



American Bakers Association

Serving the Baking Industry Since 1897

December 2, 2016

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

RE: Docket No FDA–2014– D–005: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry. 81 Federal Register 35363, June 2, 2016.

Dear Sir or Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA). ABA is the Washington D.C.-based voice of the wholesale baking industry. Since 1897, ABA has represented the interests of bakers before the U.S. Congress, federal agencies, and international regulatory authorities. ABA advocates on behalf of more than 700 baking facilities and baking company suppliers. ABA members produce bread, rolls, crackers, bagels, sweet goods, tortillas and many other wholesome, nutritious, baked products for America's families. The baking industry generates more than \$102 billion in direct annual economic activity and employs over 706,000 highly-skilled people. ABA appreciates this opportunity to submit these comments on the draft guidance, Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods. These comments incorporate and serve as a supplement to our comments regarding the draft guidance's short-term sodium reduction targets, which were submitted on October 17, 2016.

As previously noted, ABA has been a consistent participant in FDA's efforts to promote voluntary sodium reduction, as well as an industry leader in its commitment to voluntary, incremental sodium reduction. ABA shares FDA's commitment to continue these and similar efforts across the food industry through a voluntary, gradual, and incremental approach to the reduction of sodium in foods as part of industry's overall commitment to the health of Americans.

As noted in our October 17, 2016 comments, ABA has some concerns with the draft guidance:

- We are aware that the Institute of Medicine (IOM) and Centers for Disease Control and Prevention (CDC) are currently reviewing the Daily Reference Intake (DRI) for sodium. We believe, therefore, that it is premature for FDA to finalize guidance on sodium

reduction until after the IOM completes its review. Without the results of IOM's review, it is unclear whether FDA's sodium reductions are evidence-based and justified by the best available science. We ask FDA to wait to issue final guidance on sodium reduction until after the DRI has been published and can be used to develop appropriate sodium reduction targets. Ensuring FDA's targets are based on DRI is particularly important for FDA's long term sodium reduction targets, which may vary widely with even small adjustments in the DRI.

- We are concerned that FDA's methodology for tracking reductions in population intake of sodium may not accurately capture population intake of sodium for the proposed categories. Because FNDDS 5.0 food codes (which are used to capture food intake in data in WWEIA/NHANES) were not accurately mapped onto the 150 sodium reduction target categories, intake patterns of these foods would not be representative of the types and amounts of foods typically consumed in a given category. We recommend that FDA adopt sodium reduction in foods by category as the primary metric for evaluating the effectiveness of these voluntary reductions, and we request that the Agency provide more transparency on how population food intake measured in WWEIA/NHANES is mapped to the sodium reduction categories.
- We are concerned that some of the proposed long term mean and upper limit concentration values, like some of the short term values, may be too aggressive to be achievable, particularly within the proposed timeframe of ten years. Reductions in sodium may have significant and unpredictable effects for bakery products, and we caution against any reductions that could impact the shelf stability, functionality and physical properties, taste and flavor, consumer acceptance, and price of baked goods, which are particularly dependent on sodium to achieve the technical characteristics consumers expect of such products.
- Finally, as with our concerns for the feasibility of achieving the proposed short-term targets within a two-year timeframe, we are concerned that achieving the proposed long term targets within ten years will not be feasible for certain products (see discussion below). The technical requirements of analyzing current food products, reformulating various products that may exceed average or upper limit concentrations, testing consumer acceptance and market penetration, and other issues necessarily extend the timeline for achieving the proposed targets. We believe that ten years, for certain products, is not a feasible timeframe for complying with the proposed targets.

While ABA recognizes the efforts FDA has put forth in developing the voluntary sodium reduction targets, we respectfully request that FDA issue a revised draft guidance that takes into account all comments received regarding the short term and long term targets, as well as the IOM's recommendations regarding the sodium DRI. This will provide stakeholders the opportunity to review the revised draft guidance--prior to FDA issuing the final guidance--to confirm that it will not result in unintended issues. As FDA is aware, litigants and others often reference FDA guidance when asserting claims, notwithstanding FDA's statement that guidance is nonbinding, so we strongly urge FDA to carefully consider that stakeholder input will be

needed on a revised draft guidance before FDA issues its final guidance on short-term and long-term sodium reductions.

I. FDA's Voluntary Sodium Reduction Goals Must be Evidence-Based and Grounded in the Best Available Science

ABA believes that the underlying justification for both short-term and long-term sodium reduction targets--FDA's stated goal of reducing sodium intake in the general population to 2,300 mg/day--may be premature because the sodium DRI of 2,300 mg/day is currently under review by the IOM.

