to reduce the sodium content of their foods and 58 percent support a government requirement to reduce the sodium content of processed and restaurant foods.

Effective Strategies for Sustainable and Meaningful Reduction of Sodium in Packaged and Prepared Foods

CSPI urges the FDA and USDA to adopt mandatory regulations to limit sodium content of various food categories, especially the major sources of sodium. Though setting regulations would take several years to implement, such legal limits would be far more effective and durable than voluntary action. Fortunately, the FDA has useful models for reducing sodium levels. The British Food Standards Agency and the National Salt Reduction Initiative (NSRI, which is spearheaded by New York City), after consultation with industry, established voluntary sales-weighted sodium targets. It is important to recognize that those voluntary targets do not translate well into regulations. Practical regulations require limits to which all foods would have to adhere. Our Salt Assault report shows that by surveying the sodium levels among different brands in various food categories one can identify reasonable, but mandatory, limits (not just category-wide targets), and those limits could be gradually lowered over the coming years (as the IOM recommended).

The FDA should propose sodium limits for different categories of food, similar to the United Kingdom's and NSRI's approach, but on a mandatory basis.

The United Kingdom made sodium reduction a top public health priority and encouraged manufacturers and retailers to reduce sodium in their products. The program, which set targets in approximately 80 food categories, led to an almost 9 percent reduction in sodium consumption.¹⁹ (Because of a change in government, that initiative appears to have disappeared).

The NSRI has a goal of reducing salt intake by 20 percent over five years. The NSRI targets 62 categories of packaged food and 25 categories of restaurant food.²⁰ To date, 28 companies signed on to this voluntary initiative, committing to certain sodium reductions.

While the NSRI program is commendable, too many companies, including such large food manufacturers and restaurant chains as PepsiCo, ConAgra, McDonald's, and Burger King, have refused to participate. The limited participation indicates the need for the FDA and USDA to set mandatory national limits on sodium in packaged and restaurant foods.

Whatever approaches are taken, it is vital to monitor changes through the most accurate method available, 24-hour urinary excretion surveys.

While the FDA pursued a regulatory approach, it certainly should urge industry to make voluntary cuts as large and as rapidly as possible during the lengthy rulemaking process.

In any rulemaking proceeding, the FDA and USDA could set ceilings in several ways:

- One approach involves revoking the GRAS designation for major uses of salt and certain other sources of sodium, such as sodium bicarbonate and monosodium glutamate and then regulating those uses as a food additive. The exact limits on the use of salt—or on the overall sodium content of foods²¹—would vary according to the

food category. In arguing for the revocation of the GRAS status, CSPI's 2005 petition pointed out that the 1984 court decision on our lawsuit against the FDA said, "the FDA must make a decision on the GRAS status of salt after ... the voluntary programs have been in effect for a reasonable period of time and FDA has had an opportunity to assess their impact" It's time for the FDA to deny GRAS status to salt.

- An alternative approach would be to leave salt as a GRAS substance, but still set mandatory limits for the sodium content of the food categories that contribute most of the sodium. In some cases, the FDA might need to amend the "standards of identity" of foods that are significant sources of sodium to limit the sodium content.²²

The FDA has said that some uses of salt are allowed as "prior sanctions" issued by the FDA prior to 1958. However, as stated in our petition and acknowledged by the FDA, the FDA has the legal authority to amend any prior sanctions when usage levels "may render [the food] injurious to health."²³ Unquestionably, current salt levels in many foods are injurious to health. If the FDA sees prior sanctions as a problem, at the very least it should call on companies to provide evidence of prior sanctions during the rulemaking process.

In addition to setting ceilings for sodium in foods, the FDA could also seek to reduce sodium consumption through improved food labeling. For example, the FDA and USDA could help alert consumers to high sodium levels by requiring the word "High" adjacent to the word "Sodium" on Nutrition Facts labels. It also could require on bulk packages of salt a statement such as "Salt promotes heart disease. Try using half as much salt as recipes call for."

