**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service
Food and Drug Administration

# Memorandum

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From: Division of Biotechnology and GRAS Notice Review (HFS-255)
Sodium Team

Subject: Supplementary Memorandum - Target Development Example

To: Administrative Record – Sodium Reduction Draft Guidance

## Introduction

*Overview of FDA Sodium Reduction Initiative*
The 2010 Strategies to Reduce Sodium Intake in the United States (U.S.) Institutes of Medicine (IOM) Report notes that achieving lower intakes of sodium should be a critical public health focus for all Americans. The U.S. Food and Drug Administration (FDA) supports efforts to create a broad, effective, and sustainable reduction of excess sodium in the food supply, which will contribute to lower the population intake of dietary sodium.

We are announcing a draft guidance for industry entitled "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods." Our sodium reduction draft guidance is encouraging sodium reduction in the food supply, by expressing measurable voluntary goals for sodium content (from sodium chloride, commonly called "salt," as well as other sodium-containing ingredients) in commercially processed, packaged, and prepared foods. The draft guidance provides our tentative views with respect to identifying suggested goals (target mean and upper bound concentrations) for sodium across a wide variety of food categories. The category goals (2 and 10 years after publication of the final guidance) are designed to support reductions in sodium added to the food supply, keeping in mind the importance of sodium in food for microbiological safety and other technical effects. The draft goals are intended to allow both FDA and the food industry to have a common system for defining and measuring progress toward reducing sodium and to encourage continued dialogue and technological advances.

*Purpose of this Memorandum*
The purpose of this memorandum is to provide a detailed description of our approach for establishing short-term and long-term means and upper bound targets, by providing information for one selected food category, Blue/Blue-Veined Cheese (e.g., Gorgonzola, Gammelost, Roquefort, Stilton and Danablu, etc.). By providing the details of our approach on this particular food category, we hope to foster better understanding of our short-term and long term-targets and the methods we used to develop those targets, specifically our approach to establishing food categories, our methods for quantifying sodium baselines, and our process for setting goals (target means and upper bounds for categories). In the Notice of Availability for the draft guidance, we welcome comment on any issues related to the methods for developing the sodium targets and for implementation of this guidance. In particular, we are interested in comments and specific information on the food categories, our methods for quantifying sodium content, the

specific mean and upper bound targets and the challenges of implementing the voluntary goals.

## Draft Sodium Reduction Category: Semisoft Cheese: Blue/Blue-Veined Cheese

*Category Development*

Our overall development of food categories was informed by contribution to sodium intake as well as food technology factors, in addition to reviewing various food classification systems. For cheese categories, we reviewed various non-governmental organizations, Codex standards, and government classification structures (e.g., FDA product code cheese categories[1]). We ultimately used the FDA standards of identity (SOI) for cheeses (21 CFR part 133, subpart B) as a guide for our categorization process. We reviewed the distribution of sodium concentrations for each cheese category and adjusted categories to achieve the narrowest possible sodium concentration range. Subject matter experts in the Office of Food Safety at FDA then reviewed the category structure and additional adjustments were made. We also compared our cheese category structure to those of other sodium reduction initiatives (e.g., Health Canada (HC), United Kingdom (UK), New York City (NYC),). For example, the UK provides a Blue cheese category, whereas HC and NYC aggregate certain cheeses together into a category, but do not include Blue cheese.

*Baselines and Sodium Reduction Goals*

In the draft guidance, we provide baseline levels and goals (category mean targets and product upper bound targets) on a concentration basis in milligrams (mg) sodium per 100 grams (g) of food. Setting mean and upper bound sodium concentrations of a food allows for more effective tracking of sodium reduction efforts relative to a baseline year. We considered using the serving size, however, our goals are designed for industry to address sodium reduction in the foods they manufacture and are not meant for consumers to compare them to the Nutrition Facts label.

As part of the approach, we identified products on the market in 2010 that had the lowest sodium concentrations. A summary of information on the products used for the 2010 baseline calculation for the Blue/Blue-Veined Cheese category is provided in Table 1. With the understanding that these products were selling through large retail chains in 2010, and thus were acceptable to at least some consumers, we used these products as a guide to establishing goals. The short-term goals are intended to be more easily achievable and many of the products in the Blue/Blue-veined Cheese category may have already achieved the short-term goals. Figure 1 illustrates the sodium distribution of Blue/Blue-Veined Cheese products in the U.S. market in 2010. We recognize that the longer term goals could require more time and effort to be achieved. We are aware that new ingredients capable of replacing some salt and other new technological reduction strategies are under development, but more research and development will be needed.

