October 31, 2016

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

(Submitted electronically: www.regulations.gov)

Re: Docket No. FDA-2014-D-0055. Voluntary Sodium Reduction Goals: Target Mean and Recommended Maximum Concentrations for Sodium in Commercially Processed, Packaged and Prepared Foods. 81 Fed. Reg. 35363 (June 2, 3536-35367)

To whom it may concern:

The American Cheese Society (ACS) is pleased to have this opportunity to comment on the Food and Drug Administration's (FDA) voluntary sodium reduction targets. With over 1,700 members, ACS represents artisan, farmstead, and specialty cheesemakers and the vertical industry of distributors, retailers, and others who serve and support them.

ACS believes FDA's proposed changes are well-intended, and that products with excessive added salt are of concern to public health; cheese is neither a major contributor to daily sodium intake nor a product that adds any sodium beyond that which is needed to produce a safe, high-quality, wholesome product for consumers. ACS agrees with the International Dairy Foods Association (IDFA) and the National Milk Producers Federation (NMPF) conclusions that "FDA needs to go back to the drawing board on cheese standards, thoroughly revisiting its categories and reassessing the wisdom of applying a blanket percentage reduction to all cheeses, including those that are already relatively low in sodium." In addition, along with these groups, we strongly urge FDA to remove the entire cheese category from any sodium reduction targets, goals, or guidance. Salt is simply too integral to the cheesemaking process, and to the safety and quality of cheese.

There are two main areas in which the proposed sodium reduction targets would have the most serious negative consequences for our cheesemakers, Food Safety and Quality; and Economic Impact.

Food Safety and Quality

ACS cheesemaker members often produce cheeses using traditional methods that are quite unique to their products. Preventive Controls in use and development by producers to comply with FSMA often include salt as a key processing agent which can enhance the safety as well as the quality of the final product. Quality and safety would be jeopardized by lowering the

sodium to the levels proposed by FDA, particularly for certain low-acid, soft, fresh cheeses in which salt is a major factor preventing spoilage or the growth of pathogenic organisms.

Reducing sodium in cheesemaking poses many technological challenges, and in most cases is neither feasible nor practical in achieving a desired end product. Salt helps control enzyme and microbial activity, and is instrumental in achieving and maintaining taste, texture, and shelf life. Salt plays a role from the moment the cheesemaking process begins all the way until the cheese reaches the consumer, where qualities like taste, texture, mouth feel, meltability, and the like are impacted. Too little, or too much, sodium during cheesemaking can lead to flavor defects, textural problems, spoilage, and shortened shelf-life. Cheesemakers use only as much salt as is needed to produce the desired outcome, and we believe that shifting this balance to achieve FDA's proposed sodium reduction goals could do more harm than good.

Our cheesemakers, particularly those who operate smaller, artisan creameries, pride themselves on the long, safe track record of traditional cheesemaking methods. The use of salt is a natural way in which they can achieve safe, high quality results using traditional, natural processing agents and steps. The safety of natural cheeses made by artisan and specialty producers would be impacted in many ways:

- Substantial changes in sodium levels of natural cheese present significant challenges in terms of revalidation of existing food safety plans. This also holds true for any reformulations of any food, particularly as under the Food Safety Modernization Act (FSMA), food safety plans must include scientific justification to validate safety.
- Significant changes to food safety plans also require an understanding of the impact of any changes throughout production and shelf life of the product.
- The studies required to fully validate a food safety plan likely will be lengthy and not always easy based on a lack of existing research and data. This is especially true for those who are involved in affinage, the aging of cheeses following traditional methods.
- Industry and academia support will be required to help many smaller companies design and execute these food safety model challenges.
- As you have already outlined in your current document, salt plays an integral part of the overall cheese balance and eventual stability. Reduction in sodium levels of this magnitude would truly exemplify a paradigm shift in the manufacturing of natural cheese. It is unknown whether producers would be able to find an alternative to salt, yet retain the same impact on cheese stability and function.

Economic Impact

Small cheesemakers and all those who produce artisan, farmstead, natural, and specialty cheeses, face numerous financial challenges from the price of raw materials to the expense of complying with changing regulations. Local economies and communities are impacted by any changes that add additional, and in this instance impractical, financial burden for producers. Any changes must take into consideration the differences that are integral to artisan production, and which provide viable livelihoods and economic structures for farm communities. Dr. Cathy Donnelly at the University of Vermont has examined the benefit to these communities and found that for a farmer with 50 cows, annual gross revenues from fluid milk would total just $100,000. Making artisan cheese from that same milk would transform that into one million dollars, and employ many more people.

The proposed reduction of sodium in cheese could inordinately impact small producers, making their products not only less safe, but also less desirable due to taste and textural changes. Many of these businesses might risk being forced out of business. In Wisconsin, two-thirds of the growth of the cheese industry in the past 15 years has come from the specialty cheese segment – a segment that now makes up one-quarter of all Wisconsin cheese production. Ready-to-eat processed foods with excessive added salt and produced in high volume reach many more consumers, and perhaps any sodium reduction targets should be directed to those foods and relevant businesses.

