



**COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE  
REGARDING FOOD AND DRUG ADMINISTRATION AND FOOD SAFETY INSPECTION SERVICE  
APPROACHES TO REDUCING SODIUM CONSUMPTION**

**Docket No. FDA-2011-N-0400/FSIS-2011-0014  
76 Fed. Reg. 57050 (September 15, 2011)**

The Competitive Enterprise Institute (CEI) appreciates the opportunity to submit these comments regarding the Food and Drug Administration's and Food Safety Inspection Service's Approaches to Reducing Sodium Consumption. CEI is a non-profit research and advocacy organization that studies the impact of regulation on the economy, public health and welfare, and consumer choice. For the past 25 years, CEI has been extensively involved in issues of food safety, nutrition, food product regulation, and other public health and consumer protection matters.

For decades, public health advocates have been concerned that Americans consume unhealthy amounts of dietary sodium. A recent study by the Institute of Medicine (IOM) recommended a Tolerable Upper Intake Level of just 2,300 mg of sodium per day and an Adequate Intake of just 1,500 mg per day.<sup>1</sup> Average sodium intake per person, however, is estimated to be approximately 3,300 mg per day,<sup>2</sup> most of which comes from salt added to packaged foods during the production process.<sup>3</sup>

Since the 1980s, the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) have engaged in a number of activities intended to warn consumers of the potential harms associated with a high-salt diet. In more recent years, the packaged food industry has, at the public health community's urging, also undertaken various initiatives to lower the amount of sodium in their products.<sup>4</sup> These efforts have had little effect on sodium intake in the U.S., however, as consumption has remained stable for the past few decades.<sup>5</sup> This has led some advocates to recommend that the FDA and the USDA's Food Safety Inspection Service (FSIS)

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<sup>1</sup> Institute of Medicine, *Dietary Reference Intakes for Water, Potassium, Sodium Chloride and Sulfate* (Washington, D.C.: National Academies Press, 2005).

<sup>2</sup> U.S. Department of Agriculture, "What we eat in America, NHANES" [www.ars.usda.gov/Services/docs.htm?docid=13793](http://www.ars.usda.gov/Services/docs.htm?docid=13793).

<sup>3</sup> R.D. Mattes and D. Donnelly, "Relative contributions of dietary sodium sources," *Journal of the American College of Nutrition*, Vol. 10, No. 4 (1991), pp. 383-93.

<sup>4</sup> Food and Drug Administration and Food Safety Inspection Service, "Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information," *Federal Register*, Vol. 76, No. 179 (September 15, 2011), pp. 57,050-54.

<sup>5</sup> A.M. Bernstein and W.C. Willett, "Trends in 24-h urinary sodium excretion in the United States, 1957-2003: a systematic review," *American Journal of Clinical Nutrition*, Vol. 92, No. 5 (2010), pp. 1172-80.

place regulatory restrictions on the amount of salt that food processors may add to their products.<sup>6</sup> Such efforts would be premature, however.

There is now a substantial body of research exploring the health effects of dietary sodium, but the results of this research are decidedly mixed. Despite claims to the contrary, there is no clear evidence that reducing salt intake would have health benefits for the majority of Americans. Indeed, some research indicates that reductions in sodium consumption may have severe negative effects for a large minority of consumers.

Nor is it certain that reducing the amount of salt in processed foods would even achieve the hoped for reduction in sodium consumption. Research into consumer behavior suggests that individuals tend to regulate salt intake to physiologically determined levels by (consciously or subconsciously) selecting foods to meet their needs. Accordingly, CEI urges the agencies to reject proposals to restrict the amount of sodium that may be added to packaged foods and to target sodium reduction efforts to known high-risk individuals.

## I. Low-Sodium Diets Are Not Clearly Associated With Improved Health

Since the 1970s, some public health researchers have claimed that “high-salt” diets (i.e., those containing more than 3,000 mg of sodium per day) are unequivocally linked with high blood pressure and higher mortality.<sup>7</sup> In turn, various analyses have suggested that reducing average daily sodium intake to 2,300 mg per day or lower could have substantial health benefits.<sup>8</sup> Unfortunately, these estimates are based primarily on extrapolations from selected studies that show a significant association between salt consumption and blood pressure. They ignore a vast literature of research finding little or no beneficial effect from salt reduction, as well as several important studies indicating that salt reduction can cause substantial harmful effects in some individuals.

