SODIUM REDUCTION AND INTERNATIONAL TRADE

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High levels of salt consumption are common in many countries that have the high life expectancies. A number of these countries are exporters of well-established traditionally-processed foods. Thus, it is possible that a requirement for reduced salt in processed foods may be looked upon as a trade barrier by food-exporting countries and cause a dispute at the World Trade Organization (WTO).

Sanitary and phytosanitary measures are defined as measures applied to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS) restricts the use of unjustified measures for the purpose of trade protection. The basic aim of the SPS Agreement is to ensure that all regulatory measures are not misused for protectionist purposes and do not result in unnecessary barriers to international trade. The SPS Agreement, reduces possible arbitrariness of decisions and requires that sanitary and phytosanitary measures be applied for no other purpose than that of ensuring food safety and health. In particular, measures to protect health should be based, as far as possible, on the analysis and assessment of objective and accurate scientific data.

The SPS Agreement encourages governments to establish national SPS measures consistent with international standards, guidelines and recommendations. Standards are developed by leading scientists in the field and governmental experts on health protection and are subject to international scrutiny and review.

International standards are often higher than the national requirements of many countries, nevertheless, the SPS Agreement explicitly permits governments to choose not to use the international standards. However, if the national requirement results in a greater restriction of trade, a country may be asked to provide scientific justification, demonstrating that the relevant international standard would not result in the level of health protection the country considered appropriate. The Agreement checks unjustified discrimination in the use of sanitary and phytosanitary measures, whether in favor of domestic producers or among foreign suppliers.

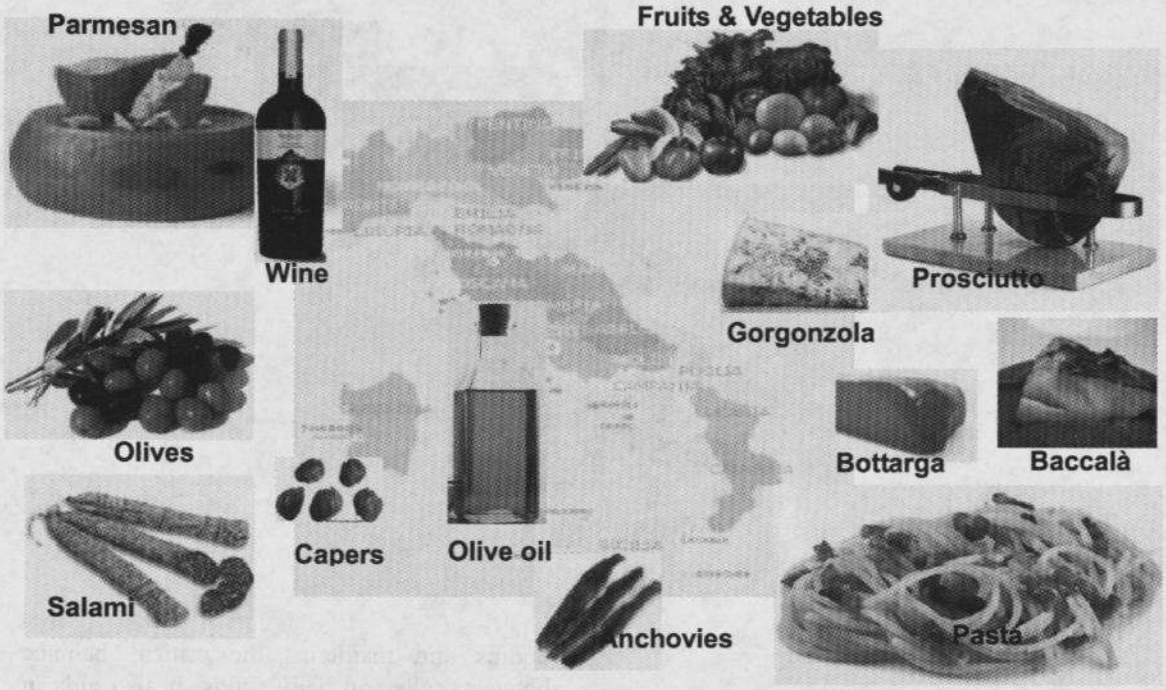
The SPS Agreement increases the transparency of sanitary and phytosanitary measures. Countries must establish SPS measures on the basis of an appropriate assessment of the actual risks involved, and, if requested, make known what factors they took into consideration, the assessment procedures they used and the level of risk they determined to be acceptable.

In a trade dispute regarding a sanitary or phytosanitary measure, the normal WTO dispute settlement procedures are used, and advice from appropriate scientific experts can be sought.

Technical regulations and product standards may vary from country to country. If regulations are set arbitrarily, however, they could be used as an excuse for protectionism. The Agreement on Technical Barriers to Trade tries to ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles and are based upon sound scientific information.
Because a large portion of dietary sodium enters the food supply through processed

foods, sodium reduction programs in the UK and Canada are directed at reducing the salt content of these products. While most consumers and policy-makers perceive processed foods to be convenience foods made by large scale manufacturers, a great many traditional foods customarily considered to be high quality are also processed and contribute significantly to the dietary sodium we consume. When any country believes they are affected by the use of unjustified measures, including health measures, which may be a non-tariff trade barrier, they are permitted to bring their claim to the WTO for resolution. When this happens, the Food and Agriculture Organization of the United Nations is usually requested to adjudicate such disputes. When doing so, the FAO convenes a panel of experts that are chosen for their objectivity and expertise in making evaluations based on the preponderance and quality of scientific evidence. If that were to be the case, what would the FAO panel of experts learn in their evaluation of the scientific data surrounding the salt and health debate?

