THE WESTON A. PRICE FOUNDATION®
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Education ♦ Research ♦ Activism

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Division of Docket Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0400
Docket No. FSIS-2011-0014

Dear FDA:

The Weston A. Price Foundation submits these comments on Docket No. FDA-2011-N-0400 and FSIS-2011-0014, Approaches to Reducing Sodium Consumption.

The Weston A. Price Foundation (WAPF) is a nonprofit organization with members in every state and internationally. WAPF was founded in 1999 to disseminate the research of Dr. Weston Price, whose studies of isolated nonindustrialized peoples established the parameters of human health and determined the optimum characteristics of human diets. WAPF is dedicated to restoring nutrient-dense foods to the human diet through education, research and activism.

WAPF strongly opposes any restriction on salt by the FDA and FSIS. Salt is an essential nutrient, critical to the preservation and promotion of human health. Government interference in people's choices as to their salt consumption will most likely harm, rather than help, most Americans' health.

By entitling the document "approaches to reducing sodium consumption," the agencies have signaled that they have already made a determination that Americans' sodium consumption should be reduced. But neither history nor the scientific evidence support this approach.

I. A brief history of salt

The use of salt by humans is intimately connected with our advance from hunter-gatherers to agriculture. Salt is needed to make agricultural products such as grains taste good and to preserve meats and dairy foods for storage and transport. Increased use of salt led to increased production of glial cells in the brain, the cells that make humans capable of creative thinking and long-term planning.

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A 1963 article published in Scientific American describes the social influence of salt.[1] The hunter-gatherer obtains the salt he needs from the blood of animals, which concentrate salt from the plants that they eat. Thus, areas where there is very little sodium in the soil will support only small numbers of humans living as hunter-gatherers. In increasing the density of human populations, salt became an important trade item. The salt trade, over land and sea, had significant military, social and political consequences.

The quest for salt led to the development of the major trade routes in the ancient world. A map of the world showing the major accessible salt deposits shows that these coincide with where civilizations developed—in Jordan, the Tigris-Euphrates, the Yellow River of China, the salt swamps in Persia, the deserts of Egypt and the Sahara; in the New World in Central America, the Andes and the Great Lakes; and finally on the seacoasts in areas of abundant sunshine, where salt could be obtained from evaporated sea water.

II. The health impacts of salt

Salt provides two elements that are essential for life and for good health: sodium and chloride. The body cannot manufacture either element itself, so they must be supplied by food.

Sodium plays a critical role in body physiology. It controls the volume of fluid in the body and helps maintain the acid-base level. About 40 percent of the body's sodium is contained in bone, some is found within other organs and cells, and the remaining 55 percent is in blood plasma and extracellular fluids. Sodium is important in proper nerve conduction, in aiding the passage of various nutrients into cells, and in the maintenance of blood pressure. Sodium-dependent enzymes are required for carbohydrate digestion, to break down complex carbohydrates and sugars into monosaccharides such as glucose, fructose and galactose; sodium is also involved in transporting these monosaccharides across the intestinal wall. Although salt is the most common dietary source for these essential elements, sodium is also available from various foods that contain sodium naturally.

Chloride ions also help maintain proper blood volume, blood pressure, and pH of body fluids. Chloride is the major extracellular anion and contributes to many body functions including the maintenance of blood pressure, acid-base balance, muscular activity, and the movement of water between fluid compartments. Chloride is the major component of hydrochloric acid, which is needed for protein digestion. Symptoms of hypochlorhydria (low hydrochloric acid) include bloating, acne, iron deficiency, belching, indigestion, diarrhea and multiple food allergies. Chloride is available in very few foods, and adequate chloride must be obtained from salt.

A. Salt restriction does not prevent high blood pressure for the majority of people

One of salt's major functions is to regulate blood volume and pressure, including the flexibility of the blood vessels. Blood pressure can be affected by stress, age, exercise, heredity and diet.

[1] MR Bloch, The Social Influence of Salt, July 1963, reprinted in Scientific American, 1978.

If salt consumption and hypertension were linked, as the agency's contend, both would be rising. But a 2010 paper by two Harvard researchers shows that while hypertension has increased among Americans over the last forty years, sodium consumption has remained flat.[2]

While excess sodium consumption does increase blood pressure in certain sensitive individuals, increased salt intake does not raise blood pressure in most people. In an average population when salt intakes are reduced, about 30 percent will experience a small drop in blood pressure (between one and four mm Hg), while about 20 percent will experience a similar increase in blood pressure. The remaining 50 percent of the population will show no effect at all of salt intake reduction. In most people, even a significant increase in salt consumption does not raise blood pressure.[3]

B. Salt restriction can cause significant health problems

As discussed above, salt plays an important role in many of our body's systems. As a result, low-salt diets have been linked to a wide range of health problems.

