



THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg
Mayor

Thomas R. Frieden, M.D., M.P.H.
Commissioner

nyc.gov/health

Sonia Angell, M.D., M.P.H.

Director of the Cardiovascular Disease Prevention and Control Program
New York City Department of Health and Mental Hygiene

Salt and Sodium: Petition to Revise the Regulatory Status of Salt and Establish Food Labeling Requirements Regarding Salt and Sodium: Public Hearing

Docket No. 2005P-0450

Submitted to Food and Drug Administration on November 29, 2007

Good Afternoon. I am Dr. Sonia Angell, Director of the Cardiovascular Disease Prevention and Control Program at the New York City Department of Health and Mental Hygiene (DOHMH). On behalf of the DOHMH, I would like to thank you for the opportunity to comment on the regulatory status and food labeling requirements regarding sodium.

Cardiovascular Disease and Sodium

Cardiovascular disease, which includes heart disease and stroke, is the leading cause of death in New York City. This remains true regardless of race, ethnicity or gender. In 2005, more than 25,000 New York City residents died from cardiovascular disease.¹

High blood pressure is a major risk factor for heart disease and stroke, and the leading cause of black-white disparities in number of life years lost.² In New York City, an estimated one quarter of all adults have hypertension.³ Over two thirds of our older residents - those for whom the risk of complications from this condition is greatest - have hypertension.⁴

High sodium intake increases blood pressure and limiting sodium benefits the population at large, not only those with hypertension or other medical conditions, such as diabetes or renal disease. For example, a recent follow-up of the Trials of Hypertension Prevention, randomized control trials of sodium reduction in a population of non-hypertensive adults 10-15 years AFTER their 18-48 month sodium reduction intervention, showed the intervention group had a 30% reduction in mortality compared to the non-intervention groups.⁵ The relevant literature is extensive and conclusive. Leading health institutions, including the Institute of Medicine and numerous professional organizations, concur in their assessment: sodium intake must be reduced.

The United States Department of Agriculture and Department of Health and Human Services, Institute of Medicine (IOM) and American Heart Association (AHA) recommend limiting sodium intake to 2,300 mg per day.^{6, 7, 8} A lower limit of 1,500 mg per day is recommended for those with hypertension, blacks, and middle-aged or older people, groups which together make up over 50% of NYC's residents.^{9, 10, 11}

However, daily sodium intake in the U.S. far exceeds these recommended limits. It is conservatively estimated to be approximately 3,300 mg per day, not including salt added at the table.¹² Many estimates put daily sodium intake at approximately 4,000 mg per day.¹³

The American Medical Association estimates that if Americans decreased lifetime sodium intake by 1,300 mg per day, 150,000 lives would be saved annually.¹⁴ But reducing sodium intake is difficult for even the most motivated consumers. Seventy-five percent of the sodium we consume is already in commercially processed food that we buy.¹⁵ To stay below recommended maximum daily intake requires a consumer to actively read, understand, and compare back-of-packaging nutrition facts panels; to add up daily totals; and then to avoid many commonly stocked products on our supermarket shelves.

It doesn't make sense that just following recommended sodium guidelines should require such a complex task, especially when current intake levels are clearly detrimental to our health. It should be easy for people to make informed, heart-healthy choices. We must change the default and make available product information simple to understand and to use.

I'd like to take us back nearly 25 years to 1983, when Dr. Arthur Hull Hayes, then FDA Commissioner, published an article that reviewed the FDA's Dietary Sodium Initiative.¹⁶ Started in 1981, the initiative included encouraging the food industry to voluntarily reduce the amount of sodium in processed foods and "to increase the amount and effectiveness of sodium-content labeling of foods." It is sobering to note that since that time, sodium intake actually has increased from 1976-1980 to 1999-2000, 18% for men and 32% for women.¹⁷ Since 1994, the mandated nutrition facts panel has provided sodium content information. But this information alone, in its current format, has not been effective in lowering salt intake.

There are government actions that can make a difference. Required front-of-package sodium warning labels make dangerous consumer choices immediately obvious. This would also create consumer demand for lower sodium products and thus also provide an incentive for voluntary industry reductions in sodium content. Accomplishing this will require guidance for the maximum amount of sodium recommended in specific product categories.

Required labeling warning consumers of high sodium products

Mandatory, prominent front-of-the-package warning labels on high sodium products would guide individuals to food choices that will help them stay within recommended intake levels. This approach would not only support individual decision-making, but more generally would create more awareness of the risks associated with high salt and potentially enhance demand for lower sodium products, thus creating incentive for voluntary industry reductions. The level of sodium in a product that would require the placement of a high sodium warning label should be determined by food category, rather than a proportion of daily allowance, taking into consideration a number of factors, such as the variability of sodium levels within that category, and the product's functional and safety needs as they relate to sodium.

Requiring high sodium warning labels is not an unprecedented approach to sodium reduction. Since 1993, Finland has required a "high salt content" warning on food packages for certain products. Currently, it is required if the salt content is more than: 1.1% by weight in bread, 1.7% in sausages, 1.3% in cheese, 1.9% in butter, and 1.6% in breakfast cereals or crisp bread.¹⁸ These levels are lower than originally instituted. These warning labels have been effective, leading to reduced average salt content of most of the important food categories, including a reduction in the average salt content in bread by 20% (from 1.5% to 1.2%) and sausages by 10%. The sales of products changed, which encouraged product reformulation and has resulted in products with lower salt content overall.¹⁹ In Finland, coronary heart disease decreased by 65% between 1972 and 1997.²⁰ While there are a number of possible causes, sodium intake has decreased substantially during that time. From 1979 to 2002, salt intake in Finland, measured by urinary sodium excretion, dropped 29% in men and 38% in women.²¹

Issue guidance on maximum recommended sodium levels by product type

Implicit in placement of front-of-package high sodium warning labels is the development and publication of clear guidance on healthy sodium levels for various food categories. Recommended maximum limits of sodium in processed foods must be established and formalized as recommended targets for industry. Industry would be expected to achieve these targets gradually within a defined timeframe. For example, when examination of a food category shows that there are some products with much higher sodium content than others, this guidance will provide a standard to help accelerate shifting down sodium content.

