



January 24, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
FSIS Docket Room
1400 Independence Avenue, SW
Patriots Plaza 3, Mailstop 3782, Room 163A
Washington, DC 20250-3700

**Re: Approaches to Reducing Sodium Consumption; Food and Drug Administration (FDA)
Docket No. FDA-2011-N-0400; U.S. Department of Agriculture (USDA) Food Safety and
Inspection Service (FSIS) Docket No. FSIS-2011-0014**

Dear Sir or Madam:

The National Restaurant Association (the "Association") appreciates the opportunity to provide comments to FDA and FSIS (the "agencies") regarding approaches to reduce sodium consumption. Founded in 1919, the Association is the leading business association for the restaurant industry, which comprises 960,000 restaurant and foodservice outlets. The Association represents more than 435,000 member restaurant establishments and is the leading business association for the restaurant industry, including tableservice, quickservice, chains, franchisees, independents, institutional foodservice providers and allied members. Food and healthy living are priorities for our every-growing industry, which employs approximately 13.1 million people.

The Association commends the agencies for opening these dockets to obtain information about approaches to lower sodium consumption. We appreciate that the dockets are aimed at identifying current and emerging practices and approaches designed to reduce excess sodium intake. At the same time, the agencies should remain mindful of the complex factors that affect sodium reduction. Incremental reductions over time are the best way that meaningful sodium reductions will occur. Mandatory targets are unrealistic, unnecessary, and fail to address head-on the primacy of how consumers purchase, prepare, and consume foods every day. Consumer education along with detailed nutrition information is instrumental in addressing and encouraging sodium reduction in the American diet. Efforts to achieve meaningful change in consumer behavior cannot occur without consumer education that emphasizes the reasons necessitating such changes. An essential goal, as the agencies note of their own initiatives in this area over the past decades, is "to promote

informed choices on the part of consumers.” We encourage the agencies to consider this vital issue ahead of any regulatory policies relating to sodium reduction.

The restaurant industry appreciates the value and importance of sodium reduction for consumers. We concur with the agencies that research is needed “on a variety of issues, including the development of possible targets for the reduction of the sodium content of foods” to assist FDA and FSIS in promoting gradual, achievable, and sustainable sodium reduction. ^{1/} We have not conducted nor are we aware of the type of peer reviewed, published research that would be necessary to support the establishment of direct sodium target levels or reductions by the agencies. We suspect that such research would prove enormously difficult to conduct due to the sheer complexity of sodium’s function in packaged and restaurant foods and the numerous factors that influence consumer choices about what foods to eat. Any such research must account for the complex variables that directly impact sodium reduction efforts.

Our members are actively engaged in efforts to provide consumers with lower sodium options and indeed many such choices are now available to consumers across our industry. Restaurant operators also have learned that sodium reduction is a complex matter that is not easily achieved. These comments provide an overview of our members’ various approaches to lower sodium and the lessons learned about effective strategies. Additionally, we explain how efforts to lower sodium are complicated by consumer preference, technology, and communication challenges.

Sodium Reduction Efforts by the Restaurant Industry

Sodium reduction for menu items is a complex, highly technical, expensive, and labor intensive task that challenges our current knowledge and food science and technology limits for product development. The restaurant industry is highly diverse, including restaurants that provide a wide range of dining options. Therefore, our members have taken an individual, tailored approach to pursuing sodium reduction. On the whole, our members have evaluated their product lines to determine the areas in which sodium can be reduced, reformulated existing menu items when feasible, and considered sodium levels as part of new product development. Specific strategies have included:

- Gradual percentage reductions
- Gradual, targeted percentage reductions of key menu items;
- Elimination of salt while cooking;
- Working with suppliers to reduce sodium in specific products;
- Use of different spices and ingredients as substitutes for salt and other condiments;
- Reduction of sodium in blended seasonings;
- Education of chefs (e.g., reliance on ingredients other than salt for flavor);
- Offering more fruits and vegetables on menus as an alternative to high salt items;
- Switching to reduced-sodium ingredients (e.g., soy sauce) and/or ingredients with no added salt (e.g., diced tomatoes); and
- Looking for new solutions, such as using value added produce with a custom packed sauce that is lower in sodium.