Writing in the journal *Science* over a decade ago, noted health journalist Gary Taubes explained that, “it is safe to say that if ever there were a controversy over the interpretation of scientific data, this is it.”<sup>9</sup> Indeed, as more and more high-quality research has been conducted on this subject during the past forty years, the link between high-sodium diets and negative health effects has become more tenuous, not more certain.

On a population-wide average, lowering salt consumption does appear to be associated with a statistically significant but very small reduction in blood pressure. But not all consumers experience the same effects. A reduced-salt diet appears to have the largest beneficial effect for

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<sup>6</sup> See, e.g., Center for Science in the Public Interest, “Petition to Revoke the GRAS Status of Salt, to Set Ceilings on the Amount of Sodium in Processed Foods, to Require a Health Warning on Packaged Salt, and to Reduce the Daily Value for Sodium,” November 8, 2005, [http://www.cspinet.org/new/pdf/fda\\_salt\\_petition.pdf](http://www.cspinet.org/new/pdf/fda_salt_petition.pdf).

<sup>7</sup> See, e.g., Gary Taubes, “The (Political) Science of Salt,” *Science*, Vol. 281, No. 5379 (1998), pp. 898-907.

<sup>8</sup> See, e.g., Kartika Palar and Roland Sturm, “Potential societal savings from reduced sodium consumption in the U.S. adult population,” *American Journal of Health Promotion*, Vol. 24, No. 1 (2009), pp. 49-57; Kirsten Bibbins-Domingo, Glenn M. Chertow, Pamela G. Coxson, et al., “Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease,” *New England Journal of Health*, Vol. 362, No. 7 (2010), pp. 590-99.

<sup>9</sup> Taubes, “The (Political) Science of Salt,” p. 899.

individuals with hypertension and for African Americans.<sup>10</sup> But reducing salt consumption does not lower every individual's blood pressure, even those with hypertension. And for consumers with normal or healthy blood pressure, the effect of reducing sodium consumption appears to be modest at best.

A 2011 Cochrane Collaboration review, examining 167 studies in the peer reviewed literature, found that reducing salt consumption lowered average systolic blood pressure in healthy individuals by just 1 millimeter of mercury (mmHg), and reduced systolic blood pressure among hypertensives by 3.5 mmHg.<sup>11</sup> This relatively modest effect has been found over and over again in numerous studies. Yet, while the FDA and FSIS claim that potential benefits from reduced sodium consumption would be large,<sup>12</sup> this vast body of scientific research indicates that the expected benefit would in fact be quite small and may be nonexistent.

Even these small average effects mask far more concerning phenomena: the wide variance in findings from study to study and the fact that some individuals experience a reduction in blood pressure after reducing salt consumption, while others experience *increases* in blood pressure. But in most studies, the majority of subjects experience neither increases nor decreases.<sup>13</sup> Importantly, many dietary constituents other than salt also have an effect on blood pressure, and sodium intake may not even be the most important factor in determining blood pressure.<sup>14</sup> Therefore, the focus on sodium alone, rather than in the context of whole diets, seems misguided.

Furthermore, lowering blood pressure by reducing salt intake does not clearly improve overall health. Lowering blood pressure substantially does appear to be associated with a reduction in heart disease, particularly among hypertensives. However, the blood pressure-reducing effect of eating less salt is so small that it does not appear to be associated with morbidity or mortality benefits. A major 2007 study published in the *European Journal of Epidemiology*, for example, found no association between sodium consumption and coronary disease or mortality.<sup>15</sup> And another study published in the *American Journal of Medicine* in 2006 found that salt consumption had a beneficial effect – that is, higher levels of sodium consumption were associated with a reduced risk of death from heart disease.<sup>16</sup>

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<sup>10</sup> Niels A. Graudal, Thorbjorn Hubbeck-Graudal, and Gesche Jurgens, "Effects of Low-Sodium Diet vs. High-Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterols, and Triglyceride," *American Journal of Hypertension*, Special Review (Nov. 2011), <http://www.nature.com/ajh/journal/vaop/ncurrent/full/ajh2011210a.html>.

