October 17, 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)

Dear Sir or Madam:

The National Milk Producers Federation (NMPF) and International Dairy Foods Association (IDFA) appreciate the opportunity to comment on the Food and Drug Administration's (FDA) voluntary sodium reduction targets. These comments are a distillation of multiple consultations that NMPF and IDFA have held with technical experts, product managers and others at dairy cooperatives and dairy processing facilities across the United States.

Below, we review the broad themes that have emerged from our conversations with our members. In some cases it was challenging to properly evaluate the short-term targets, which may reflect an unrealistic starting point or baseline and the inappropriate grouping of disparate cheeses into some of FDA's 13 cheese categories. In summary, NMPF and IDFA members feel that many of FDA's 2-year target means for cheese (category #1-13) are likely to be unachievable without sacrificing product quality, food safety and other critical product attributes.

1. Foods and Food Categories – Cheese.

FDA identified and categorized foods based on their contribution to sodium intake, amount of sodium in the food, functional role of sodium, technical potential for reduction in sodium content, etc. FDA

acknowledged[1] that cheeses are a complex part of the food supply and noted that there are several challenges in trying to classify the diversity of available cheeses.

Given the wide variety of cheeses that are manufactured – some estimate there are 900-1,000 known varieties of cheese – evaluating the appropriateness of the categories of cheese (categories #1-13) was particularly difficult. Because of the tremendous variety of cheeses that are available and the ambiguity around the names and descriptions of the cheese categories provided in the guidance, NMPF and IDFA formally requested from FDA – but have not yet received – more complete information on the cheese categories.

NMPF and IDFA are not seeking the brands of cheese but, for each cheese category, we have asked for additional information from FDA about the specific types (names or varieties as included in each product's statement of identity) that are included in the category. Without complete data about the cheeses evaluated and included in each category, it is difficult to assess the validity of the agency's decision to group certain cheeses together. Specifically where a number of cheese types are grouped together in a single category but the individual types are not specified, we lack enough information to make educated comments. For example, category #10 "Cottage and Other Soft Cheese" does not provide us with enough information to know what cheeses would be encompassed by the "other soft" descriptor.

We would like to again formally request more detailed data from FDA about the types of cheeses included in each category so that we may provide comments that are more informed prior to the December 2nd comment deadline to provide information on the 10-year targets.

Based on the information available to us in the draft guidance, we offer the following specific comments about the categories of cheese.

- Some types of cheese should be re-categorized based on their current level of sodium. While FDA may have attempted to do this with some of the cheese categories, we have noted additional changes that are warranted.

    - Monterey Jack and Other Semi-Soft Cheese (category #4) – This category contains a variety of "other" cheeses, which makes it hard to know what exactly is represented by this category. However, Queso Cotija and Queso Anejo are semi-firm or firm cheeses (not soft) and are similar in sodium content (1100-1400 mg sodium/100 g cheese) to Parmesan or Feta. Because of their typical uses, it would be appropriate to categorize these Mexican-style cheeses with Parmesan (category #13) or to create a separate category. Fontina cheese manufacturing methods require salting during aging which result in this cheese having a higher sodium level, therefore it should be grouped with Parmesan (category #13).

    - Brie and Other Ripened Cheeses (category #7) – Brie and Camembert typically contain significantly more sodium than Chevre/Goat Cheese, which is lower in sodium content.

[1] FDA (2016): "Memo: FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance."

The latter two cheeses should be removed from this category or be moved into Cream Cheese (category #5).

- Cottage and Other Soft Cheese (category #10) – As noted above, this category would benefit from additional detail about the types of cheeses the agency expects to be captured by the "other soft" descriptor. In addition, the examples given in the category description vary greatly in terms of their sodium content. While Cottage Cheese may have ~400 mg sodium/100 g cheese, Mascarpone has less than one-tenth of that amount (~30 mg) and Queso Fresco has approximately twice that amount (~700-800 mg). The "other soft" cheeses should be listed in detail and these two specific cheeses, Mascarpone and Queso Fresco, should be removed from category #10. Mascarpone should be eliminated from further sodium reduction due to its low salt content. Queso Fresco is similar to Feta cheese and could be combined (category #9) or a separate category could be created for this cheese.

- Provolone should be grouped with the Pasta Filata Cheeses (category #8), as these cheeses have similar sodium levels, and similar manufacturing equipment and processes of cooking, stretching and brining are used for both cheeses.

