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Implementing the IOM's Recommendations for Reducing Sodium in the U.S. Food Supply: Considerations and Approaches

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INTRODUCTION

There is a clear public health consensus that excessive salt in the U.S. food supply is a pressing public health concern. While it is true that sodium is an essential nutrient for healthy bodily function, it is also true that Americans eat far too much of it. According to the Centers for Disease Control and Prevention (CDC), the average American over the age of two years old regularly consumes about 3,436 mg of sodium per day.¹ This is in sharp contrast to the 2010 Dietary Guidelines for Americans, which recommend no more than 2,300 mg of sodium per day for healthy adults.² For at-risk adults (including adults with hypertension; pre-hypertension; aged 51 years and older; African Americans; and those with diabetes, chronic kidney disease, and congestive heart failure), the U.S. Dietary Guidelines recommend no more than 1,500 mg per day.³ Consuming high levels of sodium can increase blood pressure and creates a major risk factor for heart disease and stroke, which are the nation's first and fourth leading causes of death, respectively.⁴ Researchers estimate that reducing sodium intake to about 2,200 mg/day may prevent 280,000-500,000 U.S. deaths over ten years.⁵ Reducing sodium intake by 1,200 mg/day (which would be 2,236 mg per day for the average American) would also save \$10 to \$24 billion in healthcare costs annually.⁶

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¹ CENTERS FOR DISEASE CONTROL AND PREVENTION [CDC], NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, DIVISION FOR HEART DISEASE AND STROKE PREVENTION, AMERICANS CONSUME TOO MUCH SALT, <http://www.cdc.gov/features/dssodium/> (last visited Sept. 12, 2013).

² CDC, GET THE FACTS: SODIUM AND DIETARY GUIDELINES (2012), http://www.cdc.gov/salt/pdfs/sodium_dietary_guidelines.pdf.

³ *Id.*

⁴ Sherry L. Murphy et al., *Deaths: Final Data For 2010*, NAT'L VITAL STATISTICS REP., May 8, 2013, at 13, available at http://www.cdc.gov/nchs/data/nvst/nvsr61/nvsr61_04.pdf.

⁵ Pamela G. Coxson et al., *Mortality Benefits From US Population-Wide Reduction In Sodium Consumption – Projections From Three Modeling Approaches*, 61 J. HYPERTENSION 564 (2011).

⁶ Kirsten Bibbins-Domingo et al., *Projected Effect of Dietary Salt Reductions on Future Cardiovascular Disease*. 362 NEW ENG. J. MED. 590, 595 (2010).

The challenges around efforts to reduce the amount of sodium in the U.S. food supply stem largely from industry dependence on sodium in the form of sodium chloride, or salt,⁷ and its role in the food manufacturing process. Salt is the leading source of sodium in the American diet. It is inexpensive, used ubiquitously, and serves dozens of technological functions in food processing beyond taste, including functions relating to preservation and food safety.⁸ Because processed and restaurant foods have become a significant part of the U.S. diet during the past 60 years, about 77% of the sodium consumed in the U.S. comes from salt used in these foods before they ever get to a consumer's stove or table.⁹ Consequently, consumers have little control over how much sodium is in their food by the time they buy it. Nonetheless, much of the focus for sodium reduction efforts has been on educating and informing consumers about the hazards of eating too much salt, and ways to reduce salt in their diets. As understanding of the dilemma facing consumers in this area has grown, efforts to promote voluntary reductions in industry's salt usage have become of increasing interest. Recently, Food and Drug Administration (FDA) officials have publicly discussed plans to propose voluntary reduction targets for the food industry, based on models used by New York City and other government initiatives.¹⁰

While these FDA announcements reflect positive progress, the track record for voluntary reductions is mixed so far.¹¹ The recent history of fierce industry opposition to efforts by federal agencies to set voluntary, recommended standards for foods marketed to children provides reason to remain skeptical about how industry might receive sodium-based recommendations.¹²

In 2010, the Institute of Medicine (IOM) released a ground-breaking report on sodium in the U.S. food supply, *Strategies to Reduce Sodium Intake in the United States* ("IOM Report").¹³ This report called for an upstream, regulatory approach to reducing food industry and consumer usage of sodium based on a review of the evidence and regulatory history of salt and other sodium-containing compounds. The IOM's primary recommendation was that the FDA should use its regulatory authority through the "generally recognized as safe" (GRAS) process to mandate limits on the amount of sodium that industry is allowed to use in processing and preparing foods, so as to likewise decrease dietary sodium intake.¹⁴ To best protect industry's and consumers' interests, the IOM recommended mandatory but step-wise reductions in sodium use that would occur over several years. This gradual approach would allow the food industry to

⁷ Salt, or sodium chloride (NaCl), is 40% sodium and 60% chloride. This article generally focuses on salt reduction efforts; however, when reduction of all sodium, including salt, is being discussed, we use the term "sodium."

⁸ INST. OF MEDICINE, *STRATEGIES TO REDUCE SODIUM INTAKE IN THE UNITED STATES* (Jane E. Henney et al. eds., 2010) [hereinafter IOM REPORT], at 92. See also GRAS Safety Review of Sodium Chloride; Policy Notice; Solicitation of Views, 47 Fed. Reg. 26,590 (June 18, 1982) [hereinafter 1982 Sodium Policy Notice].

⁹ CDC, *SODIUM AND FOOD CHOICES* (2013), <http://www.cdc.gov/salt/food.htm>. Salt added by consumers at the table makes up only 5% of sodium intake. *Id.*

¹⁰ See, e.g., Kasey Heintz, *Update on FDA Sodium Reduction Initiatives*, Slide 8 (from Network for Public Health Law webinar titled "Reducing Sodium Consumption: Efforts, Challenges and Successes") (July 18, 2013), available at http://www.networkforphl.org/network_resources/webinar_series/; and Lauran Neergard, *Study Questions How Sharply US Should Cut the Salt*, THE BIG STORY, May 14, 2013, <http://bigstory.ap.org/article/study-questions-how-sharply-us-should-cut-salt> (reporting that the FDA "is working on a program to get food manufacturers to gradually lower sodium levels in their products") (last visited Sept. 18, 2013).

¹¹ See Michael F. Jacobson et al., *Changes in Sodium Levels in Processed and Restaurant Foods, 2005 to 2011*, 173 J. INTERNAL MED. 1285 (2013).

¹² See *infra* text accompanying notes 74-81.

¹³ IOM REPORT, *supra* note 8.

¹⁴ IOM REPORT, *supra* note 8, at 10.

research and apply new technologies and salt alternatives that might allow for similar taste and functions while beginning to reduce the health risks associated with excess sodium consumption. A gradual change would also allow consumers to adjust to new levels of sodium in their diet, and would minimize dramatic changes in the flavor and consistency of foods they frequently eat. This in turn could influence overall consumer preference for salty taste.¹⁵

This article discusses the historical and regulatory context surrounding the IOM's primary recommendation, provides an analysis of the recommendation and offers various strategies for implementing it. Part I provides a brief overview of the scientific and technological context of the IOM's recommendation. Part II discusses prior and current government efforts to address sodium usage and intake through labeling regulations, and "softer" approaches such as programs and voluntary initiatives. To aid readers in understanding how the IOM's recommendation would change the regulatory landscape, Part III provides an overview of the FDA's GRAS process and how it has been applied to salt and other sodium compounds. Part IV identifies three approaches for implementing the IOM's recommendation, including the strengths and weaknesses of each approach. Part V concludes that given the lackluster success of voluntary approaches, mandatory sodium limits appear to be necessary if significant, widespread reductions in the food supply are to be achieved.

I. REGULATING INDUSTRY SODIUM USAGE—THE SCIENTIFIC AND TECHNOLOGICAL CONTEXT

The IOM's recommended sodium reduction strategies are premised on the following considerations: 1) most of the sodium in the American diet comes from salt added to processed and restaurant foods; 2) sodium reductions must be stepwise and be spread out over time, for the benefit of both consumers and industry, and 3) government intervention is necessary because neither voluntary industry action nor reliance on individual behavioral change has resulted, or is likely to result, in sufficient reductions in sodium usage and intake.

To better understand how the IOM arrived at its recommendations, some background in the research about human perceptions of salty taste and the uses of salt in food processing and preparation is helpful.

A. *Human Perceptions of Salty Taste*

One challenging aspect of reducing sodium usage and consumption relates to the science behind how humans develop preferences for salt and what substitutes are—or are not—available to provide that same taste. Despite the importance of salt in human history and biology, much is unknown about how humans detect salt, how reductions in salt may affect other aspects of flavor or taste, and about to what extent salt substitutes are available. These gaps pose challenges for successful implementation of salt reduction strategies.

It is widely accepted in the scientific community that the sodium ion (Na⁺) is primarily responsible for saltiness, though chloride (Cl⁻) serves a "modulatory role."¹⁶ The most prominent scientific theory of how salt taste is detected is that human tongues have a set of taste receptor cells involving ion channels or pores (called "epithelial sodium channels") which allow sodium that has dissolved in saliva to move inside the taste

¹⁵ *Id.*, at 238.

¹⁶ *Id.*, at 75.

cell.¹⁷ The subsequent increase in sodium ions causes a release of neurotransmitters that signal salt taste to the brain.¹⁸ Because these channels are so specific, it seems unlikely that another substance could easily replace sodium.¹⁹ Although potassium chloride is often used as a salt substitute, it also can have a bitter taste.²⁰ Despite these biological challenges, food industry scientists are continuing to research and develop salt-substitutes or alternative formulations of salt that could be used to reduce industry usage of sodium.²¹

Another important factor, however, is that consumer preferences for salty taste seems to be malleable, so that people can come to prefer either lower or higher levels of salt over time.²² This means that for the purposes of taste, it is not necessary to simply exchange one form of salty taste for another—reductions in preference can be achieved through reducing salt use. Further, studies have shown that if salt levels gradually decrease, people can acclimate to these reductions without detecting them.²³ However, for reductions to be successful in changing salt preferences, it is believed that reductions would have to be made across an entire food category, or even across all foods, to avoid subversion of the acclimation process.²⁴

B. *Salt's Role in Food Production*

Aside from taste, another important challenge to sodium reduction efforts is the many ways that industry depends on salt during food processing. Sodium helps to reduce the growth of pathogens and organisms that cause products to spoil, thereby increasing shelf life. Some organisms and food-borne pathogens (such as the ones which cause listeria or botulism) are particularly responsive to sodium, so reducing the salt content of foods susceptible to these organisms presents particular reformulation challenges.²⁵

Salt also plays important roles in the physical properties of many foods. For example, salt is important for controlling the stickiness of some bread dough; salt can provide characteristic textures to meats, cheeses, and snack foods; and it may work as a thickening agent or emulsifier for sauces and dressings.²⁶ Solutions containing salt or sodium phosphates are often used with raw meat (so-called “enhanced meats”), to

¹⁷ *Id.* Scientists believe that humans may also have at least one other salt taste receptor. *Id.*

¹⁸ *Id.*

¹⁹ *Id.* These receptors also are responsive to lithium, but lithium is a toxic metal.

²⁰ IOM REPORT, *supra* note 8, at 85-86.

²¹ For example, based on a search of the FDA's online GRAS Notice Inventory database (<http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing>) using the terms “sodium” and “salt,” it appears that since December 2008, the FDA has received GRAS notifications for at least five salt alternatives or related substances (GRN # 272, 316, 339, 376, 403) (last visited on Aug. 6, 2013). *See also*, Press Release, Tate & Lyle, Tate & Lyle's SODA-LO™ Salt Microspheres “Most Innovative Health Ingredient of the Year” at NuW Excellence Awards 2012 (Nov. 14, 2012), *available at* <http://www.tateandlyle.presscentre.com/Press-releases/Tate-Lyle-s-SODA-LO-Salt-Microspheres-Most-Innovative-Health-Ingredient-of-the-Year-at-NuW-Excellence-Awards-2012-403.aspx>.

²² *See, e.g.*, Micah Leshem, *Biobehavior of the Human Love of Salt*, 33 NEUROSCIENCE AND BIOBEHAVIORAL REVIEWS 1, 11 (2009) and Mary Bertino et al., *Long-Term Reduction in Dietary-Sodium Alters the Taste of Salt*, 36 AM. J. CLINICAL NUTRITION 1134 (1982).

²³ Bertino et al., *supra* note 22, at 1140.

²⁴ IOM REPORT, *supra* note 8, at 2. *See also* N.Y. CITY DEP'T OF HEALTH AND MENTAL HYGIENE, NAT'L SALT REDUCTION INITIATIVE, FREQUENTLY ASKED QUESTIONS 2 (FAQ 7), *available at* <http://www.nyc.gov/html/doh/downloads/pdf/cardio/cardio-salt-nsri-faq.pdf>.

²⁵ IOM REPORT, *supra* note 8, at 96-97.

²⁶ Janice Johnson, *Technical Approaches to Reducing Sodium in Food Products*, Slides 8-9 (from Network for Public Health Law webinar titled “Reducing Sodium Consumption: Efforts, Challenges and Successes”) (July 18, 2013), *available at* http://www.networkforphl.org/network_resources/webinar_series/.

improve tenderness or increase product yield.²⁷ In developing its recommendations, the IOM summarized sodium's functions in nine food categories—grains; meats; dairy foods; sauces, gravies, stocks, salad dressings, and condiments; fruits, vegetables, beans, and legumes; mixed dishes; savory snacks; confections; and beverages.²⁸ To what extent the salt content of these food categories can be reduced depends on salt's functions in each of them, and on developing a better understanding about what levels of salt are truly needed to fulfill those functions.