^{1/} 76 Fed. Reg. 57050 , 57052 (Sept. 15, 2011).

The availability and feasibility of these and other options depends on many factors, such as the restaurant format (e.g., casual dining, quickservice), consumer expectations, the nature of the food (e.g., soup, bread), the product's taste profile (e.g., sweet, savory), available options to customize the menu item, and food science and technology limits our member have not yet been able to overcome.

Several of the largest quickservice and tableservice (casual/family dining) chains have made public commitments to significantly reduce sodium in their offerings over the next decade. Whether formally pledging participation, or otherwise devoting valuable resources and time, our industry's commitment is predicated on action. It is apparent that a one-size-fits-all approach is unworkable. One need only consider the diversity of the food industry, packaged and restaurant foods, to understand why. A restaurant menu typically will offer a range of foods that contain varying levels of sodium. The ability to lower sodium often will depend on a host of factors that are specific to a given menu item. Reducing sodium in even a handful of items can, therefore, involve distinct and substantial research and development challenges. Experience has proven that simply picking a sodium reduction target does not account for the numerous factors and barriers that exist and does not take into account the total dietary intake of a consumer over time.

Accordingly, any public policy or private industry efforts need to be unified across government agencies and flexibly in its application, as well as take into account the whole diet rather than focusing on an individual nutrient. Sodium reduction is no easier or more obtainable in a particular region of the country, for certain types of restaurants, or for the ingredient suppliers that are integral to reducing the sodium content of restaurant and packaged foods. Percentage sodium reduction goals would have to be individualized and take into account the reductions that companies have already made, so that reductions are only compared with an individual company's specific baseline rather than an industry average. It is important to note that companies have been aggressively reducing sodium over the past decade, and thus any current baseline would not necessarily reflect the successful reductions of sodium that are currently available in the marketplace. Also, such goals should account for the different barriers that exist for the very diverse ranges of restaurant foods offered to consumers. Restaurants should also be allowed to meet these goals using different methods. A "one size fits all" approach to sodium reduction is severely limiting and doomed to fail. While it may be simplistic to consider sodium reductions on an individual item basis or for a targeted category of foods; the realities of the marketplace are much more complex. One way to provide flexibility is to allow companies to measure and report sodium reductions in aggregate. The goal of any voluntary government initiative should be to incentivize companies to make commitments that are appropriate for their business and their guests and not single out any one food item or food category.

Our members have learned that consumers have different taste expectations in different parts of the country and among communities. Therefore, sensory and consumer testing is necessary to gauge acceptance of reduction efforts among various consumer groups. While such testing is highly resource-intensive, the undertaking is critical to achieve sodium reductions that will be accepted in the marketplace at an appropriate expense of time and resources.

These lessons are drawn in part from our members' experience with the National Salt Reduction Initiative (NSRI). Our members have experienced the following challenges with the initiative which are listed in no particular order of precedence

- NSRI was not premised on sensory or consumer taste testing of baseline sodium levels for restaurant categories. Consumer acceptance, and thus, testing, is essential for sodium reduction efforts to be successful.
- NSRI's scope is targeted to quickservice restaurants, particularly within the 25 restaurant target categories. The program would be more robust if it considered the offerings of family/casual dining restaurants and the abundance of other restaurant categories.
- The sodium goals are not measured against an initial baseline, but rather are based on an average of menu items based on top selling companies. The initiative does not account for food preparation or other healthful initiatives;
- The initiative establishes uniform national standards, but tastes and expectations for food choices differ across the country and among cultures.
- The approach to tracking restaurant commitments does not account for the entire category. If only one higher sodium item is removed from the menu, this can create the false illusion that sodium has decreased for the entire category.
- By using 100 gram portions, the system does not take portion size into account. Menu items of less than 100 grams are not accounted for, either.
- Currently, measurement of progress only takes into account sales-weighted data within a particular category, rather than across multiple categories.
- Established sodium reduction targets are paired with maximum targets per serving for all items.
- No cost-benefit analysis was conducted before the program was launched.