- Cheddar and Colby Cheese (category #11) – Sodium reduction strategies will vary as a cheese ages. Colby Cheese and young Cheddar Cheese should be separated from aged Cheddar Cheese. As described in later comments, relative to their fresh, lesser-aged counterparts, lower-sodium Cheddar Cheeses will be more prone to defects the longer they are aged and will require a different set of food science technologies to address sodium reduction.

- Processed Cheese/Cheese Food (category #3) – Sodium levels vary in process cheese and process cheese food due the required use of different types of sodium-based emulsifiers, limits on ingredients required in process cheese that meets the standard of identity, and the need for specific levels of sodium orthophosphate ($NaHPO_4$) levels required for food safety in shelf-stable product. Therefore, we suggest segmenting this category into four different groups: 3.a Refrigerated Processed (standard), 3.b Refrigerated Processed (non-standard), 3.c Shelf-Stable Processed (standard) and 3.d Shelf-Stable Processed (non-standard).

NMPF and IDFA would like to affirm that, with the exception of cottage cheese, only full-fat cheeses are included in FDA's guidance on voluntary sodium reduction and are considered part of any of the food categories. To develop cheese that is both lower in fat and lower in sodium represents a technological challenge. From a food science perspective, the technical potential for reducing sodium in cheeses that are also reduced in fat is significantly different from that for full-fat cheeses. As fat is removed from cheese, 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. It is the concentration of salt dissolved in the moisture of the cheese, rather than the actual concentration of salt added, that is important, and is usually measured as percent salt-in-moisture (S/M).

While the dairy industry is making strides in developing cheeses lower in fat and lower in sodium, there are numerous technological challenges that must be overcome before these types of cheeses will be safe, acceptable and widely available to consumers. In fact, in 2009, only 1.2% of natural cheese and 2.4% of processed cheese sold in supermarkets was low-fat or fat-free, according to information from Information Resources, Inc. (IRI). Given the low market share these lower fat cheeses represent, it is in the best interests of the industry to focus our sodium reduction efforts on those products that will have the most impact on dietary patterns and public health overall – which is full-fat cheeses.

Summary:

- NMPF and IDFA formally request additional data from FDA about the names/varieties of cheeses included in each category and evaluated for development of the sodium reduction targets.
- Due to product formulation challenges and market share, NMPF and IDFA affirm that, with the exception of cottage cheese, only full-fat cheeses be included for consideration for voluntary sodium reduction.
- As noted above, we are requesting revisions for many of the cheese categories to properly align the varieties of cheese in each category based on sodium levels, common manufacturing methods, and taking into consideration unique challenges of differing sodium levels in process cheese and process cheese food.

2. Baseline Sodium Concentrations – Cheese and Cream-Based Dips.

As FDA noted, baseline accuracy is critical in evaluating targets for sodium reduction. Unfortunately, as we have commented above, the complex and diverse nature of cheeses available and the lack of complete information about which cheeses are included in certain categories make it impossible to properly assess the baseline sodium concentrations for cheese. NMPF and IDFA respectfully offer the following comments, and would like to evaluate more fully the baseline sodium concentrations upon receipt of the additional data requested.

- Blue/Blue-Veined Cheese (category 1) – FDA's calculated baseline is 1240 mg sodium/100 g cheese, however, the histogram of sodium level in the food products used to calculate the baseline[2] for blue-type cheeses appears to be bi-modal (with modes of ~900 and 1300 mg sodium/100g). NMPF and IDFA request additional information about the types of cheeses evaluated to provide comment on if the current baseline is appropriate for the entire category or if it would be more appropriate to split the category into two, as represented by each distinct grouping of products on the graph.
- Cottage and Other Soft Cheese (category #10) – FDA's calculated baseline is 355 mg sodium/100 g cheese, which was reported to be low by our Cottage Cheese processor members. Much Cottage Cheese is higher than 355 mg sodium (close to 400 mg). We question whether the

[2] FDA (2016). "Sodium in the US Food Supply for Products in 2010."

baseline calculation includes "other soft" cheeses, like Mascarpone or Ricotta, which reduced the baseline for the category overall. As noted above, this baseline would not be representative for the "other" soft cheeses which differ significantly from Cottage Cheese in their sodium content (like Mascarpone, Queso Fresco, etc.).