<sup>11</sup> Ibid.

<sup>12</sup> Food and Drug Administration and Food Safety Inspection Service, "Approaches to Reducing Sodium Consumption."

<sup>13</sup> See Taubes, "The (Political) Science of Salt."

<sup>14</sup> Lawrence J. Appel, Thomas J. Moore, Eva Obarzanek, et al., "A Clinical Trial of the Effects of Dietary Patterns on Blood Pressure," *New England Journal of Medicine*, Vol. 336, No. 16 (1997), pp. 1117-1124.

<sup>15</sup> Johanna M. Geleijnse, Jacqueline C. M. Witteman, Theo Stijnen, et al., "Sodium and potassium intake and risk of cardiovascular events and all-cause mortality: the Rotterdam Study," *European Journal of Epidemiology*, Vol. 22, No. 11 (2007), pp. 763–770.

<sup>16</sup> Hillel W. Cohen, Susan M. Hailpern, Jing Fang, and Michael H. Alderman, "Sodium Intake and Mortality in the NHANES II Follow-up Study," *The American Journal of Medicine*, Vol. 119, No. 3 (2006), pp. 275.e7-275.e14.

Like the effect on blood pressure, the research on broader health outcomes associated with salt reduction is ambiguous. While some consumers do experience improved overall health outcomes after reducing salt intake, others experience worse health outcomes, and most see neither benefits nor harms. Just this year, for example, a study published in the *Journal of the American Medical Association* found that, while higher sodium consumption was associated with slightly higher blood pressure, this “association did not translate into a higher risk of hypertension or [cardio-vascular disease] complications.”<sup>17</sup> Indeed, the authors found that *lower* sodium consumption was associated with *higher* cardiovascular disease (CVD) mortality. The third of study subjects who consumed the least salt had three times the mortality as the third who consumed the most salt.

Nor is that study atypical. The 2011 Cochrane Collaboration review mentioned above found that low-sodium diets reduced blood pressure levels but “also significantly increased other risk factors for heart disease, such as cholesterol levels, triglycerides, adrenaline and rennin.”<sup>18</sup> This confirmed the findings of other Cochrane Collaboration studies, including one by a separate research team also published in 2011, in which the data “showed no strong evidence of any effect of salt reduction CVD morbidity in people with normal [blood pressure].” Individuals with raised blood pressure at baseline “also showed no strong evidence of benefit.”<sup>19</sup>

Salt affects not only blood pressure, but many other physiological functions as well, some of which benefit from reduced sodium intake and some of which are harmed by it. As salt intake is reduced, for example, the human body reacts by producing more enzymes and hormones that have the effect of raising blood pressure.<sup>20</sup> That may explain why reduced-salt diets do not universally lower blood pressure and often have the unintended effect of increasing the risk of strokes and heart attacks.

For the majority of American consumers, a reduction in sodium consumption can be expected to have no overall health benefits. For some, a reduction may well have negative effects. It is shocking, to say the least, that agencies whose purported goal is improving public health would so cavalierly disregard the possibility that their own actions could in fact have severe negative health effects for millions of American consumers. In short, the broad range of observed health outcomes associated with a reduction in salt consumption ought to give the agencies pause before mandating a reduction of salt in food products. Public health efforts would be greatly improved if they were limited to targeting known high-risk groups for sodium intake reductions.

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<sup>17</sup> Katarzyna Stolarz-Skrzypek, Tatiana Kuznetsova, Lutgarde Thijs, et al., “Fatal and Nonfatal Outcomes, Incidence of Hypertension, and Blood Pressure Changes in Relation to Urinary Sodium Excretion,” *Journal of the American Medical Association*, Vol. 305, No. 17 (2011), pp. 1777-1785.

<sup>18</sup> Graudal, Hubeck-Graudal, and Jurgens, “Effects of Low-Sodium Diet vs. High-Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterol, and Triglyceride.”

<sup>19</sup> Ibid.

