Salt Institute

**STATEMENT OF THE SALT INSTITUTE**
**TO THE FOOD AND DRUG ADMINISTRATION**
**PUBLIC HEARING ON PETITION TO REVISE THE**
**REGULATORY STATUS OF SALT AND ESTABLISH FOOD LABELING**
**REQUIREMENTS REGARDING SALT AND SODIUM**
**NOVEMBER 29, 2007**

## EXECUTIVE SUMMARY

The Salt Institute exists to help Americans enjoy the myriad benefits of salt, including salt for food use. We endorse efforts to improve the quality of the American diet to improve health outcomes. We support FDA's previous review confirming the wisdom of considering salt as a GRAS substance and urge FDA to deny the CSPI petition seeking to repeal GRAS for salt and have FDA regulate the amount of salt food manufacturers can include in their products.

Public health decisions should be based on scientific evidence, not so-called "expert opinion," even though prominent experts have weighed in on both sides of this ongoing controversy. The body of evidence on the question of whether reducing dietary salt will improve cardiovascular health does not support a population intervention. While salt is clearly a factor in determining blood pressure, blood pressure itself is an intermediate variable. Other intermediate variables create unintended metabolic consequences when salt is reduced. These include increased insulin resistance, elevated plasma renin activity and microvascular and tubulointerstitial injuries and more.

Policy should be based on endpoint outcomes like cardiovascular mortality or all-cause morality. Since only observational studies have examined this crucial question, the federal government should fund a high quality controlled trial of the question: will sodium-reduced diets improve health outcomes? The one salt-reducing population highlighted by salt reduction advocates, Finland, has a less impressive record of improved health outcomes than other European and North American countries that have not reduced dietary salt.

Likewise, there is no evidence for a second crucial assumption: that Americans who substitute low-sodium foods into their diets will achieve the forecast low-sodium diets. Since there is evidence that suggests that salt is a food limiter for other animal species, this question should be tested for humans.

Salt deserves its reputation as the original GRAS substance. It is ubiquitous in our foods. Salt performs an essential role in foods, extending far beyond taste (itself being complicated because of salt's role in modulation of "bitter" and "sweet" as well as affecting the "salty" taste). Salt contributes to product quality and identity and, importantly, to food safety. Replacing salt isn't easy, as food technologists have discovered while investing many millions of dollars over the past 30

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years. Another challenge is demonstrating the safety of any salt replacer should it be used in significant amounts instead of sodium chloride.

Any rule to limit sodium in foods would need to meet the standards of the Sanitary and Phytosanitary Agreement policed by the World Trade Organization and its effect on iodine nutrition would need to be determined since iodized salt is the mainstay of the global campaign against mental retardation caused by iodine deficiency.

A more promising approach than any single nutrient intervention would be to promote a food-based effort to improve the overall quality of the American diet. Indices of healthy eating have been associated with improvements in cancer risk, cardiovascular health and all-cause mortality. Correcting current deficiencies in potassium, calcium and magnesium by encouraging greater consumption of fruits, vegetables, whole grains and dairy products would be a superior strategy.

## INTRODUCTION

The Salt Institute was established in 1914 and for nearly a century has represented salt manufacturers in their mission of helping Americans enjoy the benefits of sodium chloride while minimizing any deleterious, unanticipated consequences. Convinced in the 1960s of the adverse impacts of highway deicing salt, for example, the Institute pioneered the concept of "Sensible Salting" to ensure environmental protection and enable roadway maintenance agencies to use salt for its lifesaving mission of preserving safe winter driving conditions. Likewise, at least since the 1970s, the Salt Institute has been an active participant in the public discussion of dietary salt and its role in human health and nutrition and we participated with FDA in devising labels in the 1980s which inform consumers of the sodium content of processed foods. We are pleased to have this opportunity to provide our comments on the CSPI citizen's petition asking that FDA consider its earlier decisions declaring salt as Generally Recognized as Safe (GRAS) and provide appropriate consumer labeling information.

Our perspective incorporates the "Background and Purpose" of the Dietary Guidelines for Americans which state:

> "Given the importance of a balanced diet to health, the intent of the *Dietary Guidelines* … recommendations [is] for an overall pattern of eating that can be adopted by the general public. These patterns are exemplified by the USDA Food Guide and the DASH Eating Plan….A basic premise of the *Dietary Guidelines* is that nutrient needs should be met primarily through consuming foods. Another important premise of the *Dietary Guidelines* is that foods should be prepared and handled in such a way that reduces risk of foodborne illness."[1]

[1] USDHHS and USDA, *Dietary Guidelines for Americans 2005*, Chapter 1, "Background and Purpose." http://www.health.gov/dietaryguidelines/dga2005/document/pdf/DGA2005.pdf.

We encourage FDA to ensure that its review contributes to practical steps that can be adopted by the general public to improve the overall quality of the American diet through better food choices.

**BACKGROUND**

Salt is likely the most ubiquitous food ingredient in the United States. Federal law classifies food ingredients as either "food additives" or GRAS substances. "Food additives" require FDA pre-market review and approval; if an ingredient is a "food additive," it cannot lawfully be added to food unless its intended use complies with a Food and Drug Administration (FDA) regulation. Substances that are GRAS, however, are exempt. A substance is GRAS if it is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . ."[2] FDA, of course, recognizes that "[i]t is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance."[3] In other words, "reasonable certainty of no harm" does not mean "certainty of no theoretical possibility of harm."

The statute provides that a GRAS determination may be based either on "scientific procedures" or common use in food prior to 1958. A GRAS determination based on common use in food requires a substantial history of consumption by a significant number of consumers, such that any adverse effects of the ingredient would be observed and recorded. Salt, of course, was a food staple for millennia before 1958. FDA has expressly identified salt as a GRAS ingredient.[4]

No food ingredient in human history has a greater "substantial history" of safe consumption than salt. From the dawn of time, salt has been humankind's most common element. Mentioned copiously throughout the Bible, salt was considered to be "the fifth element," taking an honored place alongside water, earth, air and fire as the key components necessary for the sustenance of life. However primordial the thought might seem today, the fact remains that life was borne from the sea and salt is as essential to life today as it ever was.

No other natural material has as many uses essential to our daily survival, nor has any other food ingredient been used in as broad a range of food products, across a longer span of history in as many countries around the globe. As an element of the diet, only one other nutrient has as common a need – water. Common salt, whether derived from ancient or modern seas, has been consumed by humans and animals in complete safety for longer than any other essential nutrient.

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[2] FFDCA § 201(s).

[3] 21 C.F.R. § 170.3(i).

[4] 21 C.F.R. § 182.1(a). FDA has also suggested that many uses of salt are subject to "prior sanctions" (i.e. pre-1958 authorizations), a separate statutory category under which food ingredients may be lawfully used.

It is little wonder that, during the initial evolution of the GRAS concept, salt was always portrayed as the archetype of what a GRAS substance should be. There was no other natural ingredient added to as many foods that had stood the test of time in terms of safety and utility.

The GRAS list arose out of deliberation on the 1958 food additive law, according to the FDA Oral History papers. During the Congressional hearings, the FDA Commissioner was asked to give a list of examples of ingredients that would not be regarded as a food additive since they were generally recognized as safe. The very first item he mentioned was salt. Shortly thereafter, it was decided to draw up a formal GRAS list. Indeed, according to the testimony of William W. Goodrich, whenever an example of a product on the GRAS list was called for, salt was the material always chosen.[5] This was not surprising because salt was the most ubiquitous ingredient in the entire range of foods prepared around the world and had proven to be safe for thousands of years.

Salt consumption has taken take place on every continent from the dawn of pre-civilization. Salt is added to commercial processed foods, to restaurant foods and to foods cooked at home. If consumers were not satisfied with the salt level in their foods, regardless of source, they inevitably exercised the option to voluntarily add more salt whenever they wanted. Salt is the most universal food ingredient and, after water, the most widely consumed nutrient.

If any one product exemplified what a GRAS substance is, it is salt.

Over the years, the methodology of having a substance qualify for the GRAS list has changed, however, that has not had a bearing on the status of salt. Salt is a safe component of food - a fact known by both scientist and lay person for millennia.

The current level of salt in commercial foods has been questioned because of salt's unquestioned link to blood pressure. While indisputable, this link is heterogeneous and influenced by multiple dietary and metabolic relationships suggesting that a holistic, outcomes-oriented analysis is required. We'll discuss this further below, but one key element of the salt/blood pressure relationship is that the blood pressure effects of "excess" salt intake are mitigated when individuals consume an overall quality diet. Evidence shows that the unintended adverse consequences of salt-reduced diets can be avoided with a quality diet. Further, evidence shows a strong link of overall dietary quality to improved health outcomes.

## ALLEGATIONS OF ADVERSE EFFECTS OF DIETARY SALT ARE OFF TARGET

Against the long list of organizations who advocate universal salt reduction, just a few quotes for balance. The U.S. Preventive Services Task Force (HHS) maintains:

> "There is insufficient evidence that, for the general population, reducing dietary sodium intake or increasing dietary intake of iron, beta-carotene, or other antioxidants results in improved health outcomes ("C" recommendation);

[5] Goodrich, William W. Oral history of the U.S. Food and drug Administration, Interviewed by R.T. Ottes and F.L. Lofsvold, Rockville, MD, October 15, 1986.

> recommendations to reduce sodium intake may be made on other grounds, including potential beneficial effects on blood pressure in salt sensitive persons." [6]

The Cochrane Review on "reduced dietary salt for prevention of cardiovascular disease" concludes:

> "Intensive interventions, unsuited to primary care or population prevention programmes, provide only minimal reductions in blood pressure during long-term trials. Further evaluations to assess effects on morbidity and mortality outcomes are needed for populations as a whole and for patients with elevated blood pressure."[7]

A joint statement of the Canadian Hypertension Society, the Canadian Coalition for High Blood Pressure Prevention and Control, the Laboratory Centre for Disease Control at Health Canada, and the Heart and Stroke Foundation of Canada cautioned:

> "Restriction of salt intake for the normotensive population is not recommended at present, because of insufficient evidence demonstrating that this would lead to a reduced incidence of hypertension."[8]

The late Dr. Lawrence M. Resnick, then executive editor of the *American Journal of Hypertension*, and a member of the Food and Nutrition Board/IOM panel on water and electrolytes disputed the panel's published conclusions, stating:

> "The recommendations of the panel to further reduce dietary sodium intake beyond that already recommended in the past is not justified by a fair analysis of the evidence quoted in the report. A fair discussion of the data does not allow us to come to a universal recommendation about dietary sodium for the population as a whole."

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[6] US Preventive Services Task Force/HHS. Chapter 56 on "Counseling to Promote a Healthy Diet," page 634. http://www.ahrq.gov/clinic/uspstfix.htm.

[7] Hooper L, Bartlett C, Davey Smith G, Ebrahim S. Reduced dietary salt for prevention of cardiovascular disease (Cochrane Methodology Review). In: *The Cochrane Library*, Issue 4, 2003. Chichester, UK: John Wiley & Sons, Ltd.

[8] Fodor, et. al, Joint statement of the Canadian Hypertension Society, the Canadian Coalition for High Blood Pressure Prevention and Control, the Laboratory Centre for Disease Control at Health Canada, and the Heart and Stroke Foundation of Canada, *CMAJ*, May 4, 1999; 160 (9Suppl) S29. Five years later, these same organizations revisited the issue and recommended against a universal reduction of dietary salt. In fact, their recommendation is that a majority of Canadians do not need to reduce salt intake. Salt reduction should be limited to hypertensives and those at "high risk" – defined to mean those that are both salt-sensitive and have DBPs in the 80-89 mmHg range. RM Touyz, N Campbell, A Logan, N Gledhill, R Petrella and R Padwal. The 2004 Canadian recommendations for the management of hypertension: Part III – Lifestyle modifications to prevent and control hypertension. *Canadian Journal of Cardiology* (2004) 20;1:55-59.

He went even further in an interview published by Fox News, calling the recommendations "nonsense."[9]

Last year's Presidential Address at the International Society of Hypertension was devoted entirely to the continuing controversy over whether or not to reduce population intakes of dietary salt (the incumbent President outlining his reasons for opposing universal sodium reduction and suggesting how to resolve the controversy among scientists). We commend this 37-minute video of the address, "Salt, Blood Pressure and Cardiovascular Disease"[10] to FDA in its understanding of the basis for skepticism about the evidentiary basis for universal sodium reduction.

Why are professionals in the field, recognized experts in this specialty, in such fundamental disarray on whether this is a good idea? The simple and basic reason is whether one asks: will achieving an overall reduction in dietary sodium reduce population blood pressure? Or, instead, asking: will reducing overall dietary sodium improve cardiovascular health, reduce cardiovascular and all-cause mortality and contribute to longer, healthier lives? Asked the first way – making blood pressure the endpoint variable – invites the conclusion that salt reduction confers a benefit; that "benefit" is then the modeled result of calculations showing that populations with (native) lower blood pressure levels have lower incidence of cardiovascular events. Asked the second way – making hard endpoints like heart attack rates, mortality statistics and national lifespan estimates – produces a different conclusion: that there is no overall relationship of salt intake levels and a population health outcomes improvement.