The limitations and short-comings of the initiative have not dampened our industry's commitment to lowering sodium levels. Success will best come about from a flexible approach that provides choices and nutrition information to allow our customers to make informed decisions regarding the food they eat. Additionally, any approach must be well researched and based upon current science that has considered the unintended consequences of sodium reduction.

The Association also strongly believes in the importance of providing information to consumers to empower them to make the best choices for their dietary needs. As noted, the agencies have directed decades of initiatives toward this end. Similarly the Association has led the way in ensuring consumer access to nutrition information. We joined forces with over 70 public health and stakeholder groups to advocate for a federal standard that gives families clear, easy-to-use nutrition information at the point of ordering, presented in a standardized format. Under the new federal menu labeling regulations, nutrition information, including sodium, will be available in more than 250,000 restaurant locations nationwide. With this information, consumers will be able to make informed choices when dining out. Additionally, many of our members enable consumers to customize their orders, allowing for individual variations such as lower sodium options. Increasingly, restaurant operators are striving to offer or expand the availability of lower sodium options.

The Association also recently launched a voluntary program called Kids LiveWell that provides healthful menu options for children based on stringent nutrition criteria that include a limit on sodium based upon the recommendations from the 2010 Dietary Guidelines. We currently have 42 restaurant brands representing nearly 20,000 restaurant locations that participate in the program, with participation continuing to grow. We also recently became a National Strategic Partner with USDA's Center for Nutrition Policy and Promotion to promote MyPlate messages, including messages about sodium. To educate our members and restaurant patrons about nutrition messages that are consistent with the Dietary Guidelines, the Association will use social media and

other educational tools to communicate about the development, offering, and selection of lower sodium menu options.

In addition, we will be working closely with one of our partners, Healthy Dining, who has received research funding from National Institutes of Health (NIH)/National Cancer Institute (NCI) in April 2012 for a Phase II project, *Decreasing Calories, Fat and Sodium in Restaurant Meals for Widespread Adoption*. The research aims to develop a system to assist restaurant companies in modifying standard restaurant recipes to reduce amounts of targeted ingredients, such as cheese, butter, mayonnaise, dressings, sauces, oil and/or salt. An important component of this research is finding the optimal level of reductions of the high-fat and high-sodium ingredients that will be acceptable to restaurant guests. In Phase I, Healthy Dining, worked with three restaurant companies and tested recipes containing 10 to 25% less butter, cheese, oil and salt. The results of the Phase I testing showed that many of the modified items remained appealing and acceptable to consumers. Phase II research is designed to 1) expand the number of menu items tested and explore modification limits and resulting acceptability ratings in more detail with several additional 'test restaurants' and consumers, 2) evaluate the cost savings to chain restaurants when they implement the reduction strategies permanently in all locations, 3) measure the 'test restaurants' ability to implement the reduction strategies in one or more locations, 4) analyze results and potential impact on public health, and 5) establish a viable strategy for widespread adoption of these approaches by the restaurant industry. In addition, Healthy Dining has developed an educational tool for consumers to access information around lower sodium menu items. Launched in October 2010, the "sodium savvy" section of their website (www.healthydiningfinder.com) demonstrates the commitment restaurants have to providing lower sodium menu options. Currently there are over 132 brands represented and nearly 13,000 restaurant locations providing and displaying lower sodium menu options for consumers. Based on a specified zip code radius, consumers can easily search across the country for restaurants that offer lower sodium menu options. Also, as a collaboration with Healthy Dining, the Association will soon be launching a mobile app that will provide even easier access to consumers to learn which restaurants are providing lower sodium menu options.

Real changes in sodium intake can only come about when consumers modify their behavior. It is essential that the agencies and our industry continue to find ways to educate consumers and provide them the necessary information from which they can make informed choices.

Challenges to Sodium Reduction and Reformulation

Our members have firsthand experience with the challenges of sodium reduction based on their reformulation efforts. The primary issue confronted is consumer acceptance. Additionally, sodium reduction is stymied by technological challenges that are driven chiefly by safety, quality, and taste. Finally, when sodium reduction succeeds, the marketing realities further impede changes in consumer behavior due to consumer perceptions and the highly restrictive regulation of nutrient content claims (e.g., low, reduced sodium). When considering future efforts and the role of FDA and FSIS, each of these challenges must inform federal public health policy.