<sup>20</sup> Melinda Wenner Moyer, “It’s Time to End the War on Salt,” *Scientific American*, July 8, 2011, <http://www.scientificamerican.com/article.cfm?id=its-time-to-end-the-war-on-salt>.

## **II. Mandating Sodium Reductions in Food Products May Not Even Result in Reduced Salt Consumption**

A recent report published by the Institute of Medicine recommends that daily sodium intake should not exceed 2,300 mg. It also urges the FDA to revoke salt's Generally Recognized As Safe (GRAS) classification, thereby granting regulators the legal authority needed to mandate "acceptable" levels of salt for processed foods.<sup>21</sup> However, even if the FDA and FSIS were to succeed in reducing the amount of sodium in commercial food products, it is not at all clear that doing so would result in a substantial reduction in salt consumption.

Most sodium in the American diet comes from salt added to packaged foods during the production process.<sup>22</sup> So, the rationale appears to be that regulating the amount of salt that may be added to processed foods will necessarily result in a reduction in sodium intake. However, a considerable amount of evidence indicates that individuals consciously or subconsciously adjust their diets in order to maintain salt consumption within a particular range. Consequently, a 2009 study by University of California, Davis nutritionists concludes that it may not be possible to reduce salt intake through regulation.

According to the study, published in the *Clinical Journal of the American Society of Nephrology*, measurements collected from over 19,000 individuals from 33 countries worldwide indicate that daily sodium intake is confined to the relatively narrow range of 2,700 to 4,900 mg, with a worldwide average of 3,700 mg.<sup>23</sup> This challenges the widely held belief that daily sodium consumption in the United States, which averages about 3,300 mg, is extreme or unusual. More importantly, the study also reviews decades of research describing the specific mechanisms by which the central nervous system, acting together with other organ systems, controls an individual's appetite for salt.

In one cited study, a group of nearly 600 participants took part in a three-year sodium intake intervention, with the goal of reducing daily intake to 1,850 mg.<sup>24</sup> After the first six months, researchers noted that participants were unable to reduce sodium intake below about 2,750 mg per day—close to the bottom of the normal identified consumption range. Over the following two-and-a-half years, subjects tended to regress to the mean, with a final average sodium intake of 3,160 mg per day, despite continued participation in the study designed to achieve a long-term reduction in salt consumption.

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<sup>21</sup> Institute of Medicine, *Strategies to Reduce Sodium Intake in the United States* (Washington, D.C.: National Academies Press, 2010).

<sup>22</sup> R.D. Mattes and D. Donnelly, "Relative contributions of dietary sodium sources," *Journal of the American College of Nutrition*, Vol. 10, No. 4 (1991), pp. 383-93.

<sup>23</sup> David A. McCarron, Joel C. Geerling, Alexandra G. Kazaks, and Judith S. Stern, "Can Dietary Sodium Intake Be Modified by Public Policy?" *Clinical Journal of the American Society of Nephrology*, Vol. 4, No. 11 (2009), pp. 1878-82.

<sup>24</sup> Trials of Hypertension Prevention Collaborative Research Group, "Effects of Weight Loss and Sodium Reduction Intervention on Blood Pressure and Hypertension Incidence in Overweight People With High-Normal Blood Pressure," *Archives of Internal Medicine*, Vol. 157, No. 6 (1997), pp. 657-67.

In another study, subjects received intensive dietary counseling and reduced their daily sodium intake to an average of 1,775 mg over 4 weeks.<sup>25</sup> The subjects were then randomized to receive either a 2,300 mg sodium tablet or a placebo, while still receiving counseling. Subjects receiving placebo appear to have subconsciously adjusted their diets to achieve an average sodium intake of approximately 2,750 mg. And when this group was crossed over to the 2,300 mg supplement, daily sodium intake rose to only 4,050 mg, far less than the predicted 5,050 mg.