- Swiss and Swiss-type Cheese (category #12) – FDA's calculated baseline is 221 mg sodium/100 g cheese, which was markedly low according to most Swiss Cheese manufacturers. We also note that Baby Swiss, which would presumably be part of this category, typically has a significantly higher sodium content (~400 mg sodium) than regular Swiss. Likewise, Gruyere and Emmentaler cheeses also contain higher sodium levels (600-700 mg sodium) than a regular Swiss cheese. This would appear to be supported by the histogram of sodium level in the types of cheeses evaluated for this category, which shows distinct groupings of products around 200 mg, 400-500 mg, and 700-800 mg sodium.

- Processed Cheese/Cheese Food (category #3) – The calculated baseline of 1358 mg sodium/100 g does not accurately reflect the higher levels of sodium that are used in shelf-stable products for consumers and food service use. Higher levels of sodium due to the use of sodium-based emulsifiers are critical for function such as firmness in slicing or creaminess and melting for cooking and food safety. We do not believe that the FDA baseline included all types of processed cheese and may not accurately reflect the 60% of processed cheese used in food service applications.

- Cream-based Dips (category #49) – Depending on the base used for a dip, sodium levels may be higher with sour cream and lower with cream cheese and yogurt. The higher level of sodium is not solely due to the addition of salt, as sodium is a component of the flavoring and seasonings added and the sodium-based emulsifiers that are required for consistency and to avoid quality defects such as wheying-off of the sour cream-based dips, which represent the vast majority of this category. A survey of our members manufacturing dairy-based dips found the baseline to be closer to 700 mg/100g.

Summary:

- NMPF and IDFA specifically question the baselines reported in the draft guidance document, which may be related to inaccurate information or inappropriate groupings of cheese types, and seek additional clarification from FDA and have recommended specific changes as noted above.

3. Short-Term (2-year) Target Concentration Goals – Cheese.

3-1. Role of Sodium in Cheese.

Salt plays many roles in cheese manufacture – beyond its inherent contribution to taste – which makes reducing sodium during cheese making particularly challenging from a technological

perspective. 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. Sodium contributes to the overall characteristics of cheese by:

- Controlling the fermentation by starter culture organisms (which influences pH/acid development, production of secondary metabolites and flavor compounds or flavor precursors),
- Controlling the non-starter organisms that are known as non-starter lactic acid bacteria (NSLAB), which are key for the development of the flavor profile of a cheese while it ages,
- Controlling the lysis of starter cultures and subsequent enzymatic (e.g., lipase and protease) activity,
- Drawing moisture from the curd, which impacts water content and water activity,
- Impacting functional characteristics of both melted and unmelted cheese like body (for crumbling, shredding, slicing, cutting, etc.) and texture (melt performance, stretchability, etc.).

In terms of product characteristics, salt influences protein hydration and controls syneresis and moisture. This impacts the curds being able to knit together sufficiently. Salt plays a role in body and texture in cheese, and determines how easily a cheese will be cut or sliced and its behavior during subsequent use in foods (ability to melt smoothly without oiling off, sliceability, shreddability, stickiness, etc.).

Processed cheese and process cheese foods utilize emulsifying salts as a major ingredient critical to their manufacture. The primary functions of emulsifying salts in process cheese are “calcium sequestering” (to help disrupt the calcium-phosphate-linked protein network present in natural cheese during the process cheese manufacture) and “pH adjustment.” Both of these functions help in hydrating the caseins present in natural cheese so they can easily interact with water and fat phases, thereby producing a homogeneous process cheese emulsion. The Code of Federal Regulations cite 13 emulsifying salts that are approved for use (either alone or in combination) in process cheese manufacture of standardized products (21 CFR 133.169 to 133.180) and also are used in non-standard process cheese, typically named “Process Cheese Product” or “Pasteurized Prepared Cheese Product”. These include mono-, di-, and trisodium phosphates, dipotassium phosphate, sodium hexametaphosphate, sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium aluminum phosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate. The most common emulsifying salts used for process cheese manufacture in the United States are trisodium citrate and disodium phosphate. Trisodium citrate is the preferred emulsifying salt for slice-on-slice process cheese varieties, whereas disodium phosphate (or appropriate combinations of di- and trisodium phosphates) is used in loaf-type process cheese and process cheese spreads. Emulsifying

salts for process cheese and process cheese food play a critical role in pH, hardness, and meltability and food safety and cannot be replaced by non-sodium based emulsifiers[3].

3-2. Role of Sodium in Cheese Safety.