We also urge the FDA to lower the Daily Value (DV) for sodium from 2,400 mg to 1,500 mg. While the recommended limit for healthy, young, white adults is 2,300 mg, the FDA traditionally has set the DVs of other nutrients at levels that would protect the more sensitive segments of the population.

Taste Preferences, Technological Role and Food Safety

As our recent sodium survey comparing brands of different products indicates, many companies could lower the sodium contents of their products sharply (to the levels that some of their competitors are using) without sacrificing flavor. Many people who cut sodium in their diets to lower their blood pressure say they quickly get used to less salty, or unsalted, foods.²⁴ If companies gradually reduced the sodium in their foods, consumers would become accustomed to less salty foods. In addition, according to the IOM report, "it seems likely that if salt intake from foods could be reduced on a population-wide basis, consumers' preference for salty foods would also shift downward."²⁵

According to the 2005 edition of the Dietary Guidelines for Americans, “when consumers are offered a lower-sodium product, they typically do not add table salt to compensate for the lower sodium content, even when available.”²⁶

While salt plays an important technological role in the development of physical properties of foods, such as serving as a leavening agent in baked goods, “for many products, more salt may be added than is truly needed for the desired physical property.”²⁷ In addition, for many foods, “reducing the sodium content of the product should not create food safety or spoilage concerns.”²⁸

Conclusion

Significantly, but gradually, reducing sodium in the American diet would prevent tens of thousands of unnecessary deaths and save billions of dollars in health care costs each year. Meaningful reductions are practical and achievable, but only if FDA and USDA take bold action by setting mandatory limits for various categories of processed and restaurant foods, and by requiring informational and warning labels on high-sodium products in the meantime. Reliance on food processors to make voluntary reductions in sodium has proved to be inconsistent and inadequate. We urge the FDA and USDA to carefully weigh the growing evidence calling for substantial reductions in sodium intake and issue strong rules that will protect Americans' health. Such rules are long overdue.

Sincerely,

A handwritten signature in black ink that reads "Michael F. Jacobson". The signature is written in a cursive, flowing style.