**Table 1. Summary of Product Information Used for the 2010 Baseline Calculation for Semisoft Cheese: Blue/Blue-Veined**

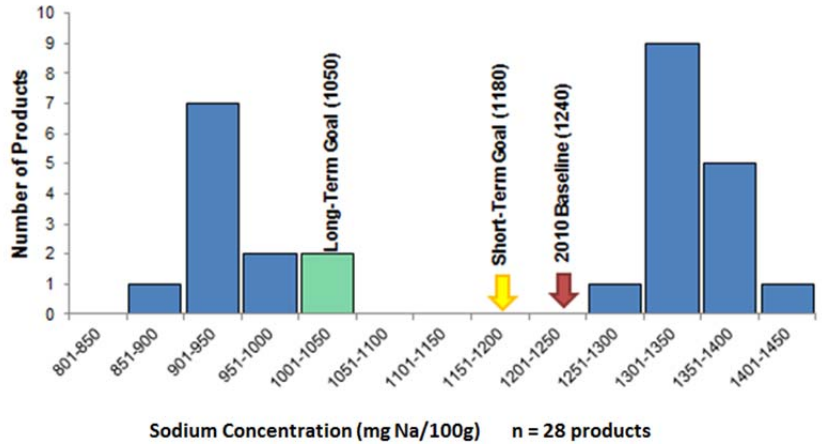
[1] http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm114704.htm

| | |
|---|---|
| Number of brands | 13 |
| Number of products | 28 |
| Sodium content of sales-weighted mean (mg/100g) sodium | 1,240 |
| Salt content of sales-weighted mean | 3.1%[1] |
| Range of sodium (mg/100g) | 853-1416 |
| Estimated lowest salt content of top selling products | 2.1%[2] |

[1]: The calculated values assumes that sodium chloride (salt) is the only sodium ingredient in the formulation and that any intrinsic sodium is negligible in the finished cheese. If other sodium salts are used in the formulation and contribute to the total sodium, the salt (sodium chloride) content could be lower.

[2]: The lowest sodium content of top 80% of sales, according to Nielsen data, is 853 gram/100g, with salt as the only sodium contained ingredient on the label. Thus, the lowest salt content is about 2,100 mg/100g or 2.1%,

**Figure 1. Sodium (mg/100g) Distribution of Semisoft Cheese: Blue/Blue-Veined Cheese Products in the U.S. Market in 2010**




In addition to assessing the feasibility of our reduction goals through market surveys of sodium content for high selling products in each category, when establishing both short- and long-term targets we reviewed information on the following:

Food Technology

- a survey of available literature on the role of sodium and sodium reduction in Blue cheese
- discussions with subject matter experts in FDA about the role of sodium in cheese
- comments to the docket from our previously issued Federal Register Notice on approaches to reducing sodium (76 FR 74039)

Other Sodium Reduction Initiatives

- targets from other sodium reduction initiatives
- comments made at industry meetings with Health Canada and the United Kingdom that were specific to cheese (publicly available information[2])

[2] http://www.hc-sc.gc.ca/fn-an/pubs/nutrition/_sodium/2009-1124-rapport-report/index-eng.php; http://www.food.gov.uk/sites/default/files/multimedia/pdfs/saltreductioninitiatives.pdf

- discussions with New York City's National Salt Reduction Initiative (NSRI) about feedback they had received from industry on the targets they proposed

*Literature Review: Salt and Blue Cheese*

Salt, together with the desired pH, water activity $a_w$ (the ratio of the vapor pressure of a food to that of pure water at a specific temperature), and redox potential, may contribute to minimization of spoilage and the growth of pathogens in cheese. Salt also encourages syneresis and controls final moisture of the cheese, the growth pattern of microflora in the cheese ripening period, enzyme activity in the final cheese, and has impacts on texture development as well as contributes to the taste of final product.

Based on epidemiological data, incidence of pathogens in milk, and characteristics of the individual species, *Salmonella* spp., *Listeria monocytogenes*, and *Escherichia* coli O157:H7 are considered high-risk microorganisms, and all three have been implicated in disease outbreaks due to the consumption of contaminated cheese (ICMSF 2005).Although there were recalls associated with *Escherichia coli* O157:H7 and Salmonella on Blue cheese (FDA, 2010) and FDA,2013), *L. monocytogenes*— a salt tolerant pathogen— is the major concern for Blue Cheese. *L.monocytogenes* needs a minimum water activity of 0.92 to grow (FDA, 2015) and Blue cheeses with a range of water activity between 0.90-0.95 may provide opportunity for outgrowth. *L.monocytogenes* may be present in raw milk or may be introduced through post-pasteurization contamination. As a food safety factor, salt reduces the water activity of food products and thus, aids in controlling the growth of pathogens in the food product. High concentrations of salt can also cause microbial cells to undergo osmotic shock, causing dehydration of the bacterial cells and thereby causing cell death or retarded growth. It should be noted that to ensure a pathogen-free Blue cheese, other food safety measures, such as avoiding pathogen exposure during cheese-making and subsequent handling of the product, are also critical.