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 significant factor in minimizing spoilage and preventing the growth of pathogens, like *Listeria monocytogenes* in natural cheeses and *Clostridium botulinum* in processed cheeses. Salt also influences the growth of undesirable microorganisms – those that contribute to flavor defects or cause spoilage (decreased shelf-life) – and ultimately impact overall quality.

For process cheese and process cheese food, numerous researchers have demonstrated the inhibitory effect of emulsifying salts on the growth of various microbes and their antibotulinal effects in process cheese spreads[4]. Tanaka et al. modeled the influence of moisture, pH, disodium phosphate and sodium chloride on toxin production in process cheese spreads. They found that lower pH and higher levels of disodium phosphate and sodium chloride produced safer process cheese spreads. The Tanaka predictive models are extensively used by the cheese industry to predict the safety for process cheese and process cheese food. Additionally, process cheese spreads, slices, and blocks that are shelf-stable and do not require refrigeration have undergone extensive microbial challenge studies to demonstrate the safety of each cheese with a specific formulation and emulsifying salt level. Therefore, any reduction in either sodium chloride or sodium-based emulsifiers will require extensive reformulation work that must include undertaking costly and time-consuming microbial challenge studies.

3-3. Sodium Reduction Efforts in Cheese.

Consequently, it is challenging to reduce sodium in cheese. Cheesemaking protocols have been developed and refined over the course of numerous decades and require the addition of salt for all of the reasons stated above, not just solely for taste. NMPF and IDFA's member companies have reported that the overall sodium content of cheese has remained relatively stable for many years. Companies have been working to lower it, while still providing high quality and safe products for their customers, but the salt and sodium in cheese products have not been increased substantially. The level of salt present in cheeses is the ideal amount to achieve the numerous functions necessary for the manufacture of cheese. Cheesemakers use the needed amount of salt, they do not add more than is necessary.

Technological tools for lowering sodium in cheese are limited, and vary across the numerous types or varieties of cheese. Capital costs and potential for market failures can be significant for manufacturers.

[3] Kappor and Metzger (2008). Process Cheese: Scientific and Technological Aspects – A Review, IFT.

[4] Tanaka et al. "A challenge of pasteurized process cheese spreads with *Clostridium botulinum* spores." J Food Prot 1979. 42:787-789.

Although progress is being made on sodium reduction in cheese, more research is needed and timelines for developing cheeses that maintain customer and consumer expectations for flavor, body, texture, shelf life and food safety are uncertain.

3-4. Sodium Reduction Potential Is Not the Same For All Cheeses.

As with our comments on the categories and the baseline sodium concentrations included in the guidance for cheeses, it is challenging to properly evaluate and to provide meaningful comment on the short-term (2-year) target concentration goals when it is not clear which cheeses are included in each category. Therefore, while we offer comments in general on the 2-year targets, we hope to provide a more thorough review once additional data are made available.

The agency went to considerable efforts to group cheeses into categories, factoring in the contribution of the food to sodium intake, the amount of sodium in the food, the functional role of sodium, the technical potential for reducing sodium, etc. Despite evaluating these numerous factors, all twelve categories of natural cheese have a proposed 2-year reduction of ~5% and a proposed 10-year reduction of ~15% (processed cheese has 2- and 10-year proposed reductions of 11% and 26%, respectively). In consultations with our members, we were repeatedly asked why the agency pursued a "one-size-fits-all" approach to the different categories of cheese. NMPF and IDFA respectfully seek clarity as to the rationale for those values and our comments suggest revision to some sodium baseline and target values.

Inappropriately assigning the same percentage reduction to all natural varieties of cheese fails to recognize the unique intrinsic parameters of each cheese (moisture content, pH, etc.), the current sodium level, the different types of starter cultures used in each cheese (starter cultures vary in terms of their growth requirements, including their tolerance to salt), and the unique contribution of sodium to the safety and functional properties of the cheese. For example, a 5% reduction (the 2-year target) is not appropriate for Swiss Cheese. There is no obvious rationale for further reductions in this category as Swiss Cheese is already a low sodium food (<140 mg sodium/50 g)[5]. Because the sodium content is at such a low level in Swiss Cheese, this category, as well as Cottage Cheese, should be excluded from the voluntary guidance. In fact, reducing the sodium in Cottage Cheese from 355 mg/100 g to 340 mg/100 g and in Swiss Cheese from 221 mg/100 g to 210 mg/100 g is within the experimental error of the analytical methods used.