A study from 1991 indicates that 7.2 g of salt is the minimum amount of salt people need. The researchers found that intake of less than 120 mmol per day of sodium, the amount found in 7.2 g of salt, caused plasma rennin levels to spike[4] and signaled the rennin-angiotensin-aldosterone system (RAS) to recoup sodium from the waste stream. Notably, a recent article in the *American Heart Journal* identified strategies for blocking excess levels of rennin and aldosterone as key steps for controlling cardiovascular disease.[5] The logical corollary is that it is best to avoid elevating RAS levels in the first place, which requires adequate consumption of salt.

The evidence of problems from low-salt diets has mounted in recent years. A 2008 study indicated that low-salt diets induce alterations in plasma lipoproteins and in inflammatory markers that are common features of metabolic syndrome (a precursor to heart attack, stroke, and diabetes) in healthy adults.[6] In a 2009 study, low-salt diets resulted in much higher rates of mortality and hospital readmissions in patients with congestive heart failure compared to similar

[2] Bernstein and Willett. Trends in 24-h urinary sodium excretion in the United States, 1957-2003: a systematic review. Am. J. Clin. Nutr. 92(5):1172-80 (2010).

[3]Miller et al. Heterogeneity of blood pressure response to dietary sodium restriction in normotensive adults. J. Chronic Dis., 40(3): 245-50 (1987).

[4] Alderman et al. Association of Renin-Sodium Profile with the Risk of Myocardial Infarction in Patients with Hypertension, 324 N. Engl. J. Med. 1098-1104 (1991).

[5] Fonarow et al. Potential impact of optimal implementation of evidence-based heart failure therapies on mortality. 161 Am. Heart J. 1024-30 (2011).

[6] Nakandakare et al. Dietary salt restriction increases plasma lipoprotein and inflammatory marker concentrations in hypertensive patients. Atherosclerosis 200(2): 410-16 (2008).

patients on a regular salt diet.[7] A 2010 Harvard study linked low-salt diets to an increase in insulin resistance, the condition that is a precursor to type 2 diabetes, within just seven days.[8] This study is consistent with earlier studies showing insulin resistance from chronic salt restriction.[9]

Recent studies out of Australia show that individuals with type 1 or type 2 diabetes die in much greater numbers when placed on a salt-restricted diet, from both cardiovascular causes and all causes of death.[10]

While the agencies assume that salt restriction can help prevent heart attacks, high blood pressure and strokes, evidence to the contrary continues to accumulate. A 2010 government-funded study published in the *Journal of the American Medical Association* finds that even modest **reductions** in salt intake are associated with an **increased** risk of cardiovascular disease and death.[11] Similarly, an examination of the largest U.S. federal database of nutrition and health (NHANES), published in the *Journal of General Internal Medicine*, found a higher rate of cardiac events and death with patients put on low-salt diets. [12]

Salt restriction harms people of all ages. A 2006 study showed that elderly people with hyponatremia (low sodium levels), have more falls and broken hips and a decrease in cognitive abilities.[13] Salt limitations also harm young children. A 2007 study found that babies with low birth weight are also born with low sodium in their blood serum because their mothers were on low-salt intakes.[14] Another study found that infants with low sodium may be predisposed to poor neurodevelopmental function between the ages of ten and thirteen.[15]

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[7] Paterna et al. Medium term effects of different dosage of diuretics, sodium, and fluid administration on neurohormonal and clinical outcomes in patients with recently compensated heart failure. Am. J. of Cardiology 103(1): 93-102 (2009).

[8] Garg et al. Low-salt diet increases insulin resistance in healthy subjects. Metabolism, 2010, http://www.sciencedirect.com/science/article/pii/S002604951000329X.

[9] Ruivo et al. Isnulin resistance due to chronic salt restriction is corrected by α and β blockade and by l-arginine. Physiology and Behavior 88(4-5):364-70 (2006).

[10] Ekinci et al. Dietary salt intake and mortality follow-up in the third national health and nutrition examination survey (NHANES III). J. Gen. Intern. Med. 23(9):1297-302 (2008). *See also* Ekinci et al. Dietary Salt Intake and Mortality in Patients With Type 2 Diabetes. Diabetes Care 34:861-866 (2011).