Because the country of Italy is so well known around the world for its gastronomic reputation and because it has such significant food exports, traditionally processed Italian foods can serve as an example.



Besides pasta, olive oil, wine, fruits and vegetables, the Italian diet contains a great many staples that are high in salt, including hard cheeses such as Parmesan and Pecorino; various olives; Baccalà or salt cod; anchovies; capers; blue cheeses like Gorgonzola; Bottarga or salted tuna roe and the large arrays of Prosciutto ham. All these traditional Italian foods have a rather high salt content. As an example, for close to a century, all ham imported into the USA has been analyzed for the parasite Trichinella spiralis and Italian Parma ham is the only product where the infection was never detected. This is attributed to the salt levels used in its traditional production.

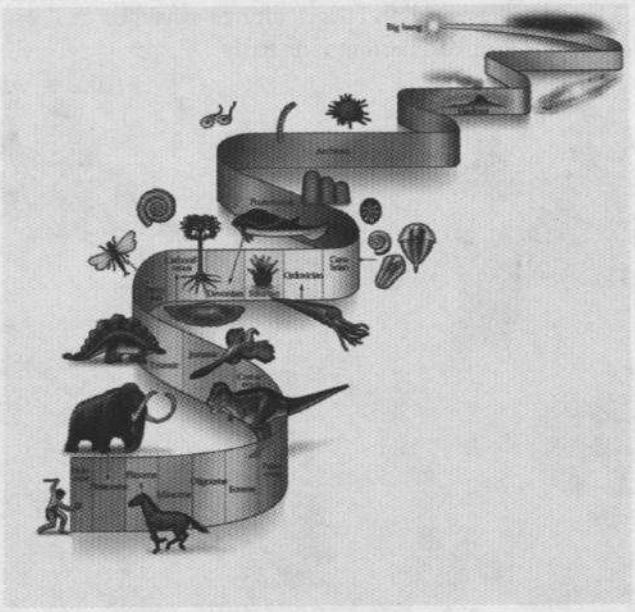
For more than 350 years, Parmesano Reggiano cheese has been artisanally made by small manufacturers in the Parma region of Italy. To cure their fresh cheese, they immerse the rounds in a saturated salt bath (some of which have been in continual operation for more than 100 years).

Yet, despite the very high salt content of the Italian diet[75], their cardiovascular figures are excellent. In fact, the per capita consumption of salt in Italy is considerably higher than in the US, Canada or the UK, yet their

[75] C. Leclercq and A. Ferro-Luzzi, "Total and domestic consumption of salt and their determinants in three regions of Italy," European Journal of Clinical Nutrition, Mar, 45(3), 151-9, (1991).

cardiovascular performance is superior.

If, in the course of executing a sodium reduction program, restrictions are placed upon the salt contents of classes of foods, many of which may have long-established standards if identity, such an action may be perceived by exporting countries as an artificial technical trade barrier and cause a dispute settlement procedure at the WTO. For example, an exporting country, such as Italy, may well claim that it has never been proven that, for the majority of the population, salt reduction has demonstrated any significant health outcome benefits. In such an argument, Italy can point to its own cardiovascular performance as proof that higher salt consumption does not have any negative impacts on health.



