National Milk Producers Federation

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"Connecting Cows, Cooperatives, Capitol Hill, and Consumers"

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Food and Drug Administration
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Food Safety and Inspection Service
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RE: Approaches to Reducing Sodium Consumption Docket No. FDA-2011-N-0400

To Whom It May Concern:

The National Milk Producers Federation is pleased to respond to your request from September 15, 2011 for information on approaches to reducing sodium consumption in the diet. The National Milk Producers Federation, based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives that they own. The members of NMPF's 31 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 40,000 dairy producers on Capitol Hill and with government agencies.

Sodium in the Diet

Sodium is widely distributed throughout the food supply – with only fruits not contributing significant amounts. The Grocery Manufacturers Association has noted that 85 percent to 90 percent of sodium in the diet comes from packaged foods and beverages and restaurant menu items.[1] The Institute of Medicine's 2010 sodium report indicated that mixed dishes—

[1] *Sodium and Salt, Science Policy Paper,* Grocery Manufacturers Association, 2008

including sandwiches, casseroles, and pizza—contribute nearly half of all sodium from foods. Other major sodium sources are meats and meat alternates, grains and vegetables.[2]

The 2010 *Dietary Guidelines for Americans* recommends that the general public limit sodium to less than 2,300 milligrams per day, while at-risk groups—those with hypertension, African Americans, and adults at least 51 years old—consume no more than 1,500 milligrams per day. Meeting these recommendations will not be easy. The estimated average intake of sodium for all Americans ages two years and older is approximately 3,400 milligrams per day.[3]

Sodium and Hypertension

Sodium is only one of many factors that affect hypertension. As a result, simply reducing sodium is not the most effective way to lower blood pressure; an overall healthy diet combined with lifestyle changes can be more effective.[4] For example, the multi-faceted *Dietary Approaches to Stop Hypertension*—the DASH diet—has been shown to be effective in reducing blood pressure when incorporated into a weight loss program.[5] The DASH diet is low in fat, saturated fat and sodium, but also emphasizes foods that are good sources of calcium, potassium and magnesium. Dairy products are important sources of all three nutrients.[6] The DASH diet emphasizes low-fat milk and milk products as well as vegetables and fruits.

The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure reported that adopting a DASH eating plan would lead to a reduction in systolic blood pressure of eight to 14 mmHg. By contrast, shifting to a sodium intake of no more than 2,400 milligrams per day alone was estimated to lead to a more modest reduction of two to eight mmHg.[7] Similarly, the United Kingdom Food Standards Agency Medical Research Council estimated that a "healthy weight reducing diet" would have a greater impact on individuals with hypertension than simply reducing sodium to 2,400 milligrams daily. It anticipated that the "healthy diet" would lead to a blood pressure benefit approximately twice that achieved by sodium reduction alone.[8] Finally, a recent study concluded that lifestyle changes can delay or prevent high blood pressure in those who do not have hypertension, delay or prevent the need for medication in those who do have hypertension, and help reduce blood pressure in those already on high blood pressure medication. This study said that the greatest and most sustained benefits are obtained when

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[2] *Strategies to Reduce Sodium Intakes in the United States,* Institute of Medicine, 2010, The National Academies Press.
[3] *Dietary Guidelines for Americans, 2010,* www.healthierus.gov/dietaryguidelines
[4] *Sodium: Insights for the Dairy Industry,* Dairy Management Inc., 2010
[5] Report of the Dietary Guidelines Advisory Committee, 2010 http://www.cnpp.usda.gov/DGAs2010-DGACReport.htm.
[6] Report of the Dietary Guidelines Advisory Committee, 2005 http://www.health.gov/dietaryguidelines/dga2005/report/default.htm
[7] Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure. NIH Publication No. 04-5230. August 2004. http://www.nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf
[8] Hentges E. Sources of sodium in the food supply, presented at the Institute of Medicine Committee on Strategies to Reduce Sodium Intake Information Gathering Workshop, March 2009, http://www.iom.edu/?id=65261

multiple lifestyle interventions—including weight loss, physical activity, and the DASH diet — are incorporated simultaneously.[9]

Several other recent studies also raise questions about sodium reduction as a strategy to reduce hypertension and cardiovascular disease.[10,11,12] There is also a strong correlation between higher potassium consumption and lower blood pressure, coronary heart disease and stroke.[13] In particular, a meta-analysis of 11 studies including nearly 250,000 participants associated higher potassium intake with lower rates of stroke and a trend toward lower risk of CHD and total CVD.[14]

The *Dietary Guidelines* recognizes that milk and milk products are the leading contributors of potassium in the diet and that there is a favorable relationship between the intake of dairy foods and blood pressure.[15] Despite this, less than five percent of Americans are consuming the recommended amount of potassium.[16] To help increase potassium intakes, the 2005 Dietary Guidelines Advisory Committee recommended adjusting the USDA Food Pattern to include more fruits and vegetables and three cups of milk and milk products daily.[17] Intakes of calcium and magnesium also have been linked to lower blood pressure.[18] Therefore, such findings reinforce the need for a balanced approach to addressing hypertension through diet.