As noted in our previous comments, because DRIs represent the most current scientific knowledge on nutrient needs, the forthcoming DRI for sodium will yield a more accurate and appropriate foundation for FDA's sodium reduction goals. We think it is imprudent to issue targets based on a sodium DRI that may change and therefore may not be supported by the best available science.¹ Particularly for long term targets, even slight variations in IOM's final report from FDA's current draft guidance may have a significant impact on the proposed reduction targets for various food categories.² The work to achieve the long-term targets in many categories will be difficult, unpredictable and costly, and this effort should not be undertaken until there is certainty as to what levels of sodium the industry needs to achieve.

ABA opposes any aggressive sodium reduction targets designed to achieve a daily intake of 2,300 mg until the IOM issues its final report. We strongly encourage FDA to wait to issue guidance on sodium reduction, and instead use the DRI to develop appropriate long-term and short-term targets.

II. FDA's Tracking Methodology Must Accurately Capture Food Intake and Mean Population Sodium Intake

The impact that the sodium reduction targets will have on public health is a critical consideration of FDA's guidance on voluntary sodium reduction. While FDA has indicated that it will track both category sodium reductions and reductions in population intake, ABA is concerned that FDA's approach to tracking reductions in population intake will not accurately capture population intake of sodium.

¹ Regulations must (1) be evidence-based and "based on the best available science;" (2) "promote predictability and reduce uncertainty;" (3) be "the least burdensome;" (4) be based on "approaches that maximize net benefits;" and (5) have benefits that justify the costs. Executive Order 13563 (Jan. 18, 2011).

² We also note that FDA itself appears to acknowledge some uncertainty in the current science as to what level of sodium intake is appropriate to best promote public health. See, e.g., *Sodium Reduction*, U.S. Food & Drug Admin., <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm253316.htm> (last visited Sept. 22, 2016).

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In the supplementary memo to the draft guidance, FDA described its approach as combining the sales-weighted category sodium content with food intake data from WWEIA/NHANES to provide an estimate of the public health impact of the sodium reduction initiative.³ There are, however, several methodological issues with how FNDDS 5.0 food codes (used to capture food intake in WWEIA/NHANES) were mapped to the 150 sodium reduction target categories.⁴ For instance, some FDA food categories had FNDDS food codes mapped to them, but these food codes were not representative of the category. One notable example is Category 79, Frozen/Refrigerated Dough and Batter. Despite the size of this category, only two unrepresentative food codes were mapped to it: cake batter and cookie dough. Intake patterns of these foods would not be representative of the types and amounts of foods typically consumed in this category.

As a result of mapping issues, food intake may not be accurately captured for the 150 sodium reduction target categories and the estimated mean population sodium intakes that could be achieved with this initiative may not be accurate. This has significant implications for measurement and accurate tracking of population sodium intake. Due to potential issues in being able to track sodium reductions at the population level, we recommend that FDA adopt the sodium reduction in foods by categories as the primary metric for evaluating the effectiveness of this voluntary effort. Additionally, we request that the Agency provide more transparency on how population food intake measured in WWEIA/NHANES is mapped to the sodium reduction categories.

III. FDA's Voluntary Sodium Reduction Goals Must Balance the Need for Meaningful Sodium Reduction with the Technological and Commercial Role of Sodium in Food Products

We agree with FDA that changes in sodium concentration should be gradual and should not negatively affect the safety or nutritional quality of the food products because of reduced sodium. Because of the technological importance of sodium in bakery products, a wide-scale reduction in sodium raises specific challenges for bakers -- particularly with long term, more aggressive reductions. FDA's long term sodium reduction targets for the various bakery products must take into account the importance of sodium for product shelf stability, functionality, taste and flavor, as well as the lack of sodium substitutes, issues of consumer acceptance, and increased expense. Some of the proposed reduction targets for certain categories

³ U.S. Food & Drug Admin., Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance (June 1, 2016).

⁴ In the docket, FDA provided a file that connects the FNDDS 5 food codes to the Agency's 150 food categories created for this sodium reduction initiative. The mapping explains how food intake from WWEIA/NHANES was linked to FDA's sodium reduction categories. *See, FNDDS Mapping File Request 082516*, U.S. Food & Drug Admin., <https://www.regulations.gov/document?D=FDA-2014-D-0055-0410> (last visited Dec. 2, 2016).

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in particular may have significant and unpredictable effects,⁵ which must be addressed to ensure the feasibility of achieving short-term and long-term targets.

A. Shelf Stability of Food Products

Sodium inhibits the growth of acid-producing bacteria. Microorganisms require water to survive and grow, and sodium preferentially ties up a portion of that water, leaving the microorganism without sufficient water to grow. In inhibiting microbial growth, sodium interacts with the acidity of the dough in production, and low sodium products are much more susceptible to mold growth. Some bakery products may compensate by increasing preservatives, but such preservatives may have adverse effects on the strength and fermentation of product. Sodium thus plays an important role in improving the shelf stability of bakery product.