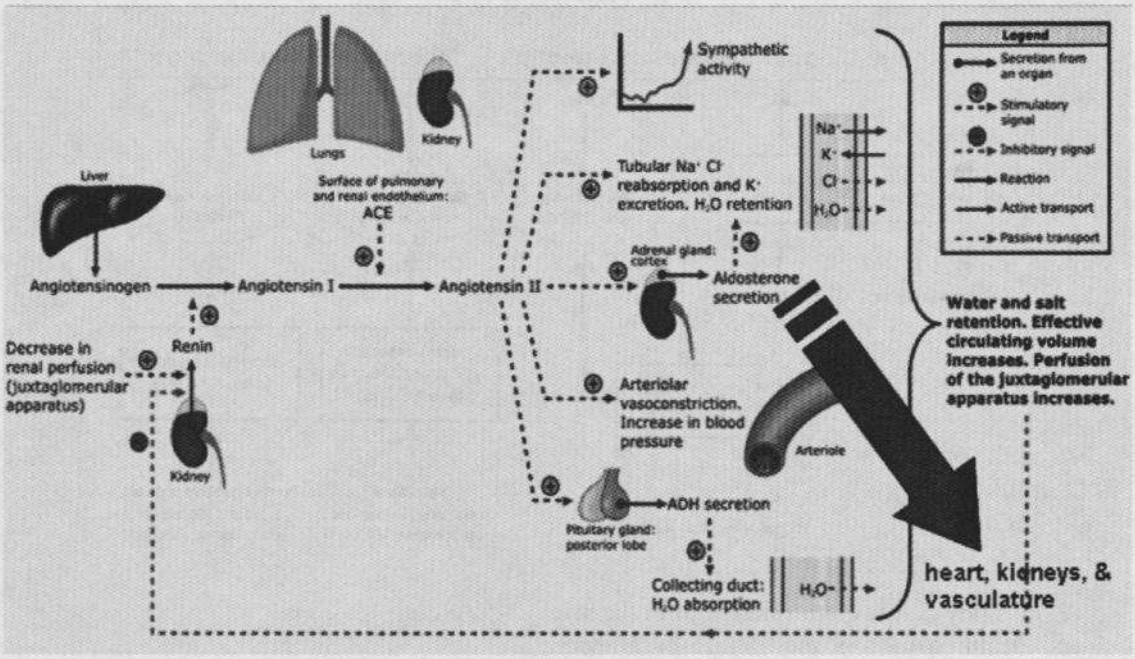
The Role of Salt

Aside from water, salt is the most ubiquitous food ingredient consumed by humankind. Salt is a nutrient that is essential to life and good health. Having originally evolved from a marine environment, the human body's salt/water ratio is critical to metabolism. Human plasma contains 0.9% salt (sodium chloride) in order to maintain the electrolyte balance. In the normal course of metabolism, we routinely eliminate sodium along with most other waste materials and the minimum balance must be replenished if we are to survive. Most of our salt intake comes from foods, and some from water. Of course, any activity resulting in excessive loss of sodium such as exercise has to be counterbalanced by increased salt consumption to make up this additional loss.

Salt controls the amount of water within our bodies and maintains the critical balance between cells and body fluids. It also aids in the contraction of muscle tissue and serves as a vital ingredient of blood plasma and digestive secretions. The sodium-potassium pump is the key to functions such as cardiac and renal activity, as well as all general transport processes into and out of the cell. The pump thus forms the basis for our ability to absorb a considerable number of nutrients, excrete waste products from the kidneys and regulate the water balance in the cells. If sodium ions were not pumped out of the cells, the latter would rapidly swell up because of infiltration water and burst.

If we do not replenish adequate sodium, our metabolic system goes into a sodium-sparing mode so that we can maintain osmotic balance and sufficient blood pressure. This has multiple significant consequences for us. Reductions in sodium intake are accompanied

by significant increases in the rennin-angiotensin-aldosterone hormone system (RAAS). Although this reaction is designed to sustain osmotic balance and pressure, an elevated RAAS has critical negative effects on the condition of our circulatory system, smooth muscle cells and inflammatory agents within the body. For people with hypertension, increased RAAS activity predicts increased potential for heart attacks and for the increased insulin resistance and type-2 diabetes that so often accompanies low-sodium diets. Thus, reduction of sodium in the diet has to be considered very cautiously.



The concerns over salt are chiefly based upon its ability to affect blood pressure, which no one disputes. However, the impact of sodium reduction upon blood pressure is heterogeneous. About 1/3 of normotensive individuals experience a drop in blood pressure, while about 20% of normotensive individuals experience an increase in blood pressure and the remainder show no effect[76, 77, 78]. So, reducing salt will not hold the same benefits for everyone and any policy designed to arbitrarily reduce salt intakes will negatively discriminate against a certain segment of the population.

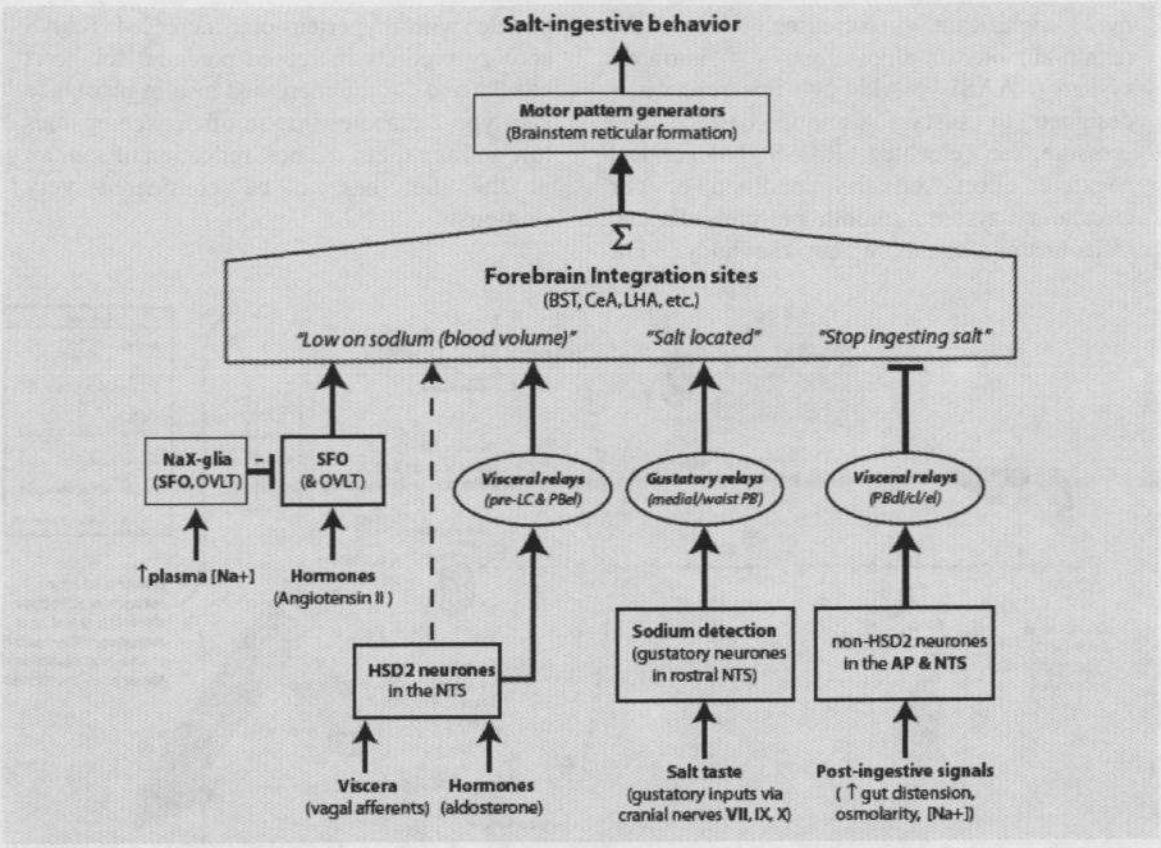
The recent paper entitled, "Central Regulation of sodium appetite," by Joel Geerling and Arthur Loewy of Washington University School of Medicine in St Louis, MO, elaborates the multiple mechanisms responsible for our appetite for salt, including neural connections and mineralocorticoid receptors[79]. This multi-factorial system is so robust and includes so many failsafe and redundant mechanisms that it continues to fully function even after large sections of its system are shut down. Employing a complex cascade of physiological functions from powerful hormones, such as aldosterone, to pressure sensitive baroreceptors in the brain, this water thirst and salt appetite mechanism moderates our behavior so that we are driven to quickly replenish the volume and osmotic balance of our blood, so that it is pressurized sufficiently for our heart to pump it throughout our circulatory system. And although this research was carried out in rats, there is good reason to believe that similarly functioning systems exist in humans.