II. GOVERNMENT EFFORTS TO REDUCE SODIUM USAGE— HISTORY AND CONTEXT

The IOM's recommendation occurs not only within a backdrop of scientific and technological considerations, but also within a wider context of government initiatives to address concerns about excessive sodium usage by industry and consumers. These initiatives have included both regulatory and programmatic efforts. This history is important for understanding the challenges and considerations around possible implementation of the IOM's recommendation with respect to the GRAS process.

Both the FDA and the USDA have authority over food labeling and other aspects of the U.S. food supply system. Until recently, these agencies' main regulatory approach to addressing concerns about industry's excessive use of sodium in food has been to impose labeling disclosure requirements for food products and set parameters for labeling claims so that consumers can learn how much sodium is in the product, and can more easily identify products that contain less sodium.

A. Labeling Regulations

In 1984, the FDA issued labeling requirements for packaged food when claims such as "sodium free," "low sodium," "reduced sodium," "without added salt," and "unsalted," were made on the label.²⁹ These regulations were expanded in 1993 after Congress enacted the Nutrition Labeling and Education Act of 1990 (NLEA), which required disclosure of sodium and other nutrients on the labels of almost all packaged food.³⁰ The more comprehensive regulations set standards for when voluntary content claims about sodium (among other nutrients) can be made by food manufacturers and retailers, including claims such as "sodium [or salt] free," "low sodium," "lightly salted," and similar claims.³¹ It should be noted that restaurant foods were largely exempt from federal mandatory nutritional labeling requirements until 2010, when the Patient Protection and Affordable Care Act (ACA) expanded these requirements to restaurants and similar retail food establishments belonging to chains that include 20 or more

²⁷ IOM REPORT, *supra* note 8, at 97-98.

²⁸ *Id.*, at 103-115.

²⁹ See Food Labeling; Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content, 49 Fed. Reg. 15,510 (proposed Apr. 18, 1984) (to be codified at 21 C.F.R. pt. 101, 105); Food Labeling; Declaration of Sodium Content of Foods and Label Claims for Foods on the Basis of Sodium Content; Extension of Effective Date, 50 Fed. Reg. 26,984 (July 1, 1985).

³⁰ P.L. 101-535, 104 Stat. 2353.

³¹ See 21 C.F.R. §§ 101.56, 101.61 (2010); 9 C.F.R. § 317.361 (2010). The sodium amounts range from 0 to up to 140 mg/serving for "free," "low," and "very low sodium" claims. For "reduced" or "light" claims, the sodium content must be reduced by at least 25% to 50% compared to the reference food, depending on the type of claim. Additionally, the NLEA requires that if a food product label includes a health claim, but the food also contains an amount of sodium (among other nutrients) above a certain quantity, an additional disclosure statement is required on the label. 21 U.S.C. § 342(r)(2)(B) (2010). The required disclosure must meet certain placement and formatting requirements, and must state: "See nutrition information for sodium content." See 21 C.F.R. §101.13(h)(1), (4) (2010).

locations.³² The ACA requires covered establishments to disclose calorie information on menus and menu boards,³³ and to provide sodium content information (among other nutritional information) in writing to consumers upon request.³⁴ Nutritional disclosure requirements are also included for vending machine owners and operators who own or operate 20 or more vending machines.³⁵ The law is not being enforced, however, because the FDA has not yet issued final regulations to implement it.³⁶

While the FDA regulates the labeling of packaged, highly processed food, the USDA has regulatory authority over the labeling of meat and poultry products. Beginning in 1993, the USDA required nutritional labeling on the packages of multi-ingredient and heat-processed meat and poultry products, with some exemptions.³⁷ In December 2010, the USDA issued a final rule (effective January 1, 2012) requiring nutrition labeling on the packaging for ground or chopped meat and poultry products, as well as on the labels or at the point of purchase for single ingredient, major-cuts of meat and poultry.³⁸ In July 2011, the USDA issued a proposed rule to establish a common or usual name for raw meat and poultry products that do not meet standard of identity regulations and to which solutions have been added (e.g., through injections or marinades).³⁹ The USDA noted that consumers may not realize that the products contain these solutions, and may also be unaware that these solutions often contain salt.⁴⁰ The proposed regulations would require that the label disclose the percentage weight that is from the added solution, and the common or usual names of the ingredient(s) in the solution, by weight, from most to least (e.g., “pork tenderloin—15% added solution of water and salt.”). The comment period for this notice closed on Sept. 27, 2011, and a final regulation is expected to be issued during spring of 2014.

1. *Pending dockets related to sodium*

Sodium continues to be on the docket of both the FDA and USDA. In 2007, the FDA issued an advance notice of proposed rulemaking that requested comments about what nutrient reference values it should use to calculate the percent daily value (DV) in the Nutrition Facts panel and Supplement Facts labels.⁴¹ Regarding sodium, the FDA asked for comments about whether sodium’s DV should be based on the tolerable upper level of intake (“UL”) of 2,300 mg/day, as suggested by the 2005 Dietary Guidelines

³² Section 4205 of the Patient Protection and Affordable Care Act of 2010, P.L. 111-148 (signed March 23, 2010). The FDA issued proposed rules implementing these amendments. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,191 (proposed April 6, 2011) (to be codified at 21 C.F.R. Parts 11 and 101). One of the issues to be decided by the final rules is the definition of “retail food establishment” and whether it includes establishments such as movie theaters and convenience stores.

³³ 21 U.S.C. §343(q)(5)(H)(I)(bb).

³⁴ 21 U.S.C. §343(q)(5)(H)(III).

³⁵ 21 U.S.C. § 343(q)(5)(H)(viii) and Food Labeling; Calorie Labeling of Articles of Food in Vending Machines, 76 Fed. Reg. 19,237 (proposed April 6, 2011) (to be codified at 21 C.F.R. Parts 11 and 101).

³⁶ The comment period closed in June 2011, but the final rules have not yet been issued.

³⁷ Nutrition Labeling of Meat and Poultry Products, 58 Fed. Reg. 632 (Jan. 6, 1993) (final rule) (to be codified at 9 C.F.R. pts. 317, 320, and 381).

³⁸ Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products, 75 Fed. Reg. 82,148 (Dec. 29, 2010) (to be codified at 9 C.F.R. pts. 317, 381).

³⁹ Common or Usual Name for Raw Meat and Poultry Products Containing Added Solutions, 76 Fed. Reg. 44,855 (proposed July 27, 2011) (to be codified at 9 C.F.R. pts. 319, 381).

⁴⁰ *Id.*, at 44,858.

⁴¹ Food Labeling; Revision of Reference Values and Mandatory Nutrients, 62 Fed. Reg. 62,149 (proposed Nov. 2, 2007) (to be codified 21 C.F.R. pt. 101).

for Americans, or be based on an Adequate Intake of 1,500 mg/day.⁴² If the FDA were to decide to base sodium's DV on the 1,500 mg AI value, this would cause the Daily Value percentage appearing on nutrition labels to be significantly higher—e.g., 600 mg of sodium would appear as 40% instead of 25%. As of December 2013, this proposed rulemaking was still pending.⁴³

More recently, in September 2011, the FDA and the USDA's Food Safety and Inspection Service jointly published a notice requesting comments, data, and evidence relevant to the dietary intake of sodium and the current and emerging approaches to promote sodium reduction, including research on industry practices in sodium reduction, consumer understanding of sodium intake's role in chronic disease, sodium consumption practices, motivation and barriers in reducing sodium intake, and issues associated with the development of targets for sodium reduction in foods.⁴⁴ Approximately 1,500 comments were submitted by the January 2012 deadline. Although the agencies have not yet formally responded to the comments as of December 2013, as noted above, FDA officials have publicly referred to plans to announce voluntary recommendations for sodium reduction targets for industry at some point in the near future.⁴⁵

2. *An early attempt at stepwise reductions in sodium*

The FDA has previously attempted to impose stepwise reductions in sodium for a small segment of food products. While implementing the NLEA, in 1993, the FDA issued proposed regulations establishing the conditions for when the claim "healthy" can be made on food labels.⁴⁶ Currently, "healthy" products can contain no more than 480 mg of sodium per serving, or 600 mg for packaged meals and main dishes.⁴⁷ Originally, however, the FDA's final rule provided that after January 1, 1998, the permitted sodium levels were to be reduced to 360 mg and 480 mg respectively.⁴⁸

In late 1996, ConAgra petitioned the FDA to eliminate the stepwise reductions or delay them indefinitely, asserting that they were not technologically feasible and

⁴² The FDA also asked for comments regarding whether, if the UL were to be used, it should be adjusted similar to how other Daily Reference Intakes are adjusted. Food Labeling: Revision of Reference Values and Mandatory Nutrients, 62 Fed. Reg. at 62,170.

⁴³ One of the supporting strategies recommended by the IOM in 2010 was that the DV for sodium be based on the AI. IOM REPORT, *supra* note 8, at 10. In a report issued in May 2013, an IOM committee reported that research on direct health outcomes of sodium intake was not currently sufficient to support prior recommendations that Americans should reduce sodium intake below 2,300 mg per day to 1,500 mg, though the committee found both the quantity and quality of relevant studies to be less than optimal. IOM, SODIUM INTAKE IN POPULATIONS: ASSESSMENT OF EVIDENCE 97-98 (2013), available at http://www.nap.edu/openbook.php?record_id=18311&page=98. While this most recent report has generated debate over how scientific findings are translated by the public, it remains undisputed that Americans consume significantly more sodium than the UL of 2,300 mg/day, and that excessive sodium consumption is associated with adverse, and even fatal, chronic diseases.

⁴⁴ Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information, 76 Fed. Reg. 57,050 (Sept. 15, 2011) [hereinafter Approaches to Reducing Sodium Consumption].

⁴⁵ See *supra* note 10.

⁴⁶ Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 58 Fed. Reg. 2,944 (proposed Jan. 6, 1993) (to be codified 21 C.F.R. pt. 101). The USDA's Food Safety and Inspection Service issued a companion proposal for labeling of meat and poultry products on the same day. See Nutrition Labeling: Use of "Healthy" and Similar Terms on Meat and Poultry Product Labeling, 58 Fed. Reg. 688 (proposed Jan. 6, 1993) (to be codified at 9 C.F.R. pts. 317 and 381).

⁴⁷ 21 C.F.R. § 101.65(d) (2010).

⁴⁸ Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 59 Fed. Reg. 24, 232, 24,249 (May 10, 1994) (to be codified 21 C.F.R. pt. 101).

would result in many otherwise “healthy” products being dropped from the market.⁴⁹ In response, between 1997 and 2005, the FDA repeatedly postponed the effective date for the reductions and issued multiple requests for comments.⁵⁰

The final rule was issued in 2005 and did not include the proposed stepwise reductions.⁵¹ In the final rule’s notice, the FDA explained that the optimum level of sodium in foods is one that “balances the health benefits of limiting sodium intake with the cost to the food industry of making product preparation more complicated and the cost to consumers of limiting product choice.”⁵² The FDA found that the comments it received in response to the proposed stepwise reductions demonstrated that there were substantial technical difficulties in finding suitable substitutes or alternatives for sodium, and that there was lack of consumer acceptance for some “healthy” products made with salt substitutes and/or reduced sodium.⁵³ Further, the FDA stated it believed that implementing the reductions would likely reduce consumer choice because it would cause many of the existing “healthy” products in the marketplace to have an undesirable flavor profile, and so food companies would stop offering them. Thus, the FDA eliminated the stepwise reduction requirement for both individual foods as well as for meals and main dishes.⁵⁴

B. *School Foods—A Stepwise Reduction Success Story?*

One of the most promising developments to date in terms of formal regulatory activity to reduce the food industry’s usage of sodium has come from the USDA. In January 2012, the USDA’s Food and Nutrition Service program issued a final rule updating the meal patterns and nutrition standards for the National School Lunch and Breakfast Programs for the first time in 15 years.⁵⁵ The new standards require schools to reduce the sodium content in meals over a ten year period starting by the 2014-2015 school year, with two interim targets. For breakfast meals, they require a 25% reduction in sodium content from baseline amounts by the end of the ten years; and for lunches, they require a reduction of about 53%. The targets were based on ULs that were modified to be appropriate for children in various age ranges, based on IOM recommendations.⁵⁶

The national school meal program rules only cover those foods sold by schools as part of National School Lunch and Breakfast Programs. But of course, schools also sell other kinds of foods—known as competitive foods—through a la carte lines, vending machines, school stores, and snack bars. Until recently, the USDA has left these types of foods largely unregulated.⁵⁷ In June 2013, USDA released an interim final rule

⁴⁹ Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 62 Fed. Reg. 15,390 (Apr. 1, 1997) (to be codified 21 C.F.R. pt. 101).

⁵⁰ *Id.*, (announcing partial stay); 62 Fed. Reg. 67,771 (Dec. 30, 1997) (advance notice of proposed rulemaking); 64 Fed. Reg. 12,886 (Mar. 16, 1999) (extension of partial stay); 67 Fed. Reg. 30,795 (May 8, 2002) (extension of partial stay); and 68 Fed. Reg. 8,163 (proposed Feb. 20, 2003) (to be codified 21 C.F.R. pt. 101).

⁵¹ Food Labeling; Definition of Sodium Levels for the Term “Healthy,” 70 Fed. Reg. 56,828 (Sept. 29, 2005) (final rule) (to be codified at 21 C.F.R. pt. 101).

⁵² *Id.* at 56,840.

⁵³ *Id.* at 56,829-30.

⁵⁴ *Id.* at 56,828.

⁵⁵ Nutrition Standards for National School Lunch and School Breakfast Programs, 77 Fed. Reg. 4,088, 4,088 (Jan. 26, 2012) (to be codified at 7 C.F.R. pts. 210, 220).