Artisan and specialty cheese are value-added products that are revitalizing rural economies, saving family farms from bankruptcy, and spurring the growth of the cheese industry. The economic viability of artisan producers would be impacted in many ways by the proposed sodium reduction targets:

- Many artisan cheesemakers are small businesses, and the potential financial impact of a reduction in salt levels would be dramatic and detrimental to their survival. High volume producers may be able to absorb such cost increases, but small producers would not often be able to do so.
- Market impacts are also a concern, as artisan and specialty cheeses demand high prices for their high quality. This consumer base has meticulous tastes; they demand quality and are willing to pay a premium for it. Small changes to the organoleptic characteristics of cheese, as expected with significant shifts in salt/sodium levels, may cause consumers to look elsewhere if they fail to obtain the level of quality and satisfaction to which they have become accustomed.
- With processed foods, when salt is reduced other ingredients are added to counter the impact. Use of potassium lactate for example, creates flavor challenges, and as a result, other ingredients must be added to counter those unpalatable bitter flavors. For manufacturers of natural cheeses compliant with the Code of Federal Regulation (CFR), such additives and adjustments are not available, nor of interest.

ACS Best Practices Guide for Cheesemakers

FDA has been kind enough to work with ACS by reviewing and sharing its comments on our recently drafted industry guide to best practices. This guide considers cheese and cheese production in terms of both quality and safety. Below is an excerpt from Chapter 6, Section 6 of the ACS Best Practices Guide for Cheesemakers on Salting which explains how pH, acidification, microbial management, taste, texture, and flavor are integrally linked to the use of salt during cheesemaking. As you can see, salt is not added in excess to cheese, but rather in precise types/amounts appropriate for each cheese type to allow for the safe manufacture of wholesome, delicious products.

--- Following from Chapter 6, Section 6, ACS Best Practices Guide for Cheesemakers ---

Sodium chloride (NaCl) is the basic salt used for cheesemaking. Cheese salt, available at many cheese supply shops, is refined, non-iodized rock salt, ultra-finely ground. Kosher salt is another good choice for cheesemaking. Kosher salt is a refined and additive-free salt, with flake texture that adheres well to cheese. Other salts are generally not as successful for a variety of reasons (noted below).

Unrefined sea salt contains trace minerals that add flavor and nutrients to cheese. These minerals will also add a slight bit of grey/brown color to the cheese. It must also be noted that

trace minerals such as copper may catalyze fat oxidation, leading to undesirable (cardboard or copper penny-like) flavor.

Iodized salt contains iodine, a necessary human nutrient added to salt to reduce the instance of thyroid deficiencies. Iodine is also an antibacterial agent and inhibits the action of the starter culture.

Coarse-grained salt does not stick easily to the surface of cheese, but some cheesemakers prefer this type of salt because of the slow dissolving rate. The use of fine-grained or flaked salt is preferred by others, as the grains will adhere better to the cheese.

Solar salt (salt naturally dried by the sun and wind) is best avoided as it has the potential to be contaminated with a wide range of undesirable and pathogenic bacteria.
Cheesemakers have attempted to use potassium chloride (KCl) to replace sodium chloride (NaCl) for low sodium cheeses with mixed results.

Salt has many functions in cheesemaking: lowering moisture, slowing acid development, enhancing flavor, and killing or slowing the growth of potential pathogens. Concentration of salt-in-moisture (S/M) is a strong determinant of many of the microbiological and biochemical changes that occur during cheese maturation.
Salt is generally applied in one of three methods.

- **Dry salting curd before pressing*:*** When salt is applied to cheese curds, it immediately begins to dissolve into the water phase at the surface of the curd. The salt should be applied in increments with a thorough mixing between applications (approximately 5 minutes). Water is drawn osmotically and expelled from the surface of the curd as the salt diffuses inwardly. During the pressing step, whey is further removed. As whey is lost from the cheese during salting, lactose is also removed, reducing the possibility of extremely low pH and poor fermentation during ripening. If excess whey remains in the curd when it is salted, too much salt may be washed out, reducing the amount of salt in the cheese curds.

- **Dry salting after pressing surface rubbed cheese**: Dry salt is rubbed onto the surface of cheese to create a rind. The rind develops as the outer layer of cheese becomes dehydrated by the salt. The thickness of the rind is controlled by the humidity and temperature in the aging chamber. Dry-rubbing the surface results in a rind with low moisture and high salt content, both of which create a selective environment that strongly influences the microbial growth on the rind and creates a thicker, stronger barrier.

- **Brining:** The cheese is immersed in a brine solution containing 23 grams of salt (NaCl) per 100 grams of solution. When the cheese is immersed in a concentrated or saturated solution (23%) of NaCl, the difference in osmotic pressure between the brine and the water in the cheese causes diffusion of salt into the cheese block. Therefore, water diffuses out of the cheese matrix to restore osmotic equilibrium. (see: Guinee TP. Salting and the role of salt in cheese. International Journal of Dairy Technology. 2004 May 1; 57(2-3):99-109.)

