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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 American Frozen Food Institute (AFFI) appreciates the opportunity to provide comments in response to the Food and Drug Administration (FDA) and United States Department of Agriculture Food Safety and Inspection Service (FSIS) request for information concerning approaches to reducing sodium consumption. ^{1/} As the voice of the U.S. frozen food industry, AFFI is the national trade association that promotes and represents the interests of all segments of the frozen food industry. AFFI members manufacture and distribute frozen foods throughout the United States and globally.

Our members share a commitment to working with FDA and FSIS to further the important public health goal of reducing sodium intake, as evidenced by the voluntary strides our members have made, and continue to make, to reduce the

^{1/} In these comments we refer primarily to sodium, a component of sodium chloride, commonly known as salt; however, we also refer to salt where appropriate and recognize that most, but certainly not all, sodium is added to food in the form of salt.

sodium content of their foods. AFFI appreciates the agencies' efforts to obtain data and evidence on the role of sodium in foods and the challenges of reducing sodium content. It is critical that any federal sodium reduction initiatives be based upon science, taking into account the complex role of sodium in the food supply, as well as industry capabilities and consumer palates. With that objective, AFFI suggests the agencies allow industry's voluntary efforts to reduce sodium content to proceed. Based on our members' experiences, AFFI recommends that any federal initiative should take a flexible and gradual approach to sodium reduction that will allow consumer preferences and technology to adjust and research efforts to continue.

Sodium Reduction Efforts by AFFI Members

Our members have taken the following approaches to sodium reduction:

- Reducing sodium in a variety of products across a variety of categories and business channels;
- Introducing new, lower sodium products to the marketplace;
- Pledging further sodium reductions across company portfolios in the coming years;
- Creating a line of products to meet the sodium and nutrition criteria of the Healthier U.S. Schools Challenge; and
- Expending significant resources and effort to work with suppliers to find sodium alternatives that will not negatively impact the organoleptic properties, shelf life, or consumer quality standards.

AFFI members have faced the following challenges in reducing sodium content:

Taste and Consumer Acceptance:

- In general, consumers are less concerned about selecting food with lower sodium, as compared with focusing on calories and fat;
- According to a 2011 year-end report by the Hartman Group on consumer trends affecting foods, consumer preferences for reduced sodium foods are decreasing; ^{2/}
- Consumers' desire to reduce sodium intake is not consistent across food categories or by food channels (i.e., retail vs. restaurant); and
- Retailers want to be assured that products with lower sodium have been consumer tested and will provide a solution to all of their consumers, not only the health-conscious niche focused on the sodium content of foods.

^{2/} Hartman Group, Looking Forward in Food Culture 2012 (2012), at 13, <http://www.hartman-group.com/downloads/hartbeat-year-end-trends-2011>,

Technological Challenges:

- There is a lack of suitable salt alternatives for a broad portfolio of products;
- Manufacturers must rely on suppliers who are behind in developing ingredients with less sodium that remain low-cost;
- Suppliers generally are very good about supplying manufacturers with a small quantity of their ingredient to test in products. However, few suppliers have the resources to work side-by-side with manufacturers to find solutions that are acceptable across a wide portfolio of products.
- The cost of replacing ingredients containing salt/sodium varies widely, depending on the food matrix. In some cases, manufacturers may need to add one or two additional ingredients to mask the salt alternative, or to enhance flavor.