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[9] Frisole TM, et al., Beyond salt: lifestyle modifications and blood pressure, European Heart Journal 2011, 32(24): 2081-7

[10] Stolarz-Skrzypek K, et al., Fatal and nonfatal outcomes incidence of hypertension, and blood pressure changes in relation to urinary sodium excretion, JAMA 2011, 305(17): 1777-85

[11] O'Donnell, MJ, et al., Urinary sodium and potassium excretion and risk of cardiovascular events, JAMA 2011, 306(2): 2229-38

[12] Graudal NA, et al., Effects of low sodium diet versus high sodium diet on blood pressure, renin, aldosterone, catecholamines, cholesterol, and trigylceride, Cochrane Database Syst Rev 2011. 11:CD00022; American Journal of Hypertension 2012 25(1): 1-15

[13] Larsson SC, et. al., Dietary potassium intake and risk of stroke: a dose-response meta-analysis of prospective studies. Stroke 2011;42(10):2746-50; D'Elia L, et al., Potassium intake, stroke, and cardiovascular disease a meta-analysis of prospective studies. Journal of the American College of Cardiology 2011;57(10):1210-9; Yang Q, et al., Sodium and potassium intake and mortality among US adults: prospective data from the Third National Health and Nutrition Examination Survey. Archives of Internal Medicine 2011;171(13):1183-91; Houston MC, The importance of potassium in managing hypertension. Current hypertension reports 2011;13(4):309-17

[14] D'Elia, L, et al., Potassium intake, stroke and cardiovascular disease a meta-analysis of prospective studies, Journal of the American College of Cardiology, 2011, 57 (1): 1210-9

[15] *Dietary Guidelines for Americans, 2010,* www.healthierus.gov/dietaryguidelines

[16] *What We Eat in America,* NHANES 2001-2002, USDA Agricultural Research Service

[17] Report of the Dietary Guidelines Advisory Committee, 2005 http://www.health.gov/dietaryguidelines/dga2005/report/default.htm

[18] Allender PS, et al., Dietary calcium and blood pressure: a meta-analysis of randomized clinical trials. Annals of internal medicine 1996;124(9):825-31; Dickinson HO, et al., Calcium supplementation for the management of primary hypertension in adults. Cochrane Database Syst Rev 2006(2):CD004639; Elliott P, et al., Dietary phosphorus and blood pressure: international study of macro- and micro-nutrients and blood pressure. Hypertension 2008;51(3):669-75; van Mierlo LA, et al., Blood pressure response to calcium supplementation: a meta-analysis of randomized controlled trials. Journal of human hypertension 2006;20(8):571-80; Chung M, et al., Vitamin D and calcium: a systematic review of health outcomes. Evidence report/technology assessment 2009(183):1-420; Dickinson HO, et al., Magnesium supplementation for the management of essential hypertension in adults, Cochrane Database Syst Rev 2006;3:CD004640

Consumer Perceptions

Consumer research shows that those who are concerned about sodium tend to be concerned about multiple food ingredients. Also, those who avoid salt are likely to avoid other ingredients and the foods associated with those ingredients.

- A study from HealthFocus reported that checking products for "low sodium" had increased 34 percent between 2002 and 2008, to 43 percent of consumers.[19]
- The same study found that weekly usage of low-sodium products doubled between 2000 and 2008, with 40 percent of consumers indicating they were maintaining—or trying to maintain—a low-sodium diet.[20]
- A survey by Dairy Management Inc. found that people who were concerned about sodium were also concerned about fats, hormones, sweeteners, antibiotics and preservatives—and were significantly more likely to avoid many of these in their diets.[21]
- The HealthFocus study found that most shoppers do not examine each food they eat for sodium content. Instead, they focus on categories of foods, such as processed foods and fast food. [22]

Once again, this suggests a whole-diet approach for helping consumers address hypertension and other chronic diseases.