This is a crucial point, of course, since if the alleged "benefit" is the product of a statistical model whose assumptions are open to scientific dispute, then FDA's further consideration of this matter becomes moot. We'll review the evidence below, but would caution that this is only the first of several important stepping stones in the path towards the objective of CSPI's citizen's petition: imposing regulatory controls over the amount of salt food manufacturers can use in their products. FDA needs to understand myriad technical considerations and one further leap in assumed relationship before it is prepared to analyze whether Americans can be expected to receive some health benefit by reducing the amount of salt in a serving of any particular food.

## LESSONS ABOUT SALT AND BLOOD PRESSURE

Beyond the point of controversy, above, about which question to ask, we have learned a number of lessons about salt and blood pressure. We know that (native) blood pressure is a useful indicator of CV health. We know that many people's blood pressure responds to changes in salt intake with, depending on definitions, about one-third of individuals experiencing a blood pressure fall when salt is restricted significantly while another quarter of the population actually increases blood

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[9] Milloy, S. Feds Press Salt Assault. Fox News, Feb. 11, 2004. http://www.foxnews.com/story/0,2933,111285,00.html.

[10] Alderman, Michael H. Dietary sodium, blood pressure, and cardiovascular disease. Presidential address to International Society of Hypertension, Fukuoka, Japan, October 18, 2006. http://webcasts.prous.com/template/player.asp?id=4760&q=128&v=wm&webcast=ISH2006

pressure in that circumstance. Most individuals respond only very modestly, but, overall, a significant reduction in salt intake should produce a modest reduction in population blood pressure. So let's not waste time on this question. If blood pressure is important, then the critical questions are: Who (and how many) will lower BP by cutting salt? Who (and how many) will increase BP by cutting salt? What explains the heterogeneity? Fortunately, we have some answers; not all. Work at the University of Indiana clearly establishes the pattern: a bell curve where some individuals respond strongly in both directions while most are unaffected.[11] What we have learned in the past decade is that the presumed genetic differences are a poor indicator of "salt sensitivity." More important, is nutrient interaction: the dietary context of salt consumption. If individuals have inadequate intakes of other dietary electrolytes – potassium, calcium and magnesium – they are much more likely to be "salt sensitive." Further evidence comes from the NHLBI-funded DASH trials. Comparing the "control" diet to the "DASH Diet" produced enormous blood pressure change (11.4 mmHg SBP for hypertensives); when a second trial added a 60% reduction in sodium, that same hypertensive group achieved only slightly "improved" blood pressure (11.5 mmHg), yet NHLBI interpreted it as proof that "The DASH diet plus reduced dietary sodium lowers blood pressure for all persons."[12] It was not until after the most recent Dietary Guidelines Advisory Committee had filed its report – that data were published showing that six of the eight subgroups had no statistically significant association.[13] We still don't have the data required to analyze this

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[11] Luft, FC and Weinberger, MH. Heterogeneous responses to changes in dietary salt intake: the salt-sensitivity paradigm. *American Journal of Clinical Nutrition* 1997; 65 (suppl):612S-7S. Also see Miller, JZ et al. Heterogeneity of blood pressure response to dietary sodium restriction in normotensive adults. *Hypertension* 1986;8(suppl II):II-127-34. Others have replicated these findings (e.g. Ruppert, M. et al. Neurohumoral and metabolic effects of severed and moderate salt restriction in non-obese normotensive adults. *Journal of Hypertension* 1993;11:743-9.

[12] NHLBI Study Finds DASH Diet and Reduced Sodium Lowers Blood Pressure for All. National Heart, Lung and Blood Institute news release December 17, 2001. Accessed November 27, 2007 at http://www.nhlbi.nih.gov/new/press/01-12-17.htm.

[13] Bray, GA et al. A further subgroup analysis of the effects of the DASH diet and three dietary sodium levels on blood pressure: results of the DASH-Sodium Trial. *American Journal of Cardiology* 2004;94:222-227) shows conclusively that there is no statistical benefit of reducing dietary salt for the vast majority in the DASH-Sodium Trial. The DASH-Sodium authors tried to find an association. They constructed a model rather than use actual data, yet they could identify no statistically significant relationship between sodium intake level and blood pressure in six of the eight DASH Diet subgroups they reported (and the authors did not report the overweight subgroup). Continued failure to disclose key portions of the subgroup analyses had been challenged earlier in the *New England Journal* ("Dietary Sodium and Blood Pressure," *New England Journal of Medicine* 2001; 344:22).

What is clear in DASH-Sodium is that:

- In every subgroup, the "DASH effect" outweighed the "Sodium effect" on blood pressure.
- For normotensives, the DASH diet eliminated "salt sensitivity" entirely.
- For hypertensives, the DASH diet greatly reduced "salt sensitivity."
- For males, the DASH diet eliminated "salt sensitivity" no matter what the blood pressure.
- For females, the DASH diet greatly reduced "salt sensitivity."
- For subjects 45 years of age and younger, the DASH diet eliminated "salt sensitivity."
- For subjects over 45, the DASH diet greatly reduced "salt sensitivity."
- For Caucasians, the DASH diet virtually eliminated "salt sensitivity" no matter what the blood pressure, gender and age).
- For African-Americans, the DASH diet substantially reduced "salt sensitivity."

study.[14] The founding chairman of the American Society of Hypertension, John Laragh (the subject of a cover story in *Time* magazine, incidentally[15]), offered his very expert view that:

> "In neither of the publications of the DASH-Sodium Trial was I able to identify a complete and objective presentation of the data that would allow an appropriate independent expert or entity to determine the validity of NHLBI's interpretation. Specifically, only a full presentation of the mean blood pressures, their SDs and sample size for each of the subgroups that NHLBI stated in the *NEJM* paper the study was 'powered' to test for, would suffice to confirm independently the validity of their public statements. Such a 'table' of the data did not appear in either publication."[16]

In summary, we have some confidence that cutting salt intake in half might lower population blood pressure by several mmHg and we know that this average BP fall masks substantial heterogeneity in the population such that if one accepts the notion that a change of this magnitude has a health consequence, we must accept that the "benefits" are offset by additional risks for those BP rises as they cut salt. We also should have substantial confidence that blood pressure improvements are a product of the interaction of dietary electrolytes, not simply the sodium intake level.

## LESSONS ABOUT SALT AND NON-BLOOD PRESSURE EFFECTS

"Excess" salt has been blamed for nearly every imaginable human malady. Like the alleged link of salt to cardiovascular risk though blood pressure, a few have some plausible pathway. For example, there is strong consensus of a direct relationship of sodium excretion and calcium excretion.[17] Some have argued this is further evidence of the need for salt reduction, but calcium experts would more likely point out the limited calcium conservation benefits of impossibly-large sodium reductions. Some would implicate salt in the high gastric cancer rate in the high-salt-consuming Japanese population, but the intake levels that apparently produce the adverse effect are far greater than the consumption range in the American diet; whatever the possible merit of the relationship, the situation would apply to very few Americans.

The other side of that coin, impacts of reduced-salt diets on other chronic disease risk factors is relevant only to offset the unwavering, laser-focused attention being given by groups like CSPI to

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[14] The Salt Institute and a number of other expert researchers have sought the simple subgroup blood pressures including the standard deviations and sample sizes. These data have been promised, though that promise has never been fulfilled. Before accepting as evidence that DASH-Sodium actually supports the authors' conclusions that all groups benefited from the intervention, FDA should demand to see these data. See McCarron, David A. DASH-Sodium trial: where are the data? *American Journal of Hypertension*, 2003; 16:92-94.

[15] Hypertension: conquering the quiet killer. *Time*, January 13, 1975.

[16] Laragh. J.H. Letter to Douglas Billings, April 1, 2003. Included as supplement to US Chamber/Salt Institute information quality petition to the National Heart, Lung and Blood Institute, May 14, 2003.

[17] Heaney, Robert P. Role of dietary sodium in osteoporosis. *Journal of the American College of Nutrition*, 2006. 25;3:271S-276S.

sodium intake levels on blood pressure to the exclusion of its other known impacts. Of these there are several including many behavioral impacts affecting the consumption of other nutrients.[18] These will be discussed in a subsequent section dealing with food issues. Let us illustrate with three examples.

First, there is abundant evidence that low-salt diets stimulate the renin-angiotensin system and strong evidence linking the resulting heightened plasma renin activity to a more than four-fold increase in heart attacks.[19]

Second, low-salt diets increase insulin resistance. Insulin resistance leads to impaired glucose tolerance, and along with reduced insulin production, to type 2 diabetes mellitus. Insulin resistance is strongly associated with other components of the Metabolic Syndrome including dyslipidemia, inflammation, and hypertension, all leading to cardiovascular disease. NHANES III data indicate that 45% of the U.S. population over age 50 have Metabolic Syndrome, a major risk factor for CV disease.[20]

And, third, that in experimental models, a potentially nephrotoxic agent or biological exerted its adverse effects only when the animals were consuming a low-salt diet; on a normal salt diet the adverse effects did not occur. Upon this discovery, the authors reviewed the literature and reported on the problematic renal impacts of elevated plasma renin activity, hyperactivity of the sympathetic nervous system and use of cyclosporine.[21] Johnson et al confirmed that afferent arteriolopathy was responsible for creating this salt sensitivity by affecting the blood vessels, particularly the diameter of the lumina, which "can markedly reduce blood flow and increase vascular resistance." The authors say it best:

> In summary, we suggest that in many cases of hypertension, the kidney is initially normal but undergoes subclinical injury over time, leading to the development of afferent arteriolopathy (arteriolosclerosis) and tubulointerstitial disease. The initiation of renal injury may be induced by hyperactivity of the sympathetic nervous system, by inappropriate activation or overstimulation of the renin-angiotensin

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[18] Morris, Cynthia D. Effect of dietary sodium restriction on overall nutrient intake. *American Journal of Clinical Nutrition*. 1997;65(suppl):687S-91S. Also see Engstrom, AM et al, Nutritional consequences of reducing sodium intake. *Annals of Internal Medicine*. 1983;98:870-2.

[19] Alderman, Michael H. et al. Association of the renin-sodium profile with the risk of myocardial infarction in patients with hypertension. *New England Journal of Medicine.* 1991 Apr 18; 324(16): 1128-30. Also see Alderman, MH, et al. Plasma renin activity: a risk factor for myocardial infarction in hypertensive patients. *American Journal of Hypertension*, 1997 Jan; 10(1):1-8.

[20] Ruvio, et. al. *Physiology and Behavior*, 2006 (need full citation), Ames, Richard P. *American Journal of Hypertension*, 2001, Feldman and Schmidt, *American Journal of Hypertension*, 1999, Petrie, et al. *Journal of Clinical Endocrinology Metabolism* ,1998, and Catanozi, et. al. *Atherosclerosis*, 2001. In all, we have identified 59 studies that found a linkage between salt intake and insulin resistance

[21] Johnson, Richard J.et al. Subtle acquired renal injury as a mechanism of salt-sensitive hypertension, *New England Journal of Medcine*, 2002 Mar 21; 346(12):913-923.

> system, or by any factor that causes renal vasoconstriction (such as hypokalemia or the use of cyclosporine).

And, they continued: "With continued vasoconstriction, afferent arteriolopathy develops, impairing blood flow and causing persistent renal ischemia." This, they say, explains why salt sensitivity increases with aging. Stated somewhat more simply, with the original injury induced in part by a restricted sodium diet, renal function can no longer maintain the sodium excretory capacity. When the kidneys are then presented with a normal sodium diet, volume expansion occurs and blood pressure increases. The animal or the human would be labeled "salt sensitive." In fact, though, the salt sensitivity is the result of a low sodium diet.

Johnson et al built on earlier work by Bill Bennett on subtle, microvascular and tubulointerstital injury that did not lead to any change in renal function as measured by normal blood tests, serum creatinine, as in the early stages such common clinical tests would not detect the type of tubulo-interstitial injury noted. The authors identified acute renal vasoconstriction as the cause. FDA should keep in mind that after the injury the animals had normal blood pressure on a low salt diet, but became hypertensive on a high salt diet.

The very "solution" sought by CSPI may be responsible for already creating among those who follow the advice to pursue a low-salt diet this subtle renal injury and producing the salt sensitivity that is an identified risk factor for CV events. As these studies show, it is likely that individuals on a low salt diet will be more vulnerable to developing subclinical renal injury from everyday events including many commonly used over-the-counter and prescription drugs. These subtle injuries will predispose them to develop salt-sensitive hypertension in the future. This risk would be particularly troublesome for the older population. Seniors experience a natural decline in renal function with age. A low sodium diet would simply increase that risk. Furthermore they are the subjects most likely to adhere to a lower sodium diet. Individuals on normal salt diets will not be as vulnerable.