[76] Luft FC, Rankin LI, Block R et al. Cardiovascular and humoral responses to extremes of sodium intake in normal black and white men. Circulation 1979; 60: 697–706.

[77] Miller JZ, Weinberger MH, Daugherty SA et al. Heterogeneity of blood pressure responses to dietary sodium restriction in normotensive adults. Journal of Chronic Diseases, 1987; 40: 245–250.

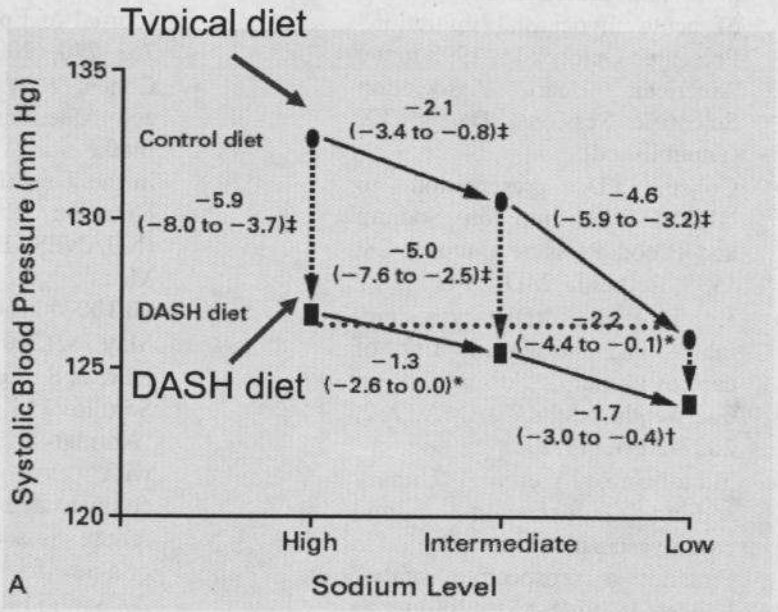
[78] Luft FC, McCarron DA. Heterogeneity of hypertension: the diverse role of electrolyte intake. Annual Reviews of Medicine, 1991; 42: 347–355.

[79] Geerling, J. C. and Loewy, A. D., "Central regulation of sodium appetite," Experimental Physiology 93(2), 178-209, DOI: 10.1113/expphysiol.2007.039891



A key study that is often referred to in the salt and health debate is the DASH or Dietary Approaches to Stop Hypertension trial. The following graphic from the paper describing that trial is familiar to many[80]. When closely examined, the FAO panel will note that, while there was an approximate 2.1 mm drop in blood pressure going from the control diet to the recommended intermediate level of 2,300 mg sodium, there was a much greater drop of 5.9 mm by simply going to the DASH diet alone without any sodium reduction at all – an almost 3 times greater drop –as can be seen from the lower red line, the DASH diet alone gave virtually the same blood pressure drop as the lowest salt level.

[80] Sacks, F. M., Svetkey, L. P., Vollmer, W. M., Appel, L. J., Bray, G. A., Harsha, D., Obarzanek, E., Conlin, R. P., Miller, ER III, Simons-Morton, D. G., Karanja, N.,. Lin P-H, DASH-Sodium Collaborative Research Group, "Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet," N Engl J Med., 344, 3–10, (2001).