3-5. Reducing Sodium in Cheese Presents Food Safety Concerns.

Even if the above concerns about an inappropriate baseline sodium concentration were addressed, a 5% reduction (the 2-year target) is not appropriate for Queso Fresco. Queso Fresco is a soft, fresh cheese,

[5] FDA did not include products that were labeled low-sodium in the survey. While Swiss Cheese meets the criteria for low-sodium, it is typically not labeled as such. However, NMPF and IDFA maintain it should be dropped nonetheless.

does not employ a starter culture, and has a near-neutral pH (little acid) and a very short shelf-life. While the sodium content may be higher in Queso Fresco than in other cheeses, this cheese is very high moisture and has a low percent salt-in-moisture (S/M), a very favorable environment for growth of spoilage or pathogenic organisms. A quick review of food safety literature (dairy food texts, CDC website, etc.) and FDA's product recall archives indicates serious food safety concerns associated with Queso Fresco. In this product, there is no real microbiological hurdle except for salt. It is simply not reasonable – and is, in fact, dangerous – to suggest lowering the sodium content of this product.

There are other cheeses where a 5% reduction in sodium causes concern from a food safety perspective as well. For example, Blue and Blue-Veined Cheeses are semi-soft cheeses that contain relatively high levels of salt because salt is relied upon as a key food safety hurdle. Salt plays a role in controlling activity of the starter culture and stimulating the germination of *Penicillium roqueforti* spores, which are an essential feature of Blue Cheeses (resulting in the expected blue veins) and, in turn, impacts deacidification of the cheese and texture and flavor development during ripening. During the 1980s, extensive research was conducted to try to reduce the sodium content of Blue and Blue-Veined Cheeses. As a result, the technological tools available have been exhausted and further reductions are not anticipated to be possible for this category. If a 5% sodium reduction were proposed for individual cheeses within this category today, the industry is not confident that such a cheese of acceptable quality could be produced safely.

3-6. <u>Challenges of Sodium Reduction in Cheese.</u>

There have been initiatives by manufacturers to reduce sodium – either 1) by substituting a portion of the salt with a non-sodium salt or 2) by adding less salt during product manufacture. Because cheese manufacturers historically have not added more salt than is needed to achieve the functional properties desired and because reducing salt levels directly impacts the salt-in-moisture levels in cheese, the latter approach is limited in terms of both product quality and food safety. Likewise, efforts to identify non-sodium salt replacers have also been challenging, have been met with mixed success, and vary considerably among different cheese types. Non-sodium salt substitutes typically impart metallic or bitter tastes, limiting their use and creating severe hurdles to consumer acceptance. Non-sodium salts and other salt substitute ingredients also are not appealing to consumers who increasingly demand "clean labels". It is important to note that consumers already view natural cheese as having a "simple" or "clean label" and as a pure food with high appeal for consumers and in food service use. If the cheese industry is required to limit salt and utilize salt substitutes, the effect will be to "muddy the waters" of a food that has shown extraordinary growth in consumption over the past 45 years in the U.S. People enjoy the taste, nutrition, and satiety provided by natural cheese and it is unlikely that they would easily accept modification to natural cheese that would include different ingredients such as salt substitutes.

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. As noted earlier, emulsifying salts also impact

the process cheese firmness needed for slicing and meltability required for food service applications and home cooking. Research is ongoing to discover emulsifiers that are not citrate- or phosphate-based and which will retain melting characteristics without adding sodium, however, there is no certainty that this will happen within the timeframe proposed by FDA, if at all.

In considering reformulation options for processed cheese products to reduce sodium, the industry must also factor economic impact on the product. The key macro-components in the cost equation for manufacture of processed cheese and process cheese food are protein, fat, emulsifiers, lactose, salt and water in the form of moisture. By Federal Standard of Identity and as required for shelf-stable products, process cheese manufacture cannot increase moisture nor add higher levels of lactose when making adjustments to formulations due to the potential for quality defects occurring, such as crystal development. The next “least cost” option to consider when reducing emulsifiers or salt would be to increase fat, however this is undesirable as dietary guidance recommends that consumers and restaurants strive to limit saturated fat. Thus, the last replacement choice is to increase protein, which will dramatically increase formula cost, and essentially reduce consumption and economic viability of process cheese products.