One example given in the *NEJM* article was that a chronic low potassium diet (common in African-Americans) induces subtle renal injury. There is a substantial body of experimental literature supporting this view. The Johnson study offers valuable insight into the particular vulnerability documented among African-Americans, older Americans and Americans consuming inadequate amounts of calcium, potassium and magnesium. It is consistent with the salutary effects of the DASH Diet that corrects these electrolyte deficiencies.

Nephrologists – and FDA regulators—clearly understand the use of ACE inhibitors to preserve renal function and slow the progression of disease, as well as preserve cardiac function. Presumably, then, it follows that these experts understand that low sodium diets, which induce the reverse physiologic effect, i.e. volume constriction and the attendant increase in the renin-angiotensin system, cannot be good for the kidney. After all, the HOPE Trial, using this rationale, suggests that heart failure and stokes are a very real potential outcome of low-sodium diets. FDA should consider the obvious inconsistency of promoting the use of ACE inhibitors to improve CV outcomes while also promoting low-sodium diets. It makes no physiological sense.

**THE NET HEALTH EFFECT OF REDUCED SODIUM DIETS**

The most important evidence, to reiterate, is not the blood pressure effect, but the health impact of any intervention, the net effect on health. There are now more than a dozen studies that have examined the health outcomes of reduced sodium diets. They all address the right question, but all are limited since they are observational studies. Their varied findings give no support to a policy of universal salt reduction. In fact, taken as a whole, they fall short of the amount of evidence usually required to justify a controlled trial. Since the current hypertension-based policy has not been confirmed by the health outcomes trials, either the policy should be abandoned or the basic question -- Will reduced-sodium diets deliver a health benefit to the general population? – needs to be tested in a controlled trial.

FDA well recognizes the concept of unintended side effects. Just because a medication is proven "safe and effective" in affecting disease risk factors and FDA authorizes it to be marketed, does not guarantee improved health outcomes. In the area of blood pressure drugs, NHLBI funded the ALLHAT study[22] to compare the health outcomes of four classes of anti-hypertensive drugs, all of which had demonstrated their ability to reduce blood pressure in relative safety. Blood pressure reduction, NHLBI explained, is only an "intermediate variable." NHLBI sought the "hard end points" to determine if any or all of the pharmacologic interventions produced a net health benefit. NHLBI's Dr. Jeffrey R. Cutler supervised the study and explained its importance:

> "Trials are based on the notion that different antihypertensive regimes, despite similar efficacy in lowering blood pressure, have other beneficial or harmful effects that modify their net effect on cardiovascular or all-cause morbidity and mortality."[23]

Halfway through the study, NHLBI stopped one arm of the trial because it determined that an approved intervention, effective in lowering blood pressure, was significantly inferior to other interventions being tested in terms of producing net positive health benefits.[24] Although the drugs were similarly effective in preventing heart attacks and in reducing the risk of death from all causes, NHLBI explained, users of the alpha-adrenergic blocker doxazosin had 25 percent more cardiovascular events and were twice as likely to be hospitalized for congestive heart failure as users of the diuretic chlorthalidone.

So it is with non-pharmacologic "antihypertensive regimes" as well. Non-pharmacologic interventions like salt reduction should be evaluated the same way. Population interventions should improve health and extend life expectancy, not just move "intermediate variables" like blood pressure. As the ALLHAT trial has shown with power and significant impact with regard to choice among pharmacologic interventions, the choice of intervention matters more than the "intermediate

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[22] http://www.sph.uth.tmc.edu/ccct/ALLHAT/default.htm

[23] Cutler, J., Which Drug for Treatment of Hypertension?" *Lancet*, 1999; 353:604-605.

[24] NHLBI Stops Part of Study — High Blood Pressure Drug Performs No Better Than Standard Treatment, NHLBI news release, March 8, 2000. Online at http://www.nhlbi.nih.gov/new/press/mar08-00.htm.

variable" blood pressure effect in terms of whether an intervention provides a net health benefit after factoring in its negative side-effects. The federal government should not be recommending that everyone change his or her diet without evidence of some overall health benefit.

The string of salt health outcomes studies actually began in 1985, though the original study by Kagan,[25] which found no population benefit in reduced-salt diets, was ignored for a decade before the prominence of the next investigator, Dr. Michael H. Alderman, made ignoring "politically incorrect" conclusions impossible. There then followed health outcomes studies by Alderman (hypertensive patients),[26] Cutler (MRFIT),[27] Pedhoe-Tunstall (Scottish Heart Health Study),[28] Alderman (again, NHANES ),[29] Valkonen,[30] Cohen (MRFIT),[31] He (NHANES),[32] Tuomilehto[33] and

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[25] Kagan, A, Popper, JS, Rhoads, GG, Yano, K. Dietary and other risk factors for stroke in Hawaiian Japanese men. *Stroke*, 1985; 16;3:390-393. This ten-year study of nearly 8,000 Hawaiian Japanese men concluded: "No relation was found between salt intake and the incidence of stroke."

[26] Alderman, M.H. et al. Low urinary sodium associated with greater risk of myocardial infarction among treated hypertensive men. *Hypertension* 1995; 25:1144-1152 (online at http://hyper.ahajournals.org/cgi/content/abstract/25/6/1144). Alderman's is an eight-year study of a New York City hypertensive population stratified for sodium intake levels found those on low-salt diets had more than four times as many heart attacks as those on normal-sodium diets – the exact opposite of what the "salt hypothesis" would have predicted. Also see Alderman, M. et al. Urinary sodium excretion and myocardial infarction in hypertensive patients: a prospective cohort study. *American Journal of Clinical Nutrition*. 1997 Feb;65(2 Suppl):682S-686S.

[27] Cutler, J.R., Presented May 30, 1997, at American Society of Hypertension annual meeting, San Francisco, CA. (unpublished). Cutler's was an analysis of the first six years' data from the MRFIT database documented no health outcomes benefits of lower-sodium diets.

[28] Tunstall-Pedoe. Comparison by prediction of 27 factors of coronary heart disease and health in men and women of the Scottish heart health study cohort study. *British Medical Journal*, 1997; 315:722-729. See Table 6, age-adjusted hazard ratios (online at: http://bmj.com/cgi/content/full/315/7110/722?view=full&pmid=9314758). This was a ten-year follow-up study to the huge Scottish Heart Health Study and found no improved health outcomes for those on low-salt diets.

[29] Alderman M.H. et al. Dietary sodium intake and mortality: the National Health and Nutrition Examination Survey (NHANES I). *Lancet* 1998; 351:781-785 (online at http://pdf.thelancet.com/pdfdownload?uid=llan.351.9105.original_research.7411.1&x=x.pdf). This is an analysis of the health outcomes over twenty years from those in the massive US National Health and Nutrition Examination Survey (NHANES I) and documented a 20% greater incidents of heart attacks among those on low-salt diets compared to normal-salt diets.

[30] 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). This paper reported a health outcomes study in Finland that failed to identify any health benefits of sodium reduction. Valkonen concluded "…our results do not support the recommendations for entire populations to reduce dietary sodium intake to prevent coronary heart disease."

[31] Cohen, J.D. presentation to NHLBI Workshop on Sodium and Blood Pressure, January 28, 1999, Bethesda, MD. This is a further analysis of the MRFIT database, this time using fourteen years' data. It confirmed no improved health benefit from low-sodium diets. Cohen conceded that there is "no relationship observed between dietary sodium and mortality."

the Cochrane Review by Hooper.[34] The Cochrane Review concluded:

> "Intensive interventions, unsuited to primary care or population prevention programmes provide only small reductions in blood pressure and sodium excretion, and effects on deaths and cardiovascular events are unclear."

A health outcomes study focused in stroke incidence done by Ascherio et al that examined the risk of stroke among U.S. men with regard to their intakes of potassium, magnesium calcium and fiber[35] and confirmed the earlier Kagan study on stroke, concluding "Neither calcium nor sodium intake (data not shown) was significantly associated with risk of total, ischemic, or hemorrhagic stroke." Two subsequent studies in high-sodium Japanese populations reached different results; one found a salt-stroke relationship (not other outcomes)[36] while another found no beneficial change in reducing dietary salt.[37]

Two further health outcomes studies and a review article have been published in 2007, as scientists continue to wrestle with the fundamental question – the question underlying CSPI's citizen's petition. Cook et al studied the NHANES database and concluded that salt reduction improves health outcomes, but the association disappears when only the sodium-reduction group is analyzed rather than lumping together the sodium-reduction and weight-loss groups in the Trials of Hypertension studies.[38] The high-quality database of the Rotterdam Study confirmed both the BP-

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[32] He, J. et al. Dietary sodium intake and subsequent risk of cardiovascular disease in overweight adults. *Journal of the American Medical Association*, 1999; 282:2027-2034 (online at: http://jama.ama-assn.org/issues/v282n21/abs/joc81748.html). This study of Americans found that less sodium-dense diets did reduce the cardiovascular mortality of one population sub-set, overweight men. The article did not explain why this obese group actually consumed less sodium than normal-weight individuals in the study.

[33] Tuomilehto J. et al. Urinary sodium excretion and cardiovascular mortality in Finland: a prospective study. *Lancet* 2001; 357:848-51 (online at http://pdf.thelancet.com/pdfdownload?uid=llan.357.9259.original_research.15524.1&x=x.pdf -- subscription required). 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.

[34] Hooper, L. et al. Systematic review of long term effects of advice to reduce dietary salt in adults. *British Medical Journal*, 2002; 325:628-636.

[35] Ascherio, A, Rimm, EB, Hernan, MA, Giovannucci, EL, Kawachi, I, Stampfer, JJ, Willett, WC. Intake of potassium magnesium, calcium and fiber and risk of stroke among US men. *Circulation* 1998; 98:1198-1204.

[36] Nagata, C. et al. Sodium intake and risk of death from stroke in Japanese men and women. *Stroke* 2004; 35:1543-1547. http://stroke.ahajournals.org/cgi/content/abstract/35/7/1543.

[37] Shimazu, T. et al. Dietary patterns and cardiovascular disease mortality in Japan: a prospective cohort study. *International Journal of Epidemiology* 2007; 36:1: 1-10. http://ije.oxfordjournals.org/.

[38] Cook, N.R. et al Long term effects of dietary salt reduction on cardiovascular disease outcomes: observational follow-up of the trials of hypertension prevention (TOHP). *British Medical Journal*, doi:10.1126/bmj.39147.604896.55 (published 20 April 2007).

lowering effect of lower-sodium diets and the absence of the predicted health benefit. Geleijnse et al[39] reported "no consistent association of urinary sodium, potassium, or sodium/potassium ratio with CVD and all-cause mortality and concluded:

> "…the effect of dietary salt on clinical cardiovascular endpoints and overall mortality within the range of intake commonly observed in Western countries has not yet been established."

Thus, when the president of the International Society of Hypertension devoted his Presidential Address to "Salt, Blood Pressure and Cardiovascular Disease" last year,[40] he echoed the points we've made above and when Walker, et al.[41] addressed the topic: "Does reducing your salt intake make you live longer?" in a "best evidence" review in a forthcoming *Interactive Cardiovascular and Thoracic Surgery* this Fall, their conclusion was hardly surprising:

> "We conclude that restricting sodium intake to levels below 6 g per day as most international guidelines such as those of the AHA, the US Dietary Guideline Committee and the Scientific Advisory Committee on Nutrition recommend, clearly reduces blood pressure and in turn may reduce the need for antihypertensives by as much as 30%. However, the ability of dietary sodium restriction to reduce the incidence of cardiovascular events is more controversial due to the lack of adequately powered randomised trials or observational studies conducted with sufficient rigour.

**HEALTH OUTCOMES IN FINLAND**

A year ago, salt reduction advocates finally embraced the concept of health outcomes when they endorsed a study of Finland's national experiment in reducing dietary salt. The purpose of the salt reduction was assertion that lowering salt would improve cardiovascular health outcomes, using the same rationale as CSPI employs in its citizen's petition. CSPI has joined in the chorus endorsing Heikki Karppanen and Eero Mervaala's celebration of Finland's extraordinary success in lowering population sodium intakes and the health improvements they claim flow directly from that salt

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http://www.bmj.com/cgi/rapidpdf/bmj.39147.604896.55v1

[39] Geleijnse, J.M. et al. Sodium and potassium intake and risk of cardiovascular events and all-cause mortality: the Rotterdam Study. *European Journal of Epidemiology* 2007; 10.1007/s10654-007-9186-2. http://www.springerlink.com/content/1032k6374735085u/fulltext.pdf

[40] Alderman, MH, Salt, Blood Pressure and Cardiovascular Disease, Presidential Address to International Society of Hypertension 2006 annual meeting, Fukuoka, Japan. Video online at http://webcasts.prous.com/template/player.asp?id=4760&q=128&v=wm&webcast=ISH2006.