In examining the issue, the FAO panel will learn blood pressure is not a health outcome per se, but one factor among many that project a risk for cardiovascular disease.

Examining a single risk factor is not considered a prudent approach, because other important risk factors may be ignored. We saw this most recently when the ACCORD trials for diabetes had to be stopped because the intensive approach to reduce a single risk factor, blood sugar, ended up killing more people because of the unintended consequences the approach was causing. Of course, you can lower blood pressure, but if, at the same time, you increase other risks, the net result is not really what you want. That's why the panel will not consider a singular focus on blood pressure a wise or valid approach to managing cardiovascular disease. You must determine the benefits of salt reduction on cardiovascular disease itself, not any one specific risk factor. In fact, the effect of salt reduction on cardiovascular disease was reviewed in 2003[81] and again in 2008[82] by the Cochrane Collaboration, the world's most respected institute for evidence-based medicine. They found salt reduction to hold no significant benefit for cardiovascular disease.

[81] Hooper, L., et al., "Systematic review of long term effects of advice to reduce dietary salt in adults," British Medical Journal, 325, 628-636, (2002).

[82] Hooper L, Bartlett C, Davey Smith G, Ebrahim S., "Advice to reduce dietary salt for prevention of cardiovascular disease (Review)," Cochrane Database of Systematic Reviews, Issue 4, 2008.

The panel will review these reports.

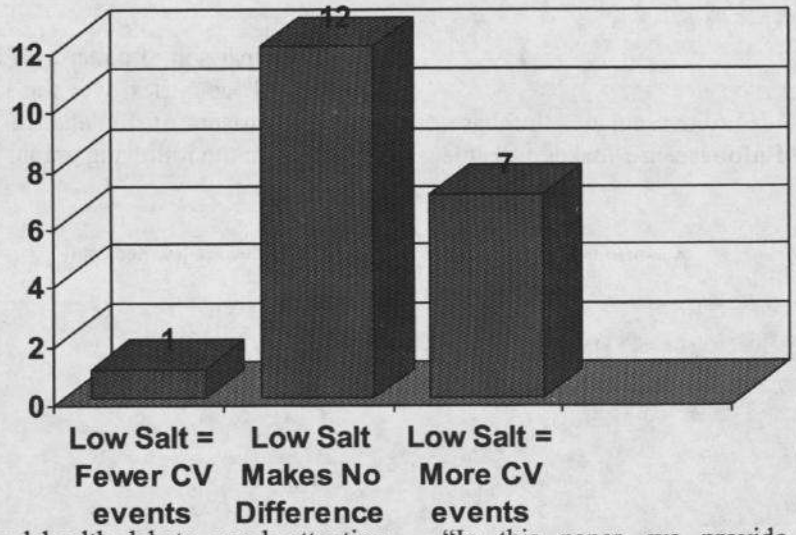
There have been several other studies examining the health outcomes of dietary salt reduction:

- Kagan, A., et. al., "Dietary and other risk factors for stroke in Hawaiian Japanese men," Stroke, 16, 390-396, (1985).
- Alderman, M.H., et al., "Low urinary sodium associated with greater risk of myocardial infarction among treated hypertensive men," Hypertension, 25, 1144-1152, (1995).
- Cutler, J.R., Presented May 30, 1997, at American Society of Hypertension annual meeting, San Francisco, CA. (unpublished).
- Tunsall-Pedoe, H., "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, 315, 722-729, (1997).
- Alderman, M.H., et al., "Dietary sodium intake and mortality: the National Health and Nutrition Examination Survey (NHANES I)," Lancet, 351, 781-785, (1998).
- 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).

- Cohen, J.D. presentation to NHLBI Workshop on Sodium and Blood Pressure, January 28, 1999, Bethesda, MD.
- He, J., et al., "Dietary sodium intake and subsequent risk of cardiovascular disease in overweight adults," JAMA, 282, 2027-2034, (1999),
- Tuomilehto, J., et al., "Urinary sodium excretion and cardiovascular mortality in Finland: a prospective study," Lancet, 357, 848-851, (2001).
- Hooper, L., et al., "Systematic review of long term effects of advice to reduce dietary salt in adults," British Medical Journal, 325, 628-636, (2002).
- Grobbee, D.E., et al., "Sodium and potassium intake and risk of cardiovascular events and all-cause mortality: the Rotterdam Study," presented to the 13th European Meeting on Hypertension in Milan, Italy, June 13-17, (2003).
- Nagata, C. et al., "Sodium intake and risk of death from stroke in Japanese men and women," Stroke, 35, 1543-1547, (2004).
- Cohen, H., et al., "Sodium intake and mortality in the NHANES II follow-up study," American Journal of Medicine, 119, 275, (2006).
- 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, published online on 20 April 2007.
- 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, 22(11), 763–770, (2007).
- Cohen, H.W., Hallpern, S. M., and Alderman, M. H., "Sodium Intake and Mortality Follow-Up in the Third National Health and Nutrition Examination Survey (NHANES III)," J Gen Intern Med., DOI: 10.1007/s11606-008-0645-6, May 18, (2008).
- Paterna S ; Gaspare P ; Fasullo S ; Sarullo FM ; Di Pasquale P., "Normal-sodium diet compared with low-sodium diet in compensated congestive heart failure: is sodium an old enemy or a new friend?" Clin Sci (Lond). 2008; 114(3):221-30 (ISSN: 1470-8736).
- Hooper L, Bartlett C, Davey Smith G, Ebrahim S., "Advice to reduce dietary salt for prevention of cardiovascular disease (Review)," Cochrane Database of Systematic Reviews, Issue 4, 2008.
- Cook, N., et al, "Joint Effects of Sodium and Potassium Intake on Subsequent Cardiovascular Disease," Arch Intern Med. 2009;169(1):32-40.
- Paterna, S., et al., "Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients with Recently Compensated Heart Failure," American J. Cardiol 2009; 103:93–102.