A. Consumer Acceptance

A paramount challenge for sodium reduction is consumer taste preference. Consumers seek dining experiences that meet their needs, such as convenience, value, and taste. Our members tailor their businesses to respond to these demands. However, their consumer testing shows that many consumers equate lower sodium foods with poor or bland taste. Illustrating this point, the 2011

International Food Information Council Food and Health Survey found that 40 percent of consumers believe taste suffers when sodium is reduced. ^{2/} Thus, consumers are less likely to order low sodium menu items due to this perception.

FDA has previously recognized these challenges. When the agency established its final rule defining “healthy” in 1994, it set two tiered sodium levels and planned for a transitional period of about three-and-a-half years (until January 1, 1998) after which the qualifying sodium levels would be reduced to the “low sodium” claim levels. ^{3/} FDA’s intent was to encourage innovation and further reduction in sodium levels. At the time, the agency acknowledged that if it “were to define ‘healthy’ to include a ‘low sodium’ requirement, the appeal of many products would be diminished because of an unacceptable flavor profile, especially in foods where sodium has been added as a flavoring agent to compensate for the removal of fat. Thus, if consumers abandon the product or add salt to taste at the table, the food would lose its usefulness in assisting consumers in achieving dietary recommendations with respect to sodium intake.” ^{4/}

After 11 years and issuance of several stays, FDA ultimately was persuaded to eliminate the more restrictive sodium requirements because their use would risk substantially eliminating existing “healthy” products from the market place because of “unattainable nutrient requirements or undesirable and thus, unmarketable flavor profiles.” ^{5/} In announcing this decision, the agency summarized comments received that “documented substantial technical difficulties in finding suitable alternatives for sodium and demonstrated the lack of consumer acceptance of certain ‘healthy’ products made with salt substitutes and/or lower sodium.” The agency also acknowledged that reductions in sodium may result in increased levels of other nutrients of public health concern, such as fat and sugar, to balance out the taste.

The issue of consumer acceptance of reduced sodium products continues to present the same challenges today. When FDA and FSIS experimented with regulatory mandates for sodium, the effort ultimately proved unworkable because the limits were not technically feasible and mandated sodium reductions were deemed unacceptable to consumers. Industry (and the government) cannot control or dictate how foods, whether packaged or served in restaurants, are purchased, ordered, prepared, and consumed by consumers. Nor can the food and restaurant industry drive consumption of lower sodium food simply by shifting promotional resources or lowering sodium levels to arbitrary amounts without regard for consumer acceptance.

As FDA acknowledged, consumers cannot experience the benefits of lower sodium foods if they do not choose to eat them. There are numerous examples in the marketplace of sodium-reduced products designed to attract consumer purchases that were rejected by consumers because they did not like their taste. Therefore, in order to be successful sodium reduction efforts must be developed based on evidence that indicates people will find the foods acceptable. This is a pain-staking and resource intensive process. Our members also have learned that consumers have different taste expectations in different parts of the country and among communities. Additionally, sensory and consumer testing is necessary to gauge acceptance of reduction efforts among various consumer

^{2/} 2011 International Food Information Council Food and Health Survey http://222.foodinsight.org/Resources/Detail.aspx?topic=2011_Food_Health_Survey_Consumer_Attitudes_Toward_Food_Safety_Nutrition_Health

^{3/} 59 Fed. Reg. 24232 (May 10, 1994).

^{4/} *Id.* at 24239.

^{5/} 70 Fed. Reg. 56828, 56829-30 (Sept. 29, 2005).

groups. This is a highly resource-intensive undertaking, but also is critical because failures for sodium reduced foods to be accepted in the marketplace are far too costly.

Technological Challenges

Sodium plays a different technical function for different food categories, including serving as a preservative, controlling fermentation, or as a processing aid. In some foods, salt is naturally occurring and cannot readily be reduced. Salt and sodium-containing additives are chemically necessary in other foods, including leavened products (providing leavening functionality in baked goods), cheese (requiring salt as part of the cheese-making process), smoked fish (requiring maintenance of salt levels for food safety purposes), and cured meats (requiring salt for microbial control). Further complicating matters, salt often is used for a variety of different technical functions in a single food. Therefore, factors such as safety and quality must be evaluated when considering sodium reduction. In many instances, our members have found that the foods available today already contain the lowest possible levels of sodium for necessary functions.