Measurement of the salt content of cheese is an important quality control step in cheese production. Blue cheeses have higher salt contents (2% to 5%) than some other cheeses. *L. monocytogenes* has not been reported to grow in Blue cheese during the ripening period (even with a favorable pH), indicating that high salt content (4.26-4.85%) might play a main role in inhibiting pathogen growth (Papageorgiou and Marth, 1989). Blue cheeses are characterized by the growth of the mold *Penicillium roqueforti*, giving them their typical appearance and flavor (Fox et al. 2004). It has been reported that germination of *P. roqueforti* conidia is stimulated by 1-3% sodium chloride (NaCl) for most strains (Godinho and Fox, 1981a). *P. roqueforti* may contribute to inactivation of the pathogen *Listeria monocytogenes* through proteolysis and lipolysis and resultant production of free fatty acids in blue cheese. Thus, the growth of *P. roqueforti* is important for Blue cheese. The high salt content of Blue cheese aids in selecting growth of this desired mold, inhibiting the growth of salt sensitive and sometimes defect-causing microorganisms (Johnson et al., 2009). Morris (1981) reported that it is common commercial practice to add 1% w/w, NaCl to Blue cheese curd before hooping,[3] possibly to stimulate spore

[3] Placing cheese curd into a hoop or cylinder, which gives it a distinctive shape

germination, although it also serves to give the cheese a more open structure, which facilitates mold growth.

Since most Blue cheeses are surface salted, a salt gradient from the surface to the center exists for a considerable period after manufacture. Bernini et al. (2013) investigated the microbiota of the rinds of Italian blue-veined, mold-ripened cheese associated with the detection of *L.monocytogenes* in the paste and rind, and reported that *L. monocytogenes* was not recovered in the paste but was presented on the rind after ripened for 50 and 80 days. It was also reported that *L.. monocytogenes* contamination in Gorgonzola is most frequently associated with the cheese rind and even if rinds are contaminated, the paste does not necessarily contain the pathogen (Cocolin et al., 2009). A high initial level of salt in the outside zone of the cheese may inhibit spore germination at a critical time. A mold-free zone on the outside of the cheese is a common defect in Blue cheese (Godinho and Fox, 1981b) as the cheese can lose its characteristic quality and have increased risk for pathogen growth. This can become important, for example, if post contamination (e.g., during handling and storage) occurs and if the optimum level of salt is not selected.

Through its effects on the microflora and enzymes, salt has a major effect on the ripening, flavor, and quality of cheese. The concentration of NaC1 and degree of lipolysis and proteolysis (especially the increase in low molecular weight peptides) influence the water activity ($a_w$) significantly in Blue cheese (Fox et al. 2004). The ripening of Blue cheese is characterized by extensive lipolysis and proteolysis. Fox et. al. 2004 reported that lipolysis in Blue cheese is influenced by salt concentration, with maximum activity occurring at 4-6%, w/w, NaCl. However, the concentration of methyl ketones (major flavor contributors) were relatively independent of salt concentration, suggesting that flavor contribution from lipolysis was not affected much by salt (Fox et al. 2004). Proteolysis contributes to the development of cheese texture and flavor in the ripening process. Fox et. al. 2004 also reported that there was a strong negative correlation between salt concentration and proteolysis levels in Blue cheese. Proteolysis was invariably lower in the outer (high salt) region than in the middle or center (lower salt) zones (Fox et al. 2004). This suggests that lower sodium content might increase protolysis activity, which could potentially create undesirable flavors and texture in the final products. It also should be noted that biochemical changes due to the proteolytic activity of molds during ripening can increase the pH, thus influencing the evolution of the microflora and favoring potential contamination (Godinho and Fox, 1982, and Bernini et al., 2013). Careful reformulation with lower sodium is very important from both quality and safety perspectives.