Sodium and Cheese

Milk is a nutrient-dense food and naturally provides nine essential nutrients – including calcium, vitamin D and potassium, three of the four nutrients of concern – and the majority of dairy products (milk, yogurt, ice cream) are naturally low in sodium. While consumers often think of cheese as a high salt product, sodium levels vary among different varieties of cheeses. Cheese is a nutrient-dense food, contributing less than eight percent of U.S. sodium intake, while providing 21% of the calcium, 11% of the phosphorus, 9% of the protein and vitamin A, and 8% of the zinc.[23]

Reducing sodium in cheese making is particularly challenging from a technological perspective because of the multiple roles of sodium in cheese. Salt helps control enzyme and microbial activity – both desirable and undesirable – to maintain various characteristics associated with cheese, including body, flavor, texture and shelf life.[24] In natural cheeses, sodium affects the rate and type of fermentation – ultimately affecting the pH, water activity and organic acid level of the cheese – which are all inherent to assuring food safety. Salt is a

[19] *Trends Report,* HealthFocus, 2009
[20] *Trends Report,* HealthFocus, 2009
[21] Proprietary Sodium Survey, Dairy Management Inc., 2010
[22] *Trends Report,* HealthFocus, 2010
[23] Hentges E, Sources of sodium in the food supply, presented at the Institute of Medicine Committee on Strategies to Reduce Sodium Intake Information Gathering Workshop, March 2009, http://www.iom.edu/?id=65261
[24] Tanaka N, et al. Evaluation of factors involved in antibotulinal properties of pasteurized process cheese spreads. J Food Prot 49:526. 1986; Glass K and Doyle ME, Safety of processed cheese: A review of the scientific literature. FRI Briefings, Food Research Institute, University of Wisconsin, 2005

significant factor in minimizing spoilage and preventing the growth of pathogens, like *Listeria monocytogenes,* in natural cheeses. In processed cheeses, both salt and sodium-based emulsifying salts play important roles in preventing the growth and toxicity of pathogens, such as *Clostridium botulinum*. The emulsifying salts, typically sodium citrates or sodium phosphates, also play a role in the texture of the cheese (meltability, sliceability, stretchability) in melted and unmelted forms. Research is ongoing to discover emulsifiers that are not citrate- or phosphate-based and which will retain melting characteristics without adding sodium.

Options for lowering sodium in cheese are limited. Capital costs and the potential for market failures can have significant implications for manufacturers, since lower-salt cheeses often have off-flavors. Potassium chloride can be used as a partial replacement for sodium, but its use is limited by development of bitter, metallic, and other off-flavors. The dairy industry has proactively responded to public health concerns by reducing the fat in cheese. However, when fat is removed, it is replaced with water to maintain texture. This increase in water also requires an increase in salt to maintain the ratio of salt-to-moisture, a key attribute in assuring the same degree of food safety.

Although progress is being made on sodium reduction in cheese, more research is needed. Timelines for developing cheeses that maintain expectations for flavor, body, texture, shelf life and food safety are uncertain. If manufacturers are forced to meet mandatory sodium reduction targets too quickly, there is potential for consumer rejection and risk of food safety issues. Given the benefits of cheese and the current technological hurdles, this argues for a "go-slow", industry-initiated approach.

Standards of Identity Issues for Cheese

Seventy-two standards of identity for cheeses and cheese products in the Code of Federal Regulations protect the names of commonly used foods.[25] However, these standards can have implications in the process of reducing sodium in cheese. Using salt substitutes, for example, may result in a product that can no longer be called cheese. Cheddar cheese made with potassium chloride as a partial substitute for sodium must be called "Cheddar cheese product," a label change that can reduce consumer acceptance. It is possible for a standardized food product to deviate from the standard, but only if an approved nutrient content claim is made.

To qualify for a "reduced sodium" claim, a cheese must have 25 percent less sodium than the regular product. To qualify for additional sodium-related nutrient claims—"sodium free," "low sodium," and "no salt added"—larger reductions are required. But these changes can affect consumer acceptance. For example, low-sodium Cheddar cheese has been in the market for decades, yet it accounts for only a tiny percentage of total retail Cheddar cheese sales. More moderate sodium reductions of 5 percent to 15 percent have been proposed, and could result in a wider array of lower-sodium cheese options, but these would likely require formulation changes – and would ultimately result in a product that no longer conforms to the standard of identity.

[25] 21 CFR Part 133

One additional FDA labeling policy deserving of mention is the 50-gram rule. The rule requires that products with a serving size of 30 grams or less, including cheese, meet nutrient standards that apply to a larger, 50-gram serving. For Cheddar cheese to be called "low sodium" under the 50-gram rule, the sodium must be reduced to 140 milligrams per 50 grams of cheese. That equates to only 84 milligrams of sodium per 30-gram serving, or a reduction of more than 50 percent. Without the 50-gram rule, Cheddar cheese could be called "low sodium" with a more modest reduction of approximately 20 percent. The National Milk Producers Federation strongly urges FDA to modify the 50-gram rule to lower the low-sodium threshold for cheese. This change would offer cheese manufacturers a greater incentive to incrementally reduce sodium, with associated benefits to consumers.