Michael F. Jacobson, Ph.D.
Executive Director

Endnotes

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- ¹ Sacks FM, Svetkey LP, Vollmer WM, et al. Effects on blood pressure of reduced dietary sodium and the dietary approaches to stop hypertension (DASH) diet. *N Engl J Med.* 2001; 344:3–10.
- ² Cook NR, Cutler JA, Obarzanek E, Buring JE, Rexrode KM, Kumanyika SK, Appel LJ, Whelton PK. *BMJ.* 2007 Apr 28; 334(7599):885.
- ³ U.S. Department of Health and Human Services, U.S. Department of Agriculture. *Nutrition and Your Health: Dietary Guidelines for Americans.* 1980.
<http://www.cnpp.usda.gov/Publications/DietaryGuidelines/1980/DG1980pub.pdf>
- ⁴ U.S. Department of Health and Human Services, U.S. Department of Agriculture. *Dietary Guidelines for Americans.* 2010.
<http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf>
- ⁵ Centers for Disease Control and Prevention, *MMWR*, October 21, 2011, Vol. 60, No. 41.
- ⁶ Centers for Disease Control and Prevention, *MMWR*, March 27, 2009, Vol. 58, No. 11.
- ⁷ NHANES, 2005-06. “What We Eat in America.” www.ars.usda.gov/foodsurvey. That dietary-recall survey estimated sodium consumption at 3,400 mg, but actual daily consumption is closer to 4,000 mg, because NHANES omits salt added at the table or in cooking and NHANES’s respondents often underestimate their actual consumption. Sodium consumption is reported in Zhou BF, Stamler J, Dennis B, et al. Nutrient intakes of middle-aged men and women in China, Japan, United Kingdom, and United States in the late 1990s: The INTERMAP study. *J Hum Hypertens.* 2003; 17:623-30. Kumanyika SK, Cook NR, Cutler JA, et al. Sodium reduction for hypertension prevention in overweight adults: further results from the Trails of Hypertension Prevention Phase II. *J Hum Hypertens.* 2005; 19:33-45.
- ⁸ Palar, K, Sturm, R. Potential societal savings from reduced sodium consumption in the U.S. adult population. *Am J of Health Promot.* 2009 Sept/Oct;24(11):49-57.
- ⁹ Havas S, Rocella EJ, Lenfant C. Reducing the public health burden from elevated blood pressure levels in the United States by lowering intake of dietary sodium. *Am J Pub Health.* 2004; 94: 19-22.
- ¹⁰ Institute of Medicine, National Academies. *Strategies to Reduce Sodium Intake in the United States.* Washington, DC: National Academies Press, 2010. Pp. 7-8.
- ¹¹ Institute of Medicine, National Academies. *Strategies to Reduce Sodium Intake in the United States.* Washington, DC: National Academies Press, 2010. Pp. 5-8.
- ¹² Sloves, Juli Mandel. “Campbell Continues to Provide Consumers with an Array of Lower-Sodium Choices.” Campbell Soup Company. July 20, 2011.
<http://investor.campbellsoupcompany.com/phoenix.zhtml?c=88650&p=irol-newsArticle&ID=1586923&highlight=> (accessed November 1, 2011).
- ¹³ “Unilever makes a commitment to reduce salt across its portfolio.” Unilever House. April 21, 2009.
<http://www.unilever.com/mediacentre/pressreleases/2009/Unilevermakesacommitmenttoreducesaltacrossitsportfolio.aspx> (accessed November 28, 2011).
- ¹⁴ Institute of Medicine, National Academies. *Strategies to Reduce Sodium Intake in the United States.* Washington, DC: National Academies Press, 2010. Pp. 6-7.
- ¹⁵ International Food Information Council. *Consumer Sodium Research: Concern, Perceptions, and Action.* August 2011. http://www.foodinsight.org/Content/3651/Sodium%202011_Final%20Report_0916.pdf
- ¹⁶ *Ibid.*
- ¹⁷ American Heart Association. Most Americans don’t understand the health effects of wine and sea salt, survey finds. April 25, 2011. <http://newsroom.heart.org/pr/aha/1316.aspx> (accessed December 8, 2011).
- ¹⁸ CDC. Usual sodium intakes compared with current dietary guidelines---United States, 2005–2008. *MMWR* 2011; 60: 1413-17.
- ¹⁹ Food Standards Agency. Dietary sodium levels surveys. June 22, 2008.
<http://www.food.gov.uk/science/dietarysurveys/urinary> (accessed November 28, 2011).
- ²⁰ New York City Department of Health and Mental Hygiene. Cutting Salt, Improving Health.
<http://www.nyc.gov/html/doh/html/cardio/cardio-salt-initiative.shtml> (accessed November 28, 2011).
- ²¹ The FDA could regulate total sodium (as opposed to salt) as it has regulated certain other families of food ingredients by setting a maximum on the total amount, such as in the case of peroxyacids, where the maximum concentration permitted is 220 parts per million as peroxyacetic acid (21 CFR 173.370).

²² Such as cheeses, bakery products, cereal flours and related products, macaroni and noodle products, fruit pies, canned vegetables, vegetable juices, frozen vegetables, egg products, fish and shellfish, margarine, and food dressings and flavorings.

²³ 21 C.F.R. 181.1(b)

²⁴ Institute of Medicine, National Academies. *Strategies to Reduce Sodium Intake in the United States*. Washington, DC: National Academies Press, 2010. Pp. 79-80.

²⁵ Institute of Medicine, National Academies. *Strategies to Reduce Sodium Intake in the United States*. Washington, DC: National Academies Press, 2010. P. 81.

²⁶ U.S. Department of Health and Human Services, U.S. Department of Agriculture. *Dietary Guidelines for Americans*. 2005. <http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter8.htm>

²⁷ Institute of Medicine, National Academies. *Strategies to Reduce Sodium Intake in the United States*. Washington, DC: National Academies Press, 2010. P. 98.

²⁸ Institute of Medicine, National Academies. *Strategies to Reduce Sodium Intake in the United States*. Washington, DC: National Academies Press, 2010. P. 95.