As with many research and development projects, developing new products takes a significant amount of resources. The research needed just to identify new approaches for reducing sodium in products takes significant time and financial investment. New processes may require new equipment, new monitoring instruments or additional energy inputs. Additional ingredients, including salt substitutes, are almost always more expensive than salt (for example, potassium chloride is more expensive than sodium and must be used in greater concentrations if it is substituted for sodium chloride in cheese, resulting in an increased cost as much as 11 times as much as sodium chloride in cheese). After new products are developed, new labeling must be designed and printed and out-of-date labeling may need to be discarded. After incurring these costs, companies have two options: either pass the higher costs of the lower sodium product on to the final customer, or lose money on a product that may or may not become popular with consumers.

3-7. Federal Standards of Identity Limit Salt Substitution.

Many food products have federal, or state, standards of identity. This is especially common in dairy products; there are 72 standards of identity for cheeses and cheese products in 21 Code of Federal Regulations (CFR) Part 133. In order to use the names that are allowed in the standard of identity and are commonly used and understood by consumers, the product as sold to consumers must adhere to requirements of the standard, including ingredients that are allowed or banned, and compositional requirements, such as moisture or fat levels.

There is some allowance for a standardized product to deviate from the standard's requirements, but only if an approved nutrient content claim is made. If the product makes an approved claim, such as "Reduced Fat Cheddar Cheese," that product may contain other ingredients that are not normally allowed for in the standard, such as an ingredient that simulates the mouthfeel of full-fat Cheddar, or it may contain moisture levels that are higher than usually allowed to offset the removal of fat. Currently, there are five nutrient content claims related to sodium or salt: "sodium free," “very low sodium,” "low

sodium," "reduced sodium" and "no salt added." The claim that would allow for the smallest reduction is "reduced sodium" which would mandate 25% less sodium than regular cheese.

As noted above, cheeses with a federal standard of identity, such as Mozzarella, Cheddar, Processed American cheese and almost all named cheeses, are precluded from using a salt substitute or other functional ingredient not usually allowed by the standard, unless the sodium reduction is sufficient to meet one of the permitted nutrient content claims. A lesser reduction in sodium (5-15%, as proposed in the current guidance) is not possible by simply using less sodium during product manufacture and would require formulation changes – and would ultimately result in a product that no longer conforms to the standard of identity and cannot be called "cheese". For example, 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.

3-8. <u>Sodium Reduction Impact on Product Quality and Consumer Acceptance.</u>

Reductions in sodium may be technically feasible but result in changes to product attributes that will be unacceptable to consumers. In some products, such as Cottage Cheese, salt plays a role as a flavor potentiator, enhancing the fresh cheese flavor. Replacing sodium with a non-sodium salt, like potassium chloride, in Cottage Cheese can only be beneficial to a certain degree because potassium salt will contribute bitterness to cheese. Similarly, reducing sodium to levels near the short-term target without adding a sodium substitute will result in a product that exhibits pronounced flavor defects. While Cottage Cheese products are commercially available that are lower in sodium, their consumer acceptability has been poor due to their inconsistent quality and more common flavor defects.

In cheeses like Cheddar Cheese and Monterey Jack, reductions in sodium level result in significant increases in flavor defects and texture defects in the cheese – predominantly sour and unclean flavor notes in Cheddar Cheese, and a pasty texture and significant increases in unclean flavor in Monterey Jack. Use of sodium substitutes may aid somewhat in flavor development, but then have a negative impact on product functionality and do not result in acceptable product quality during product aging and shelf-life. For all of the natural cheeses, reductions in sodium level to the short-term targets would result in a noticeable reduction in the quality of the flavor and texture of the cheese.

Some cheeses, like Cheddar Cheese, that have been aged for more than 60 or 90 days, would be significantly affected by the short-term targets. Cheeses made for aging usually have a lower moisture content and higher salt-in-moisture (S/M) to control microbial activity and flavor development. During aging, salt plays a critical role in controlling the growth of non-starter culture lactic acid bacteria (NSLAB), which determines the flavor profile of the cheese. Loss of control of NSLAB, due to reduced sodium, will result in undesirable flavor characteristics, namely bitter peptides and flavor defects. While the impact of a decrease in sodium (at the short-term target level) may be less noticeable in a fresh or young Cheddar Cheese, the same sodium reduction in an aged Cheddar Cheese will result in an overall unacceptable quality product. Reducing sodium in cheese is not a matter of needing adjustment time for consumers' preference for salty tastes, but is about limiting the ability of the industry to make a quality product.