The results observed in these studies, in light of other behavioral and physiological evidence in the peer reviewed literature, strongly suggest that individuals naturally adjust their dietary sodium intake within a defined range without consciously intending to do so. Given these findings, it seems likely that restricting the level of salt in processed foods would be ineffective in achieving a sustained reduction in sodium consumption because individuals would subconsciously adjust their diets to compensate. As the U.C. Davis study authors put it, sodium intake “is unlikely to be malleable by public policy initiatives, no matter how well intended,” so attempts to change consumption would “expend valuable national and personal resources against unachievable goals.”<sup>26</sup>

### **III. Conclusion**

FDA’s and FSIS’s goal of improving public health is laudable. However, the agencies’ apparent belief that a general reduction in sodium consumption would be an unalloyed positive relies on the untenable belief that salt reduction, while perhaps not a panacea, at least can do no harm. It is now well established that individuals respond to salt intake differently. Consequently, it is not at all clear that a population-wide reduction in sodium consumption would have the intended effect of reducing blood pressure for any but a minority of American consumers. Nor could it be expected to reduce morbidity or mortality more broadly. Indeed, for a small but significant portion of Americans, a forced reduction in sodium intake could very well have serious negative health effects.

It is also likely that regulating the amount of sodium that may be added to processed foods would not even reduce substantially the American public’s consumption of salt. Decades of research suggest strongly that human bodies have “evolved mechanisms to assure that their physiologic needs for sodium are defended when dietary access to it is limited.”<sup>27</sup> Forced reductions in the level of salt in processed foods could therefore be expected to be met by dietary changes that maintain sodium intake at a level above the IOM’s Tolerable Upper Intake Level of 2,300 mg per day.

Public health analysts who continue to advocate for mandatory sodium reductions have selectively highlighted only those research results that suggest a clear and direct link between sodium consumption and higher blood pressure. They have ignored or attempted to explain away contrary findings. In some cases, analysts even appear to have cherry-picked individual

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<sup>25</sup> David A. McCarron, Alan B. Weder, Brent M. Egan, et al., “Blood Pressure and Metabolic Responses to Moderate Sodium Restriction in Isradipine-Treated Hypertensive Patients,” *American Journal of Hypertension*, Vol. 10, No. 1 (1997), pp. 68-76.

<sup>26</sup> McCarron, Geerling, Kazaks, and Stern, “Can Dietary Sodium Intake Be Modified by Public Policy?” p. 1881.

<sup>27</sup> Ibid.

observations from within studies that reveal both positive and negative associations between salt consumption and blood pressure in order to bolster arguments that the link is definitive.

In some ways, this type of behavior is unsurprising. It is well-established that researchers often exhibit what is sometimes known as “White Hat Bias,” the propensity to give preferential treatment to studies or data that confirm a widely held “politically correct” view on scientific issues. A study of White Hat Bias published last year in the *International Journal of Obesity* found that, when referring to the results of previously published research, authors frequently cite data incorrectly and cite only findings that confirm the commonly accepted or politically correct view.<sup>28</sup> An accompanying editorial explained further that “negative results may be ignored and secondarily positive analyses are cited as the conclusions of the study.”<sup>29</sup>

The belief that high-salt diets are necessarily detrimental to health has become so commonly accepted that studies finding contrary results are viewed as unusual and unexpected. But as the literature reviews discussed above show clearly, “[f]or every study that suggests that salt is unhealthy, another does not.”<sup>30</sup> Claims that government regulation of sodium is necessary to promote improved public health therefore cannot be justified. Neither the FDA nor the FSIS would countenance this kind of data dredging behavior from food product manufacturers wishing to support the healthfulness of their products. It would be hypocritical for the agencies to do the same now in an effort to justify restrictions on salt consumption. Consequently, CEI encourage the FDA and FSIS to reject proposals to restrict the amount of sodium that may be added to packaged foods.



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<sup>28</sup> M.B. Cope and D.B. Allison, “White hat bias: examples of its presence in obesity research and a call for renewed commitment to faithfulness in research reporting,” *International Journal of Obesity*, Vol. 34, No. 1 (2010), pp. 84-88.

<sup>29</sup> R.I. Atkinson and I. Macdonald, “White hat bias: the need for authors to have the spin stop with them,” *International Journal of Obesity*, Vol. 34, No. 1 (2010), p. 83.

<sup>30</sup> Moyer, “It’s Time to End the War on Salt.”