⁵⁶ *Id.*

⁵⁷ States and local government units can set nutrition standards for these types of foods, and some have chosen to do so. *See, e.g.*, M.G.L.A. 111 § 223 (2012). *See also*, CDC, COMPETITIVE FOOD AND BEVERAGES IN U.S. SCHOOLS, A STATE POLICY ANALYSIS (2012), available at <http://www.cdc.gov/healthyyouth/nutrition/pdf/compfoodsbooklet.pdf>.

establishing minimum nutrition standards for all other foods sold in schools outside of the national school meal programs.⁵⁸ Starting July 1, 2014, snack items and side dishes may contain no more than 230 mg of sodium, and entrees may contain no more than 480 mg. On July 1, 2016, the limit for snack items/side dishes decreases to no more than 200 mg of sodium; the limit for entrees remains the same.⁵⁹ Figure A below summarizes the sodium standards included in the two new USDA school food rules.

It remains to be seen, of course, whether the stepwise reduction targets will be met as planned, or if extension requests will be filed. Nonetheless, these new rules represent promising progress in sodium reduction efforts for an important population.

FIGURE A: SCHOOL FOOD SODIUM LIMITS—STEPWISE REDUCTIONS

Final Rule: Sodium Reduction Timeline and Amount				
School Grade	Baseline: Current average sodium levels as offered (mg)	Target 1: Must be met by 7/1/14 (mg)	Target 2: Must be met by 7/1/17 (mg)	Final target: Must be met by 7/1/22
School Breakfast Program				
K-5 (elementary)	573	≤540	≤485	≤430
6-8 (middle)	629	≤600	≤535	≤470
9-12 (high)	686	≤640	≤570	≤500
National School Lunch Program				
K-5 (elementary)	1,377	≤1,230	≤935	≤640
6-8 (middle)	1,520	≤1,360	≤1,035	≤710
9-12 (high)	1,588	≤1,420	≤1,080	≤740
Competitive Food Interim Regulations				
Food category	Target 1: Must be met by July 1, 2014 (mg)		Final target: Must be met by July 1, 2016 (mg)	
Snacks/sides	≤230		≤200	
Entrees	≤480		≤480	

Sources: Nutrition Standards for National School Lunch and School Breakfast Programs, 77 Fed. Reg. 4,088, 4,098 (Jan. 26, 2012) and Nat'l School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010, 78 Fed. Reg. 39,068, 39,078 (June 28, 2013).

C. Recent Voluntary Sodium Reduction Initiatives in the U.S.

Food manufacturing companies and retailers have made efforts to reduce sodium in food products, through both government initiatives as well as individual company

⁵⁸ Nat'l School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010, 78 Fed. Reg. 39,068 (June 28, 2013) (interim final rule) (to be codified at 7 C.F.R. pt. 210 and 220).

⁵⁹ *Id.*

efforts. Generally, industry has taken two main approaches to sodium reduction. One approach has been to reformulate products so that they qualify for sodium content claims, and marketing those products specifically to consumers interested in low-sodium products. This approach has not been very successful in the marketplace.⁶⁰ The other approach has been to make gradual reductions, largely without advertising them to the public.⁶¹

Food companies have made some progress in reducing the sodium in food during the past few decades, with reductions ranging from 10% to as much as 50% for *some* products.⁶² However, the IOM concluded that industry as a whole has not shown sufficient success in this area,⁶³ and that restaurant industry efforts have lagged in comparison with efforts by food manufacturers and retailers.⁶⁴

Federal, state, and local governments have also tried a variety of programmatic, educational, and research activities designed to promote voluntary industry reductions in sodium usage and educate consumers about the hazards of excessive sodium consumption.⁶⁵ Frequently, these programs have taken the form of initiatives that provide recommendations and structure for consumers, industry, and governmental organizations to work towards voluntary reductions of sodium use by the food industry and consumers.

The following highlights the major recent programs in the U.S.⁶⁶ These governmental efforts (including both regulatory and voluntary initiatives), along with some of the key industry-led efforts, are summarized in Figure B below.

⁶⁰ See, e.g., Food Labeling; Definition of Sodium Levels for the Term “Healthy,” 70 Fed. Reg. at 56,830 (noting that comments submitted to the FDA “demonstrated the lack of consumer acceptance of certain ‘healthy’ products made with salt substitutes and/or lower sodium”).

⁶¹ IOM REPORT, *supra* note 8, at 168-169.

⁶² *Id.*, at 7.

⁶³ *Id.*, at 7-8.

⁶⁴ *Id.*, at 183.

⁶⁵ See *id.*, at 32-33, and Appendix B, for a more complete listing and summary of public health recommendations, initiatives, and actions to address sodium intake in the U.S. between 1969 and 2010. The IOM Report also discusses industry initiatives around sodium reduction. See *id.*, at 167-73 (food manufacturers and retailers); and at 181-83 (restaurant industry).

⁶⁶ Sodium reduction initiatives have been undertaken by other countries as well. For more information about those initiatives, see IOM REPORT, *supra* note 8, at 357-404 (App. C).

FIGURE B: OVERVIEW OF KEY REGULATORY AND VOLUNTARY INITIATIVES RELATED TO SODIUM CONTENT

Regulations and Government Initiatives														
FDA labeling regulations	USDA regulations	Initiatives												
<p>Sodium's Daily Reference Value</p> <ul style="list-style-type: none"> Currently 2,400 mg/day <p>FDA is considering changing to:¹</p> <ul style="list-style-type: none"> 2,300 mg/day (tolerable upper level of intake per 2005 Dietary Guidelines for Americans); or to 1,500 mg/day (Adequate Intake level per IOM) 	<p>Final National School Breakfast Program Guidelines²</p> <ul style="list-style-type: none"> 25%-27% reduction in sodium content, from 2004-'05 baseline numbers 3-step reduction (2, 4, and 10 yrs) Sodium targets based on IOM 2004 sodium ULs <table border="1"> <thead> <tr> <th>Grades</th> <th>Baseline (mg)</th> <th>Final (mg)</th> </tr> </thead> <tbody> <tr> <td>K-5</td> <td>573</td> <td>≤ 430</td> </tr> <tr> <td>6-8</td> <td>629</td> <td>≤ 470</td> </tr> <tr> <td>9-12</td> <td>686</td> <td>≤ 500</td> </tr> </tbody> </table>	Grades	Baseline (mg)	Final (mg)	K-5	573	≤ 430	6-8	629	≤ 470	9-12	686	≤ 500	<p>National Sodium Reduction Initiative launched in 2009</p> <ul style="list-style-type: none"> New York City Dep't of Health and Mental Hygiene initiative Goal: 20% reduction in sodium intake by 2014 Sodium targets for 62 packaged foods and 25 restaurant food categories (2012 interim and 2014 final targets) 28 companies have committed to meeting either or both targets
Grades	Baseline (mg)	Final (mg)												
K-5	573	≤ 430												
6-8	629	≤ 470												
9-12	686	≤ 500												
<p>"Healthy" label sodium limits:³</p> <ul style="list-style-type: none"> Individual products: ≤ 480 mg/serving Packaged meals or main dishes: ≤ 600 mg/serving <p>Stepwise reductions that were proposed but not implemented:</p> <ul style="list-style-type: none"> Individual products: ≤ 360 mg/serving Packaged meals or main dishes: ≤ 480 mg/serving 	<p>Final National School Lunch Program Guidelines⁴</p> <ul style="list-style-type: none"> 53%-54% reduction in sodium content, from 2004-'05 baseline numbers 3-step reduction (2, 4, and 10 yrs) Sodium targets based on IOM 2004 sodium ULs <table border="1"> <thead> <tr> <th>Grades</th> <th>Baseline (mg)</th> <th>Final (mg)</th> </tr> </thead> <tbody> <tr> <td>K-5</td> <td>1,377</td> <td>≤ 640</td> </tr> <tr> <td>6-8</td> <td>1,520</td> <td>≤ 710</td> </tr> <tr> <td>9-12</td> <td>1,588</td> <td>≤ 740</td> </tr> </tbody> </table>	Grades	Baseline (mg)	Final (mg)	K-5	1,377	≤ 640	6-8	1,520	≤ 710	9-12	1,588	≤ 740	<p>CDC Sodium Reduction in Communities Program (2010)</p> <p>Funding six communities to increase availability of healthy foods and reduce sodium intake</p> <ul style="list-style-type: none"> 2 California communities (L.A. & Shasta counties) 3 New York communities (NYC, Broome & Schenectady counties) Shawnee County, Kansas <p>Covers variety of food environments (schools, restaurants, stores, worksites)</p>
Grades	Baseline (mg)	Final (mg)												
K-5	1,377	≤ 640												
6-8	1,520	≤ 710												
9-12	1,588	≤ 740												

FDA labeling regulations	USDA regulations	Initiatives									
<p>“Free”/“Light”/“Reduced” claims:⁵</p> <ul style="list-style-type: none"> • “Free,” “low,” and “very low sodium” claims: 0 - 140 mg sodium/svg (or per 100 g for meals and main dishes) • “Reduced,” “less,” “light” or “light in sodium” claims: sodium content must be reduced by at least 25% to 50% compared to reference food, depending on type of claim • For “lightly salted” claims: 50% less sodium than normally added to reference food, and information panel must include additional disclosure if the food is <i>not</i> “low sodium” <p>Additional disclosure requirement if health claim made on food label:⁷</p> <p>“See nutrition information for sodium content” disclosure where 1) health claim is made; and 2) sodium content exceeds the following levels:</p> <ul style="list-style-type: none"> • Individual products: >480 mg/reference amount customarily consumed (RACC) or per labeled svg; • Main dishes: >720 mg/labeled serving • Meal products: >960 mg/labeled svg 	<p>Competitive School Foods Interim Rule⁶</p> <ul style="list-style-type: none"> • Based on existing voluntary standards • Designed to be consistent with national school meal programs <table border="1" data-bbox="356 768 530 1213"> <thead> <tr> <th></th> <th>7/01/14 (mg)</th> <th>7/01/16 (mg)</th> </tr> </thead> <tbody> <tr> <td>Snacks/side</td> <td>≤230</td> <td>≤200</td> </tr> <tr> <td>Entrees</td> <td>≤480</td> <td>≤480</td> </tr> </tbody> </table>		7/01/14 (mg)	7/01/16 (mg)	Snacks/side	≤230	≤200	Entrees	≤480	≤480	<p>Interagency Working Group on Food Marketed to Children (2011): Proposed nutritional guidelines focused on foods most heavily marketed to children (ages 2-17)</p> <p>Sodium stepwise reduction goals:</p> <ul style="list-style-type: none"> • Individual foods: <ul style="list-style-type: none"> ≤ 210 mg/serving (interim), ≤ 140 mg/RACC (2021) • Main dishes and meals: <ul style="list-style-type: none"> ≤ 450 mg/ serving (interim), ≤ 300 mg/serving (2021)
	7/01/14 (mg)	7/01/16 (mg)									
Snacks/side	≤230	≤200									
Entrees	≤480	≤480									
<p>Additional disclosure requirement if health claim made on food label:⁷</p> <p>“See nutrition information for sodium content” disclosure where 1) health claim is made; and 2) sodium content exceeds the following levels:</p> <ul style="list-style-type: none"> • Individual products: >480 mg/reference amount customarily consumed (RACC) or per labeled svg; • Main dishes: >720 mg/labeled serving • Meal products: >960 mg/labeled svg 	<p>Labeling of meat products:</p> <ul style="list-style-type: none"> • Since 1993, nutritional labeling required on most packages of multi-ingredient and heat-processed meat/poultry products.⁸ • As of Jan. 1, 2012, nutrition labeling is required on:⁹ <ul style="list-style-type: none"> - packaging for ground or chopped meat/poultry products. - labels or at point-of-purchase for single ingredient, major-cuts of meat and poultry <p>“Enhanced” meat labeling (July 2011)¹⁰</p> <p>USDA proposed to establish common/usual names for raw meat and poultry products that don’t meet standard of identity regulations and to which solutions have been added (e.g., through injections or marinades).</p> <p>E.g., “Pork tenderloin—15% added solution of water and salt.”</p>	<p>CDC</p> <p><i>Improving the Food Environment through Nutrition Standards: A Guide for Government Procurement</i></p> <ul style="list-style-type: none"> • A resource designed to provide practical guidance to states and local governments in designing, developing, and implementing food procurement policies. 									