The Important Role of Sodium in Food

AFFI members believe the complex and critical role of sodium in the food supply must be taken into account when considering the scope and pace of any federal initiative to reduce sodium consumption. Although commonly recognized for its role in altering taste, sodium compounds were first used as a preservative to inhibit spoilage. This preservative function is still important today. In its 2010 Report, *Strategies to Reduce Sodium Intake in the United States*, the Institute of Medicine (IOM) recognized that sodium continues to play a critical role in food safety by reducing the growth of pathogens that spoil food products and reduce their shelf-life. ^{3/} The IOM report noted that reducing sodium in some foods would risk increasing the presence of pathogens, and that more research is needed on the food safety of reduced-sodium formulations and processes. ^{4/}

Beyond its role as a preservative, sodium affects the functional and physical properties of food. It also helps develop a characteristic texture in food that consumers expect. For example, sodium is used as a leavening agent, a seasoning agent, a formulating and processing aid, and a dough conditioner. ^{5/} Further, sodium compounds improve the tenderness of leaner cuts of meat, and provide texture and control moisture in cheese. In bread, salt enhances color, improves crumb structure, prevents excessive yeast action and inhibits the growth of acid-producing bacteria. ^{6/} In short, sodium plays a complex and essential role in food processing.

^{3/} IOM Sodium Reduction Report at 91.

^{4/} *Id.* at 95.

^{5/} 76 Fed. Reg. 57050, 57052 (Sept. 15, 2011).

^{6/} Statement of Lee Sanders, Senior Vice President of Government Relations and Public Affairs, American Bakers Association, FDA Public Hearing, Regulatory Hearing on Salt and Sodium, Nov. 29, 2007, at 101.

Challenges to Sodium Reduction

A. Taste and Consumer Acceptance

AFFI has found that consumer tastes present a crucial challenge to sodium reduction. Indeed, the International Food Information Council's 2008 Food and Health Survey indicated that taste remains the number one driver for food purchases for consumers. ^{7/} As such, consumer palatability and expectations are crucial factors in the success of any efforts to reduce sodium intake.

Significantly, salt imparts more than just a salty taste to overall food flavors; salt also suppresses bitter tastes. As the IOM report stated, in a variety of foods, "salt was found to improve the perception of product thickness, enhance sweetness, mask metallic or chemical off-notes, and round out overall flavor while improving flavor intensity." ^{8/} In fact, without salt, many baked goods have an insipid taste. ^{9/}

Consumer palates are trained to expect a certain level of sodium in their food; at a lower level, taste suffers. There is currently no sodium alternative that effectively mimics the taste of salt, as the closest alternative, potassium chloride, has a bitter flavor and after-taste to some people. ^{10/} More research regarding salt substitutes and salt alternatives is needed, and given the complex technical role that sodium plays in food, that research will take time. Although consumer preferences can be retrained to some extent to require less sodium, based on our members' experiences, AFFI believes a gradual approach to sodium reduction that allows for scientific research and for tastes to adjust over time would be most effective.

B. Technological Challenges

As noted above, due to the versatile role of sodium in the food supply, the identification of an appropriate sodium-alternative has proved to be a significant challenge. Salt provides functionality, flavor, and is one of the cheapest ingredients available; not surprisingly, no viable cost effective alternative to salt has been found. Further, in the absence of an effective sodium-alternative, adding additional ingredients to improve the taste, texture, and processing of foods increases costs.

Beyond the challenges of finding reduced-sodium alternatives, the existing sodium-reduction technology is limited. AFFI members have found that reducing salt by 10 percent or so is achievable, but going further is difficult. ^{11/} For example, technological advances that allow sodium reduction are not commercially viable for

^{7/} IFIC, Food and Health Survey: Consumer Attitudes Toward Food, Nutrition, & Health (2008).

^{8/} IOM Sodium Reduction Report at 72.

^{9/} *Id.* at 104.

^{10/} *Id.* at 85-86.

^{11/} See, e.g., Michael Moss, *The Hard Sell on Salt*, N.Y. TIMES, May 29, 2010.

all food products across all food matrixes. ^{12/} Further, the current FDA low sodium claim levels are so low that it is difficult for industry to achieve them using the current sodium reduction technologies. ^{13/}

Given the constraints of existing technology, tremendous research and development efforts will be needed not only to develop reduced-sodium alternatives and technologies but also for product development and for testing consumer demand and preferences. AFFI maintains that a successful sodium reduction strategy should be mindful of the industry's capabilities and limitations.