If short-term targets are achievable for specific cheeses, there may be unintended consequences and undue economic burden on the food industry beyond the costs associated with product development. For example, pasta filata cheeses such as mozzarella, provolone and string cheese are brined products, with the salt content and cooling of the brine responsible for controlling microbial growth. Most mozzarella has a sodium content in the range of 600-730 mg sodium/100 g cheese, although many manufacturers focus on the higher end of this range (as shown in the histogram for sodium in packaged products for the category) for food safety concerns and for optimal flavor development. If a lower-sodium mozzarella were produced that met the short-term targets, this would result in a shorter shelf-life product (due to greater spoilage) or would require a change in the distribution chain, requiring transport under freezing conditions instead of refrigeration to minimize spoilage and product loss. Increases in spoilage and food waste or increased transportation costs would not be desirable consequences.

3-9. <u>Short-Term Timelines For Sodium Reduction Goals.</u>

Even if technological tools to meet the short-term sodium reduction targets are available, or become available in the future, the timeline of 2 years is insufficient for our industry to properly evaluate the impact of those reduction techniques on some of our products. While FDA proposes achieving the short-term targets through gradual reductions over time, what has been not taken into account is – for products, like cheese, where sodium plays numerous key roles related to food safety and product quality – every change in formulation requires extensive research to support that the modification in sodium levels will not adversely impact the safety of the product or its quality and sale-ability. These numerous "minor" product reformulations cannot all be properly evaluated in a two-year timespan. Additionally, some cheeses (e.g., Cheddar, Gouda) may be aged in excess of two years or are required to be aged per their standards of identity (e.g., Parmesan, Asiago, Romano). To evaluate the impact of sodium reduction on the quality and safety of these products requires additional time from start of a project to market.

For processed cheese, if there were to be technological tools available to allow industry to manufacture a processed cheese that meets the short-term targets, industry is uncertain about the impact of this reduction on consumer acceptability. The processed cheese category has been declining for 20 years. When asked, consumers most often cite a lack of flavor as their primary complaint about these products. Reducing sodium, even if technically possible, will further reduce flavor, leading to further deterioration in the category. Because of the significant impact that sodium has on product quality of processed cheese, it will take significant time – much longer than two years – to both identify technological solutions to reformulation and to change consumer acceptance.

Therefore, IDFA and NMPF respectfully request that FDA increase the time allowed to reach the first target level of sodium reduction of foods from two to five years.

Summary:

- Salt plays many roles in cheese manufacture, impacting both product quality and safety, which presents unique challenges for reducing sodium. Salt is not added to cheese beyond levels necessary for functionality and for food safety parameters.

- NMPF and IDFA seek additional information as to how the agency determined the specific reductions for each category of cheese (which are the same across all categories of natural cheese).

- Technological tools for reducing sodium in cheese are limited, and are constrained by resources, current regulations and the impact of sodium on product quality.

- While some reductions may be technically feasible, the final product may not be sale-able or acceptable to consumers and food service use due to flavor defects. Potential unintended consequences of sodium reduction may include increased food waste and decreased shelf-life. In some cases, reducing sodium will result in product that would present a significant food safety risk.

- The timelines for reaching the short-term targets are not feasible for some products that require significant research on consumer acceptability or that have longer times from product manufacture to market (i.e., aged cheeses). The time allowed to reach the first target level of sodium reduction of foods should be increased from two to five years.

4. Sodium Reduction Goals for Butter.

NMPF and IDFA evaluated Category #14 "Butter" and have concluded that this category should be removed from FDA's guidance for sodium reduction goals for the following reasons:

- Unsalted butter is already available for consumers as an option.

- Sodium plays a functional role in butter, and reduction of sodium in salted butter will result in a shorter shelf-life and greater microbial spoilage and development of off-flavors (e.g., rancid) over time. Unsalted butter has a shelf-life of 120-180 days, salted butter has a shelf-life of 200-240 days.

- Sodium in butter also plays a role in food safety. Any reductions in sodium should only be made after validation of the modified formulation through microbial challenge studies, including consideration of consumer behavior (i.e., leaving butter on a counter to soften).

- Reductions in sodium content are constrained by the fact that salt- or sodium-substitutes are not permitted in the standard of identity. Per its standard, "butter" must be made exclusively from milk and/or cream, and only salt or coloring are permitted as optional ingredients. Unlike other dairy standards of identity, which were established through regulation by the FDA, the

standard of identity for butter was established by statute[6]. Amending the optional ingredients permitted in butter is outside the authority of the agency and would require Congressional action.