[41] Walker, J. et al. Does reducing your salt intake make you live longer? *Interactive Cardiovsacular and Thoracic Surgery* (in press).

reduction.[42] The authors describe an aggressive national anti-salt campaign involving newspapers, food labels, "consensus" exhortations from government and scientific groups and the food industry. In short, the model that is being pursued in the UK and which CPSI advocates for the US. They claim reduction in Finnish salt intake from 14 g/day to 8 g/day, making Finland the global example of the "benefits" of salt reduction. Karppanen and Mervaala explain:

> "In this paper, we provide evidence that strongly suggests that the progressive decrease in salt intake which has continued in Finland for 25 to 30 years, has played an important role both in the impressive fall in the average blood pressure of the population and in the pronounced 75% to 80% decrease in both stroke and coronary heart mortality in the population younger than 65 years.
> …
> "Evidence is presented to indicate that the comprehensive salt reduction has also played an important part in the remarkable 5-6 year increase in the life expectancy of the Finnish population during the past 25-30 years.
> …
> "Finland, so far, appears to be one of the few countries where it has been possible to produce a marked population-wide reduction in salt intake."

Surely, we agree that Finland may be the only country which has reduced salt intake over this period. In the US, per capita salt intake levels are virtually unchanged over the past century and CSPI asserts they have risen.[43] So the contrast of what American health outcomes on what some call "high" salt levels (actually, US consumption is slightly below the global average) should be illuminating. Indeed, reported salt intakes and recorded population blood pressures behaved exactly as predicted; they fell sharply. World Health Organization data[44] also confirm a dramatic reduction in ischaemic heart disease (IHD) in Finland. Data from the U.S. Census confirm a significant 5.5 year increase in Finn's life expectancy.[45] Case closed? After all, these are the very health outcomes benefits predicted by CSPI and the organizations crusading for salt reduction.

Let's look a bit more closely, remembering the enthusiasm with which salt reduction advocates attribute the results to the decline in salt intakes and their concern that current salt intake levels are responsible for a claimed 150,000 American deaths each year. The fact is: during the years that Finland reduced its national salt intake, World Health Organization data clearly show that

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[42] Karppanen, H. and Mervaala, E. Sodium intake and hypertension, *Progress in Cardiovascular Diseases*, 2006. 49 (2): 59-75.

[43] While, overall, the American public certainly has ingested more salt over the past quarter century, not only are there more Americans consuming that salt, but the NHANES data tracks only that portion not added at home or in cooking. Since the latter categories have been declining over the past century, the rise in salt used by food processors does not represent an increase in overall salt intake since it is offset by this steady erosion of consumers' use of table salt at home.

[44] Global Cardiovascular Infobase at http://www.cvdinfobase.ca/

[45] U.S. Census Bureau at http://www.census.gov/ipc/www/idb/tables.html

improvements in cardiovascular health and population longevity lag well behind its neighboring countries in Europe and in both the U.S. and Canada – all of which countries have held their salt intake levels relatively constant through this 30 year experiment. If anything, this research demonstrates that adopting a lower salt diet deprived Finns of health benefits that would have been theirs had they not reduced their salt intake. Let's compare Finland and the US over the period. The rate of IHD declined in both Finland and the US. In the late 1960s, the US rate was significantly higher than Finland's (at this point, Finland had the much higher salt intake level; the US, with the projected "healthier" lower salt intake had more IHD). By the year 2000, much had changed. Finland had reduced both salt and IHD; the US had no salt reduction, but its IHD rate had plunged more steeply. The same pattern exists in the other Scandinavian and Northern European countries, the UK and in both the US and Canada: those countries that did not reduce salt reduced their IHD rate more sharply than Finland. The second claimed advantage, extended life expectancy, confirms the pattern again. Finland increased life expectancy by 5.5 years, but, without reducing salt, the US increased life expectancy by 8 years. All the other reference countries except the Netherlands had better records in extending their citizen's mortal tenures than the salt-reducing Finns.

**IT'S TIME TO RESOLVE THE HEALTH OUTCOMES QUESTION**

The Salt Institute has long advocated a controlled trial of the fundamental question of whether salt reduction will confer the predicted health benefit. We met a year ago with senior HHS officials and presented the outline of a practical research protocol based on the proven Trials of Hypertension Prevention, phase II trial that achieved and maintained a nearly 1,000 mg/day reduction in dietary sodium over a three year period. We believe that we could resolve this scientific controversy that has so long divided experts within 5-6 years. Given the vast billions of dollars of health care costs that cardiovascular disease imposes on the US economy – to say nothing of the human tragedies of lives prematurely shortened – this is an investment that can pay great dividends. Let's do the study and find out the truth.

**WHERE WOULD THAT LEAD?**

If a controlled trial confirmed our view that salt is not the culprit, establishing that fact would remove the blinders from our public health nutrition policy and we could begin to address other options. We'll review our recommendation below. We could apologize for the 25 year digression and focus resources on the real problems. The real cost of our current policy isn't the public relations costs incurred by the government nor even the billions of dollars already invested in pursuing the path of providing consumers with a wide choice of sodium-reduced foods, it is the fact that we haven't made any headway in reducing dietary salt – and, if we had, we might well have ended up with higher health costs imposed by unanticipated adverse consequences of our pursuit of low-salt diets.

If, on the other hand, the controlled trial confirmed CSPI's contention that salt reduction will improve Americans' health, we can move on to issues of implementing low-salt diets. There are many issues and you'll likely hear today from food manufacturers about the significant and expensive challenge it is to reduce the salt content of foods – since they are well along that path

already. Should the controlled trial document a health benefit for salt reduction, then, the question becomes: how?

**WILL INCREASED INTAKES OF LOWER-SODIUM FOODS LOWER DIETARY SODIUM INTAKE LEVELS?**

The current policy of encouraging Americans to substitute low-sodium foods for those higher in sodium is eminently logical. But it is totally untested. This is the second "leap of faith" inherent in the current approach (the first, of course, being that the lowered sodium intake would be healthier). The assumption is made that if a person were to substitute a low-sodium soup, for example, for a "regular" soup with, say 300 mg more sodium, that the individual would reduce their total sodium intake by about that amount. Substitute enough and you drive down total sodium intake to "recommended" levels. That may be true. But to base the entire strategy on the untested assumption that this is the outcome seems like an expensive bet. As plausible as is this scenario, there is another that should give us pause – at least a pause long enough to gather some empirical evidence. This research could even be conducted during the 5-6 years during which the health outcomes trial is being conducted.

The competing paradigm is that salt itself may be the feed limiter. Individuals may have a built-in "appetite" for salt, totally unconscious. Their "appetite" would have nothing to do with taste. Their bodies may sense whether they have consumed the "right" amount of salt. If these are individual people, the notion is untested. But for cows, sheep, horses, chickens, etc., such an "appetite" is established fact. The question is: do humans share this attribute of livestock and cattle? Just how much like these animals is the human animal? FDA well understands and accepts that various animal species have predictable intake ranges for salt. We meter essential trace minerals to animals knowing how to mix the feed based on the relative amounts of salt and the trace mineral. We do the same for some medications. And when we want to induce the animals to take in additional calories, we simply reduce the salt-to-calorie ratio of their diet.

With our efforts over the past 25-30 years to reduced dietary salt intake, we have not reduced daily salt intake, but we have observed the salt-to-calorie ratio of Americans' diets have moved towards lower salt density. Perhaps we should test whether salt is a food limiter for humans as it is for animals. In that case, instead of labels encouraging low-sodium density foods, we might well do just the reverse: encourage greater sodium density to encourage lower over all caloric intake. We believe it would be prudent to test the idea. CSPI faults FDA for failing to

> "set limit on the amount of salt in processed foods because it wanted to see if voluntary actions by the food industry would lead to a reduction in salt consumption. That effort failed miserably…."

The food industry, of course, has made enormous strides in reducing salt in processed foods, yet CSPI is correct, the huge investments in providing low-sodium foods to the public hasn't dented sodium intake. Rather than be surprised, we should rather be asking ourselves if the basic

assumption upon which FDA's and CSPI's disappointment is flawed and that flaw, responsible for the outcome.

## SALT'S ESSENTIAL ROLE IN FOODS

A great untold story in food processing in this country has been the quiet embrace of the government's goal of reducing the salt-density of foods as a means of making diets healthier. Whether it will work isn't the question here. Without doubt, food manufacturers are embracing the effort and investing heavily to make it work.

But all the efforts of food processors may still be unsuccessful.

Salt is an essential part of the foods we eat. Reducing the sodium content of food and meeting consumer aesthetic (and economic) preferences is an enormous challenge – as food processors can well attest. They've paid their dues.

The number of applications fulfilled by salt in foods are as varied as the number of different foods there are. These range from a taste enhancer to a taste suppressant; as a mediator of water activity and a regulator of texture, mouthfeel, juiciness and friability. Blanching in salt water retains color and crispness in vegetables destined for freezing and salt initiates granule formation and tyrosine crystallization producing the unparalleled taste and texture of Parmesano Reggiano cheese.

Salt is not only our oldest known food preservative, but it fulfils a critical anti-microbial function in the most modern hurdle technologies employed in the production of high quality minimally processed chilled foods that have become so popular in recent years.

Despite the myriad established uses of salt in food preparation at home and in the food industry, the overarching attraction of salt for people is sensorial. Simply put -- salt makes food taste very, very good. Salt doesn't just deliver salty flavor, it delivers flavor in many ways. BASF advertises that its unseen contribution to a consumer product doesn't make the product, it makes the product better. So does salt.

## SALT AND TASTE ACCEPTABILITY

While a full treatise on the physiology of salt in taste and texture is beyond this paper, there are a number of organoleptic characteristics of salt that are readily apparent.

Humans and animals like the taste of salt. Salt is the oldest, most common and most important single flavoring substance.[46] From a food appeal point of view, salt cannot be considered to be merely desirable, but by far the most satisfying of flavor components for all starchy and proteinaceous foods. This propensity for humans and animals to prefer a salty taste may originate from our marine evolution or may simply be a mechanism to ensure we receive an adequate amount

[46] Multhauf, R. P., *Neptune's Gift – A History of Common Salt*, Johns Hopkins University Press, Baltimore, 1996.

of this essential nutrient in our diet. When faced with foods that don't meet their taste expectations, most people will simply take up a salt shaker as add enough to satisfy their needs.

Thus, in a country such as Italy, where bread baking traditions result in regional products that vary from high to very low salt, consumers at home and diners in restaurants will readily make up any taste deficit by voluntarily adding salt at the table prior to consumption. The same can be said for the consumer response to all other food products – those that demonstrate a deficiency in taste will be corrected by the consumer on a voluntary basis. This high esteem for salt as a flavoring ingredient is not a new phenomenon resulting from its low cost and ready availability. Throughout history, even during periods when it was a very costly commodity, salt was considered to be an economic necessity of life. With the discovery of cooking, salt became even more necessary because these foods are often bland and the salt content of cooked foods is often reduced. In the case of roasted foods, salt was critical in reducing bitterness.

There is a body of thought which states that consumers can be "weaned" off of a preference for salty taste. A few trials with a small number of individuals over a limited time period support this notion. However, this does not coincide with the far more common experience we have seen after periods of war or incarceration where people who have been involuntarily separated from salt for extended periods. In all cases, with large populations, consumers return to their previously established higher level after an extended time.

Salt does much more than deliver a salty taste.

One of the most important uses of salt in taste is to moderate bitterness in certain foods. For example, some of or most nutritious vegetables, such as broccoli, spinach, Brussels sprouts, cabbage, kale, mustard greens, radicchio will not be acceptable to consumers unless a certain amount of salt is added. This is particularly true for children as the most recent results of tests from Ohio State University reveals.[47] Restricting the amount of salt that consumers can add to these foods risks their access to the nutritional benefits they hold. Likewise, many people add salt to coffee, beer or chocolate to moderate bitterness. Of course, bitter natural foods such as olives would not be an edible food commodity unless they were fully debittered with salt.

When added in small amounts, salt intensifies the sweetness of many foods such as caramel, taffy, fudge, fruits, mild vegetables and various sauces. For example, lightly salting a slice of watermelon makes it taste sweeter. Salt also make food taste more palatable by suppressing other unpleasant flavors. In these instances the goal of the consumer or manufacturer is not to make a food taste salty, but rather to enhance the overall taste profile and acceptability of the food.

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[47] Delwiche, J., Dose-response curve of sodium chloride on vegetable palatability, Ongoing research project, Ohio State University, Department of Food Science and Technology, May 18, 2007.

**BENEFITS BEYOND TASTE**

Although it is inevitably associated with food flavors, salt has a profound effect on the texture of an incredible array of food products. Because of its functional impact on the gelation properties of proteins, salt is used to respond to consumer preferences for texture, mouthfeel and ease of swallowing for all national and imported cheeses and cheese products, processed meat and fish products. Items such as bologna, frankfurters, restructured beefsteaks, chicken pieces , dry-cured ham, surimi from all fish sources, battered calamari rings, minced fish balls, etc., etc., serve as some examples. Salt has a critical impact on the texture, color and cooking loss of a range of fresh, processed and dehydrated vegetables, such as runner beans, carrots, cucumbers, broccoli and cauliflower. Salt improves the texture acceptability of peanut butter, heat-coagulable egg white products and all smoked fish, cheese and meats products.