[11] Stolarz-Skrzypek et al. Fatal and Nonfatal Outcomes, Incidence of Hypertension, and Blood Pressure Changes in Relation to Urinary Sodium Excretion. JAMA 305(17):1777-85 (2011).

[12] Cohen et al. Sodium intake and mortality follow-up in the Third National Health and Nutrition Examination Survey (NHANES III). J Gen Intern Med. 2008 Sep;23(9):1297-302 (2008).

[13] Renneboog et al. Mild Chronic Hyponatremia Is Associated With Falls, Unsteadiness, and Attention Deficits. Am. J. of Med, 119(1): 71.e1-71.e8 (2006).

[14] Shirazki et al. Lowest neonatal serum sodium predicts sodium intake in low birth weight children. Am J Physiol Regul Integr Comp Physiol. 292(4):R1683-9 (2006).

III. Dangers from salt alternatives

The government's proposal comes as a new salt substitute, Senomyx, is ready to enter the marketplace. The Senomyx salt substitute is a chemical product that works in the body as a neurological agent, causing an individual to perceive a salty taste. It would seem to be nothing more or less than a neurotrophic drug.

Because the maker of the Senomyx product calls it a food, it does not require the extensive testing that would be required for a neurotrophic drug. To our knowledge, there has been no testing of the Senomyx salt substitute for safety, and it is so potent that the amount needed in food is below the amount requiring FDA approval. Furthermore, it will never be disclosed on food labels as "Senomyx", but rather hidden under the term "artificial flavor."

While consumers can make informed choices about how much salt to consumer because of the labeling requirements, Americans will be unable to make informed choices about consuming Senomyx, a novel and potentially dangerous food additive.

Reducing salt content in foods and replacing it with Senomyx is also likely to lead to many increased health problems by reducing salt consumption below the minimum needed for health, as outlined above. It may also increase rates of obesity because our bodies really do need salt. What happens when we eat foods that taste salty but don't satisfy our requirements for salt? We will feel the urge to eat more and more until our requirements for salt are satisfied.

IV. The loss of nutrient-dense foods

The agencies specifically requested comments related to "avoiding potential unintended consequences for food safety, nutrition, or food manufacturing technologies." Unfortunately, salt restrictions will unavoidably harm the production of many nutrient-dense foods.

Cheeses, in particular, often rely on salt as part of the overall food safety protocols as well as for flavor. Artisan cheeses are of particular concern. Consumers choose artisan cheese not only for superior taste but also for nutritional value. Cheese made from whole milk of pasture-fed cows is a highly nutritious, complete food, providing calcium, phosphorus and a gamut of minerals, a range of B vitamins including B6 and B12, fat-soluble vitamins A, D, E and K and even vitamin C. Numerous researchers have reported bactericidal and/or bacteriostatic effects on pathogenic bacteria in cheese because of reduced moisture, low water activity, low pH as the result of organic acid production, competing flora, biochemical metabolites, bacteriocins, ripening, **and**

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[15] Al-Dahhan et al. Effect of salt supplementation of newborn premature infants on neurodevelopmental outcome at 10–13 years of age. Arch Dis Child Fetal Neonatal Ed. 86(2): F120–F123. doi: 10.1136/fn.86.2.F120 (2002).

salt either singly or in combination.[16] In brief, raw milk cheese can be produced so as to create an environment in which pathogens cannot multiply. But restrictions on salt content could result in unsafe cheeses or the abandonment of several kinds of popular artisan cheeses.

Lacto-fermented vegetables also often contain high levels of salt. There is a rapidly growing market in the U.S. for lacto-fermented vegetables for both their taste and their nutritional value. The process of lacto-fermentation was traditionally used to preserve vegetables for long periods without the use of freezers or canning machines. Like the fermentation of dairy products, preservation of vegetables and fruits by the process of lacto-fermentation has numerous advantages beyond those of simple preservation. The proliferation of lactobacilli in fermented vegetables enhances their digestibility and increases vitamin levels. These beneficial organisms produce numerous helpful enzymes as well as antibiotic and anticarcinogenic substances. Their main by-product, lactic acid, not only keeps vegetables and fruits in a state of perfect preservation but also promotes the growth of healthy flora throughout the intestine. Other alchemical by-products include hydrogen peroxide and small amounts of benzoic acid.