  The quantity of water lost by the cheese is about twice the quantity of salt gained. The Center for Dairy Research (CDR), UW-Madison recommends that the brine solution should be acidified to the same pH as the cheese. This aids in preserving the outer rind and keeps protein from being sloughed off. CDR also states that calcium chloride

($CaCl_2$) added to the brine solution aids in the prevention of surface and rind defects. This is because the calcium migrates in, or out, of the cheese in an attempt to equalize the concentration (osmosis). To control this migration, make sure the calcium level in the brine matches the calcium level in the cheese. Thus, a typical calcium level for Swiss cheese brine is 0.1%, while mozzarella brine would be 0.07% calcium.

For more on brining, see: Wisconsin Center for Dairy Research Dairy Pipeline, A Technical Resource for Dairy Manufacturers Volume 17 Number 1. "Salting your cheese—how to get it right", by Mark Johnson and Karen Paulus, Wisconsin Center for Dairy Research

One major difference between hard and soft cheeses is the rate of acidification and the point at which salt is added. Hard cheese typically reaches a desired pH and is salted in one day. Conversely, soft cheeses often ferment overnight to the desired acid level and are salted the next day. The opportunity for pathogens to grow is directly dependent on the rate of acid production and the time at which salting occurs.

Hazards

- Non-uniform particle size of salt altering salt uptake or resulting in uneven salt distribution.
- Impurities of salt, creating flavor and moisture control issues or introducing contaminants.
- Uneven distribution of salt during the application process, allowing harmful organisms to grow in low salt areas.
- Pockets of low salt and high moisture in cheese, which can lead to sourness and fermentation defects.
- Excess moisture may cause fine salt to be flushed out of cheese during whey loss, reducing the final salt content.
- Improper maintenance of brine concentration, which reduces salt uptake by the cheese.
- Improper temperature when salting can result in cheese defects or loss of salt in whey/brine.
- Improper humidity and temperature control in the aging cooler.
- Growth of harmful bacteria if salt is added before acidity levels develop.
- Pathogenic bacteria such as *Listeria, Staphlococcus aureus, enterohaemorrhagic E. coli, Yersinia enterocolitica,* and several *Salmonella* species may survive in brine solutions less than 10g salt/100g water (10%). Yeasts and coliforms are also known to survive in brine tanks.
- Water impurities in the brine makeup.

Controls

- Add and mix salt into curds to achieve the correct Salt/Moisture (S/M) content of the cheese.
- Monitor pH of cheese during salting to aid in prevention of pathogenic growth.
- Maintain moisture content of cheese when salt is added.
- Monitor and maintain temperature of:
    - cheese curds during addition of dry salt,
    - curds or cheese block during brine process,
    - aging and storage of cheese before/after salting (as well as humidity).
- Maintain salt concentrations, temperature, and pH of the brine solution.
- Use good manufacturing practices (GMPs) focusing on cleaning and sanitation of brine tanks and surfaces.

- Verify water potability.
- Test brine for microbial contamination.

Records to maintain

- Receipt and inspection of salt including lot numbers.
- COA from salt supplier.
- Cheese production records including acid development, temperatures, and other essential information for the production of safe cheese.
- Monitor salt brine concentrations, and corrective actions if not to specification.
- All test results for water, such as brine concentration and microbial contamination.
- Cleaning and sanitation records.
- Salt/Moisture Phase (S/M) testing results for cheese.
- Temperature and humidity records in regards to storage and brine tanks.

--- Above from Chapter 6, Section 6, ACS Best Practices Guide for Cheesemakers ---

In closing, as cheese is not a major contributor to the daily sodium intake of Americans, we believe attempts to lower sodium in natural cheeses to meet FDA's proposed levels would be detrimental to the quality and safety of the cheeses produced without any real or measurable health benefit to consumers. For small producers, the financial and technological burdens such a guideline imposes would be neither feasible, practical, nor desirable. In addition, for those making cheese using long-established, traditional methods, finding and attempting to utilize salt alternatives runs contrary to their established business practices, and to the types of products their customers demand. ACS does not feel these targets should be applied, encouraged, or required by producers of natural cheese. Based on input from producers, industry experts, and other stakeholders, we strongly urge FDA to remove the entire cheese category from any sodium reduction guidance.

Submitted by,

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About the American Cheese Society

The American Cheese Society (ACS) is the leading organization supporting the understanding, appreciation, and promotion of farmstead, artisan and specialty cheeses produced in the Americas. Over 1,700 members strong, ACS provides advocacy, education, business development, and networking opportunities for cheesemakers, retailers, enthusiasts, and the extended industry. ACS strives to continually raise the quality and availability of cheese in the Americas. Since its founding in 1983, ACS proudly hosts North America's foremost annual educational conference and world-renowned cheese judging and competition. For more information, visit www.cheesesociety.org.