Of course, not only food processors love salt. The use of salt by consumers to improve the texture of foods is very common. Preparing for the holidays, a cursory search on Google using the terms 'brining turkey' yields more than 800,000 citations! As an example, a quote from the San Francisco *Chronicle* reads, "The Chronicle Food section cooked 28 turkeys to find the best method of producing a plump, juicy bird. Our favorite -- by far -- was the turkey that we brined before roasting."

Consumers know from experience that it's not simply the taste that is improved, but the color and texture of vegetables are optimized if they are cooked in salted water – if not, they would simply add salt at the table! The proverbial 'pinch of salt' does wonders for color and texture. Indeed, salt's unique contribution to the texture of so many foods parallels its importance as a taste enhancer.

**WE WOULDN'T ENJOY OUR FOOD WITHOUT SALT**

It will be helpful to examine the role of salt in the foods we love.

***Bread***

The level of salt used in bread manufacture significantly affects the physical nature of the final product. Most standard bread is made from doughs containing about 2% salt by weight of flour, accounting for approximately 1.3% by weight in the final product. Salt has a significant physical effect on the properties of wheat gluten, resulting in a less sticky, more manageable dough. Salt also affects the rate of fermentation, and its addition is timed after the dough has been partly fermented. The role of salt in controlling fermentation is not only due to the increase in osmotic pressure, but also to the actions of sodium and chloride ions on the semi-permeable membranes of yeast cells. Inadequate levels of salt will result in excessive yeast fermentation, resulting in gassy,

soured doughs[48] that are difficult to process and result in loaves with an open grain and poor texture.[49]

Many types of flat bread have become widely available in recent years. These include single-layered, leavened dough products such as naan, pizza crust, ciabatta and focaccia, batters such as crepes and pancakes as well as double layered products such as pita bread, and unleavened products like chapattis, paratha and tortillas. Salt is an essential ingredient in most formulations, many of which are sourdough or yeast-leavened products.[50] Salt, temperature, aeration and flour quality are all used to control bread quality.

***Biscuits/Crackers***

Salt affects the physical nature and properties of biscuit doughs, especially hard doughs, in a similar way to bread.[51] In doughs with significant gluten development,[52] such as crackers and semi-sweet types, salt toughens the gluten and gives a less sticky dough. It may also slow down the rate of yeast fermentation. Typical levels of addition are generally less than 2%, based on flour, resulting in about 1.5% in the final product.

***Meat and Meat Products***

Salt has a variety of technological functions in meat products. While many of the major effects relate to preservation, especially in cured and salted products, it also has other, direct effects on the nature and quality of the product. Some of these involve texture and flavor as noted above.

The addition of salt to raw, lean meat products increases their water-holding capacity and yield after cooking. The net result is a tenderizing of the meat. Water losses after cooking are minimized by a salt level of 5-8% of the total water content of the product.[53] The most effective salt concentration range is that at which muscle proteins (actin and myosin) are solubilized. Salt also increases meat binding. The proteins that are extracted into solution effectively form a bond between the individual pieces of meat, which binds them together. Fat binding in highly comminuted meat products is also increased by salt, with the fat being emulsified by the solubilized protein. These properties of salt

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[48] Matz, S.A., *Cookie and Cracker Technology*, Pan-Tech International, McAllen, TX, (1992).

[49] Cauvain, S.P. and Young, L.S., *Technology of Breadmaking*, Blackie Academic and Professional, London. (1998).

[50] Qarooni, J., *Flat Bread Technology*, Chapman & Hall, London (1996).

[51] Wade, P., *The principles of the craft, Biscuits, Cookies and Crackers, Vol. 1*. Elsevier Applied Science, Barking (1988).

[52] Manley, D., *Technology of Biscuits, Crackers and Cookies*, 2nd ed., Ellis Horwood, Chichester (1991).

[53] Ranken, M.D., Kill, R.C. and Baker, C.G.J., *Food Industries Manual*, 24th ed., Blackie Academic and Professional, London, (1997).

are absolutely critical in products such as all forms of sausages. In this type of product, the binding should be strong enough for the sausage to actually snap when bent. In coarser products, such as burgers, the effects are reduced and the result is a product that retains its shape and juiciness during cooking, but retains a crumbly, fibrous texture upon eating.

At the other end of the scale, the meat-binding properties of salt are employed in the production of reformed pieces and steaks, which are popular because of their reduced fat content and their relatively low cost.

Although salt increases the solubility of muscle proteins, at too high a level, it promotes undesirable rancidity changes in the fat components.[54] This issue, together with average consumer taste preferences, act as a limiting factor to the level of salt that can be practically used, despite the fact that it has a major role to play in meat product preservation. Salt is not added to foods with impunity – only enough is added to carry out the required function.

***Cheeses***

Salt is used in the manufacture of both hard and soft cheeses. The amount that is added, the method by which it is added, and its precise effects vary from one cheese to another.[55] For example, addition of dry salt to Cheddar cheese occurs before the cheese is put into moulds, a process which only takes about 15-20 minutes. In contrast, the salting of some of the most famous Italian, Swiss and Dutch cheeses is carried out after they are formed into rounds. The rounds are then immersed in saturated salt brine, for up to 20 days. The role of salt is in the final ripening and maturation of the cheese. For many traditional manufacturers, the saturated brine baths are a source of pride, some having been in continuous operation for more than 100 years (showing perfectly cubic sodium chloride crystals from 5-6 inches on a side, sitting in crystal clear brine).

Salt's effects on the quality of cheese include inhibition or stimulation of the starter-culture microorganisms, modification of enzyme activity, and direct effects on water content, leading to specific textures and characteristic amino acid crystallization.

The ripening of cheeses such as Roquefort, Danish Blue, Gorgonzola, Camembert and Brie is dominated by the mold *Penicillium*, whose spores will only germinate in the presence of salt – not salt replacers. The action of pepsin and chymosin on milk casein is optimally stimulated by 5% salt solutions, and this level of salt is also necessary to prevent the development of bitterness in these cheeses. Changing the levels of salt in these products will completely change their character.

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[54] Girard, J.P.), *Technology of Meat and Meat Products*, Ellis Horwood, Chichester, (1992) and Lawrie, R.A., *Meat Science*, 6th ed., Woodhead Publishing, Cambridge, (1998).

[55] F Guinee, T.P. and Fox, P.F., Salt in cheese: physical, chemical and biological aspects', in Fox, P.F. (Ed.), *Cheese: Chemistry, Physics and Microbiology,Vol. 1, General Aspects*, Elsevier Applied Science, Barking (1987) and Spahr, U. and Url, B., Behaviour of pathogenic bacteria in cheese – a synopsis of experimental data, *Bulletin of the International Dairy Federation*, Vol. 298, pp. 1-16, (1994).

Given the complex and vital nature of the effect of salt in cheese, reducing salt levels in the final product would result in changes so significant as to make the final product unacceptable and in non-compliance to the agreed standards.

***Fermented Foods***

Salt is a very critical ingredient in the production of fermented foods, such as sauerkraut, pickles, tempeh, soy sauce and other foods and condiments, through its control of the microbiological flora. It also helps provide the conditions for the type of fermentation required by the specific requisite organisms.[56] In fact, salt specifically contributes to the precise fermentation conditions required for the final products.

Replacing salt with an alternative will never reproduce the same effects on a range of desired and undesired microorganisms. In addition, as previously noted, salt is involved in the texture changes occurring during the processing of pickled vegetables and confers a firmness in the product that is desirable in most pickle-type products.[57]

The range of fermented foods consumed by new immigrants is exceptional. As an example, soy sauce is usually produced from a soybean/wheat kernel mixture by fermentation using the *shoyu* yeast. Salt levels of 17-18% have traditionally been used in *shoyu* fermentation for optimum development of flavor and in 1996, it was demonstrated that this was the optimum level for production of key volatiles that contribute to the characteristic flavor of the sauce.

***Batters and Coatings***

In addition to the sensory properties, salt serves several processing functions in batters and coatings. For example, in batters it helps prevent immediate freezing when applied to frozen products and therefore facilitates crumb application. If flour dusts are used on frozen products, such as frozen fish, salt is added to improve the adhesiveness. The same phenomenon is applies to several other battered and dusted frozen entrees and snacks.

**CONSUMER TASTE CAN'T BE LEGISLATED**

The millennia-old practice of voluntarily adding condiments to food to improve palatability began with salt. Salt remains the most common condiment voluntarily added to food prior to consumption. Whether from iodized table salt in the ubiquitous tabletop salt shaker or the newly popular exotic sea salts from an ornate sterling salt cellar, consumers continue to judge how much salt they prefer to consume with any particular food.

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[56] Reddy, K.A. and Marth, E.H., Reducing the sodium content of foods: a review, *Journal of Food Protection*, Vol. 54, No. 2, pp. 138-50, (1991).

[57] Binstead, R., Devey, J.D. and Dakin, J.C., *Pickle and Sauce Making*, 3rd ed., Food Trade Press, London, (1971).

The enjoyment of taste is wholly in the sensory context of food consumption. For example, both children and adults will universally reject the taste of salty water, but will find the exact same level of salt in a soup very acceptable and preferable to the same soup without salt. Bread that has a very low salt content will inevitably have salt added to or to the olive oil that it may be dipped into. The same can be said for fresh, cooked or canned vegetables, although the preference levels may differ for each product.

A predictable result of the law of unintended consequences is that restricting access to palatable foods increases the desire of consumers to obtain and consume those foods. Salt restriction must be an entirely voluntary act if it is to be sustainable. For most consumers, limiting salt in processed foods will not reduce its consumption, it will simply realign the source from where it is obtained. It is sheer naivety to think that salt in processed food can be reduced without any consequence. The fact that processed food accounts for 70-75% of salt consumption is the very same reason that voluntary salt use is so low. Should the amount of salt in processed food be reduced, it is likely that much of that will be made up through voluntary salt addition at the table.

**SALT'S CRUCIAL ROLE IN FOOD SAFETY**

Salt is the oldest food preservative known to humankind – it has been used for thousands of years. In modern food processing, with certain well-known exceptions, such as salted cod, snapper and threadfin fish, anchovies, capers, botarga and caviar, the amount of salt used is not sufficient by itself to have a total preservative effect, but it does critically contribute, in combination with other processing factors and preservatives, to the production of safe end-products. In vegetable fermentations, the appropriate concentration of salt extracts nutrients from plant tissue and allows the selective growth and development of lactic acid bacterial cultures, which, in turn suppress the growth of spoilage and pathogenic organisms through the acid they produce, complementing the direct effect of the salt. Inadequate salt levels in such fermentations result in unacceptable quality and risky, unsafe foods.[58]

The main mechanism of salt preservation is through the reduction of water activity. Microorganisms require water to survive and grow and salt preferentially ties up a portion of the water, leaving the microorganisms without sufficient free water. In inhibiting microbial growth, salt interacts with both the acidity (pH) of the medium and its temperature, as well as other factors present.

The use of salt in reducing water activity means that the levels of other preservatives or processes can be reduced. This means that reduced heat or irradiation will be sufficient to maintain microbiological stability of the final product, or that the degree of acidity can be reduced, or that the use of other chemical preservatives (such as sulfur dioxide and benzoic acid) can be reduced or even eliminated. Reduction of heat processing often results in a product of vastly improved organoleptic and nutritional quality as a result of the improved retention of other nutrients, specifically the heat-sensitive vitamins.

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[58] Sofos, J.N., Antimicrobial effects of sodium and other ions in foods: a review, *Journal of Food Safety*, Vol. 6, No. 1, pp. 45-78, (1984).

***Minimally Processed and Chilled Foods***

This sector has seen tremendous market growth in the last decade and covers a very wide range of product types. In vacuum-packed or modified atmosphere packed products, where oxygen is excluded, the risk of growth of *Clostridium botulinum* is real and salt is one of several hurdles contributing to the extended shelf-life of these chilled products. A salt level of 3.5% in the aqueous phase throughout these processes can provide an adequate preservative action in combination with the chill temperatures.[59] A lower salt level can be used but only when carried out in combination with reduced pH, other chemical preservatives or additives that will additionally reduce water activity.

In other chilled products, where oxygen is present, *Listeria monoytogenes* is a very risky pathogen to consider because of its tendency to survive throughout the cold chain and grow at chill temperatures. Under ideal conditions, a level of about 10% salt in the water phase would be required to prevent growth.[60] Although *Listeria* is not a major risk for healthy people with fully competent immune system, it is a real and present life-threatening risk for people whose immune systems are temporarily or permanently compromised, such as all infants, pregnant women, people with HIV, those undergoing radiation treatments and anyone over the age of 60.

***Meat Products***

Meat products were among the first foods to be preserved with salt. Some of the more popular meat products that use salt for its preservative effects are ham, fermented and non-fermented sausages, frankfurters, salami, corned beef and bacon. Before refrigeration, high levels of salting and smoking were required to preserve meat products such as ham, bacon and corned beef. Refrigeration has permitted these levels to be significantly reduced, but salt is still an essential ingredient in the modern preservation of cured meats.