In total, of the 20 major studies on the impact of dietary salt reduction, 1 has shown fewer cardiovascular events, 7 have shown more cardiovascular events occurring and the remaining 12 show little or no impact. These will all be reviewed by the panel of experts.



In the salt and health debate, much attention has been paid to the Yanomamo Indians of Brazil. The salt reduction advocates state that the Yanomamo Indians have no age related rise in blood pressure because of their very low salt consumption. However, the Yanomamo Indians have a life span of 47 years, compared to an average of 80 years or more for most modern developed societies. The idea of comparing modern societies with those that have greatly different lifestyles, environmental stresses, eat far, far fewer calories, and consume much more fiber from raw fruits and vegetables is not considered scientifically defensible. Besides, the Yanomamo Indians as most Amerindians have an almost total absence of the D/D genotype - the very genotype that is directly associated with hypertension and cardiovascular disease[83, 84]. That is why they don't have an age-related rise in blood pressure.

There has been ho much publicity about how Finland reduced its per capita salt consumption from 14 g/day down to 8 g/day, after 30 years of intensive anti-salt campaigning. This was brought on by the recent publication of a research article by Heikki Karppanen and Eero Mervaala [85]. They boldly stated:

"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 disease mortality in the population younger than 65 years."

The authors refer to an aggressive national anti-salt campaign involving influential newspapers, labeling programs and a consensus agreement of government and scientific organizations with the food industry. The result of this effort was a drop in per capita salt consumption from 14 g per day down to 8 g per day - close to a 50% reduction. Finland is the only country which has managed to do this.

To strengthen the case for salt reduction, the authors went on to state that:

"Evidence is presented to indicate that the comprehensive salt reduction has also played an important part in the remarkable 5- to 6-year increase in the life expectancy of the Finnish population during the past 25 to 30 years."

The figures in that paper clearly show a dramatic drop in per capita salt intake in Finland. As the authors state, "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".

They go on to state that salt consumption in the United States was not reduced during that same time period. Unfortunately, they did not actually record the US cardiovascular data for comparison a relatively straightforward

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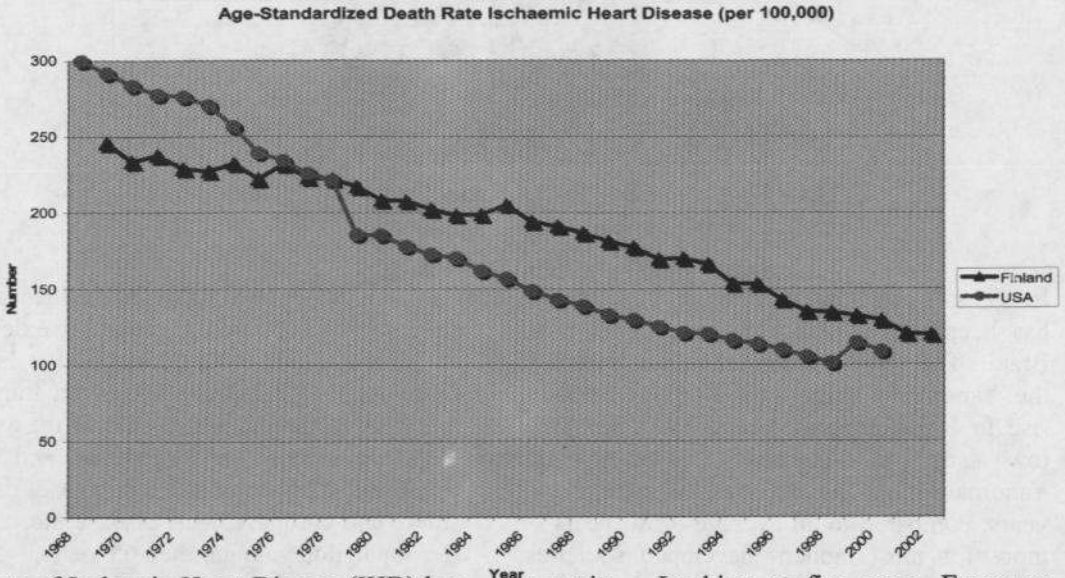
[83] Weiss, K.M., R.E. Ferrell, and C.L. Hants, "A New World syndrome of metabolic diseases with a genetic and evolutionary basis," Yearbook Phys. Anthropol, 27, 153-178, (1984).

[84] Mitchell, B.D., M.P. Stern, S.M. Haffner et al., "Risk factors for cardiovascular mortality in Mexican Americans and non-Hispanic whites. The San Antonio Heart Study," Am. J. Epidemlol, 131, 423-433, (1990).