Additional Considerations for Reducing Sodium in Cheese

There are other challenges with reducing sodium in cheese, including increased formulation costs. Potassium chloride is more expensive than sodium and must be used in greater concentrations if it is substituted for sodium in cheese. As a result, it could cost as much as 11 times as much as sodium in cheese. Other potential replacements could be even more expensive.

Another challenge with respect to sodium reduction is monitoring. The IOM committee called for a robust monitoring system to underpin an aggressive dietary sodium reduction program.[26] Included was tracking the sodium content of foods, tracking sodium intakes, monitoring changes in taste preferences, monitoring changes in consumer knowledge, and tracking potential unintended consequences of reducing sodium in foods, including food safety problems. If funding for this monitoring is not available, the ability to track and record this information will not be possible.

Finally, there is the issue of exports, which account for about 4 percent (about 420 million pounds, or $790 million) of total U.S. cheese production. World trade is typically based on international standards that allow potassium chloride, but no other salt replacers. Global acceptance of other salt replacers cannot be guaranteed, thus putting the international marketability of cheese at risk.

Voluntary Industry Actions

Industry has voluntarily and proactively committed to reduce the sodium in cheese through a number of initiatives. For example, some manufacturers have reduced sodium content across entire product lines, and others have done so selectively. Other manufacturers have formulated reduced-sodium processed and blended cheeses specifically for the school market, products with at least 25 percent less sodium per serving. In addition, the salt content of mozzarella cheese in USDA's Food Distribution program has been reduced approximately 25 percent.

[26] *Strategies to Reduce Sodium Intakes in the United States,* Institute of Medicine, 2010, The National Academies Press

The Health and Wellness Committee of the Innovation Center for U.S. Dairy® is an industry-wide partnership that fosters innovation in dairy products. This committee has identified sodium reduction in cheese as a priority. A task force, representing approximately 80 percent of cheese production nationally, has identified three areas of focus:

- Maintaining food safety and preserving taste and functionality in lower-sodium products
- Updating controls to better measure sodium during the cheese making process
- Educating key audiences about sodium's role in cheese making and the industry's efforts to voluntarily reduce sodium levels while maintaining food safety and taste expectations

As part of this effort, baseline research determined the sodium content of more than 1,600 cheeses available nationwide. The results, published as part of a peer-reviewed article in the *Journal of Dairy Science,* showed a wide variation in sodium levels (related to type of cheese, brand, manufacturing variability, etc.). For some brands, opportunities were identified to reduce sodium amounts without sacrificing flavor. Efforts of the task force have also led to sensory research, to better understand how sodium affects consumer perception and acceptance of cheeses and foods containing cheese.

Additional information on the work of the task force is available in comments submitted to the docket by the National Dairy Council. Given the significant efforts proactively made by individual dairy companies, as well as the resources dedicated to this issue by the entire industry, federally mandated sodium reduction initiatives are not necessary. The industry will continue to work toward understanding the functional properties of sodium in cheese to make progress in this area.

Conclusions

The National Milk Producers Federation is cautious about recommendations to reduce sodium consumption in the absence of other diet and lifestyle changes. Research supports a whole-diet approach to addressing hypertension and other chronic illnesses. Approaches such as the DASH diet – which addresses the nutrient content, caloric content *and* sodium content in an achievable manner – along with lifestyle modifications, are likely to be the most effective in improving public health.

NMPF is also cautious about recommendations to reduce sodium consumption too quickly, for example, through federal restrictions on sodium content in foods. Reducing sodium in cheese is particularly challenging, since sodium plays multiple roles in cheese manufacturing. The dairy industry will continue to research ways of modifying sodium content to make safe, acceptable and affordable products for consumers; however, there is no single "magic bullet". The dairy industry is making progress through voluntary initiatives, and this will continue to be an ongoing effort.

There are additional issues with reducing sodium in cheese – including cost, dietary monitoring, exportability and standards of identity. In particular, we urge a reevaluation of

labeling policies related to cheese and sodium reduction. Because of these policies, cheese faces a higher bar in terms of reformulation targets and product labeling (i.e., the 50-gram rule, use of standardized terms, and nutrient content claims).

Significant information gaps also should be filled before an aggressive sodium reduction plan, or change to the GRAS status of salt, are adopted. In particular, additional research is needed to recognize any potential unintended consequences from both public health and food processing perspectives.

Thank you for this opportunity to share our perspective. Please contact NMPF for additional information.

Sincerely,

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