The salt concentrations in these meat products have dropped by almost half since widespread refrigeration was introduced in the 1930s.[61] As stated above, salt is not added to foods with impunity – only enough is added to carry out the required function.

In meat curing, salt and other ingredients serve to replace the natural meat flora (mainly *pseudomonads,* which are responsible for spoilage) with *lactobacilli* and *micrococci*. This will still result in spoilage eventually, but the rate of spoilage is dramatically reduced. Generally speaking

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[59] Betts, G.D., Code of practice for the manufacture of vacuum and modified atmosphere packaged chilled foods with particular regard to the risks of botulism, *Guideline No. 11*, Campden & Chorleywood Food Research Association (1996).

[60] Cole, M.B., Jones, M.V. and Holyoak, C., The effect of pH, salt concentration and temperature on the survival and growth of Listeria monocytogenes. *Journal of Applied Bacteriology*, Vol. 69, No. 1, pp. 63-72 (1990).

[61] Sofos, J.N., Antimicrobial effects of sodium and other ions in foods: a review, *Journal of Food Safety*, Vol. 6 No. 1, pp. 45-78. (1984).

3.5% salt in the aqueous phase is the minimum level for shelf-stable canned cured meats, such as canned hams.

The common preservation of cured meat products is through a complex interaction of salt, nitrite, pH and heat treatment. Levels of salt up to 4% brine in the presence of 50-100 ppm nitrite are still not 100% effective in preventing *C. botulinum* growth in certain sausages, but the pressures to reduce salt continue. There are numerous examples of research on the growth of *C. botulinum* in meat products which support the belief that the currently used procedures and levels of curing salts have been reduced to the limit of safety and further reductions would result in a microbiologically risky product unless other preservative measures such as greater heat treatment or radiation were incorporated.

***Fish Products***

Salt is a significant component in the preservation of smoked fish. Levels are generally 2.0-2.5%, but can be up to 5% for salmon or sea trout. For products prepared from salmon, trout and mackerel, for which there is a small but significant hazard from the presence of *Clostridium botulinum*, a minimum salt concentration of 3% in the water phase is recommended. This results in a level of up to 2.5% in the finished product.[62] As well as being effective in combination with other factors in preventing *Listeria monocytogenes* growth, it also prevents *C. botulinum* type A and E toxin production.

Salt is also used as a brine pickle for fatty fish, such as herring and other white fish. Dry salting is not very suitable for fatty fish because rancidity readily occurs on exposure to the air. In brine pickling of this type, the eviscerated fish are packed in a wood barrel with solid salt. This draws moisture out of the flesh and the salt dissolves to form a saturated pickle which covers the fish and preserves it.

In dry salting of cod, the fish is packed in layers with solid salt to form stacks; the saturated brine which forms via moisture extraction from the fish flesh is allowed to drain away, and the fish eventually become impregnated with a saturated salt solution (about 25% salt). The preservative action of salt in salted fish is through a combination of direct microbial inhibition, enzyme inhibition and a significant dehydration effect in the fish tissue.

Salt is also used in fish marinades, where it acts in combination with acetic or lactic acid to produce a product that is stable for several months at 48º C. Herring is the principal marinated fish, and herring rollmops are one example. The level of salt required is usually lower than that used in salted fish.

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[62] Burt, J.R. (Ed.), Dried and smoked fishery products: preparation and composition, *Fish Smoking and Drying*, Elsevier Applied Science, London, (1988).

Salting is also critical for the killing of fish parasites. Storage of herring in 21% salt brine for ten days destroys the more common parasites such as the herring tapeworm worm (*Anisakis simplex*), which is a human pathogen that has infected people after eating raw or inadequately cured fish.[63]

***Culinary Sauces***

Salt is a major ingredient of all culinary sauces such as Worcestershire sauce, tomato ketchup, soy sauce, mayonnaise, mustards, mint sauce, hot sauces and horseradish sauce. Typical levels are 2.3% in tomato ketchup and 1.5 – 2% in mayonnaise. In addition to contributing to the savory flavor of the sauce, salt has a critical preservation effect in these products. The main ingredients responsible for the safety of these products are acetic acid, salt and sugars. Using the appropriate levels of these ingredients, sauces can be shelf-stable at ambient temperature without the need for additional preservatives or heat processing, thus making them highly suitable as convenience products. Once opened, they have to be refrigerated, although many people ignore this. Fortunately, the salt and acetic acid continue their preservative actions.

***Use of Salt in Religious Treatment to Extract Blood from Meats (Koshering)***

The process of koshering meat revolves around the use of salt to draw out residual blood. The process has been employed for thousands of years. Once completed, the meat is rinsed to remove the salt and extracted residue. This process results in a finished product that is noticeably more salty, however, not to the extent that makes it unpalatable. In fact, some consider the meat to be improved in organoleptic quality, but that assessment is largely subjective. One clearly objective improvement is the significantly lower microbial load in treated products.

**REPLACING SALT ISN'T EASY**

Commercial food grade salt is remarkably pure—almost all of it above 99.5% sodium chloride. The only appreciable impurity is calcium sulfate which is completely tasteless. Although calcium and magnesium chlorides are bitter impurities they are present in such trace quantities as to be below the threshold level of taste. As a result, food grade salt has an intense, clean characteristic taste that is impossible to duplicate – even to the untrained palate.

The most common salt replacer is potassium chloride. This potassium salt contributes very little typical 'salty' taste and has a tendency to skew the overall taste profile of treated products. It is thus very difficult to use as a salt replacer in isolation and must be used in conjunction with other materials to help balance out flavors. This poses a daunting research challenge for all food companies and represents a critical barrier to trade for smaller firms that do not have to facilities and technical resources to carry out the complex research required. Aside from being a poor replacement for the taste of sodium chloride in well known foods, potassium chloride has not been

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[63] Ranken, M.D., Kill, R.C. and Baker, C.G.J., *Food Industries Manual*, 24th ed., Blackie Academic and Professional, London (1997).

tested as a replacement for salt in the majority of other foods and it is impossible to predict the flavor consequences resulting from potassium rather than sodium interactions.

In the case of taste enhancers such as the 5-ribonucleotides, another range of risks exist in replacing the taste function of salt. The 5-ribonucleotides metabolize down to uric acid, the crystalline material that lodges in joints to cause gout. The Joint Expert Committee on Food Additives (JECFA) initially would not approve 5-ribonucletides because of its metabolic breakdown pattern.[64] Approval was later given because the level of consumption of 5-ribonucleotides was so low. If these materials were now to be used in a much wider replacement of salt, their consumption level will increase dramatically and will once again have to go before JECFA because of the very real risk of gout among consumers. The lack of experience with increased consumption of all other salt replacers would require that they be fully tested for their impact on health.

As is clear from the above-highlighted applications, taste is only one of the hundreds of other well established functional uses of salt in foods. In almost all cases, the replacement of salt for its other functional roles will involve more complex chemicals that have not been tested for safety at the level intended for broad consumption.

**INTERNATIONAL ASPECTS**

While different societies have developed unique and differing cuisines over the eons, salt is a condiment that is universally enjoyed by all. Indeed there are only a very few small, isolated and primitive societies that do not voluntarily add salt to foods, relying instead upon the salt naturally contained in the foods they hunt and gather. There are many societies such as in Japan and the Mediterranean region that consume much greater levels of salt than in the US. When comparisons of overall health status, including cardiovascular disease are made with these high salt-consuming societies, it becomes clear that their health status is better than the UK or Finland, despite the higher levels of salt consumption. Indeed, many of the traditional foods they consume domestically and export are higher in salt content than equivalent products produced in the US.

One of the most significant American contributions to the establishment of the WTO was the insistence that food and agricultural products had to comply with the standards of the Sanitary and Phytosanitary Agreement. A key precept of this agreement was that all measures applied to foods that were intended to protect life and health had to be based upon "sound scientific principles." As detailed above, the current active and often acrimonious debate swirling around the issue of salt and health is unresolved and the needed controlled trial remains unfunded. Thus, there is no definitive scientific data that would pass the standards of the SPS Agreement linking reduced salt to improved health outcomes.

Salt is also the lynchpin in the current global priority campaign to virtually eliminate Iodine Deficiency Disorders. The World Health Organization may be urging overall salt reduction, but it

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[64] Jonas, D.A. et al., Safety considerations of DNA in food, *Ann. Nutr. Metab*., Vol 45, p235–254, (2001).

has specific policy that this policy goal must be compatible with its crusade to achieve universal salt iodization.

Indeed, without question, iodized salt is the most effective dietary intervention of the 20th century. Although the effectiveness of iodine in treating goiter had been known since 1821, it was a full century before the successful management of this disease became a fact of life. During World War I, doctors in Michigan were shocked at the number of young draftees that had to be turned away from the military because of goiter (which ran as high as 64% in some areas). Goiter proved to be the largest single cause of medical disqualification for military service.

In 1922, physicians in Michigan met to promote the addition of iodine to salt. Two years later, after a series of local trials, they presented a referendum to the Michigan State Medical Society asking for its endorsement of iodized salt. This was approved on March 15, 1924. A little more than a month later, iodized table salt produced by the Diamond Crystal and Mulkey companies first appeared on the shelves of Michigan grocers. In the fall of 1924, Morton Salt Company produced and marketed iodized table salt for country-wide consumption. From that moment on, with a simple jiggle of the salt shaker, American salt manufacturers dispatched the scourge of iodine deficiency diseases - goiter, cretinism and hypothyroid coma (myxedema) - into the dustbin of medical history.

What was not known at the time was that the fourth and most devastating horseman of the iodine deficiency apocalypse was mental retardation. In the past it was not uncommon for significant numbers of children in certain regions to be considered 'dull' or 'dim-witted', without any connection made to iodine deficiency unless the condition was so severe as to be regarded as cretinism. However, within the last two decades it has been demonstrated that where 5% or more of school age children have goiter, the average cognitive ability in the entire population is reduced by 10 -15 IQ points - a drop sufficient to move a child into the mildly retarded category! As WHO claims one teaspoon of iodine is all a person requires during an entire lifetime, yet iodine deficiency at critical stages of development in fetal life and early childhood remains the world's single most important and preventable cause of mental retardation[65].

Paradoxically, in the country that led the development of salt iodization, a cloud has descended over what was once considered to be an unassailable public health success. The National Health and Nutrition Examination Surveys (NHANES) carried out over the last 30 years have shown a dramatic drop in urinary iodine. The median urinary iodine excretion in adults declined from 320 μg per liter in 1971–1974 to 145 μg per liter in 1988–1994 and 168 μg per liter in 2001–2002. More disturbing, in pregnant women, the frequency of moderate iodine deficiency (considered to be a urinary iodine excretion > 50 μg per liter) jumped from 1 percent in1971–1974 to 7 percent in both 1988–1994 and 2001–2002 surveys[66, 67]. While the current levels are not low enough to declare a public health emergency, the trend is a matter of great concern.

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[65] World Health Organization, Progress towards the elimination of Iodine Deficiency Disorders (IDD), *WHO/NHD/99.4.* Geneva: WHO, 1999.

[66] Hollowell J.G., Staehling N.W., Hannon W.H., et al., Iodine nutrition in the United States: trends and public health implications: iodine excretion data from National Health and Nutrition Examination Surveys I and III (1971-1974 and 1988-1994). *J. Clin. Endocrinol. Metab.,* **83**:3401-8, 1998.

Moreover, recent research has raised the troubling prospect of a direct link between low iodine intakes and incidence of cardiovascular disease.[68] Again, Finland is offered as a case study with evidence presented showing that the areas of Finland with the highest iodine levels have the lowest rates of cardiovascular disease.[69] Hoption Cann speculates that iodine produces vasorelaxation decreasing peripheral resistance and modulate releaseof endogenous vasoactive mediators such as prostacyclin, nitric oxide, endothelin, adenosine, histamine, serotonin, bradykinin, and others and concludes:

> Although sodium restriction may improve immediate physiological variables such as blood pressure, the adverse effects of concomitantly reduced iodine intake (in regions where salt is iodized) over the long term are unknown.
>
> Natural physiological roles for iodine, independent of its role in thyroid hormones, exist but have not been investigated as they relate to disease. It would be intriguing to determine whether these various anti-inflammatory, anti-proliferative and anti-microbial properties of iodine could play a role in the prevention of cardiovascular disease. Cardiovascular diseases remain leading causes of morbidity and mortality in the developed, and increasingly, the developing world. Prospective studies are needed to resolve what role iodine, as well as selenium status plays in the etiology of cardiovascular diseases.

**RETHINKING SINGLE NUTRIENT INTERVENTIONS: THE CASE FOR ADVANCING OVERALL DIETARY QUALITY**

A generation ago, every professional with nutrition credentials accepted the dictum that "there are no good foods and no bad foods, only good diets and bad diets." The luster of that truism has been allowed to tarnish, but all evidence suggests that it remains valid – and exceptionally pertinent. It is particularly true and pertinent to the issues under discussion here today.

