

E-ALERT | Food & Drug

May 17, 2013

INSTITUTE OF MEDICINE RELEASES REPORT ON SODIUM INTAKE ASSESSMENT

On May 13, 2013, the Institute of Medicine (IOM) released a report assessing sodium intake in the general population and special subpopulations.¹ Significantly, the report concluded that although adults still consume an average of 3,400 mg of sodium daily, which is well above the current federal guideline of less than 2,300 mg per day, the evidence does not support further lowering to 1,500 mg per day, as was suggested for many subpopulations by the 2010 Dietary Guidelines for Americans. In addition, the report found no evidence on health outcomes to support treating population subgroups differently from the general US population. Given this divergence from existing federal policy on sodium intake, the report has important implications for future public health policy and will likely be an important consideration during the development of the 2015 Dietary Guidelines.

BACKGROUND AND SUMMARY OF IOM REPORT

Although the 2010 Dietary Guidelines Advisory Committee recommended that Americans consume no more than 1,500 mg of sodium per day, the 2010 Dietary Guidelines ultimately suggested a reduction of sodium to *less than* 2,300 mg per day for the “general population.”² But the Guidelines recommended a further reduction to 1,500 mg of sodium per day among persons who are 51 or older and those of any age who are African American or have hypertension, diabetes, or chronic kidney disease, noting that the 1,500 mg per day recommendation applies to about half the population.³

In 2012, the Centers for Disease Control and Prevention (CDC) asked IOM to convene an expert committee to examine the designs, methodologies, and conclusions of the emerging evidence on efforts to reduce sodium intake. This evidence links excessive dietary sodium to high blood pressure, a surrogate marker for cardiovascular disease (CVD), stroke, and cardiac-related mortality; however, several recent reports suggest a low sodium intake may adversely affect consumers with certain risk factors. For this report, the IOM committee was specifically asked to review and assess the benefits and adverse outcomes (if any) of reducing sodium intake in the population, particularly in the range of 1,500 to 2,300 mg per day, with an emphasis on relevant subgroups. These subgroups, for which the 2010 Dietary Guidelines recommended sodium intakes of 1,500 mg per day, include individuals with hypertension and prehypertension, those 51 years of age and older, African Americans, and those with diabetes, chronic kidney disease, and congestive heart failure.

¹ The IOM Report, *Sodium Intake in Populations: Assessment of Evidence*, is available at <http://www.iom.edu/Reports/2013/Sodium-Intake-in-Populations-Assessment-of-Evidence.aspx>.

² For additional information, see our client alerts on the 2010 Dietary Guidelines, [USDA and HHS Announce 2010 Dietary Guidelines for Americans](#) (Feb. 2, 2011), and DGAC Report, [2010 Dietary Guidelines Advisory Committee Releases Report](#) (Jun. 16, 2010).

³ See Dietary Guidelines for Americans 2010 at 21-24, <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf>.

This is not the first time IOM has considered the impact of sodium intake on health outcomes. In 2010, IOM released its report, *Strategies to Reduce Sodium Intake in the United States*.⁴ There, IOM urged FDA to modify the generally recognized as safe (GRAS) status of salt, concluding that the current level of sodium in the food supply is too high to be “safe” and that FDA should set mandatory national standards for the sodium content in foods.

Although high blood pressure is a widely accepted biological predictor of risk for CVD and stroke, for the 2013 report, IOM considered many recent studies that looked at the direct effects of sodium on actual health outcomes. Despite limitations in this research, the IOM committee concluded that evidence supports a positive relationship between higher levels of sodium intake, such as the current average daily intake of 3,400 mg, and risk of CVD.

The IOM committee also concluded that studies on health outcomes are inconsistent in quality and insufficient in quantity to determine that sodium intakes below 2,300 mg per day either increase or decrease the risk of heart disease, stroke, or all-cause mortality in the general US population. As such, the committee concluded that the evidence is not consistent with efforts that encourage lowering the dietary sodium intake of the general population to 1,500 mg a day.