We realize that there are some products - such as cured meats, or ingredients, such as seasonings - that pose special challenges, and for which specific provisions would need to be carefully developed, but other governments, besides Finland, are tackling these issues and so should ours. The UK has successfully negotiated industry reductions across 85 food categories, demonstrating the feasibility of near universal reductions.²² Reductions of sodium in processed food are not only feasible, but when implemented gradually and across multiple brands, can be accomplished without a change in consumer acceptance.^{23,}

This strategy to assure healthier sodium levels across all products relies on a partnership between government and industry that can work. But it is worth observing that the long-ago FDA dietary sodium initiative noted earlier gave as its final point of action “to consider the need for legislation in the event this voluntary program does not succeed.” We echo these words and urge that a timeline be set for the development of guidance for maximum recommended salt content and its adoption by industry. If this process fails, a regulatory strategy addressing sodium content should be implemented.

Conclusion

The New York City Department of Health and Mental Hygiene (DOHMH) urges the FDA to implement mandatory, national labeling that would require front-of-package high sodium content warning on foods that contain high sodium for their food category. NYC DOHMH also urges the FDA to issue federal guidance on maximum recommended sodium content in commercially processed food products by product category.

Despite decades-long efforts to reduce the prevalence of hypertensive disease, and despite the widespread availability of effective drugs, we have made limited advances in the prevention and control of this leading risk factor for heart disease. Population-wide sodium reduction both can prevent hypertension and consequent heart disease and stroke, and is more effective and far less expensive than pharmacological treatment of high blood pressure – although of course it will only reduce, not eliminate, the need to treat. Reducing dietary sodium intake in processed food is the most important public health strategy available to reduce the occurrence of hypertension and its subsequent health impact. We encourage the FDA to act now.

¹ NYC DOHMH, Office of Vital Statistics. NYC Vital Statistics 2005, Accessed on EpiQuery, 2007.

² Wong M, et al. Contribution of Major Diseases to Disparities in Mortality. *N Engl J Med*, Vol. 347, No 20. November 14, 2002.

³ NYCHANES 2004, unpublished data

⁴ NYCHANES 2004, unpublished data

⁵ Cook NR, et al. Long term effects of dietary sodium reduction on cardiovascular disease outcomes: observational follow-up of the trials of hypertension prevention (TOHP). *BMJ*. 2007; 334:885.

⁶ Dietary Guidelines for Americans, 2005. Accessed on 11/27/07 at: <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/Chapter8.pdf>

⁷ “Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate,” The Institute of Medicine, National Academies Press, 2004, Chapter 6.

⁸ American Heart Association. Sodium: AHA Recommendations. Accessed on 11/23/07 at <http://www.americanheart.org/presenter.jhtml?identifier=4708>

⁹ Dietary Guidelines for Americans, 2005. Accessed on 11/27/07 at: <http://www.health.gov/dietaryguidelines/dga2005/document/pdf/Chapter8.pdf>

¹⁰ American Heart Association. Sodium: AHA Recommendations. Accessed on 11/23/07 at <http://www.americanheart.org/presenter.jhtml?identifier=4708>

-
- ¹¹ NYC Community Health Survey, 2005.
- ¹² Data Tables: 1994 Continuing Survey of Food Intakes by Individuals.
- ¹³ Havas S, et al. Reducing the public health burden from elevated blood pressure levels in the United States by lowering intake of dietary sodium. *Am J Public Health*. 2004; 64:19-22.
- ¹⁴ Dickinson BD, Havas S. Reducing the Population Burden of Cardiovascular Disease by Reducing Sodium Intake. *Arch Intern Med*. 2007; 167:1460-1468.
- ¹⁵ Mattes RD, et al. Relative contributions of dietary sodium sources. *J Am Coll Nutr*. 1991.
- ¹⁶ Hayes AH. FDA's Dietary Sodium Initiative-in the War Against Hypertension, a New Weapon. *Public Health Reports*. 1983; 96:207-210.
- ¹⁷ Briefel RR, et al. Secular trends in dietary intake in the US. *Annu Rev Nutr*. 2004. (NHANES)
- ¹⁸ Personal communication with Pirjo Pietinen on June 28, 2007.
- ¹⁹ Karppanen H, Mervaala E. *Progress in Cardiovascular Diseases* (Vol. 49, pp. 59-75).
- ²⁰ Vartiainen E, et al. Cardiovascular risk factor changes in Finland, 1972-1997. *Intl Journal of Epidemiology* 2000;29:49-56.
- ²¹ Laatikainen T, et al. Sodium in the Finnish diet: 20-year trends in urinary sodium excretion among the adult population. *European Journal of Clinical Nutrition*, 2006.
- ²² Food Standards Agency, Review of salt reduction targets. Accessed on 11/27/07 at: <http://www.food.gov.uk/healthiereating/salt/salttargetreview>
- ²³ Adams S, et al. Consumer acceptance of foods lower in sodium. *J Am Diet Assoc*. 1995; 95:447-453.
- ²⁴ Williams P, et al. A case study of sodium reduction in breakfast cereals and the impact of the Pick the Tick food information program in Australia. *Health Promotion International*. 2003; 18: 51-56.