A month ago, quite without intending to do so, delegates to a Salt Conference organized by the Grocery Manufacturers Association-Food Products Association and co-sponsored by CSPI rediscovered this truth and its relevance to the salt and health issue. Conferees included physicians, nutritionists, dieticians and policy makers – and FDA. The goal was to reach consensus on how best to reduce, significantly, the per capita consumption of sodium which has been virtually unchanged over the past century. Advocates of salt reduction recounted the medical evidence and representatives presented rosy assessments of the single-nutrient campaigns against salt in the UK

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[67] Caldwell K.L., Jones R., Hollowell J.G., Urinary iodine concentration: United States National Health and Nutrition Examination Survey 2001-2002. *Thyroid*, **15**:692-9, 2005.

[68] Hoption Cann, Stephen A. Hypothesis: dietary iodine intake in the etiology of cardiovascular disease. *Journal of the American College of Nutrition*. 2006 25(1) 1-11.

[69] Hasanen, E. Iodine content of drinking water and disease of the circulartoy system. *Ann Med Exp Fenn* 1970. 48:117-121.

and Finland. The delegates then divided into working groups which identified different strategies to achieve salt reduction, each group voting on its preferred strategy. After all the deliberations and all the votes of the working groups, there was consistent endorsement of two conclusions: 1) a singular focus on salt reduction was neither a proven solution nor a viable strategy and 2) a superior approach would be a more holistic approach to improve overall dietary quality in order to improve health outcomes. We were part of that discussion and support that conclusion. Specifically, the GMA/FPA-CSPI Salt Conference attendees overwhelmingly rejected the notion to focus on sodium or any other single nutrient, an affirmation by the professional community that it was far more important to promote a balanced diet than to regulate the intake of salt.

Nutrition is a complicated subject because the human body is a complicated mechanism. Then consider that our environmental exposures are varied. Finally, note that nutrients interact with each other. And, we don't consume "nutrients," we choose "foods" each carrying unique a unique amalgam of nutrients; whatever the basis for our food choice, we "buy" the entire package of nutrients for each food we include in our diet. Add to these facts, the policy preference that any dietary change should not only be evidence-based and credible, it must be potentially achievable by people who are getting frustrated trying to follow unrealistic and ever-changing advice and then being told that their efforts have been counter-productive and the population is regressing in the health impacts of its eating patterns. Again, as the Dietary Guidelines reminds us, our policy objective is "recommendations for an overall pattern of eating that can be adopted by the general public."[70]

An insight of Dr. Stephen Covey, a best-selling management consultant/author, may help us resolve these complex issues. Dr. Covey notes that complexity characterizes many problems in life and in business. Often, applying a simple explanation to these complex interrelationships turns out to be simplistic and utterly wrong. Success comes to those who persevere, however. Persistent trial and error seeking to dissect a complex problem is motivated by the hope that stripping away erroneous simplistic "solutions" will bring us to "the far side of complexity" – a relatively simple, and correct, understanding that unites all previously thought to be indecipherably complex.[71] Einstein's Theory of Relativity is such "simplicity on the far side of complexity."

Evidence suggests that we are emerging "on the far side of complexity," particularly with regard to the health outcomes associated with dietary salt intakes.

- First, however we feel about the salt/blood pressure relationship, evidence now suggests that where dietary sodium has a putative negative health effect, the issue is likely less an issue of "excess sodium" and more likely an issue of "deficient potassium," "deficient calcium" or "deficient magnesium" among a number of possibilities. When people consume recommended amounts of these other electrolytes, their "salt sensitivity" disappears. When a study identifies an effect of sodium, what is actually being discovered is a poor quality diet; evidence of a negative effect of dietary sodium has

[70] USDHHS and USDA, *Dietary Guidelines for Americans 2005*, Chapter 1, "Background and Purpose." op. cit.

[71] Covey, Stephen R. *The 7 Habits of Highly Effective People*. Free Press, 1990.

only been identified in subjects with inadequate intakes of other vital nutrients. Sodium intake levels in otherwise healthy individuals replete in other minerals have not been shown to represent additional risk for adverse health conditions or, especially, health outcomes.

- Second, population dietary recommendations based on hard outcomes, avoiding intermediate or surrogate markers like blood pressure, make it possible to avoid what one researcher terms "the slippery slope of surrogate outcomes."[72] Many factors affect intermediate variables. Accounting for confounding variables is always difficult. The important fact is that a population dietary recommendation demands clear data establishing that the intervention has a net health benefit. No expert in osteoporosis would argue for reduction of sodium chloride; he or she would insist first, second, third, etc. on mineral repletion or adequacy along with sufficient vitamin D. No expert in kidney stone disease would argue for restricting salt; he or she would recommend water and mineral repletion. No expert in gastric cancer would look at salt restriction (though he or she might recommend that those consuming an Asian diet high in salted and pickled foods might moderate that intake); he or she would, rather, recommend a diet high in fruits and vegetables.

These themes unite in the April 2000 study in *JAMA* by Ashima Kant et al. entitled "A Prospective Study of Diet Quality and Mortality in Women."[73] Diet quality is the "simplicity on the far side of complexity." Dr. Kant, implicitly, endorsed a diet like the DASH Diet or the Mediterranean Diet in her health outcomes conclusion:

> "The results from this large cohort of women with prospective follow-up suggest that dietary patterns characterized by consumption of fruits, vegetables, whole grains, low-fat dairy, and lean meats are associated with lower risk of mortality. Given the simplicity of the diet quality score used in this study, increasing the intake of recommended foods – **without undue emphasis on learning about hidden fat, total amount and type of fiber, or individual vitamins and minerals** – may represent a practical recommendation for improving health." (emphasis added)

The impressive reduction in risk of adverse outcomes in the Kant study is similar for all-cause mortality stroke, coronary heart disease and all-sites cancer. The following charts illustrates the health outcomes of improving dietary quality; the charts depict the risk among the four quartiles of dietary quality arrayed from worst to best, left to right.

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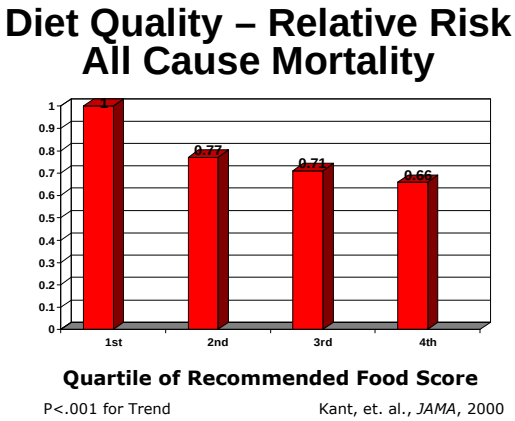
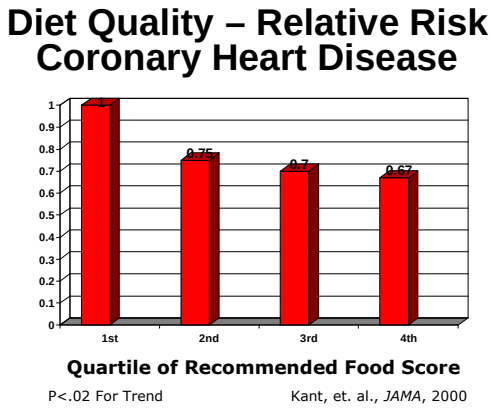
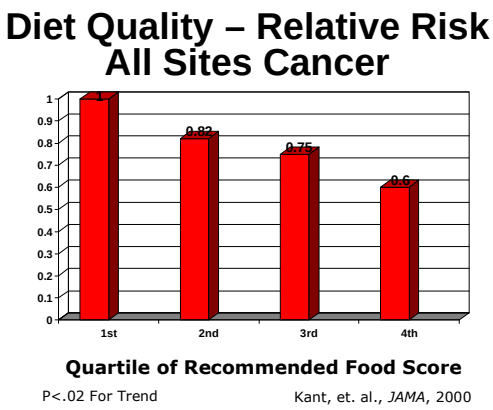
[72] D'Agostino, Jr. RB. The slippery slope of surrogate outcomes. *Curr Control Trials Cardiovasc Med* 2000, 1: 76-78.

[73] Ashima, AK, Schatzkin, A, Graubard, BI, Schairer, C. A Prospective Study of Diet Quality and Mortality in Women. *JAMA 283; 16:2109-2115.*








Since the early 1950s the health promoting qualities of the Mediterranean diet have been universally acknowledged. The Mediterranean diet "is characterized by abundant plant foods (fruit, vegetables, breads, other forms of cereals, beans, nuts and seeds), fresh fruit as the typical daily dessert, olive oil as the principal source of fat, dairy products (principally cheese and yogurt) and fish and poultry consumed in low to moderate amounts, zero to four eggs consumed weekly, red meat consumed in low amounts, and wine consumed in low to moderate amounts, normally with meals. This diet is low in saturated fat (less than or equal to 7-8% of energy) with total fat ranging from less than 25% to greater than 35% of energy throughout the region."[74] In fact, the famous DASH diet was designed using the Mediterranean diet as the model. What is never revealed, however, is that the level of salt in the Mediterranean diet is considerably higher than that the levels recommended for the US diet.

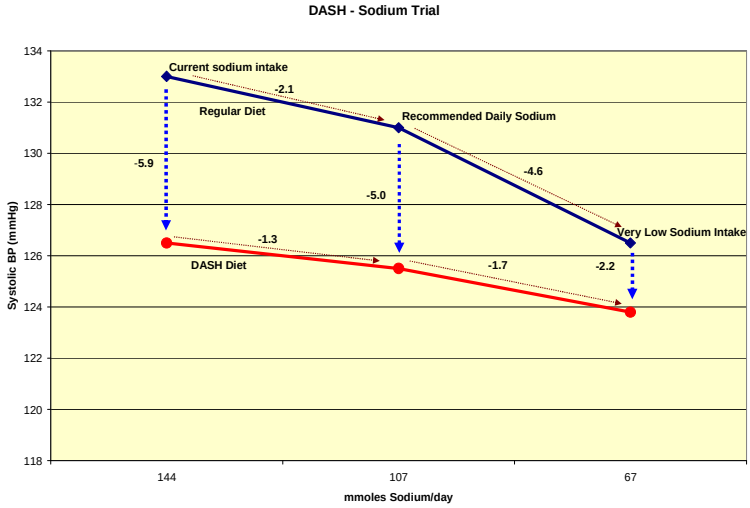
Leclercq and Ferro-Luzzi of the World Health Organization Collaborating Centre for Nutrition, at the National Institute of Nutrition in Rome, Italy reported in that Italian males consume 4400mg

[74] W. C. Willett, et al, Mediterranean diet pyramid: a cultural model for healthy eating, *American Journal of Clinical Nutrition*, June 1995 61(6S):1402S-1406S.

sodium per day based upon 24 hr urinary excretion, equivalent to 11grams of salt per day[75] and that the discretionary intake of salt for adults varied from 36% (males) to 39% (females) of the total intake. The discretionary intake of salt alone in Italy amounts to almost 75% of the total RDI of sodium in the US (2300mg). Since many of the Mediterranean foods are naturally well salted (cheeses, olives, salted fish (cod, anchovies), fish eggs, etc., it is natural to expect that a majority of the discretionary salt is used to improve the palatability of the variety of vegetables that are such a conspicuous and essential part of the diet.

When the DASH Sodium trial is examined, it is immediately apparent that moving to a DASH-type diet has a far greater impact on blood pressure than lowering salt consumption. Dropping from the current level of sodium consumption to the recommended dietary level dropped the systolic pressure by an average of 2.1 mmHg. However, simply changing from a regular to the DASH diet, without any changes to sodium consumption, reduced the systolic blood pressure by 5.9 mmHg, almost three times the drop resulting from the sodium reduction.

This clearly explains why Mediterranean people enjoy excellent an cardiovascular status despite their high salt consumption. With a DASH diet, the impact of sodium on the blood pressure of hypertensives is minimal -- and is of no significance to normotensive people – the majority in the population[76] as illustrated in this chart.




Considering that significantly increased fruit and vegetable consumption is a key element to the DASH/Mediterranean diet models, it is entirely realistic to question whether the current recommended daily intake of sodium (2300mg/day) is realistic, given the Italian example above. Standouts among the most important foods are the bitter cruciferous vegetables. While they have so much nutrition to offer, without salt, they are not palatable to adults or children (who are even more sensitive to bitterness). In addition to the benefits of the DASH/Mediterranean diet for cardiovascular disease outcomes, all other health parameters are significantly improved. Based on all the scientific evidence we have available, fruits and vegetables are the cheapest, most readily available, and most beneficial foods we can consume to give a significant degree of protection from the modern health challenges we face. This was convincingly demonstrated by Joceline Pomerleau

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[75] C. Leclercq and A. Ferro-Luzzi, Total and domestic consumption of salt and their determinants in three regions of Italy, *Eur J Clin Nutr*. 1991 Mar;45(3):151-9.