Industry Initiatives		
<p>Children's Food & Beverage Advertising Initiative (2006)</p> <ul style="list-style-type: none"> • 17 food company participants • Applies only to foods advertised primarily to children 11 & under, with a narrow definition of "advertising" • Set sodium limits (and other limits) for 13 food categories • To be implemented by 12/31/ 2013 <p>Sodium limits (in mg):</p> <ul style="list-style-type: none"> • Individual products : ≤ 110-≤ 540 • Main dishes: ≤ 600 • Meals: ≤ 740 	<p>National Restaurant Association Kids LiveWell (July 2011)</p> <p>Participating restaurants must:</p> <ul style="list-style-type: none"> • Offer at least one meal that meets nutritional criteria • Offer at least one additional side item meeting nutritional criteria • Provide nutritional profile of "healthful" menu options upon request • Promote/identify "healthful" menu options • Sodium limits for "healthful" options: <ul style="list-style-type: none"> - ≤ 250 mg for side items - ≤ 770 mg for meals 	<p>Individual Company Efforts</p> <p>In recent years, several food companies, restaurants, and food service providers have made public commitments to reduce sodium in their products.¹¹</p>

ENDNOTES FIGURE B

1. Food Labeling: Revision of Reference Values and Mandatory Nutrients, 62 Fed. Reg. 62,149 (advanced notice of proposed rulemaking) (Nov. 2, 2007).
2. Nutrition Standards for National School Lunch and School Breakfast Programs, 77 Fed. Reg. 4,088, 4,098 (January 26, 2012) (codified at 7 C.F.R. pts. 210, 220) [hereinafter, National Nutrition Standards].
3. 21 C.F.R. § 101.13(h)(1-3). See also 21 C.F.R. § 101.14(a)(4) (regarding general requirements for health claims).
4. National Nutrition Standards, 77 Fed. Reg. at 4,098.
5. 21 C.F.R. § 101.65(d)(ii).
6. Nat'l School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger-Free Kids Act of 2010, 78 Fed. Reg. 39,068, 39,078 (June 28, 2013) (interim final rule) (to be codified at 7 C.F.R. pts. 210 and 220).
7. 21 C.F.R. §§ 101.56, 101.61, and 9 C.F.R. § 317.361.
8. Nutrition Labeling of Meat and Poultry Products, 58 Fed. Reg. 632 (Jan. 6, 1993) (to be codified at 9 C.F.R. pts. 317, 320, and 381).
9. Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products, 75 Fed. Reg. 82,148 (Dec. 29, 2010) (to be codified at 9 C.F.R. pts. 317 and 381).
10. Common or Usual Name for Raw Meat and Poultry Products Containing Added Solutions, 76 Fed. Reg. 44,855 (proposed July 27, 2011) (to be codified at 9 C.F.R. pts. 319 and 381).
11. See INSTITUTE OF MEDICINE, STRATEGIES TO REDUCE SODIUM INTAKE IN THE UNITED STATES 170-171, 181-182 (2010).

1. *National Salt Reduction Initiative (NSRI)*

Processed food represents one of the largest sectors of the U.S.'s manufacturing industry.⁶⁷ Processed and restaurant foods are also the greatest contributors of sodium in the American diet.⁶⁸ Recognizing this, the New York City Department of Health and Mental Hygiene ("NYC Department of Health") launched the NSRI in 2008 with a goal to reduce sodium intake 20% by 2014.⁶⁹ The NSRI is a partnership of more than 90 state and local health authorities and national health organizations, and over 27 packaged food and restaurant companies.⁷⁰ The NYC Department of Health developed sodium targets for 62 packaged foods and 25 restaurant food types, and included interim 2012 and final 2014 targets.⁷¹ The program's effectiveness is evaluated using baseline and post-implementation measurements of population sodium intake using 24-hour urine samples of a sampling of New York residents. On February 11, 2013 Mayor Bloomberg announced that 21 NSRI partner companies had met one or more of their voluntary commitments to reduce sodium content by 2012.⁷²

2. *CDC initiatives*

The CDC also actively supports programmatic sodium reduction efforts. In 2010, it began the "Sodium Reduction in Communities" program.⁷³ Initially, the CDC provided funding and support to six cities and counties around the U.S. to implement programs that promote access to healthy foods and reduce the amount of sodium intake in their communities. This program has yielded sodium reduction successes within government facilities, public schools, convenience stores, in senior living facilities, and other community settings. The CDC is continuing the program with another round of grants for 2014. In addition, the CDC recently made available a guide targeted at state and local government to aid them in developing and implementing food procurement policies that include healthy nutritional standards (including for sodium). (See Figure B.)

3. *The Federal Interagency Working Group on Food Marketed to Children (IWG)*

The IWG experience provides a less hopeful example of how government-initiated voluntary guidelines may fare. Prior to the release of the new USDA school food rules and the stepwise sodium reductions called for therein, a group of federal agencies

⁶⁷ *Id.*, at 154.

⁶⁸ SODIUM AND FOOD CHOICES, *supra* note 9.

⁶⁹ More information about the program can be found at N.Y. City Dep't of Health & Mental Hygiene, Nat'l Salt Reduction Initiative, <http://www.nyc.gov/html/doh/html/diseases/salt.shtml> (last visited Sept. 15, 2013).

⁷⁰ *Id.*

⁷¹ For more information about the targets and food categories used, see N.Y. CITY DEP'T OF HEALTH & MENTAL HYGIENE, NAT'L SALT REDUCTION INITIATIVE PACKAGED FOODS CATEGORIES AND TARGETS, <http://www.nyc.gov/html/doh/downloads/pdf/cardio/cardio-salt-nsri-packaged.pdf> (last visited Sept. 15, 2013) and N.Y. CITY DEP'T OF HEALTH & MENTAL HYGIENE, NAT'L SALT REDUCTION INITIATIVE RESTAURANT FOOD CATEGORIES AND TARGETS, <http://www.nyc.gov/html/doh/downloads/pdf/cardio/cardio-salt-nsri-restaurant.pdf> (last visited Sept. 15, 2013).

⁷² Press Release, Office of the Mayor, Mayor Bloomberg, Deputy Mayor Gibbs and Health Commissioner Farley Announce Results of National Effort to Reduce Sodium in Pre-Packaged Foods (Feb. 11, 2013), http://www.nyc.gov/portal/site/nycgov/menuitem.c0935b9a57bb4ef3daf2f1c701c789a0/index.jsp?pageID=mayor_press_release&catID=1194&doc_name=http%3A%2F%2Fwww.nyc.gov%2Fhtml%2Fom%2Fhtml%2F2013a%2Fpr058-13.html&cc=unused1978&rc=1194&ndi=1.

⁷³ CDC, SODIUM REDUCTION IN COMMUNITIES, http://www.cdc.gov/dhdsp/programs/sodium_reduction.htm (last visited Sept. 15, 2013).

issued proposed recommendations relating to improving the nutritional quality of foods marketed to children and youth that also included a stepwise sodium reduction. In contrast to the USDA's school food regulations, these recommendations for voluntary standards were never finalized.

In 2009, Congress directed the creation of the IWG, made up of representatives from the Federal Trade Commission (FTC), CDC, FDA, and the USDA.⁷⁴ Congress instructed the IWG to conduct a study and develop recommendations for standards for foods marketed to children 17 years old or younger, and/or foods that represent a significant component of children's diets. In April 2011, the IWG issued a set of proposed, recommended voluntary nutritional principles for food manufacturers and marketers and requested comments.⁷⁵ The proposed principles encouraged the marketing of healthy foods to children and sought to minimize marketing of foods that contain significant amounts of nutrients that could have a negative impact on health or weight, including sodium.⁷⁶ For sodium, the proposed principles included a call for a stepwise reduction by 2021 for foods marketed to children:

No more than 210 mg per serving for individual foods (450 mg per serving for main dishes and meals). This is an interim level and applies per serving only, not per [Reference Amount Customarily Consumed or RACC] or per 50 g. Industry should work toward reducing sodium content by 2021 to 140 mg per RACC for individual foods, and 300 mg per serving for main dishes and meals.⁷⁷

Industry opposition to the proposed recommendations was intense.⁷⁸ The proposed recommended sodium limits were reportedly one of the more contentious components.⁷⁹ Nonetheless, at the end of the comment period, the Children's Food and Beverage Advertising Initiative, an industry-created self-regulatory "pledge" program made up of 17 children's food and beverage companies, issued its own set of nutrition principles—including sodium standards but not stepwise reductions—which take effect by the end

⁷⁴ Congress directed the creation of the IWG in the 2009 Omnibus Appropriations Act (H.R. 1105).

⁷⁵ INTERAGENCY WORKING GROUP ON FOOD MARKETED TO CHILDREN, PRELIMINARY PROPOSED NUTRITION PRINCIPLES TO GUIDE INDUSTRY SELF-REGULATORY EFFORTS (2011) [hereinafter IWG PROPOSED NUTRITION PRINCIPLES], available at <http://www.ftc.gov/os/2011/04/110428foodmarketproposedguide.pdf>.

⁷⁶ The proposed principles focused on the ten categories of foods most heavily marketed to children and adolescents based on FTC data. These foods are: breakfast cereals; snack foods; candy; dairy products; baked goods; carbonated beverages; fruit juice and non-carbonated beverages; prepared foods and meals; frozen and chilled deserts; and restaurant foods. See FTC, *MARKETING FOOD TO CHILDREN AND ADOLESCENTS: A REVIEW OF INDUSTRY EXPENDITURES, ACTIVITIES, AND SELF-REGULATION: REPORT TO CONGRESS (2008)*, available at <http://www.ftc.gov/os/2008/07/P064504foodmktngreport.pdf> [hereinafter 2008 FTC FOOD MARKETING REPORT].

⁷⁷ IWG PROPOSED NUTRITION PRINCIPLES, *supra* note 75, at 13.

⁷⁸ Lindsey Layton & Dan Eggen, *Industries Lobby Against Voluntary Nutrition Guidelines for Foods Marketed to Children*, WASH. POST (July 9, 2011) available at http://www.washingtonpost.com/politics/industries-lobby-against-voluntary-nutrition-guidelines-for-food-marketed-to-kids/2011/07/08/gIQAZSZu5H_story.html.

⁷⁹ Elaine Watson, *GMA: There Is No Middle Ground on Kids Marketing Proposal*, FOOD NAVIGATOR-USA.COM (Oct. 14, 2011), <http://www.foodnavigator-usa.com/Market/GMA-There-is-no-middle-ground-on-kids-marketing-proposals>.

of 2013.⁸⁰ (See Figure B.) The FTC has publicly stated that there are no plans to finalize the IWG guidelines.⁸¹

As this history illustrates, the political and legal landscape is in flux with regard to sodium and other nutritional concerns. The nutritional quality of foods, particularly foods marketed to children and in schools, is under increased scrutiny both by advocates and governments. Regarding sodium specifically, a number of proposals for stepwise reductions have been made over the past 20 years, and most have been withdrawn under industry opposition. But developments within the past five years suggest that conditions may be becoming more conducive to a broader regulatory proposal for stepwise sodium reductions. Although the food industry undoubtedly continues to wrestle with technical challenges in finding appropriate substitutes for salt and/or in adjusting food formulations for salt reductions, progress is clearly being made on multiple fronts.⁸² Moreover, the FDA's recent announcement of a proposal to revoke the GRAS status of partially hydrogenated oils (the primary source of artificial *trans* fats in the U.S. food supply) is a timely reminder that GRAS status is not immutable.⁸³ Thus, the atmosphere may be ripening for the FDA to develop proposals for implementing the IOM's recommendation that it use its GRAS authority to gradually reduce the food industry's high rate of sodium use.

In the next section, we explain the GRAS process, how it has been applied to salt, and present options for implementing the IOM's recommendation.

III. THE CURRENT GRAS REGULATORY STRUCTURE, ITS EVOLUTION, AND APPLICATION TO SALT

The phrase "generally recognized as safe" or GRAS comes from the Federal Food, Drug & Cosmetic Act (FDCA), 21 U.S.C § 301 et seq. (2010). The GRAS process, as applied to food ingredients, was created by the 1958 Food Additives Amendment (FAA) to the FDCA.⁸⁴ This amendment was intended to subject the increasing number of chemicals and other substances being added to food to the same kind of government regulation and oversight as new drugs.⁸⁵ Essentially, the amendment added requirements to the FDCA that "food additives" must be approved by the FDA before foods containing

⁸⁰ CHILDREN'S FOOD AND BEVERAGE ADVERTISING INITIATIVE, CATEGORY-SPECIFIC UNIFORM NUTRITION CRITERIA (2011), available at <http://www.bbb.org/us/storage/16/documents/cfbai/CFBAI-Category-Specific-Uniform-Nutrition-Criteria.pdf>. In addition, at the same time, the National Restaurant Association also launched its "Kids LiveWell" program, another voluntary program to encourage restaurants to offer at least one healthy children's meal and one healthy individual item for children, and which includes some nutritional criteria for these products. Nat'l Restaurant Ass'n, Kids LiveWell, <http://www.restaurant.org/Industry-Impact/Food-Healthy-Living/Kids-LiveWell/About> (last visited Sept. 15, 2013).

⁸¹ E.J. Schultz, *FTC Attempt to Limit Food Marketing to Kids Loses Steam*, AD AGE (May 7, 2012), available at <http://adage.com/article/news/ftc-attempt-limit-food-marketing-kids-loses-steam/234583/>. At the end of 2011, citing concerns that the guidelines would be costly and cause job losses, Congress mandated a cost-benefit analysis of the voluntary guidelines and withheld funding to finalize the guidelines until the cost-benefit analysis is completed. Pub. Law 112-74 (Dec. 23, 2011) Consolidated Appropriations Act of 2012, § 626, available at <http://www.gpo.gov/fdsys/pkg/PLAW-112publ74/pdf/PLAW-112publ74.pdf>. Because the voluntary guidelines do not impose any requirements or mandatory costs, a cost-benefits analysis would be difficult to produce.

⁸² See *supra* note 21.

⁸³ Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information, 78 Fed. Reg. 67,169 (Nov. 8, 2013) (notice and request for comments) [hereinafter Tentative Determination Regarding Partially Hydrogenated Oils].

⁸⁴ Food Additives Amendment of 1958, P.L. 85-929, 72 Stat. 1784.

⁸⁵ Frederick H. Degnan, *Rethinking the Applicability and Usefulness of the GRAS Concept*, 46 FOOD DRUG & COSM. L. J. 553, 554 (1991).

these additives could be marketed to consumers. The definition of “food additives,” however, specifically exempts, 1) substances that are considered GRAS under conditions of their intended use and 2) substances that would otherwise be food additives but for the fact that they were expressly approved by the FDA for use in food prior to the effective date of the 1958 law (so-called “prior-sanctioned” uses).⁸⁶ As one commentator noted after describing the legislative history of these exemptions:

The exclusion of GRAS substances and prior-sanctioned substances was premised on the recognition by Congress that additional testing was not necessary to ensure the safety of many long-used foods and food substances. Implicit in this recognition was the notion that to indiscriminately broaden the scope of the FAA might disrupt the food supply.⁸⁷

Thus, the GRAS process was intended to provide flexibility for the FDA, and strike a balance in addressing safety concerns while minimizing inefficient interventions in the food supply. The following sections of this article explain how GRAS determinations are made, including the standards that are applied and the focus on the *use* of a substance, rather than the substance itself. A brief summary is then provided of how the GRAS process has evolved over time, and its application to salt.