A partial list of lacto-fermented vegetables from around the world shows the universality of this practice. In Europe the principle lacto-fermented food is sauerkraut. Described in Roman texts, it was prized for both for its delicious taste as well as its medicinal properties. Cucumbers, beets and turnips are also traditional foods for lacto-fermentation. Less well known are ancient recipes for pickled herbs, sorrel leaves and grape leaves. In Russia and Poland one finds pickled green tomatoes, peppers and lettuces. Lacto-fermented foods form part of Asian cuisines as well. The peoples of Japan, China and Korea make pickled preparations of cabbage, turnip, eggplant, cucumber, onion, squash and carrot. Korean kimchi, for example, is a lacto-fermented condiment of cabbage with other vegetables and seasonings that is eaten on a daily basis and no Japanese meal is complete without a portion of pickled vegetable. American tradition includes many types of relishes--corn relish, cucumber relish, watermelon rind--all of which were no doubt originally lacto-fermented products. The pickling of fruit is less well known but, nevertheless, found in

[16] *See, e.g.,* Babel, F. J. 1977. Antibiosis by lactic culture bacteria. J. DAIRY SCI. 60:815–821; Bachmann, H.P., and U. Spahr. 1995. The fate of potentially pathogenic bacteria in Swiss, hard and semihard cheeses made from raw milk. J. DAIRY SCI. 78(3):476–483; Daly, C., W. E. Sandine, and P. E. Elliker. 1972. Interaction of food starter cultures and food-borne pathogens: Streptococcus diacetylactis versus food pathogens. J. MILK FOOD TECHNOL. 35(6):349–357; Dominguez, L., J. F. F. Garayzabal, J. A. Vazquez, J. L. Blanco, and G. Suarez. 1987. Fate of L. monocytogenes during manufacture and ripening of semi-hard cheese. LETT. APPL. MICROBIOL. 34:95–100; Ehlers, J. G., M. Chapparo-Serrano, R. Richter, and C. Vanderzant. 1982. Survival of Campylobacter fetus subsp. jejuni in Cheddar and cottage cheese. J. FOOD PROT. 45:1018–1021; Frank, J. F., and E. H. Marth. 1977. Inhibition of enteropathogenic Escherichia coli by homofermentative lactic acid bacteria in skim milk. J. FOOD PROT. 40:749–753; Gilliland, S. E., and M. L. Speck. 1972. Interactions of food starter cultures and foodborne pathogens: Lactic streptococci versus staphylococci and salmonellae. J. MILK FOOD TECHNOL. 35(5):307–310; Moustafa, M. K., A. A. -H Ahmed, and E. H. Marth. 1983. Behavior of virulent Yersinia enterocolitica duri\ng manufacture and storage of Colbylike cheese. J. FOOD PROT. 46(4):318–320; Reiter, B. 1985. Interaction between immunoglobulins and innate factors such as lysozyme, lactoferrin, lactoperoxidase. J. Schaub (ed.) compos. Physiol. Prop. Human Milk, Proc. Intern. Workshop, Elsevier, Amsterdam pp. 271–284; Ryser, E. T., and E. H. Marth. 1999. Incidence and behavior of L. monocytogenes in cheese and other fermented dairy products. L. monocytogenes, Listeriosis and food safety, 2nd ed. Revised and expanded. L. MONOCYTOGENES IN FERMENTED DAIRY PRODUCTS, pp.411-503; Schaak, M. M., and E. H. Marth. 1988. Interaction between lactic acid bacteria and some foodborne pathogens: A review. CULTURED PROD. J. Nov: 14–20; Spahr, U., and B. Url. 1994. Behaviour of pathogenic bacteria in cheese – A synopsis of experimental data. IDF BULLETIN 298:2–16; Speck, M. L. 1971. Control of foodborne pathogens by starter cultures. J. DAIRY SCI. 55:1019–1022.

many traditional cultures. The Japanese prize pickled umeboshi plums, and the peoples of India traditionally fermented fruit with spices to make chutneys.

Imposing restrictions on salt would harm the production and consumption of these nutrient-dense foods, further harming Americans' health.

V. Conclusion

While salt restriction may benefit a small percentage of people with high blood pressure, the science shows no health benefits – and significant health problems – due to salt restriction in the majority of the population. If FDA and FSIS fail to re-examine the basic premise of their current proposal, the result will be increased health problems in young and old, diminished brain function, increased confusion, and a general decrease in Americans' health. The Weston A. Price Foundation urges FDA and FSIS to halt their plans for restrictions on salt, whether voluntary or mandatory, and conduct a thorough review of all the relevant science.

Sincerely,

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