Should FDA not agree to remove this category from the sodium reduction guidance, we suggest this category be re-named to "Salted Butter" and the description modified to specifically exclude unsalted butter. It is clear from the histogram plot of the category that unsalted varieties were not included in the survey by FDA and were not included in calculating the baseline mean. This would be consistent with FDA's statement that the guidance does not focus on foods that contain only naturally-occurring sodium.

5. Conclusions.

In general, there is a substantial amount of concern about many of the two-year targets and, in some cases, reducing sodium levels in cheese will not materially reduce the amount of sodium consumed in a typical diet. After milk, cheese is the #2 source of calcium[7], yet it contributes less than 4% of the sodium to the diet[8]. Per-capita consumption figures for the various major cheese types can be compared with the sodium levels in each type to determine what percent the sodium in each cheese would constitute out of a daily 3,400 mg of consumption, the current U.S. average. In essence, the highest-sodium cheese categories contribute very little to sodium in the diet because their per capita consumption is low. For example, Parmesan's sodium content is high at 1,554 mg per 100 grams, but per capita consumption is so small that it equates to only 0.56% of daily sodium intake.

When presenting the two-year targets, FDA justified their proposed values, saying they were "feasible using existing technology and are within the range of currently available commercial products". As we have commented, the two-year targets may appear to be in the range of current commercial products because of inappropriate groupings of distinctly different cheese types.

NMPF and IDFA have serious concerns about the appropriateness, accuracy and impact of the voluntary sodium reduction targets for cheese, butter, and cream-based dips as proposed. Not only might they reduce consumer demand for these products through adverse impacts on quality, but in some cases the safety of the product may be seriously adversely affected. FDA should not put pressure on industry to take actions that will jeopardize the safety of the U.S. food supply.

NMPF and IDFA believe 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. Though our

[6] Butter Act 21 USC 321a.

[7] Keast DR, Fulgoni VL, Nicklas TA, et al. Food sources of energy and nutrients among children in the United States: National Health and Nutrition Examination Survey 2003-2006. Nutrients 2013;22;5(1):283-301. O'Neil CE, Keast DR, Fulgoni VL, et al. Food sources of energy and nutrients among adults in the US:NHANES 2003-2006. Nutrients 2012;4(12):2097-120.

[8] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2010. 7th Edition. Washington, D.C.: U.S. Government Printing Office. December 2010.

organizations believe the FDA's intentions toward public health are good, and recognizes the need for modifications to the U.S. food supply in order to reduce sodium content overall, we believe the agency has much more work to do before finalizing these draft standards for cheese.

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Overall, after much discussion and consultation with our members and dairy foods experts, NMPF and IDFA encourage FDA in the strongest way possible to remove the entire cheese category from the sodium reduction guidance. Salt plays a crucial role in the manufacture and ripening of natural and processed cheeses and impacts overall product functionality, safety, and quality. Unlike in other foods, sodium is added in specific amounts for specific purposes in each specific cheese type, is not added in excess, and is not added in amounts beyond that needed for microbial safety, stability and physical integrity.

The dairy industry faces significant barriers to sodium reduction, and our efforts to find safe and effective means of reducing sodium in our products have been extensive and will continue. However, in good faith we cannot agree to the proposed targets when we cannot be assured of technology to achieve those targets within the given timeframes without compromising on product safety and quality.

Should the agency disagree with our conclusions on sodium reduction in natural and processed cheese, we would welcome the opportunity to discuss our concerns with you in more detail. We would greatly appreciate an opportunity to review and to provide comment on any revisions to the proposed guidance.

Respectfully Submitted by,

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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 they own. The members of NMPF's cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies. Visit www.nmpf.org for more information.

International Dairy Foods Association (IDFA) represents the nation's dairy manufacturing and marketing industries and their suppliers, with a membership of 550 companies within a $125-billion a year industry.

IDFA is composed of three constituent organizations: the Milk Industry Foundation, the National Cheese Institute, and the International Ice Cream Association. IDFA's 200 dairy processing members run nearly 600 plant operations, and range from large multi-national organizations to single-plant companies. Together they represent more than 85 percent of the milk, cultured products, cheese, ice cream, and frozen desserts produced and marketed in the United States.