A. *How GRAS Determinations Are Made*

The term “GRAS” refers to a substance that: 1) is intended to become (or can reasonably be expected to become) a component of food or “otherwise affect the characteristics of any food,” and 2) has been “*generally recognized*” by scientific experts and through scientific procedures (and/or by experience, for a substance used in food prior to January 1, 1958) “*to be safe* under the conditions of its *intended use*.”⁸⁸ (Emphases added.) The FDA has issued regulations to implement the GRAS process which further define the GRAS concept and provide parameters for what substances may qualify for GRAS status and under what conditions.⁸⁹ The following is an overview of these regulations and other law that govern the GRAS process.

1. *GRAS status requires reasonable scientific certainty of safety, based on publicly available information*

The eligibility requirements for GRAS status are set forth in 21 C.F.R. § 170.30. Essentially, GRAS status requires both technical evidence of safety and a basis to conclude that this evidence is generally known and accepted within the scientific community.⁹⁰

a. *Factors defining “safe”*

The FDA defines “safe” as requiring “a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”⁹¹ To qualify as a “safe” use for the purposes of GRAS status, the use also

⁸⁶ 21 U.S.C. § 321(s) (2010).

⁸⁷ Degnan, *supra* note 85, at 560.

⁸⁸ 21 U.S.C. §321(s) (2010).

⁸⁹ *See, e.g.*, 21 C.F.R. §§ 170.3(i), 170.30, 182, 184, and 186 (2010).

⁹⁰ Substances Generally Recognized as Safe, 62 Fed. Reg. 19,938, 18,940 (proposed April, 17, 1997) (to be codified at 21 CFR pts 170, 184, 186, and 570) (hereinafter GRAS Interim Rule Notice).

⁹¹ 21 C.F.R. § 170.3(i) (2010).

must be in accordance with “good manufacturing practice.”⁹² For GRAS purposes, “good manufacturing practice” means that the quantity of the substance added to food must not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect,⁹³ and that any amounts that may become part of the food through manufacture, processing, or packaging also be reduced as much as reasonably possible.⁹⁴

Finally, GRAS substances must also comply with applicable food grade specifications, and must perform “an appropriate function” in the food or food packaging in which they are used.⁹⁵ Thus, a “safe” use for GRAS purposes means that the substance is used no more than necessary to accomplish its specific purpose.

b. *How safety is determined*

The type of data and information that will demonstrate safety depends on the: 1) substance’s characteristics, 2) the estimated dietary intake, and 3) the population that will consume the substance.⁹⁶ In addition, any other safety factors that qualified, scientifically-trained experts in food safety generally recognize as appropriate should be considered.⁹⁷

A substance’s dietary intake depends upon both how much is used and in what food categories.⁹⁸ The FDA has provided guidance about how dietary intake should be calculated, stating: “The key determinant in the safety evaluation of a substance found in or added to the diet is the relation of its probable human intake to the level at which adverse effects are observed in toxicological studies.”⁹⁹

For substances used *after* January 1, 1958, GRAS status can be established *only* by using scientific procedures.¹⁰⁰ “Scientific procedures” encompasses human, animal, and analytical, and other scientific studies.¹⁰¹ Establishing GRAS status through scientific procedures ordinarily requires published, peer-reviewed studies showing the substance’s safety, though unpublished studies and other data may be used as corroboration.¹⁰² The same quality and quantity of scientific evidence as that needed to obtain approval for the substance as a food additive is required.¹⁰³

⁹² See 21 C.F.R. § 182.1(b) (2010).

⁹³ A list of physical or technical effects for which substances may be added to food can be found at 21 C.F.R. § 170.3(o) (2010).

⁹⁴ 21 C.F.R. § 182.1(b) (2010); *see also* 21 C.F.R. § 110.5 (2010) (defining “current good manufacturing practice” for food manufacturing, packaging, or storing for the purposes of determining whether food has been adulterated).

⁹⁵ 21 C.F.R. § 170.30(h) (2010).

⁹⁶ FDA, CTR. FOR FOOD SAFETY & APPLIED NUTRITION, GUIDANCE FOR INDUSTRY: FREQUENTLY ASKED QUESTIONS ABOUT GRAS (2004) [hereinafter GUIDANCE FOR INDUSTRY ABOUT GRAS], *available at* <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm>.

⁹⁷ 21 C.F.R. § 170.3(i) (2010). *See also* 21 U.S.C. § 348 (c)(5) (2010) (factors for safety for food additives).

⁹⁸ GUIDANCE FOR INDUSTRY ABOUT GRAS, *supra* note 96, (answer to question #5). The list of food categories used by the FDA for the purposes of establishing tolerances or limitations for GRAS substances and food additives can be found at 21 C.F.R. § 170.3 (n) (2010).

⁹⁹ GUIDANCE FOR INDUSTRY ABOUT GRAS, *supra* note 96 (Introduction).

¹⁰⁰ 21 C.F.R. § 170.30(c)(1) (2010).

¹⁰¹ 21 C.F.R. § 170.3(b) (2010). The GRAS notification rule proposed broadening the definition somewhat, but because this rule has not been finalized, this article does not rely on the broader definition. *See* GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,942-43.

¹⁰² 21 C.F.R. § 170.30(b) (2010).

¹⁰³ 21 C.F.R. § 170.30(b) (2010).

Pre-1958 substances, which include salt, may qualify for “common use” GRAS. “Common use in food” requires that there be a substantial history of consumption of a substance in food, by significant numbers of people.¹⁰⁴ These substances still must be proven safe, however—evidence of common use prior to 1958 “serves only as a means of showing safety.”¹⁰⁵ Further, a pre-1958 substance that qualifies under common-use GRAS may still need to be assessed under the scientific procedures standard for additional uses that were not common prior to 1958,¹⁰⁶ which might be relevant to some salt uses.

For common-use GRAS, the quality or quantity of proof need not be equivalent to that required for food additives. Instead, GRAS status “shall ordinarily be based upon generally available data and information.”¹⁰⁷ The regulations favor data and information based on the experience of common use in the U.S.; where common use occurred “exclusively or primarily” in other countries, the information relied on must meet specific additional requirements.¹⁰⁸

c. *How “general recognition” is determined*

To be considered “general recognition,” there must be *reasonable* scientific certainty that the substance is harmless when used as intended.¹⁰⁹ A consensus of scientific opinion is sufficient—unanimity is not required.¹¹⁰ However, “a severe conflict among experts . . . precludes a finding of general recognition.”¹¹¹ For a consensus to exist, information about the substance’s safety typically will be publicly available, to show that there is “common knowledge” about the substance’s safety throughout the relevant scientific community.¹¹² This is the main difference between the type of proof required to show safety under the food additive regulations and the GRAS regulations—for food additives, manufacturers may rely on scientific evidence that is not publicly available.

2. *GRAS applies to the use—not the substance—and GRAS status can be changed*

It is especially important to note that “it is the *use* of a substance, rather than the substance itself, that is eligible for the GRAS exemption.”¹¹³ Thus a substance may be GRAS for one use but not another; or may be GRAS in one food but not others.

For example, the GRAS regulation for caffeine states that it is GRAS at tolerance levels of up to .02 percent, “when used in cola-type beverages in accordance with good manufacturing practice.”¹¹⁴ Around 2000, manufacturers of alcoholic beverages began

¹⁰⁴ 21 C.F.R. § 170.3(f) (2010).

¹⁰⁵ *Fmali Herb, Inc. v. Heckler*, 715 F.2d 1385, 1390-91 (9th Cir. 1983). *See also* GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,950 (noting that “relevant data or information that bears on the safety of the substance under its intended conditions of use” is not precluded in GRAS determinations for pre-1958 substances).

¹⁰⁶ GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,950.

¹⁰⁷ 21 C.F.R. § 170.30(c)(1) (2010).

¹⁰⁸ 21 C.F.R. § 170.30(c)(2) (2010).

¹⁰⁹ 21 C.F.R. § 170.3(i) (2010).

¹¹⁰ GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,941.

¹¹¹ *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 177 (D.D.C. 2000) (quotations omitted).

¹¹² 21 C.F.R. § 170.30(a) (2010).

¹¹³ GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,939 (emphasis added).

¹¹⁴ 21 C.F.R. § 182.1180 (b), (c) (2010). In 1980, the FDA proposed to revoke the GRAS status of caffeine in cola beverages but allow its continued use through an interim regulation while studies of the health effects of artificially-added caffeine could be studied. Caffeine; Deletion of GRAS Status, Proposed Declaration That No Prior Sanction Exists, and Use on an Interim Basis Pending Additional Study, 45 Fed.

marketing caffeinated alcoholic beverages in the U.S. In 2009, in response to escalating concerns about the effects of these drinks from public health advocates, scientists, and state attorneys general, the FDA sent letters to almost 30 producers of caffeinated alcoholic beverages, questioning whether it was safe to add caffeine to alcoholic beverages.¹¹⁵ The FDA ultimately sent warning letters to four manufacturers stating that it considered caffeine an unsafe food additive when used in alcoholic beverages and thus that caffeinated alcoholic beverages would be considered adulterated.¹¹⁶ The FDA specifically rejected one manufacturer's GRAS determination because it related only to the safety of caffeine in general, and not to the use of caffeine in *alcoholic* beverages.¹¹⁷

As this example illustrates, GRAS status is contingent on how the substance is used. At a minimum, however, GRAS status requires that the substance be used in accordance with good manufacturing practice. The FDA also may impose further conditions or limitations, which are referred to as "conditions of use." The FDA may determine that a substance is GRAS only when used with certain good manufacturing practices (GMPs), and that if used with other GMPs, it *may or may not be* GRAS. If the substance is used under significantly different conditions, the manufacturer must make a separate GRAS determination.¹¹⁸ Or, the FDA may determine that a substance is GRAS but with specific limitations on its use; if so, any uses not in compliance with these limitations would require a food additive regulation.¹¹⁹ Finally, the FDA may affirm that a substance is GRAS for a specific use, without evaluating whether other uses are or are not GRAS, or without evaluating the substance in general.¹²⁰

For example, sodium benzoate has been affirmed as GRAS under the following conditions: when used as an antimicrobial agent, as a flavoring agent and adjuvant, and

(d) [when] used in food at levels not to exceed good manufacturing practice. Current usage results in a maximum level of 0.1 percent in food. (The Food and Drug Administration has not determined whether significantly different conditions of use would be GRAS.)¹²¹

In determining whether specific conditions of use are necessary to ensure safe use of the substance for GRAS purposes, the FDA considers the following factors:¹²² 1) the amount and extent of the use of the substance in food; 2) the magnitude of the safety factor that exists for the substance; and 3) whether the substance's use is technologically self-limiting, meaning that if it is used above a certain level, it will make the food unpalatable or otherwise unfit to eat.¹²³

Reg. 69817 (proposed Oct. 21, 1980). Ultimately, after an audit of a key study of caffeine's teratogenicity revealed some important limitations and flaws, and after proposing to recognize a prior sanction for use of caffeine in nonalcoholic carbonated beverages in 1987, the FDA closed these matters without finalizing any of the proposed actions. PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW* 417 (3d ed. 2007).

¹¹⁵ Press Release, FDA, FDA to Look into Safety of Caffeinated Alcoholic Beverages (Nov. 13, 2009), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm190427.htm>.

¹¹⁶ See FDA, Caffeinated Alcoholic Beverages (Nov. 17, 2010), <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm190366.htm>.

¹¹⁷ FDA Warning Letter to Phusion Projects, LLC, (Nov. 17, 2010), <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm234023.htm>.

¹¹⁸ 21 C.F.R. § 170.30(i) (2010); 21 C.F.R. § 184.1(b)(1) (2010).

¹¹⁹ 21 C.F.R. § 170.30(j) (2010); 21 C.F.R. § 184.1(b)(2) (2010).

¹²⁰ 21 C.F.R. § 170.30(k) (2010); 21 C.F.R. § 184.1(b)(3) (2010).

¹²¹ 21 C.F.R. § 184.1733(c), (d) (2010).

¹²² Substances Generally Recognized as Safe, 48 Fed. Reg. 48,457, 45,458 (Oct. 19, 1983) (codified at 21 C.F.R. 184, 186) (final rule).

¹²³ GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,948.

Finally, as the FDA's recent artificial *trans* fat proposed revocation demonstrates, it is important to note that GRAS status is not fixed or immutable—the regulations specify that new information may require a substance's GRAS status to be reconsidered.¹²⁴ Thus, the FDA can alter or even revoke the GRAS status of substances based on new scientific studies.