With limited information regarding the possibility of sodium reduction in Blue cheeses, we require additional information on what reductions are feasible in this category, considering safety and quality. Johnson and Paulus (2008) reported that industry reduced the salt of blue-veined cheeses by 25% (3%to 2.25 % salt), as many blue-veined cheeses have typical salt contents of over 3%. However, the authors expressed doubt as to whether it is possible to go below 2.25%. It is conceivable that the ripening process in Blue cheeses would be altered by lowering the salt content. Additionally, the control of growth and functions of lactic starter cultures, Non Starter Lactic Acid Bacteria (NSLAB) and *P.roqueforti* could be deleteriously impacted, leading to changes in the degree of lipolysis and proteolysis in Blue cheeses, and flavor changes in the final

products. In addition, lowering the salt content could alter the -hurdles for pathogen growth, and appropriate ingredient replacements or adjusted processes would need to be utilized to ensure the safety of the final products.

*Standards of Identity*
There are 72 standards of identity (SOI) for related cheese and cheese products in 21 Code of Federal Regulations (CFR) Part 133.[4] SOIs for certain Blue cheese/Blue-veined (Blue, Gorgonzola, and Roqefort) indicate salt (sodium chloride) addition in the manufacturing procedure, but do not contain *specific* requirements related to the amount of sodium chloride added. To maintain the use of the name of the food required by the SOI, food products must adhere to the requirements of the standard, including compositional requirements (e.g., moisture levels, milkfat content) required or permitted ingredients, as well as the manufacturing procedure. Some standards for cheeses require salting as a processing step (e.g., Asiago fresh and asiago soft cheese, Cheddar cheese). The SOIs for other cheese list salt as an optional ingredient, but do not list potential salt substitutes as optional ingredients (e.g. Mozzarella cheese, scamorza cheese). Currently, if an approved nutrient content claim is made, there are certain ways in which a standardized product may be allowed to deviate from the standard's requirements. The label claim that would allow for the smallest reduction in sodium content is "reduced sodium" which would mandate 25% less sodium than regular cheese. We also acknowledge that for certain standardized cheeses, temporary marketing permits and/or changes to the SOI regulations may be needed to facilitate sodium reduction efforts.

*Targets from Other Initiatives*
The United Kingdom set a sodium reduction target for Blue cheese that was also a sales weighted average for the category “Blue cheese.” Their 2012 sodium reduction target was 840 mg sodium per 100 g (approximately 2.1% salt content if only using salt in the formula). Their 2017 target is 800 mg sodium per 100 g (2% salt content).

*Draft Guidance Goals (Mean Targets and Upper Bounds)*
When we designed the short-term and long-term goals for particular categories, we aimed to determine meaningful goals that are also technologically feasible, with milestone dates that encompass sufficient time for reformulation and marketplace adjustments. Based on the 2010 baseline assessment and the technology considerations, the target mean and upper bound of short-term and long-term goals for Blue cheese are shown in Table 22.

**Table 22. 2010 Baseline, Short- and Long-Term Sodium Reduction Goals for Semisoft Cheese: Blue/Blue-Veined Cheese**

| Semisoft Cheese: Blue/Blue-Veined Cheese | | |
|---|---|---|
| **2010 Baseline** | **Short-Term Goals** (2 years after final guidance) | **Long-Term Goals** (10 years after final guidance) |

[4] SOIs for all cheeses can be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=133

| Current Sales-Weighted Mean (mg Na/100g) | Sales-Weighted Target Mean (mg Na/100g) | Upper Bound (mg Na/100g) | Sales-Weighted Target Mean (mg Na/100g) | Upper Bound (mg Na/100g) |
|---|---|---|---|---|
| 1240 | 1180 | 1430 | 1050 | 1340 |

It is important to note that both the short-term sales weighted mean (1180 mg sodium per 100g, 3% salt content) and the long-term sales weighted mean (1050 mg sodium per 100 g, 2.6% salt content) goals are higher than the lowest sodium Blue cheese product that was selling on the market (853 mg sodium per 100g, 2.1% salt content). Additional details for establishing baselines and goals are presented in the Supplementary Memorandum to the Draft Guidance.

*Conclusion*

We recognize that sodium (in the form of salt) is typically an integral ingredient in cheese making. We acknowledge that some Blue cheese products such as Roquefort (4.1% salt content) might have additional challenges achieving the longer term goals. We also recognize that larger companies may be better equipped to take the lead on reaching short-term and long-term target goals. FDA's mission includes ensuring the safety and quality of food products. Cheese contributes beneficial nutrients to many American consumers' diets and we understand that consumer acceptance of products is of paramount importance. We welcome industry engagement and feedback on our approaches to establishing categories, baselines, and goals for sodium reduction. We anticipate that broad, gradual reduction of excessive sodium in the U.S. food supply will have a significant and beneficial impact on public health.

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