These functional challenges are well established, as acknowledged by the agencies in the Federal Register notice. We encourage the agencies to consult with our country's leading culinary institutes and research institutes located on many college and university campuses to learn about the trials, failures, and accomplishments arising from the sophisticated, ongoing efforts to reduce sodium.

There also are shortages of alternatives to sodium that provide the same effect for taste. Within the restaurant and food service setting, one of the bigger challenges with sodium reduction is accessing suppliers that can provide ingredients and/or products with a meaningful sodium reduction that does not negatively affect taste, quality, or drive a cost increase. Many restaurant operators are finding it challenging to access sodium alternatives. Additionally, specification changes for sodium can result in a cost increase for suppliers and restaurant operators, as well as a possible need to purchase new cooking equipment, retro fit existing equipment, and/or adjust cooking times. Any changes in specifications need to be planned with extensive lead times so that new specifications can be rolled out to all restaurant locations, including any franchisees, which may receive products from several suppliers that are made to the new specification.

Further complicating specification changes, a sodium replacement that has the same taste and flavor profile as salt does not yet exist. Successful sodium reduction efforts, including specification changes, involve robust consumer and sensory testing for each individual ingredient and also for all of the ingredients combined. This approach ensures that taste (and demand) will not be impacted. Our members' sensory testing has found that salt replacers, such as potassium chloride and magnesium chloride, impart off-flavors and odors or a bitter taste, resulting in poor results in sensory and consumer tests. Furthermore, reliance on preservatives in place of sodium also is a challenge because consumers are seeking "clean labels" with only ingredients they recognize and know. Due to these challenges, the valued suppliers in the foodservice sector have not yet been able to solve the challenges faced in realizing broader and more significant reductions in sodium levels. Additionally, the few sodium replacement options currently available are expensive (especially when compared with the cost of salt). A further complication is that the few so-called salt alternatives have not been in the food supply long enough to understand the unintended consequences of long term consumption of these ingredients.

Such functional and taste challenges were recognized by FDA when it decided in 2005 not to lower the sodium levels for the “healthy” regulation. A petition seeking a stay in the sodium reduction levels cited several technological concerns with lowering sodium levels because of the functional role of salt, such as impact on the microbial stability of perishable products, changes in product texture, effect on flavor characteristics of other ingredients, and impact on total electrolyte levels that play a critical role in product safety. ^{6/} Later comments to the agency reiterated these concerns. ^{7/} FDA acknowledged “the manufacturing difficulties that are presented by the absence of a suitable substitute for salt.” The absence of a federal sodium reduction mandate has not slowed innovation and commitment of the food industry. Nor should one expect that technological barriers can be overcome merely by setting standards that cannot be validated as achievable by industry or acceptable to consumers.

Sodium reduction also can pose significant cost barriers when considering the robust testing that is needed to assess safety, quality, and taste. Reformulation poses a major challenge for restaurants because the majority of restaurants do not have research and developments departments or teams to work on reformulation of their current recipes. A significant investment of time and resources is necessary to effect even marginal sodium reductions. In fact, one of our largest restaurant members has found sodium reduction to be the most expensive research and development project in the history of the company. Also, one of our larger chain members have already invested \$1 million over the past two years towards sodium reduction with limited progress, including only a 10% reduction in two major ingredients.

Additionally, the costs required for sodium reduction are not typically offset with any incremental sales. In some instances, there also are concerns that sales would be negatively affected by sodium reductions or that the costs of reformulation will not be recouped due to communication challenges (discussed below). Our membership is mainly comprised of small business owners, including franchisees that may not be able to make the financial investment needed to develop lower sodium options or have the flexibility to pass such costs on to consumers.