3. *GRAS status is usually determined by manufacturers*

If a manufacturer determines that a use of a substance is GRAS as set forth in the FDA's regulations, it need not seek premarketing approval from the FDA to use the substance in food in that way.¹²⁵ This means that manufacturers are responsible for establishing the GRAS use of substances they wish to add to food.¹²⁶ Manufacturers may choose—but are not required—to notify the FDA of their GRAS determinations.¹²⁷ The procedures for notifying the FDA of a GRAS exemption claim is set forth in an interim rule that was first proposed in 1997.¹²⁸ The proposed interim rule replaced a process by which parties petitioned the FDA for affirmation of their GRAS determinations.¹²⁹

The interim rule (which has not been finalized but is still being applied through a pilot program)¹³⁰ provides that manufacturers can choose to notify the FDA of a GRAS determination. If they do so, the notice must describe the applicable conditions of use, including the food(s) in which the substance is being used, levels of use, and the purpose(s) for which it is used, “including, when appropriate, a description of the population expected to consume the substance” (referring by way of example to ingredients used in infant formula, or medical foods).¹³¹ Then the FDA will review the notice and accompanying material and strive to respond within 180 days, typically by issuing one of three types of letters: 1) a letter stating that it has no questions about the company's GRAS determination (a “no questions letter”); 2) one stating that the FDA concludes that the notice does not provide a sufficient basis to support a GRAS determination; or 3) one stating it has ceased review at the company's request.¹³² Although the regulations still include provisions for the submission of petitions requesting affirmation of a GRAS determination, the FDA is not committing resources to this process and does not review these petitions.¹³³ According to the FDA, companies have incentives to voluntarily submit notices to obtain “no questions” letters because purchasers of GRAS substances may prefer or require that the FDA has reviewed the substances.¹³⁴

¹²⁴ 21 C.F.R. § 170.30(l) (2010).

¹²⁵ GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,939.

¹²⁶ *See* 21 C.F.R. § 170.30(i) (2010); 21 C.F.R. § 184.1(b)(1) (2010); *see also* U.S. v. An Article of Food, 752 F.2d 11, 15 (1st Cir. 1985).

¹²⁷ GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,934-42.

¹²⁸ *Id.* at 18,938. The procedure is also explained on the FDA's website. *See* FDA, How to Submit a GRAS Notice, <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm083062.htm> (last visited Sept. 15, 2013).

¹²⁹ *See* 21 C.F.R. § 170.35 (2010).

¹³⁰ The proposed interim rule was re-opened for comment in December 2010, with comments due in March 2011. Substances Generally Recognized as Safe; Reopening of the Comment Period, 75 Fed. Reg. 81,536 (Dec. 28, 2010). As of December 2013, the docket is still open.

¹³¹ GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,947.

¹³² FDA, History of the GRAS List and SCOGS Reviews, <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm084142.htm> (last visited Sept. 13, 2013).

¹³³ GUIDANCE FOR INDUSTRY ABOUT GRAS, *supra* note 96 (answer to question 10).

¹³⁴ U.S. GOV'T ACCOUNTABILITY OFFICE, FOOD SAFETY: THE FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) 11 (2010) [hereinafter GAO GRAS OVERSIGHT REPORT]. Nonetheless, a recent study by the Pew Charitable Trusts found that an estimated 1,000 chemicals have been self-affirmed as GRAS by manufacturers without notice or review by the FDA.

B. *Limitations of the GRAS Process*

One important consideration implicated by the IOM's recommendation is that the GRAS process overall may require strengthening to be an effective tool. Perspectives on the efficacy of GRAS regulation tend to divide along lines of whether one views GRAS primarily as a mechanism for making the food additive regulatory process manageable for the FDA, or as a means of assuring consumers that the types and amounts of substances added to their food are truly safe for consumption. Many GRAS substances (including salt) have never been proven safe by scientific procedures, but were grandfathered in to GRAS status because they had been widely used without causing serious, apparent harm to consumers:

...scientific proof of safety was clearly not the issue the [FDA] addressed in proposing and finalizing this first GRAS list. Rather, the issue was "general recognition" of safety, which, in turn, was based on some unexplained amalgam of scientific opinion and common use of the compound in food prior to January 1, 1958.¹³⁵

Essentially, the GRAS process was designed to give the FDA flexibility to decide how to address concerns about substances added to foods, and particularly, to allow it to allocate its resources to those substances that appeared more likely to cause health concerns and thus require heightened regulation. According to a U.S. Government Accountability Office report issued in 2010, entitled *Food Safety, FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)* ("GAO GRAS Oversight Report"), FDA officials have appeared relatively unconcerned about the agency's dearth of knowledge about companies' GRAS determinations because, "as some food scientists have indicated, GRAS substances generally pose a relatively low risk to public health."¹³⁶ Thus, the GRAS process does seem to serve the purpose of promoting regulatory efficiency to a great degree.

The GAO GRAS Oversight Report identified some key limitations of the GRAS process. Several of the GAO's concerns related to the fact that companies do not have to notify the FDA of their GRAS determinations.¹³⁷ The GAO found that because of the voluntary nature of the notification program, the FDA generally will not have information about a company's GRAS determinations unless the company chooses to submit notices to the FDA.¹³⁸ Thus, the FDA cannot ensure the sufficiency of all new GRAS determinations—or companies' compliance with documentation requirements—

THE PEW CHARITABLE TRUSTS, FIXING THE OVERSIGHT OF CHEMICALS ADDED TO OUR FOOD: FINDINGS AND RECOMMENDATIONS OF PEW'S ASSESSMENT OF THE U.S. FOOD ADDITIVES PROGRAM 5 (2013), available at http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/Food-Additives-Capstone-Report.pdf.

¹³⁵ Degnan, *supra* note 85, at 562.

¹³⁶ GAO GRAS OVERSIGHT REPORT, *supra* note 134, at 13.

¹³⁷ The FDA has stated that it does not believe it has authority to *require* that companies notify it of their GRAS determinations, and so Congress would have to give it that authority. Further, FDA officials have expressed concern about the burdens such a requirement would impose both on companies and the FDA. *Id.*, at 19. With respect to the FDA, the concerns about burden are understandable. But because food companies already are required to determine GRAS status and have been advised by the FDA that they should maintain documentation of these determinations, it would seem that requiring them to submit that documentation for review would not pose an additional significant hardship for the companies.

¹³⁸ *Id.*, at 12, 16. The same is true in situations involving reconsideration of a company's GRAS determinations (the GAO Report notes that some companies have chosen to share updated scientific information with the FDA). *Id.*, at 25.

because it only reviews the information voluntarily sent to it.¹³⁹ Although the FDA stated in 1997 that it intended to conduct random audits of GRAS data and information maintained by companies, it has yet to do so.¹⁴⁰

Similarly, the GAO found that there is no mechanism for systematically ensuring the independence and sufficiency of the expert determinations that companies may rely on for their GRAS determinations.¹⁴¹ To show that there is a consensus among qualified experts about the safety of the use of a substance, companies may assemble scientific review articles, convene a panel of experts, or use reports from authoritative bodies, or some combination of these methods.¹⁴² According to FDA staff, about half of the GRAS determination notices it receives include expert panel reports, most of which have not been published in peer-reviewed journals.¹⁴³ However, the FDA does not provide guidance about conflicts of interest for these experts, nor does it require companies to provide information or assurances about the independence or potential conflicts of interest of these expert panelists.¹⁴⁴

Further, a company need not wait for a “no questions” letter from the FDA before marketing the substance or foods containing the substance. So even if the FDA finds that the notice provides an insufficient basis for the GRAS determination, the company may already be marketing the food.¹⁴⁵

A third major concern about the GRAS process is that the FDA does not “systematically ensur[e] the continued safety of current GRAS substances.”¹⁴⁶ The GAO noted that despite the fact that FDA regulations specifically contemplate that a substance’s GRAS can change “and must be reconsidered as new information comes to light or new methods of evaluating its safety arise,”¹⁴⁷ the FDA has no process in place for such a systematic review.¹⁴⁸ Further, the FDA has been slow to take action in response to new evidence and/or concerns about existing GRAS uses of substances. For example, the GAO noted that the safety of 35 substances (including salt, as described below) had been questioned by a special committee of scientists commissioned by the

¹³⁹ *Id.*, at 8-9.

¹⁴⁰ *Id.*, at 16.

¹⁴¹ GAO GRAS OVERSIGHT REPORT, *supra* note 134, at 24.

¹⁴² GRAS Interim Rule Notice, *supra* note 90, 62 Fed. Reg. at 18,942-43.

¹⁴³ Memorandum from Linda S. Kahl, Ph.D., Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition, FDA, (Nov. 4, 2010), at 5 (on file with author).

¹⁴⁴ GAO GRAS OVERSIGHT REPORT, *supra* note 134, at 15. *See also* Thomas G. Neltner et al., *Conflicts of Interest in Approvals of Additives to Food Determined to Be Generally Recognized as Safe: Out of Balance*, 173 *JAMA Intern Med.* 2032, 2034 (2013) (reporting that in a review of 451 GRAS determinations made between 1997 and 2012, a significant percentage reflected troubling conflicts of interest by those making the determinations, including a finding that although 64.3% were made by an expert panel selected by the manufacturer or a firm that was a consultant to the manufacturer, none were made by a standing expert panel selected by a third party).

¹⁴⁵ *Id.*, at 9.

¹⁴⁶ *Id.*, at 20.

¹⁴⁷ *Id.*, at 20. The GAO report notes that in addition to cyclamate salts, the FDA has also revoked the GRAS status of cinnamyl anthranilate in 1985, and changed the GRAS status of sulfites to prohibit their use on fresh fruits and vegetables. *Id.*, at 22. Further, as noted in the text above, the FDA has taken the position that caffeine added to alcoholic beverages is not GRAS, and indeed is an unsafe food additive when added to alcoholic beverages.

¹⁴⁸ *Id.*, at 21. In contrast, the Flavor and Extract Manufacturers Association (FEMA) is an industry group that makes GRAS status determinations for its member companies, and periodically reconsiders these determinations and publishes the results of this review. FEMA also informs the FDA of its determinations, but not through the formal notification procedure. GAO GRAS OVERSIGHT REPORT, *supra* note 134, at 17-18, 25.

FDA to review the GRAS status of many substances.¹⁴⁹ For thirty of these substances, the committee stated the GRAS status should be revoked if no additional evidence of safety was provided to the FDA. For the remaining five, the committee found that current evidence did not support a finding that the substance was not harmful (salt was in this group). Thirty years later, as of December 2009 (when the GAO GRAS Report was completed), the FDA had affirmed 17 of the 35 substances and issued regulations for them, but had neither affirmed nor revoked the GRAS status of the other 18 substances.¹⁵⁰

C. *The Current and Historical Application of GRAS to Sodium*¹⁵¹

Either through a petition process or on its own initiative, the FDA has identified many substances that are GRAS when used for the purposes indicated in the regulations and in accordance with good manufacturing practice. The FDA's regulations include three lists of GRAS substances. In the first list found in Title 21, Part 182 of the Code of Federal Regulations, salt is named as a "common food ingredient" that is considered safe for its "intended" uses, without conditions, along with pepper, vinegar, baking powder, and monosodium glutamate.¹⁵² It is this simple language which has enshrined the use of salt by the U.S. food industry.

This language was barely ten years old, however, before the FDA's dilemma about how to address concerns about excessive sodium use began. Between 1969 and 1997, the FDA undertook to reevaluate the GRAS status of many substances and determine whether they should continue to qualify as GRAS, should be regulated as food additives, or should be prohibited from being used in food.¹⁵³ This process led to the creation of two lists of substances affirmed as GRAS to use in food—one for substances added directly to foods, and another for substances added indirectly to foods (i.e., through packaging).¹⁵⁴ Salt was one of the substances on the FDA's list for re-evaluation.

To aid with this re-evaluation, the FDA contracted with the Life Sciences Research Office of the Federation of American Societies for Experimental Biology, which in turn created a committee of consulting scientists called the Select Committee on GRAS Substances ("SCOGS") to conduct the review.¹⁵⁵ The SCOGS review of salt as used in food stated: "It is the prevalent judgment of the scientific community that the [U.S.] consumption of sodium chloride in the aggregate should be lowered," and went on to conclude that the evidence of harm due to salt intake that it had reviewed was "insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in a manner now practiced."¹⁵⁶ In contrast, regarding the use of salt

¹⁴⁹ See *infra* text accompanying notes 155-157.

¹⁵⁰ *Id.*, at 21.

¹⁵¹ This article does not include information about every GRAS and sodium-related activity that has occurred since 1958, but rather focuses on key events. A more detailed timeline of events is included in a petition that the Center for Science in the Public Interest (CSPI) (a national advocacy group) filed in 2005 asking the FDA to revoke salt's GRAS status. See CSPI, Petition to Revoke the GRAS Status of Salt (filed Nov. 8, 2005), available at <http://www.fda.gov/ohrms/dockets/dockets/05p0450/05p-0450-cp00001-02-vol1.pdf> [hereinafter CSPI 2005 Salt GRAS Status Revocation Petition].

¹⁵² 21 C.F.R. § 182.1(a) (2010). Sodium chloride is also listed as GRAS when used in cotton and cotton fabrics for dry food packaging (21 C.F.R. § 182.70), and in paper and paperboard products (21 C.F.R. § 182.90 (2010)).

¹⁵³ See 21 C.F.R. § 182.1(d) (2010).

¹⁵⁴ 21 C.F.R. § 184, 186 (2010).

¹⁵⁵ History of the GRAS List and SCOGS Reviews, *supra* note 132.

