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I wanted to start by expressing my appreciation to the FDA for addressing the salt issue for the first time in 25 years by holding this hearing. This hearing is focusing on the issues raised by CSPI's 2005 petition that called for the regulation of salt and other sodium-containing ingredients in processed foods. I hope that the witnesses testifying at the hearing and filing written comments will stimulate the FDA to fulfill its public health responsibility—and opportunity—by taking actions that will substantially lower sodium levels in our food…and saving thousands of lives.

The extraordinary importance of lowering sodium consumption was highlighted in a dramatic way in a 2004 article in the American Journal of Public Health coauthored by Claude Lenfant, then the director of the NHLBI. The article estimated that reducing the sodium content of packaged and restaurant foods by half would prevent *150,000 deaths due to cardiovascular disease per year*. Other researchers have calculated roughly similar benefits. That indicates the tremendous potential for effective government action to save lives. *In fact, there is probably no other single thing that the FDA could do that would have a greater benefit to public health*. Of course, that's not to say that a high-sodium diet is the only contributor to cardiovascular disease. It's also important for policy makers to encourage weight loss, more physical activity, diets richer in fruits and vegetables, and smoking cessation.

Other than a few individuals who still oppose public health actions to reduce salt, the health community is united that Americans, and others around the world, are consuming much too much sodium. The U.S. Departments of Health and Human Services (HHS) and of Agriculture (USDA), the Institute of Medicine, the American Heart Association, the World Health Organization, and many other expert bodies have all advocated sharp reductions in sodium levels in foods and sodium consumption. The Grocery Manufacturers Association, the nation's largest food trade association, is urging its members to reduce sodium levels. Indeed, CSPI was proud to cosponsor a conference on sodium-reduction with GMA a month ago

FDA action to lower sodium consumption is long overdue. It was almost 30 years ago in the form of a 1978 petition—when CSPI first called for FDA action to reduce sodium levels, 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, what with the publication of the DASH-sodium study,¹ which confirmed the effect of lowering sodium levels on blood pressure. More recently, a long-term follow-up of the "trials of hypertension prevention" (TOHP) found that the 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 first Dietary Guidelines for Americans report advised Americans to consume less salt...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*. Clearly, salt should be considered "generally recognized as *dangerous*," not safe.

Unfortunately, over the past several decades, the FDA, U.S. Department of Agriculture, which regulates meat and poultry products, and Congress have done precious little to lower sodium levels in the food supply. We do have nutrition labeling on most foods, which is a godsend to people watching their sodium. And the FDA has placed sodium limits on foods that claim to be "low in sodium" or that use the health claim "diets low in sodium may reduce the risk of high blood pressure." But those measures have had a minimal effect on overall sodium intake. Clearly, not everyone reads labels as assiduously as many of us would like. After a quarter-century of pallid measures, perhaps it should not surprise that sodium consumption is actually *higher* now than it was in 1980, according to the NHANES surveys.

Limited research suggests that people are getting about 75 percent of their sodium from processed and restaurant foods. Food labels indicate that some packaged foods are loaded with sodium: [**slide 2**]

•	Marie Callender's Classic One Dish Chicken Teriyaki	2,270 mg
•	Swanson's Hungry Man XXL Roasted Carved Turkey	5,410 mg
•	Mott's Mr. and Mrs. T Bloody Mary Mix, 12 oz.	2,100 mg

But the amounts in typical packaged foods pale in comparison to what you'll find at countless restaurants. Companies' own data and CSPI's analyses show that many menu items contain far more than a day's worth of sodium: [slide 3]

•	Denny's Lumberjack Slam (2 eggs, 3 pancakes	4,460 mg
	with margarine, ham, 2 strips of bacon, 2 sausage links)	
•	Reuben sandwich from a deli	3,270 mg
•	Dunkin' Donuts Salt Bagel	4,520 mg
•	House Lo Mein at a typical Chinese restaurant	3,460 mg

All those foods contain one to two days' worth of sodium. While companies may maintain that they add only enough sodium to provide the flavor or other function, the sodium contents of competing brands of the same products vary greatly. For instance, **[slide 4]**

• Jamestown Hardwood Smoked bacon has **50 percent more sodium** than Gwaltney Premium Sliced Hardwood Smoked bacon (2,360 vs. 1,550 mg/100 g)

- Safeway Lucerne Whole Milk Ricotta Cheese has **three times as much sodium** as Sorrento's ricotta cheese (240 vs. 80 mg/100 g)
- Bumble Bee solid white albacore tuna has **more than twice as much sodium** as Crown Prince's product (450 vs. 190 mg/100 g).

International comparisons also suggest opportunities to reduce sodium levels. **[slide 5]** Consider McDonald's McNuggets, French Fries, Big Mac, and Sausage and Egg McMuffin. On average, those products in the U.S. contain 46 percent more sodium (per 100 grams) than in the United Kingdom. Similarly, Kellogg's Corn Flakes, Rice Krispies, and Special K have an average of 36 percent more sodium (per 100 grams) in the U.S. than the UK.

Examples like those demonstrate that some companies use far more sodium than is necessary in some of their products and could lower the levels greatly and still have perfectly marketable, safe foods.

Some in the food industry will probably maintain that their voluntary actions should suffice to lower sodium to safe levels. And, indeed, several multinational companies, partly because the British Food Standards Agency has made sodium-reduction a top priority, have been reformulating some of their products.