The Need For A Gradual and Flexible Approach to Sodium Reduction

FDA and FSIS should continue to explore the issue of sodium reduction, taking into account the challenges discussed above, and allowing voluntary efforts such as those taken by AFFI members to come to fruition. AFFI recommends that any potential federal initiative to reduce population sodium intake take a gradual and flexible approach. This type of approach has been endorsed by the Institute of Medicine. ^{14/} A gradual approach allows for consumer education and for palates to adjust.

It also permits continued research in the many areas in which the IOM recommended further research, including:

- Understanding salt taste reception and taste development;
- Developing innovative methods to reduce sodium levels in food while maintaining palatability, physical properties, and safety;
- Enhancing current understanding of factors impacting consumer awareness and behavior relative to sodium reduction; and
- Monitoring sodium intake, sodium in the food supply, and salt taste preference. ^{15/}

Further, additional research is needed into potential unintended negative health consequences of reducing sodium intake, such as increased all-cause and cardiovascular disease mortality. The food industry has worked towards reducing sodium content in foods in response to calls from public health agencies, under the assumption that there is no resulting harm to health. Recent data, however, calls this assumption into question. ^{16/} Accordingly, FDA and FSIS should conduct a

^{12/} See, e.g., Statement of Patricia Packard, Director of Nutrition, ConAgra, FDA Public Hearing, Regulatory Hearing on Salt and Sodium, Nov. 29, 2007, at 95-96.

^{13/} *Id.* at 96.

^{14/} IOM Report on Sodium Reduction, at 285.

^{15/} *Id.* at 311.

^{16/} Adam M. Bernstein and Walter C. Willett, *Trends in 24-h Urinary Sodium Excretion in the United States, 1957-2003: A Systematic Review*, 92 AM. J. CLIN. NUTR. 1172 (2010); David A. McCarron et al., *Can Dietary Sodium Intake Be Modified by Public Policy?*, 4 CLIN. J. AM. SOC.

thorough review of the emerging research describing potential unintended consequences of reducing sodium intake. AFFI requests that the agencies share their findings with the public and suggests that the agencies evaluate this critical research before undertaking any potential federal sodium reduction initiative.

Our members remain committed to reducing the sodium content of their products, but can only do so as fast as research, innovation, and consumer demand allows. To that end, AFFI believes that a gradual approach is most likely to be effective.

Thank you for the opportunity to provide these comments. If AFFI can assist the agencies with additional information or perspectives, please do not hesitate to contact us.

Respectfully submitted,



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NEPHROL. 1878 (2009); Martin J. O'Donnell, Salim Yusuf, Andrew Mente et al., *Urinary Sodium and Potassium Excretion and Risk of Cardiovascular Events*, 306 J. AM. MED. ASSOC. 2229 (2011); Katarzyna Stolarz-Skrzypek, *Fatal and Nonfatal Outcomes, Incidence of Hypertension, and Blood Pressure Changes in Relation to Urinary Sodium Excretion*, 305 J. AM. MED. ASSOC. 1777 (2011); Merlin C. Thomas et al., *The Association Between Dietary Sodium Intake, ESRD, and All-Cause Mortality In Patients With Type 1 Diabetes*, DIABETES CARE, Feb. 9, 2011; Elif I. Ekinci et al., *Dietary Salt Intake and Mortality in Patients With Type 2 Diabetes*, DIABETES CARE, Feb. 2, 2011; Niels A. Graudal et al., *Effects of Low-Sodium Diet vs. High-Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterol, and Triglyceride (Cochrane Review)*, 25 AM. J. HYPERTENSION 1 (2012); MJ O'Donnell, S. Yusuf, A. Mente et al., *Urinary Sodium and Potassium Excretion and Risk of Cardiovascular Events*, 306 J. AM. MED. ASSOC. 2229 (2011).