¹⁵⁶ FDA, *Database of Select Committee on GRAS Substances (SCOGS) Reviews: Sodium Chloride*, <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=291> (last visited

in packaging, the SCOGS report found that there was no reasonable ground to suspect that this use posed a hazard to public health when used “in the manner now practiced or that might reasonably be expected in the future.”¹⁵⁷

The FDA took no action to affirm or revoke salt’s GRAS status, neither in response to the SCOGS report, nor to petitions filed in 1978 by the Center for Science in the Public Interest (“CSPI”) asking the FDA to revoke the GRAS status of sodium.¹⁵⁸ Instead, in 1982, the FDA issued a Policy Notice.¹⁵⁹ In this notice, the FDA announced that it had considered the following five regulatory options for responding to concerns about salt intake within the U.S.:

1. Revoke salt’s GRAS status, declare it to be a food additive, and issue appropriate regulations;
2. Revoke salt’s GRAS status, declare it to be a food additive, and issue interim food additive regulations pending additional study;
3. Defer action on salt’s GRAS status, but require that all manufactured foods containing salt have a label declaring their total salt content;
4. Affirm salt as GRAS but with specific limitations, which were to be “informative labeling that would adequately alert the public to the health risks associated with a high level of sodium intake”;
5. Defer action on salt’s current GRAS status until the impact of the sodium labeling regulations being proposed at the time (relating to claims of “sodium free,” “low sodium,” and the like), and manufacturers’ voluntary efforts to reduce salt and sodium content in their products, could be assessed.¹⁶⁰

The FDA stated that it intended to pursue the fifth option for the following reasons: salt occurs naturally in foods; salt added to processed foods constituted about one-third to one-half of Americans’ sodium intake;¹⁶¹ consumers control the amount of salt added at the table, not manufacturers, and consumers are not directly subject to the FDA’s authority.¹⁶² Accordingly, the FDA believed that providing consumers with information about sodium content in food would enable them to allocate their sodium intake as they chose, and that this would be more feasible than attempting to restrict consumers’ sodium usage. The FDA declared, however, that if informational sodium labeling was not adopted, and if the sodium content of process foods was not “substantially reduced,” it would consider additional regulatory options, including changing salt’s GRAS status.¹⁶³

In explaining why it did not believe the other four options were viable, the FDA focused on the difficulty of setting and enforcing limitations on salt use in processed foods due to the many technical or functional effects for which salt is used (more than 32 different effects), and the many food categories it is used in (over 43 food categories). The FDA asserted that it would have to establish a limitation for each technical effect for

Sept. 13, 2013).

¹⁵⁷ *Id.*

¹⁵⁸ See CSPI 2005 Salt GRAS Status Revocation Petition, *supra* note 151, at 4 (describing petitions). Citizens may petition the FDA to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action, by following the procedures set forth in 21 C.F.R. §10.30.

¹⁵⁹ 1982 Sodium Policy Notice, *supra* note 8, 47 Fed. Reg. at 26,590.

¹⁶⁰ 1982 Sodium Policy Notice, *supra* note 8, 47 Fed. Reg. at 26,592.

¹⁶¹ More recent studies indicate that about 75% of sodium comes from sodium added to food during commercial processing. See, e.g., Cliona Ni Mhurchu et al., *Sodium Content of Processed Foods in the United Kingdom: Analysis of 44,000 Foods Purchased by 21,000 Households*, 93 AM. J. CLINICAL NUTRITION 594 (2011); and CDC, SODIUM AND FOOD CHOICES, *supra* note 9.

¹⁶² 1982 Sodium Policy Notice, *supra* note 8, 47 Fed. Reg. at 26,592-93.

¹⁶³ *Id.*

which salt is used, in each food category, and would also have to account for situations where salt is used for multiple technical effects in a single food.¹⁶⁴

The FDA also believed that many uses of salt are prior-sanctioned, referring to a variety of food standards of identity¹⁶⁵ that were promulgated before 1958. It described its burden in regulating prior-sanctioned ingredients as much greater than for food additives because it can take action against prior-sanctioned substances only under the adulteration standard of the FDCA (21 U.S.C. §342(a)(1)).¹⁶⁶ Under this standard, the FDA asserted that it would have to show that salt is a “poisonous or deleterious substance” that injures human health, and it believed that the science was not sufficiently clear to support such a showing.¹⁶⁷

The FDA also noted that salt is not like substances that are generally toxic above known levels, and that the threshold level of chronic toxicity for salt in specific populations was not known.¹⁶⁸ Ultimately, the FDA rejected this alternative because it believed that a voluntary program could achieve the same results with less regulatory burden, and it wanted to give industry the opportunity to act voluntarily.

Since this Policy Notice was issued, there of course has continued to be concern about salt consumption in the U.S., as well as calls for changing salt’s GRAS status. In 2005, CSPI submitted another petition to the FDA urging the agency to revoke salt’s GRAS status.¹⁶⁹ In response to that petition, the FDA held a 2007 public hearing on sodium intake reduction.¹⁷⁰ In the Notice announcing this hearing, the FDA referred to the concerns it expressed in the 1982 Policy Notice about the many technical effects and food categories for which salt is used, and the difficulty of setting “fair use” limits for salt for all these effects and categories that would be safe and effective for all consumers, regardless of their susceptibility to hypertension.¹⁷¹ It also referred again to the high burden it would have if it tried to regulate prior-sanctioned uses of salt. The FDA went so far as to question the utility of efforts to regulate those “remaining uses” of salt if it could not meet its burden under the adulteration standards for prior-sanctioned uses. It stated that in those circumstances, the practical effect might be “quite small” and thus issuing and enforcing limitations for those uses would be “an extraordinary regulatory burden for FDA.”¹⁷² The FDA docket for this petition remains pending.

The extent to which food standards of identity and prior-sanctioned uses pose a challenge to using the GRAS process to reduce sodium use is unclear. Despite the concerns the FDA expressed in 1982 about salt included in food standards of identity, more recently, the FDA has also acknowledged that food standards of identity generally

¹⁶⁴ *Id.*

¹⁶⁵ Food standards of identity are essentially recipes that define what a food product is, including required and optional ingredients, so that the product contains what consumers expect it to contain (e.g., that “cheddar cheese” in Wisconsin is essentially the same thing in Texas). The USDA’s Food Safety and Inspection Service sets identity standards for meat and poultry products, and the FDA sets them for other products. In addition to ingredients, food identity standards may also prescribe the manufacturing process, and/or may focus on composition (e.g., how much fruit or sugar must be in “jam”). See Food Standards; General Principles and Food Standards Modernization 70 Fed. Reg. 29,214, 29,215-16 (May 20, 2005).

¹⁶⁶ 1982 Sodium Policy Notice, *supra* note 8, 47 Fed. Reg. at 26,594.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ CSPI 2005 Salt GRAS Status Revocation Petition, *supra* note 151.

¹⁷⁰ Salt and Sodium; Petition to Revise the Regulatory Status of Salt and Establish Food Labeling Requirements Regarding Salt and Sodium; Public Hearing; Request for Comments, 72 Fed. Reg. 59,973 (Oct. 23, 2007) [hereinafter 2007 Salt and Sodium Hearing Notice].

¹⁷¹ *Id.*, at 59,976-77.

¹⁷² *Id.*, at 59,977.

do not identify *specific* amounts of salt that are required or optional, and that its regulations allow deviations from certain requirements of identity standards if needed to make a food eligible to bear an “unsalted” or “low sodium” or similar claim on its label.¹⁷³ Thus, food companies could reformulate these standardized foods to contain lower amounts of salt, so long as the intended technical effect(s) of the added salt could still be accomplished.¹⁷⁴

With respect to prior-sanctioned uses, in contrast to the FDA, the IOM characterized prior-sanctioned uses as a “technical issue,” the impact of which it expected to be “insignificant” or “minor” in terms of sodium contribution to the food supply.¹⁷⁵ Although to what extent prior-sanctioned uses for salt exist is unclear, FDA regulations provide a means for discovering those uses.¹⁷⁶ Specifically, FDA regulations state that if a substance’s use is being evaluated or its GRAS or food additive status is being assessed, and the FDA is aware of any prior-sanctioned use, it must concurrently propose a regulation covering such prior-sanctioned uses.¹⁷⁷ If the FDA is unaware of any prior-sanctioned uses, it must state that in any GRAS or food additive regulation it proposes, and anyone who intends to assert or rely on a prior-sanctioned use must submit proof of its existence or risk waiving the right to assert or rely on it in the future.¹⁷⁸ Additionally, FDA’s regulations provide for the amendment of prior-sanctioned uses to add limitations or conditions (or prohibitions) as needed to ensure the safety of a food ingredient’s use, if scientific data or information shows that the use of the prior-sanctioned substance may be “injurious to health.”¹⁷⁹ Thus, it appears that if the FDA were to undertake modification of salt’s GRAS status, the issue of the scope and existence of prior-sanctioned uses could be adequately addressed.¹⁸⁰

Finally, the FDA has questioned whether it has authority to regulate levels of added salt in all processed and restaurant foods that do not become part of interstate commerce. The GAO acknowledged these concerns, noting that “foods harvested and prepared intrastate (as in some restaurants) would not be within FDA’s statutory authority. However, processed foods in interstate commerce used by restaurants are subject to FDA’s regulatory authority.”¹⁸¹

With this history and context in mind, we now turn to a discussion of how the IOM’s recommendation could be implemented.

¹⁷³ *Id.*, at 59,975. See 21 C.F.R. §130.10 (2010).

¹⁷⁴ See 21 C.F.R. §130.10(c).

¹⁷⁵ See IOM REPORT, *supra* note 8, at 221, 262.

¹⁷⁶ The IOM noted that the FDA does not maintain a listing of prior-sanctioned uses, and the Committee could not identify any such uses of salt or sodium in food (as opposed to in food packaging). *Id.*, at 220. The IOM Committee concluded, however, that such uses likely existed.

¹⁷⁷ 21 C.F.R. §181.5(d) (2010).

¹⁷⁸ *Id.*

¹⁷⁹ 21 C.F.R. §181.1(a) (2010).

¹⁸⁰ One could also reasonably hypothesize that if companies had compelling evidence of prior-sanctioned uses, such evidence would have been likely to surface in the various comment periods relating to sodium’s GRAS status that have occurred during the past 30 years. In fact, as part of the SCOGS review process, the FDA specifically requested information about prior-sanctioned uses of salt. See 43 Fed. Reg. 41,277 (Sept. 15, 1978) (public hearing notice).

¹⁸¹ GAO GRAS OVERSIGHT REPORT, *supra* note 134, at 45 (Appendix I: Additional Information on Selected Generally Recognized as Safe (GRAS) Substances).

IV. IMPLEMENTING THE IOM GRAS RECOMMENDATION— ALTERNATIVES AND CONSIDERATIONS

The IOM's primary recommendation envisions that the GRAS process would be used to reduce salt content in food in a stepwise manner by setting ultimate maximum salt content levels for foods by categories, to be achieved by a set date, with higher interim maximum levels that decrease over time in a stepwise manner in periodic increments. Additionally, the IOM suggests that, depending upon what the evidence may show about the impact of labeling on consumer behavior, labeling could be used during the interim period.

A. *Approaches for Implementation*

There are at least three alternatives for how the GRAS regulatory structure could be used to reduce the salt content of the U.S. food supply. Each alternative is discussed below.

1. *"Safe harbor" approach—salt would be affirmed as GRAS with limited conditions, and other uses may or may not be GRAS*

Under the "safe harbor" approach, some uses and use levels of salt would be affirmed as GRAS (presumably by food category, and/or technical effect, and even by specific foods), and other uses or use levels may or may not be GRAS. Essentially, food manufacturers adhering to the GRAS uses would be assured of compliance with the FDCA—a "safe harbor" would be established for the uses (or levels) that are affirmed as GRAS, and would help to emphasize the fact that other uses may not be GRAS.

If a food manufacturer wished to use a higher level of salt in a food product, it would be responsible for making its own determination that the use is also GRAS. If it could not establish that the use was GRAS, it would be required to seek a food additive regulation for the use. In this situation, the manufacturer would still have to show that the proposed use is safe, but it could rely on information that is not widely available to the public.

The benefits of this alternative are that it would set conditions for the use of salt, which do not exist currently (other than general good manufacturing practice), but would still allow manufacturers to use different levels of salt so long as they establish and document that such uses are safe. Additionally, this alternative continues the approach of making food manufacturers responsible for establishing that other uses are GRAS, as opposed to the FDA. At the same time, it would provide the flexibility for food manufacturers to use other levels of salt if appropriate.

The weaknesses of this approach include the general weaknesses of the GRAS process described above, which are not insignificant—the FDA will not necessarily receive information about companies' additional GRAS determinations, nor is there a system in place for the FDA to review or assess these determinations.

2. *All GRAS salt uses would be determined, so that other uses would require a food additive regulation or be prohibited*

Under this alternative, all uses and use levels of salt that are GRAS would be determined and affirmed. Any use outside of the specified limitations would require a food additive regulation, or some other kind of exemption (what other kind of exemption would be possible is not clear).¹⁸² There is at least one substance (calcium silicate) for

¹⁸² See 21 C.F.R. §170.38 (2010).

which certain uses have been approved as GRAS and additional uses have been approved under a food additive regulation.¹⁸³

The advantages of this approach over the “safe harbor” approach is that the FDA would define all of the GRAS uses, and require any other uses to either be covered by a food additive regulation or be prohibited. Thus, it would clearly delineate uses that are GRAS and not GRAS. Further, it would ensure that the FDA has full knowledge of what salt uses are GRAS because these uses would be established through a public rulemaking (as opposed to leaving these determinations to internal company processes). A disadvantage to this approach is that determining and establishing all of the GRAS uses of salt likely will require extensive time and resources, both for the FDA and for food companies. As explained above, the FDA has previously expressed skepticism that the regulatory burden likely to be created by the food additive rulemaking process would be justified.

Both of the above-described approaches could incorporate stepwise reductions that are established through one rulemaking. Alternatively, reductions could be implemented over time through subsequent rulemaking processes, as warranted by new research and as technology continues to evolve.