Finally, the complexity of establishing sodium reduction targets cannot be underestimated in light of these technical challenges. Sodium reduction targets must be uniquely tailored to the technical effects of salt in different foods and food categories, particularly in the cases where salt has functional effects such as acting as a preservative. This challenge is further complicated by the fact that salt often is used for a variety of technical effects in a single food. Furthermore, there is complexity around reducing sodium in multiple menu items due to the interaction of reduced sodium ingredients with other ingredients, including other reduced sodium ingredients which may result in undesirable flavor outcomes. In addition, any limits on the use of salt as a flavoring agent would be extremely subjective. Ultimately, the most important consideration to any sodium reduction approach is sensory analysis that ensures consumer acceptance. In sum, our members have not identified available technology that will allow for a significant reduction in sodium without flavor loss, dramatic cost increase, or adding additional questionable ingredients, both from a consumer and restaurant perspective. Therefore, consideration should be given to allowing companies to utilize an aggregated approach that takes these technological limitations and variables into account.

B. Communication Challenges

^{6/} 62 Fed. Reg. 15390 (Apr. 1, 1997).

^{7/} 70 Fed. Reg. at 56833-34.

How restaurants communicate product benefits to consumers has a bearing on the commercial success of a given menu item. (Of course, our members' experience shows that no amount of advertising will save a product that consumers do not enjoy). We would like to highlight two significant challenges for communication of sodium reduction efforts. First, there is a disconnect between consumer interest in lower sodium foods and stakeholders' concerns about excessive sodium consumption. This is in part due to the need for additional consumer education, as noted above. In addition, our members' experience shows that directing consumers to lower sodium menu options is itself a turn-off. Consumers tell us, and their behavior reveals, that "sodium" messaging is equivalent to communicating "undesirable taste." Because taste is a primary driver of consumer purchase, communications based on sodium content can often undermine, not advance, the ability to support sustainable sales of such menu items.

Second, this problem is exacerbated by current federal labeling regulations – in particular the regulation of nutrient content claims. Communication of a sodium reduction message that may positively influence consumer purchases is largely prohibited although low sodium claims are typically associated with poor taste in a consumer's mind. Under the agencies' regulations, claims such as "reduced sodium" and "lower sodium" are only permitted if a food contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference food. 8/ How can a restaurant communicate sodium reductions that fall short of a 25 percent reduction and also are consistent with the nutrient content claim regulations?

Due to these concerns, a large number of our members have expressed to the Association that they currently have or are in the process of reducing sodium that have not been communicated to consumers or have been made public only through public relations materials, but not through direct advertisements to consumers. Much of the current strategy around reducing sodium in menu offerings is specifically designed to not make the consumer aware of these changes due to concerns about rejection; however, our members would be more apt to communicate the changes if they were not constrained by the nutrient content claim regulations.

Mandatory targets are unrealistic, unnecessary, and fail to address directly the primary ways consumers purchase, prepare, and consume foods every day. Conversely, incremental reductions over time are precisely the way that meaningful sodium reductions will occur, but very real concerns face the food industry in this regard. Government regulation that impedes truthful, non-misleading information about incremental reductions in sodium undermines the goals all stakeholders share. We encourage the agencies to consider this vital issue ahead of any regulatory policies relating to sodium reduction. Any public health recommendations should be based on a whole diet approach rather than on individual nutrients as this will promote a more consumer acceptable public health agenda.

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The restaurant industry is engaged in robust efforts to reduce sodium. Our members have learned that sodium reduction is a complex issue that is not easy to address. There is a great need for additional research on viable alternatives to sodium. Until such alternatives are developed, sodium reduction efforts will be necessarily constrained by limits on safety, quality, and taste. The Association supports the agencies' current initiative to gather information about sodium reduction efforts. The need to understand the current state of play underscores the importance of forging

8/ 21 C.F.R. § 101.61(b)(6); 9 C.F.R. § 317.361(b)(6); 9 C.F.R. § 381.461(b)(6).

calls to mandate or encourage specified reductions until the agencies obtain necessary information to support the viability of such an approach. Our collective efforts must recognize that the informed consumer will ultimately drive the goal of reducing excessive sodium consumption if provided with the options and knowledge. The Association is committed on behalf of its membership to support consumer knowledge and access to information. Our members also are committed to developing lower sodium food options, but they face numerous challenges in this regard.

Please do not hesitate to contact us if further information would be helpful or to collaborate further with the agencies in this information collection effort.

Sincerely,

Joy Dubost PhD RD CSSD
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