However, we have a health crisis on our hands, and history suggests that more certain and more permanent measures are needed. In the early 1980s, the FDA, with a hypertension expert at its helm, rejected a regulatory approach and called for vigorous voluntary action. The FDA stated, "The commissioner believes that a voluntary program will produce the desired results with less regulatory burden." Three of the more responsible companies agreed to lower sodium levels, but even they made only marginal reductions. We evaluated the changes in products that were produced in 1984 and still produced in 2004 and found just modest changes (in terms of milligrams per 100 grams): **[slide 6]**

•	McDonald's (16 foods)	-9%
•	Quaker (8 foods)	-23%
•	Comphall (12 cound)	100/

• Campbell (13 soups) -10%

The weighted average of those reductions over 20 years was just 12 percent, or 0.6 percent per year. More broadly, the FDA's optimism proved totally unwarranted, and sodium consumption has actually **gone up**, **not down**....and tens of thousands of people have unnecessarily died prematurely.

In addition, CSPI has conducted an ongoing survey of a market basket of 71 brand-name foods and fast foods. **[slide 7]** The average change in sodium content of those foods was only an 11 percent decrease between 1983 and 2007, a decline of less than 0.5 percent per year—a far lower rate than would be needed to achieve the 50 percent decrease over 10 years that the National High Blood Pressure Education Program Coordinating Committee and other experts have recommended. That general lack of voluntary industry action on a critically important health issue that could save tens of thousands of lives annually

indicates the urgent need for *mandatory* regulations, not just another polite request to companies to cut the salt.

Thus, as we stated in our petition, we urge the FDA to adopt regulations to limit the sodium content of various categories of food. Though setting regulations would take several years to accomplish, such legal limits would be more effective and durable than voluntary action. Fortunately, the FDA would have a great head start in setting ceilings, because the targets that the British government, after consultation with industry, set generally would be applicable to the American food supply. Of course, while the FDA pursued a regulatory approach, it certainly should urge industry to make voluntary cuts as big and rapidly as possible during the rule-making process.

The FDA could set ceilings in several ways: [slide 8]

- One approach would be to revoke the GRAS designation for major uses of salt (and possibly other sources of sodium, such as sodium bicarbonate) and then regulating those uses as a food additive. The exact limits on the use of salt—or on the overall sodium content of foods^{*}—would vary with the food category. In arguing for the revocation of the GRAS status, our 2005 petition pointed out that the 1984 court opinion on our lawsuit against the FDA said, Athe 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.
- Another approach would be to leave salt as a GRAS substance, but still limit the salt or sodium content of various categories of foods to safe levels. If it would facilitate the process, the FDA could amend the "standards of identity" of foods that are significant sources of sodium to limit the salt (or sodium) content.[†]

The FDA has said that many uses of salt are allowed as "prior sanctions" issued by the FDA prior to 1958.³ However, as stated in our petition and acknowledged by the FDA in its October 23rd Federal Register notice, the FDA has the legal authority to amend any prior sanctions when usage levels "may render [the food] injurious to health."⁴ And current salt levels in many foods certainly 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 by March 28th, the end of the comment period of this proceeding.

While people are cooking less these days, most households still have canisters of salt in their cupboards. So, as part of a holistic campaign to reduce sodium, our petition called

^{*} 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).

[†] 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.

for health messages on packages of salt. Such a message, for example, could say "Salt promotes heart disease. Try using half as much salt as recipes call for."

The last thing our petition called for was to lower the Daily Value for sodium. The current Daily Value is 2,400 milligrams, but the Institute of Medicine said that roughly half the population—people over 50, African-Americans, and people with hypertension—should limit their diets to 1,500 milligrams. While the recommended limit for healthy, young, white adults is 2,300, the FDA traditionally has set the DVs at levels that would protect the more sensitive segments of the population.

In addition to the actions called for in our petition, we recommend that the FDA require that in categories of food that provide substantial amounts of sodium products that are especially high in sodium disclose that fact prominently on the label. Since June 1993, the Finnish government has required that six major sources of salt—bread, sausages, cheese, butter, breakfast cereals, and crisp bread—carry a "high salt content" consumer alert if the salt content exceeds specified limits, such as 1.3 percent salt by weight for bread and 2 percent for butter. Such labeling has spurred companies to reduce the sodium content of most products to below the level that triggers the "high salt" notice. We understand that the Finnish government is considering lowering the sodium levels and also setting labeling thresholds for more categories of food. While longstanding government publicity efforts and pressure on companies to make voluntary reductions were responsible for the bulk of the reduction in sodium levels, the labeling requirement also played a role. **[slide 9]** Overall, average daily per capita consumption of sodium in Finland declined from about 5,600 milligrams in 1972 to 3,600 in 2002.

Finally, the FDA and HHS should encourage the U.S. Department of Agriculture to develop a parallel rulemaking to reduce sodium levels. After all, USDA regulates cured meats, broth-injected poultry, and meat-containing meals that are significant sources of sodium. Unfortunately, USDA has shown little interest in addressing this vital public health matter.

In summary, the FDA has an opportunity to reduce the extraordinarily high health, social, and financial burdens imposed on the American public by companies marketing foods high in sodium. The Center for Science in the Public Interest urges the FDA to take advantage of this opportunity by simultaneously urging voluntary action by manufacturers and restaurant companies and by implementing regulations.

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 47 Fed. Reg. 26590 (June 18, 1982) at 26593.

⁴ 72 Fed. Reg. 59973 (October 23, 2007) at 59974.