3. *Some salt uses could be established as GRAS; others could be permitted under interim food additive regulations*

A third alternative could be used to designate multiple allowable levels of salt use for the same food category and technical effect. This alternative would combine GRAS and interim food additive regulations.¹⁸⁴ Under this approach, certain uses or use levels of salt would be designated as GRAS, while other levels, (including possibly less strict, stepwise-higher limits), could be established as interim food additive regulations. This would allow companies to use salt in these ways while the safety of the use is being determined without putting the companies at risk for violating the law.¹⁸⁵ Because this approach is premised on an assumption that there is uncertainty about whether certain levels of salt use in food are harmful to public health, and what those levels may be,¹⁸⁶ it would seem to be an appropriate fit.

The interim food additive regulations may be used “when new information raises a substantial question about the safety or functionality of the substance but there is reasonable certainty that the substance is not harmful and that no harm to the public health will result from the continued use of the substance for a limited period of time” while further studies are conducted.¹⁸⁷ The FDA may propose interim food additive regulations on its own initiative. Studies “adequate and appropriate” to resolve the questions about the substance’s safety must be undertaken within 60 days of the regulation’s effective date, either by interested parties or the FDA.¹⁸⁸ The FDA can grant extensions “if necessary to review and act on proposed protocols.”¹⁸⁹ If studies are not undertaken and no commitment to undertake them is made, the interim food additive

¹⁸³ See 21 C.F.R. §172.410 (2010) (food additive regulation for calcium silicate); 21 C.F.R. §182.2227 (2010) (GRAS regulation for calcium silicate).

¹⁸⁴ See 21 C.F.R. §180.1 (2010) (interim food additive regulations).

¹⁸⁵ 21 C.F.R. §170.38 (2010).

¹⁸⁶ See 21 C.F.R. §180.1(b) (2010).

¹⁸⁷ 21 C.F.R. §180.1(a) (2010).

¹⁸⁸ 21 C.F.R. §180.1(c)(2) (2010).

¹⁸⁹ *Id.*

regulation must be revoked.¹⁹⁰ Additionally, the FDA is responsible for monitoring the progress of these studies, by reviewing semiannual reports.¹⁹¹

As explained above, in 1982, the FDA considered a somewhat similar option—it considered revoking salt’s GRAS status, and instead regulating its use through interim food additive regulations to allow the continued use in food while studies were conducted about the health effects. The FDA rejected this option at that time for several reasons. One reason it offered was its belief that many uses of salt are prior-sanctioned, and so interim food additive regulations could not be used.¹⁹² The FDA also expressed concern that it would have to define what studies were needed and monitor their progress, and expressed doubt about whether an appropriate study could even be designed. It asserted that what was needed was a “general advance in scientific knowledge” about the relationship between salt consumption and hypertension.¹⁹³ It concluded that interim food additive regulations thus were not appropriate because specific studies could not be promptly undertaken.

Regarding the FDA’s concerns, as noted previously, the question of to what extent there are prior-sanctioned uses of salt has not been resolved, and FDA regulations include mechanisms for discovering and addressing these uses.¹⁹⁴ As for the state of scientific knowledge—arguably, the intervening three decades have seen the necessary advance in knowledge, as demonstrated by the IOM Report and the many studies it is based on. Finally, as to whether safety studies could be undertaken promptly: while the FDA’s rationale is consistent with the language of the regulations, it should be noted that at least two interim food additive regulations appear to have been on the books for over 30 years: that for mannitol and saccharin.¹⁹⁵ Thus, it appears that the FDA’s concerns about the ability of “definitive” studies being promptly undertaken have not necessarily prevented other substances from being regulated through interim food additive regulations.

Interim food additive regulations could be a useful mechanism for establishing temporary salt limits that are higher than hypothetical GRAS limits (assuming that they are still reasonably safe). Of course, the long history of mannitol and saccharin “interim” food additive regulation provides reason to question whether “interim” really means temporary, or if “interim” salt use regulations also could linger on for decades.

B. *Additional Considerations*

Regardless of which alternative is pursued, the FDA would need to engage in “considerable information gathering,” including “detailed input from stakeholders, in-depth analysis of the food supply [and the uses or functions of salt], simulation modeling of the effects of different levels of sodium on total intake, examination of consumers’ eating behaviors, adjustments for food safety concerns and studies of economic impact,”¹⁹⁶ including, specifically, sensitivity to the burdens on small businesses as well

¹⁹⁰ *Id.*

¹⁹¹ 21 C.F.R. §180.1(c)(3) (2010).

¹⁹² 1982 Sodium Policy Notice, *supra* note 8, 47 Fed. Reg. at 26,594.

¹⁹³ *Id.*

¹⁹⁴ See *supra* text accompanying notes 176-180.

¹⁹⁵ See 21 C.F.R. §§180.25, 180.37 (2010) (respectively). Mannitol has been regulated under an interim food additive regulation since 1974, after the FDA initially proposed to affirm its GRAS status in 1973. Food Additives Permitted in Food on an Interim Basis or in Contact With Food Pending Additional Study; Mannitol, 69 Fed. Reg. 65,540 (Nov. 15, 2004) (to be codified 21 C.F.R. pt 180).

¹⁹⁶ IOM REPORT, *supra* note 8, at 298.

as to “potential unintended consequences.”¹⁹⁷ As the IOM noted, rather understatedly, “This, in turn, will require resources and time.”¹⁹⁸

The FDA and the USDA have already made significant inroads in gathering this type of information—most recently, through the request for information published in the fall of 2011 (which is still pending).¹⁹⁹ A key issue the FDA will need to address is the science—what are the levels and uses of added salt in our food that would satisfy the GRAS standard of “‘reasonable certainty of no harm,’ based on today’s science, and using a total population ‘exposure’ approach in determining safety of salt or sodium.”²⁰⁰ In seeking information to answer this central question, there are several types of information that would be useful.

1. *The need for information regarding salt uses in categories of foods, including technical effects*

The GRAS status of a salt use is likely to depend on the type of food (among other things) to which the salt is being added. Thus, deciding the appropriate food categories for which salt GRAS uses would be established would be a crucial step.²⁰¹ These categories would need to take into account “the relative dietary contribution of the food category, functional and safety issues, and as appropriate, the lessons learned from others who have developed standards for sodium in foods on the basis of food categories”²⁰² To establish these categories, the FDA would need to gather information to help it determine what the appropriate interim and final limits should be for each category and relevant technical effect, and the appropriate timeframes for reaching each step. The IOM suggested that GRAS status should be given to “the uses and use levels of salt that allow persons to consume such foods as part of a normal diet with a reasonable likelihood of keeping their total daily intake of sodium consistent with the *Dietary Guidelines for Americans*”²⁰³ Further, there would need to be consideration of what processes are needed to enable the FDA to respond in a timely and responsive manner to petitions for non-GRAS uses and use levels.²⁰⁴

As recently as 2007, the FDA has publicly expressed concern about the difficulty of setting appropriate limits across so many different categories of foods and so many different technical effects. However, sodium reduction initiatives have begun to bloom all over the U.S. and the world, and there are many more models and data for the FDA to build on than even existed six years ago. Further, it is possible that the FDA could narrow the scope of this task by, for example, choosing to focus initially on those processed foods that are most highly consumed and have the highest salt content levels. Of course, this approach will likely not be as effective in reducing salty taste preferences in general, and thus may not be preferable.

In addition, in determining appropriate limits and timeframes, it could be helpful to have as much information as possible about how salt or sodium was used in food prior to 1958, including for what technical effects, what levels of use, and in what food categories. To what extent can the pre-1958 salt content of relevant food categories be

¹⁹⁷ *Id.*, at 306.

¹⁹⁸ *Id.*, at 298.

¹⁹⁹ Approaches to Reducing Sodium Consumption, *supra* note 44, 76 Fed. Reg. at 57050.

²⁰⁰ IOM REPORT, *supra* note 8, at 219.

²⁰¹ *Id.*, at 298-99.

²⁰² *Id.*, at 306.

²⁰³ *Id.*, at 305.

²⁰⁴ *Id.*, at 306.

determined? And what are the lowest levels of salt content that can be verified for relevant food categories across time? This data is likely to be difficult to gather, particularly as much of it may be proprietary (if it exists at all). But if it is available, such data would be highly relevant to evaluating current industry uses of sodium.

2. *The importance of harmonizing sodium labeling regulations*

In addition to the need for information and research gathering, the issue of how to harmonize the various existing sodium labeling regulations would need to be considered.

The IOM Report suggests that negative labeling could be used for products that contain more than GRAS usage level of salt, but which would still be permitted to be marketed through some kind of exemption, if data gathered by the FDA supported the inclusion of exemptions. The goal of the labeling would be to 1) to stimulate industry to reformulate/reduce sodium content more quickly, and/or 2) warn consumers about foods that contain relatively high amounts of sodium.²⁰⁵ As explained above, there are several other sodium-content-related labeling regulations. Efforts aimed at reducing salt in processed foods will likely necessitate reassessment and modifications of current sodium-related labeling regulations to ensure they are consistent with any new GRAS-related regulations, to minimize the likelihood of allegations that the FDA has acted in an arbitrary and capricious way in setting the GRAS limits.²⁰⁶

3. *The use of stepwise limits and GRAS*

The IOM recommends that GRAS be used to reduce salt content in food in a stepwise manner, which could mean that each step must itself qualify as GRAS. If a higher amount of salt in a food is GRAS, it may be difficult for the FDA to justify a simultaneous conclusion that *only* a lower amount is GRAS. The GRAS standard requires that the use of the substance be proven “safe” — not “relatively safe” or “safer.” Unlike “healthy” labeling, where the FDA balanced nutritional concerns with economic and “consumer choice” concerns in deciding what levels of salt could qualify for a “healthy” claim, the safety determination that must be made for GRAS may not allow for the same kind of balancing. If the FDA were to promulgate a regulation affirming the GRAS status of salt based on interim conditions of use that are not in fact considered “safe” ultimately, it could risk some challenges of inconsistency. For example, challengers might allege that the FDA lacks authority to take the position that a certain level of salt content, in the same type of food, used for the same purpose or technical effect, is now temporarily GRAS, and at another point two years in the future, for example, will not be GRAS, absent new data or evidence.

There are compelling counterarguments to such critiques, however. Because the FDA would be regulating sodium in a manner that is designed to ensure its safety, one would argue that it must have the flexibility to exercise its authority in a manner that is consistent with sound scientific and medical practice. As explained above, Congress intended for the GRAS process to allow the FDA flexibility to protect public health, while at the same time, minimizing inefficient disruptions of the food supply. Setting interim limits to allow for stepwise sodium reductions over time would be consistent with that goal. The FDA’s proposal to revoke the GRAS status of partially hydrogenated oils provides an example of this balancing; it specifically contemplates that should the FDA determine that partially hydrogenated oils cannot be safely used in food at all, there should be a deferred compliance deadline to allow time for the food

²⁰⁵ *Id.*, at 305.

²⁰⁶ See 5 U.S.C. §706 (2)(A) (2010) (court may set aside agency action, findings and conclusions if they are found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law”).

industry to reformulate products.²⁰⁷ A similar approach could be taken with sodium, so that the FDA would defer enforcement of lowered GRAS limits, to allow revised GRAS levels to be implemented in a stepwise manner. The fact that GRAS status is contingent upon good manufacturing practices presents some additional potential flexibility. Good manufacturing practice requires that no more salt than necessary is used in food. Assuming that there has been and continues to be technological progress in developing salt alternatives and product reformulations so that less salt is needed to achieve technical effects or food safety functions, for example, one could envision that the good manufacturing practice requirement could serve as a basis for adjusting GRAS salt levels downward over time.

V. CONCLUSION

Over thirty years ago, in response to concerns about salt usage, the FDA concluded that a “wait and see” approach to sodium reduction was appropriate to allow time for voluntary industry efforts to be implemented. In the intervening decades, voluntary industry efforts have led to sodium reductions in some products, but the results overall remain uneven and insufficient. The American food supply continues to include excessive amounts of sodium, and consumers continue to suffer the health-related consequences.

Given this history, we suggest that it is time for the FDA to apply its regulatory authority to modify the GRAS status of salt and set gradually decreasing limits on the amount of salt allowed in processed and prepared food products. Mandatory caps, like those in the National School Lunch and Breakfast Programs, can be implemented gradually to provide the food and restaurant industries with time to reformulate products, and allow consumers to adapt their taste sensitivities to the lower sodium content in foods. Although developing and complying with mandatory limits undoubtedly will be difficult and complicated, the food industry has shown great resources and capacity for innovation and adaptation when needed (e.g., *trans* fat content in processed foods decreased once federal law required its disclosure).²⁰⁸ Mandatory sodium limits appear to be necessary if significant, widespread reductions in the food supply are to be achieved.

For the FDA, modifying salt’s GRAS status and setting sodium limits will involve at least one complicated rulemaking. Further, because the IOM’s recommendation includes a call for continuous monitoring and evaluation prior to each stepwise reduction to assess whether any adjustments are needed, multiple rulemakings may be inevitable. However, it also may be possible for the FDA to modify salt’s GRAS status through one rulemaking with many steps. The recent successful rulemakings involving the national school food rules provide a partial model. The FDA’s proposal to revoke the GRAS status of partially hydrogenated oils seems likely to provide another helpful model.

Regardless of the path used by the FDA to set sodium limits, it is clear that there is no easy or simple regulatory solution to the problem of high sodium usage by the food industry. The GRAS process remains an imperfect tool, and implementing the IOM’s recommendation will pose many challenges. Nonetheless, the GRAS process remains the most promising tool available to decrease the usage of sodium, and to improve and lengthen the lives for millions of Americans across generations.

²⁰⁷ Tentative Determination Regarding Partially Hydrogenated Oils, *supra* note 83, 78 Fed. Reg. at 67,174.

²⁰⁸ See, e.g., Dianna Doell et al., *Updated Estimate of Trans Fat Intake by the US Population*, 29 FOOD ADDITIVES AND CONTAMINANTS PART A 861 (2012).