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

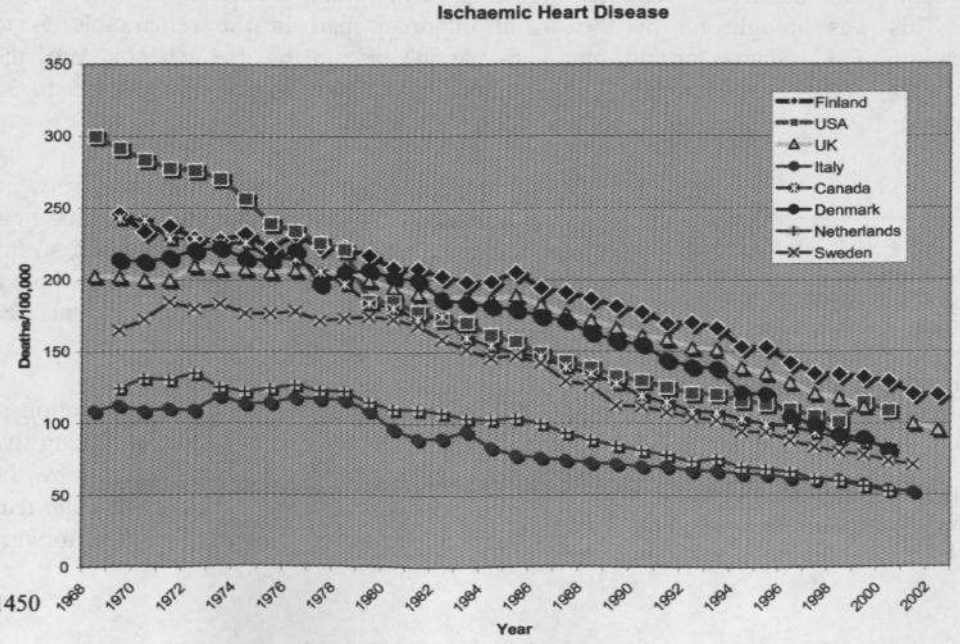
matter.

The Global Cardiovascular Infobase, (**http://www.cvdinfobase.ca/**) makes possible a clear comparison of patterns of heart disease (IHD) in all countries over the last 35 years. The comparison of Finland to the U.S. is illustrated in the following graph:



The rate of Ischemic Heart Disease (IHD) has decreased in both countries. In fact, the degree of heart disease reduction is far superior in the U.S., having started at a significantly higher rate in the late '60s and dropping down to a lower rate by the year 2,000. Yet, unlike Finland, where the per capita salt intake has steadily declined from 14g/day down to 8g/day, U.S. per capita food salt consumption has fluctuated in the range between 7g/day and 11g/day.

Karppanen and Mervaala were clearly wrong in attributing reduced cardiovascular disease to a reduction in salt consumption. If anything, the evidence would suggest just the opposite. Looking at five more European countries and Canada confirms the relationship. All of these countries significantly reduced their ischemic heart disease mortality over the past 30 years, yet none but Finland claim any reduction in dietary salt. In fact, in the early '70s, the closest risk rate to Finland's was that of Canada. By the year 2,000, with no salt reduction in Canada, Canadians had reduced their IHD mortality by twice as much as Finns. Finland had the **least** impressive improvement of the entire group and, as the authors boldly remind us, Finland was the only country to achieve a significant and sustained reduction in per capita salt consumption.



The authors' second health outcome metric is longevity. They claim that the 5-6 year increase in life expectancy experienced in Finland is also the result of the reductions in salt intake. Again, using the same country set, the U.S. led the group in increased life expectancy, improving fully 45% more than in Finland. In fact, Finland's improved life expectancy appears modest when compared to most of its neighbors. As the authors point out, Finland was the only country to achieve salt reduction, but, as far as increases in life expectancy are concerned, earned a sub-par health benefit for all this effort; countries with consistent salt consumption levels set the pace for extending their citizens' lives as shown in the following table derived from the International Data Base of the US Census Bureau (**http://www.census.gov/cgi-bin/ipc/agggen**).

Country	30-Year Increase in Life Expectancy (years)
USA	**8.0**
Canada	**6.8**
Italy	**6.7**
Sweden	**6.0**
Denmark	**5.5**
UK	**5.5**
Finland	**5.5**
Netherlands	**4.5**

It is difficult to see how the authors attribute both the reduction in heart disease and the increase in life expectancy uniquely to a pattern of salt reduction without any attempt to compare this to real data readily available to anyone.

The evidence of health impacts of reduced salt consumption invites reconsideration of public health policy on universal sodium reduction. The study from Finland has crystallized the impacts for all to see. Finland achieved significant salt reductions, yet its progress in improving health outcomes was retarded compared to its neighboring countries and countries that share similar social, economic, food and medical systems, but did not reduce salt intakes. Despite an almost 50% reduction in the consumption of salt in Finland, there were no health benefits attributable to this intervention – the most definitive lesson thus far that salt reduction will accomplish nothing.