Further, the committee found no evidence for benefit and some evidence suggesting risk of adverse health outcomes associated with sodium intake levels in ranges approximately 1,500 to 2,300 mg per day among those with diabetes, kidney disease, or CVD. Accordingly, the committee stated that evidence does not support recommendations to lower sodium intake to or below 1,500 mg per day for these subgroups, and there is no evidence on health outcomes to support treating population subgroups differently than the general population.

The IOM report also outlines an agenda for future research. Noting a number of methodological gaps in the studies reviewed, the committee expresses a need for standardized approaches to measure sodium intake and account for confounding factors in dietary studies, such as the influence of total daily caloric intake on observational associations between sodium and health outcomes. In addition, the committee concludes that more randomized controlled trials will be needed, particularly in higher risk subgroups, such as African Americans and adults 51 years of age and older. The committee also states a need to collect and reanalyze data from existing clinical trials that were designed to evaluate sodium and health.

IMPLICATIONS FOR FUTURE FEDERAL POLICY

The IOM recommendations clash with existing federal policy under the government’s 2010 Dietary Guidelines. The Dietary Guidelines provide the federal government’s advice for people two years and older about good dietary habits, and they play an important role in guiding federal nutrition policy at all levels as all federally-issued dietary guidance for the general public is required by law to be consistent with the Guidelines. For example, the Healthy, Hunger-Free Kids Act of 2010 requires USDA to promulgate regulations to establish nutrition standards for foods sold in schools that are consistent with the most recent Dietary Guidelines. Following the Guidelines, USDA implemented a timeline for aggressive reduction of sodium levels in school breakfast and lunch programs by 2022.⁵ USDA also issued a proposed rule earlier this year with stringent sodium requirements for foods sold in schools outside the school lunch and breakfast programs.⁶

⁴ For a summary of the 2010 IOM Report, see our client alert, [Institute of Medicine Releases Report on Strategies to Reduce Sodium Intake in the United States; FDA Considering Recommendations](#) (Apr. 22, 2010).

⁵ 7 C.F.R. § 210.10(f); 77 Fed. Reg. 4088 (Jan. 26, 2012).

⁶ 78 Fed. Reg. 9530 (Feb. 8, 2013).

The Dietary Guidelines are reviewed and updated every five years, and planning has already begun for the 2015 Dietary Guidelines. HHS announced the establishment of the 2015 Dietary Guidelines Advisory Committee on February 5, 2013.⁷ That committee is expected to convene five meetings, with the first in Spring/Summer 2013.⁸ Given that the majority of Americans still consume more sodium than the recommended 2,300 mg per day, the Guidelines will likely continue to push for a reduction in sodium intake. Whether the government will alter its policy on further reduction in intake, particularly for specific subgroups, remains to be seen. A change in policy may be challenging for initiatives already in motion, such as the sodium reductions scheduled for the school lunch and breakfast programs.

The report also has implications for industry on voluntary reduction of sodium in foods. Despite reports that voluntary reduction of sodium by industry is ineffective, as stated by a paper authored by Michael Jacobson with the Center for Science in the Public Interest published on May 13, 2013,⁹ the IOM report could provide evidence to support the position that the government should not establish salt limits through regulation.

Covington will continue to monitor these issues and provide client alerts throughout the process of updating the Dietary Guidelines.

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⁷ 78 Fed. Reg. 8147 (Feb. 5, 2013).

⁸ HHS and USDA plan to post information on the 2015 Dietary Guidelines process at <http://www.health.gov/dietaryguidelines/>.

⁹ See Michael F. Jacobson, *Study Finds Inconsistent and Slow Reduction in Sodium Levels in Processed and Restaurant's Food*, JAMA INTERN. MED. (May 13, 2013), <http://media.jamanetwork.com/news-item/study-finds-inconsistent-and-slow-reduction-in-sodium-levels-in-processed-and-restaurants-food/>.