[76] Freedman, David A. Freeman and Petitti, Diana B., Salt, blood pressure and public policy, *International Journal of Epidemiology*, 31(2), 319-320, (2002).

et al in their publication, "The burden of disease attributable to nutrition in Europe," published in Public Health Nutrition in 2002[77] and reconfirmed on a global basis in their 2005[78]. Bulletin of the World Health Organization Considering the hierarchy of positive health impacts, maintaining the DASH/Mediterranean diet is far more significant than reducing salt – the one safe condiment that has traditionally made this diet so agreeable.

FDA's decision in the 1980s to address sodium concerns through labeling was a reasonable course of action. As a next step, the most constructive and effective way to promote reduced risk of cardiovascular disease is to promote healthy diets. For example:

- Increased consumption of fruits, vegetables, and low-fat dairy products would be expected to have a greater effect on public health than sodium restrictions.

- Labeling policies and requirements (e.g., existing health claims) that confuse or obscure current recommendations to consume more fruits, vegetables, and low-fat dairy products should be re-evaluated. For example, a health claim that focuses solely on the relationship between sodium and hypertension omits important information about healthful dietary patterns relevant to blood pressure and does not further current dietary guidelines.

**FDA AFFIRMATION OF GRAS FOR SALT**

In previously declining to change the GRAS status of salt, FDA recognized the unique role of salt in the food supply, found sodium intake to depend on the total diet and not the salt content of any individual food, and found the sodium sensitivity of hypertensive patients to vary widely. While this latter point has been further confirmed in that we have fairly consistent evidence that "salt sensitive" blood pressure is produced by intake deficiencies of calcium, magnesium and potassium, the relevance of blood pressure, as mentioned earlier, has faded as attention is now focused on health outcomes, not such intermediate variables as blood pressure (also plasma renin activity, insulin resistance, etc.). The TOHP-2 trial demonstrated that intense counseling can keep study populations on sodium-reduced diets for 36 months, but also showed that the body adjusts to the lack of salt and blood pressure returns to the pre-intervention level over time even when the intervention is maintained. Thus, it is clear that blood pressure is an indicator of system performance, but not the appropriate target for the intervention (that, of course, is cardiovascular system health and overall health). For the same reason, while research has now shown clearly that being overweight is a far more important variable affecting blood pressure than is salt, and that variable would seem to have salience in the midst of a declared "obesity epidemic," in fact, the relevance of this information is also diminished by the appropriate focus on health outcomes.

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[77] Pomerleau, Joceline, McKeel, Martin, Lobstein, Tim and Knai, Ce´cile, The burden of disease attributable to nutrition in Europe, *Public Health Nutrition* 6(5), 453–461, (2002).

[78] Lock, Karen, Pomerleau, Joceline, Causer, Louise, Altmann, Dan R., and McKeel, Martin., The global burden of disease attributable to low consumption of fruit and vegetables: implications for the global strategy on diet, *Bulletin of the World Health Organization*, Volume 83, Number 2, 81-160,(2005).

FDA also has noted the many practical difficulties that would complicate prescribing and enforcing limitations for salt. These considerations remain valid today. The original rationale, as recounted in the notice for this hearing continues to be valid and compelling:

> FDA considered revoking the GRAS status of salt and declaring it to be a food additive in 1982, but rejected this approach for several reasons, including the following: (1) The agency would have to establish a limitation for each technical effect for which salt is used in each food category, and it would be extremely difficult to prescribe and enforce 'fair use' limitations for salt that would be safe and effective for all consumers (including those hypertensive patients on severe sodium restrictions) given the fact that salt has numerous technical functions in a wide variety of processed foods and may often be used for several different technical effects in a single food and (2) many uses of salt are prior sanctioned and the agency would have to show that salt in food is a 'poisonous or deleterious substance' for it to take regulatory action against a prior sanctioned ingredient. Failing to do this, the practical effect of regulating those remaining uses of salt not authorized by prior sanction might be quite small and the issuance and enforcement of limitations for uses of salt would therefore constitute an extraordinary regulatory burden for FDA. …. FDA is not aware of any fundamental changes to these considerations since it published the 1982 policy notice.

Neither are we. In fact, there have been no fundamental changes to these considerations and, as described earlier, the emergence in the past decade of a relatively consistent body of health outcomes studies that fail to substantiate a health benefit from universal sodium reduction further strengthens FDA's foresight in resisting the call to rescind salt's GRAS status.

**ADVERSE EFFECTS OF A REPEAL OF GRAS FOR SALT**

As earlier mentioned, salt is added for myriad good reasons extending well beyond taste. Moreover, it is integrally related to other dietary considerations.

FDA must recognize that reclassifying the GRAS status of sodium despite the fact that the risk of harm, if any, can be largely mitigated by a healthful diet would appear to set a precedent. Risks that are most appropriately addressed via diet and nutrition arguably should not be included in assessing whether a "harm" to health is posed within the meaning of the GRAS standard.

Even if a controlled trial were to establish improved health outcomes from reduced-sodium diets and another trial were to establish that diets in which sodium-reduced products are substituted for "regular"-salt products, there still remains a substantial difference between encouraging development of sodium-reduced products for a possible public health benefit and classifying a common food ingredient as a "food additive" that cannot be safely used absent FDA approval.

The ubiquity of salt in foods in our diets is a fact we must deal with. In fact, as statistics show, about half American women are already consuming 2,300 mg Na or less – and about 20% of men. Yet they tell pollsters they aren't on "low-sodium" diets and will resist such prescribed diets. That commends an overall dietary quality approach.

- Since salt plays an important role in palatability, including the palatability of foods such as vegetables, FDA would want to have solid evidence that attempts to restrict sodium will not hinder more important public health efforts to increase potassium and/or vegetable intake.

- Since the U.S. and all public health agencies worldwide have agreed that iodizing salt is the preferred strategy to combat Iodine Deficiency Disorders, FDA would want to have solid evidence that any regulatory regime would not adversely impact our already-declining population intake of dietary iodine – particularly in pregnant women and children.

- FDA will want to consider the potential threat of induced deficiencies for persons trying to achieve low-salt diets. We would not want to repeat the disaster sowed when a infant formula manufacturer, seeking to lower newborn infants' sodium intake, removed salt from the formula and produced chloride-deficient infants with permanent brain damage. Salt is, after all, a major source of dietary chloride as well, another essential nutrient.

- Since salt is vital to the microbiological stability, FDA would want solid evidence that reduced-salt foods do not compromise food safety standards.

- Since salt content is often part of the defining character of certain foods as indicated previously, FDA would want to consider whether it is even possible to fashion a regulatory regime that does not result in the banning of foods long proven to be safe in national diets around the world. These issues could raise concerns with the World Trade Organization.

As suggested above, the lack of any evidence demonstrating whether diets that incorporate greater numbers of low-sodium foods actually result in low-sodium diets, would handicap any effort by FDA to actually be able to achieve the stated objective of the petition. There is no roadmap for how a "food ingredient" regulation could deliver that objective. FDA certainly does not plan to ban the sale of table salt used in home food preparation and at the table. Since consumer taste for salt varies widely (as distinct from actual sodium intakes), allowing individuals to add salt to taste has the potential to frustrate the objective entirely. The British are grappling with this dilemma, BBC reports. Finding that significant numbers of school children refuse to eat the "healthy" food in the school cafeteria, the Scottish Centre for Social Research advocates that the Glasgow school board institute a policy of locking the children into the school at lunchtime to prevent them from leaving to find more palatable options and intends to police the nutritional quality of lunches they bring from home.[79] No word yet on how they intend to police the kids' after-school snacks for the nutritional sufficiency of family meals.

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[79] Call for school lunchtime lock-in. BBC news. November 13, 2007. Accessed online November 28, 2007 at http://news.bbc.co.uk/1/hi/scotland/glasgow_and_west/7093676.stm.

**RESPONSES TO FDA "QUESTIONS FOR DISCUSSION"**

Issue 1: FDA determination of GRAS status for salt

1. The Salt Institute agrees with FDA's assessment:

> "The agency would have to establish a limitation for each technical effect for which salt is used in each food category, and it would be extremely difficult to prescribe and enforce 'fair use' limitations for salt that would be safe and effective for all consumers (including those hypertensive patients on severe sodium restrictions) given the fact that salt has numerous technical functions in a wide variety of processed foods and may often be used for several different technical effects in a single food, and (2) many uses of salt are prior sanctioned and the agency would have to show that salt in food is a 'poisonous or deleterious substance' for it to take regulatory action against a prior sanctioned ingredient. Failing to do this, the practical effect of regulating those remaining uses of salt not authorized by prior sanction might be quite small and the issuance and enforcement of limitations for uses of salt would therefore constitute an extraordinary regulatory burden for FDA. These facts and the uncertainty about the precise role of salt as a basic causative factor in essential hypertension left unclear whether the use of salt in a particular food would render that food uniformly injurious to health. Therefore, FDA concluded in 1982 that informative labeling would be more responsive to the health concerns about sodium (47 FR 26590). FDA is not aware of any fundamental changes to these considerations since it published the 1982 policy notice."

It would be "extremely difficult" to construct a food additive regulation limiting salt. We believe it would be impossible to craft such a regulation that offers any public health benefit. FDA should affirm the GRAS status of salt.

2. As discussed above, it <u>is</u> possible to reduce salt modestly in foods. This has been done. The question remains: <u>why</u> should it be done? There is no evidence of a probable health benefit. The matter should be left to marketplace decisions of health-conscious consumers and consumer-conscious food marketers.

3. We disagree with the CSPI petition in virtually all but its underlying premise: that dietary improvements can have a positive impact on America's public health. We strongly endorse a vigorous effort to improve the overall quality of the American diet, particularly to overcome current deficiency-level intakes of vital nutrients such as potassium, calcium and magnesium. We endorse, however, a food-based approach, eschewing the focus on nutrients generally and any single nutrient specifically, such as sodium. Evidence does not indicate that, even if successful, an effort to reduce population sodium intakes will improve Americans' health. Of course, we continue our support for ingredient labeling that allows consumers to make informed food purchase decisions.

4. Industry could partner, but the federal government should take the lead in developing an effective public health nutrition program regarding dietary sodium by funding the research necessary to confirm at least the two fundamental and unexamined questions. First, would reducing

population dietary sodium improve health outcomes such as cardiovascular and all-cause mortality? And, second, would changing individuals' diets to incorporate lower-sodium foods (including "low sodium" processed foods) result in overall reduction of dietary sodium to the currently-recommended levels? Any further investment of public resources in developing more rules and regulations or private resources in developing technologies to reduce dietary salt depend on the answers to these questions.

Issue 2: FDA nutrition labeling issues

5. We are unaware of any effect of FDA regulations on reducing Americans' salt intake. Americans' salt intake has been unchanged for the past century, the time period during which we have been able to measure it with some degree of accuracy.

6. We believe that sodium statements on food labels mislead consumers into thinking that the sodium content of the foods they purchase affects their health. No quality evidence is available to support this link. We believe research would confirm our fear that a single-nutrient focus on sodium has undermined consumers' ability to achieve overall higher quality diets as mentioned above.[80]

7. This question is beyond the scope of our expertise. We question the premise that FDA should provide incentives, certainly until science establishes that some health benefit can be expected.

**SUMMARY AND CONCLUSIONS**

Salt rightly enjoys its status as the original GRAS substance and contributes enormously to the quality of American life, including the quality of the American diet. FDA should affirm its earlier findings that salt should be Generally Recognized as Safe. FDA should deny the CSPI petition.

Further, FDA should join the Salt Institute in encouraging a controlled trial of the basic question of whether a population reduction in dietary salt would improve public health. The protocol for such a trial is proven and available. This is an investment well worth making. Policy should be based on endpoint outcomes like cardiovascular mortality or all-cause morality. The NHANES data offer no support for the current policy of universal sodium reduction. The health outcomes in Finland following its salt reduction "success" suggest that salt reduction may retard achieving other health improvements. Let's do the study and find out the truth.

We lack evidence even on the basic assumption of this proceeding, namely that if consumers would only consume more "low sodium" foods they would fashion for themselves sustainable low-sodium diets. Let's test that assumption with solid research, too.

Salt contributes to product quality and identity and, importantly, to food safety. Replacing salt isn't easy, as food technologists have discovered after extensive – and expensive – efforts. Finding a

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[80] Morris, Cynthia D. op cit.

replacement that tastes like salt, behaves like salt in various food functions and is proven safe when used in significant amounts has been a daunting challenge.

A more promising approach than any single nutrient intervention would be to promote a food-based effort to improve the overall quality of the American diet. Indices of healthy eating have been associated with improvements in cancer risk, cardiovascular health and all-cause mortality. Correcting current deficiencies in potassium, calcium and magnesium by encouraging greater consumption of fruits, vegetables, whole grains and dairy products would be a superior strategy.

So, in sum, FDA should put its efforts behind quality research and emphasize overall dietary quality while affirming the GRAS status of salt and resisting efforts to demonize this safe and essential nutrient.

Thank you.