We have heard much about the successful salt reduction program in the UK. The UK has spent a lot of money on media campaigns such "Sid the Slug" and "Your Food Is Full of It" to reduce the salt in foods. Companies who do not reduce the salt content of their foods are named and shamed on public television by the government. The FSA have claimed a significant drop in the amount of salt that people are eating. However, the FAO panel will see from the Intersalt study done in 1988 that the 24 hour urinary sodium level was approximately 150 mmols, while the most recent Medical Research Council report in June 2008, 20 years later, shows 148 mmols of sodium – statistically no difference.

United Kingdom (1988) Intersalt study

Belfast	149.9
Birmingham	150.0
South Wales	151.8

24 hr UNa

National Centre *for* Social Research

MRC Human Nutrition Research

June 2008

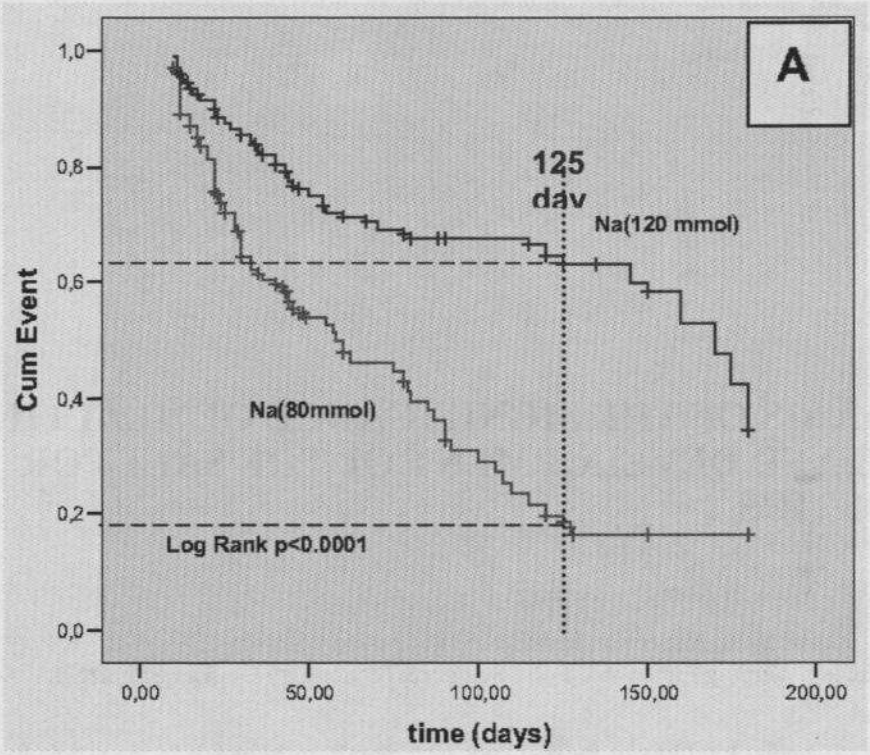
	Age group				
All	19-24	25-34	35-49	50-64	Total
Mean	177	154	144	139	148

24 hr UNa

In fact, many companies have cut the salt level in foods only to have consumers make up that salt in other ways – such as using the shaker or worse, eating more food and calories just to get at the sodium

The most recent data on salt and health outcomes was published in January of 2009[86]. It shows what happens to patients that have had an episode of congestive heart failure. One group was placed on a low salt diet, while an identical group of patients, under the same medications were placed on a regular salt diet. As you can see from the curve, the survival rate is radically better for those patients on the regular salt diet.

[86] Paterna et al., "Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients With Recently Compensated Heart Failure," Am J. Cardiol.,January, 2009.



Kaplan Meier curves on different sodium diets (the fraction of patients living for a certain amount of time after treatment)

The panel will want to know if reducing salt in processed foods will actually result in people consuming less salt. The latest scientific evidence indicates we have multiple systems controlling salt appetite and have individually specific salt requirements. If salt was reduced in processed foods, we will simply make it back up by adding salt or sodium from other sources. From a commercial view, we have seen that light cigarettes induced people to smoke more and light beer encourages people to drink more.

Although the UK program spent considerably on advertising, there were no specific plans to analyze the impact of its program on the actual health of consumers. They have calculated salt reduction in foods; but that neither indicates how much salt consumers are eating, nor does it give any indication of how salt reduction is affecting the health of consumers. The FAO panel will ask to look at metrics for hypertension and cardiovascular disease, correcting, of course, for the tremendous drop we have already seen take place, without salt reduction, over the past 30 years. They will ask for metrics on insulin resistance, sympathetic nerve activity as well as elevation of serum renin and aldosterone.

Salt reduction requires enhancement of the salty taste or replacement of salt with other complex chemicals. Because these other chemicals have never been consumed by humans in the quantities they are projected to if they replace salt, it is likely that they will come under re-review by the FAO Joint Expert Committee on Food Additives. The 5-ribonucleotides, which metabolize down to uric acid are a perfect example of this.

While salt reduction may assist some individuals in reducing blood pressure, access to a better Mediterranean or DASH-type diet will not only help the entire population with blood pressure but will also help with many other health outcomes, such as cancer and diabetes.

Studies have repeatedly shown that a good diet with plenty of fruits and vegetables is critical to reducing the overall burden of disease.

Will the panel consider salt reduction in processed foods to be an unjustified trade barrier? I believe they will.