B. Functionality & Physical Properties of Foods

Unlike many other food products, sodium and other sodium-containing ingredients such as baking soda and leavening acids perform specific, non-flavor functions in baked goods. For example, sodium enhances the golden color of bread by facilitating caramelization. Sodium also has a strengthening and tightening effect on the gluten in dough, contributing to the crumb grain, texture, and resilient characteristics of yeast-raised bakery products. Sodium chloride aids in maintaining the osmotic pressure in the bubble structure and the raising process in yeast-raised products, resulting in more consistent fermentation and better overall bread texture quality (i.e., for muffins and cakes).

Typically, a sodium-based leavening is balanced with an acid-based leavening in the same formula for items such as cookies, wafers, and crackers in order to get open cell structures, and a reduction in sodium-based leavening could lead to a denser structure without adequate substitution. Sodium is also in the formulation for baking soda, which is used for chemical leavening in wheat flour-based products that do not incorporate yeast (i.e., for tortillas, muffins, pancakes).

⁵ As noted in our previous comments, several examples highlight how proposed categorizations should be reconsidered to ensure the proposed targets are feasible for all included bakery products and to prevent adverse impacts on the shelf life and other features from reduced sodium. For instance, the description for proposed Category #79 “Frozen/Refrigerated Dough and Batter” includes an extremely diverse group of bakery products reaches hundreds of different products, but FDA’s histogram shows only 6 examples. Entire groups of important products may be swept in yet not included in the FDA’s evaluation of the baseline sodium concentration. Because the proposed category is too diverse and the baseline may not be representative of the category, sodium reduction efforts by industry will not be reasonable or achievable. Similarly, the description for proposed Category #80 “Bakery Dry Mixes” includes bakery mixes that make sweet bakery items like cakes, muffins and cookies, as well as products like pancakes and biscuits, which are savory and not sweet. It is not reasonable for biscuit or pancake mixes to have the same targets as sweet bakery mixes, and such a categorization may have severe adverse implications for the ability of industry to meet the proposed targets. Additionally, we recommend that buns should be grouped with Category #58 white bread or #59 wheat and mixed grain bread.

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Sodium can also be used to control the stickiness of dough as a dough conditioner, and the impact of sodium reduction can be minimal or significant depending on the usage level of sodium-based ingredients currently intended for use in conditioning the dough. Because of these important technological properties, there is a limited amount of sodium that can be reduced/removed from bakery products before they begin to fail to meet consumers' expectations for both quality and consistency.⁶

C. Taste & Flavor

Taste is a driving factor of consumer purchasing decisions for baked goods as well as other foods, and historic research shows that sodium makes food taste better, and that the nutrient's ability to do so goes far beyond imparting a salty taste. Consumers perceive saltier foods to have improved texture, enhanced sweetness, fewer off-flavors and improved flavor intensity.

While the exact mechanism by which sodium accomplishes these actions is still not well understood, it is widely known that sodium plays a critical role in not only providing salty flavor in items such as cookies, wafers, and crackers, but also enhancing the presence of other flavors in bakery products such as donuts, cakes, and pies. Some research suggests that sodium's positive impact on flavor is a consequence of its ability to suppress bitter tastes, while other research hypothesizes that sodium's impact on water activity allows other flavors in products to become more concentrated. For bakery products in particular, sodium can play a critical role in suppressing bitterness and improving palatability.⁷ Sodium, therefore, has a crucial, if not irreplaceable, effect on palatability. Industry has few alternatives to sodium in these products to achieve a similar result.

Particularly for breads and rolls, achieving the long-term sodium targets will be extremely difficult. These products are bland-flavored by nature, and any significant reduction in sodium will be noticeable to consumers. These products are also the lowest cost with the most sensitivity to bearing a cost increase due to the use of an expensive sodium replacer, making achieving the same taste and flavor particularly problematic if the sodium reduction targets are too aggressive. Further, breads and rolls are also highly sensitive to changes in the crumb structure due to salt reduction. Reducing sodium too aggressively would result in a coarse, open crumb structure that will appear weak, crumbly, dry and stale to consumers.

D. Lack of Sodium Substitutes

⁶ As some examples, salt plays a critical structural role in breads, rolls, and crisps. It would be difficult to drop below 1.6% (Baker's percent) for many high-speed bread and roll products and straight dough, and for artisan-style breads and rolls it would be difficult to drop below 1.8%.

⁷ As an example, whole wheat and whole grain breads have a bitter flavor from the whole grain that many consumers do not like. Sodium (as well as other ingredients) are added to moderate the bitter flavor that is naturally present in the whole grain or whole wheat, resulting in improved consumer acceptance. Reducing sodium in whole grain or whole wheat breads could result in reduced consumer acceptance.

While significant research and development investment has been put into finding good alternatives for sodium and sodium-containing functional ingredients, currently there is no single, existing sodium substitute that works for all bakery products. While sodium bicarbonate is one of the most common leavening agents, potassium bicarbonate and ammonium bicarbonate are potential replacements. These ingredients, however, are not suitable in some applications due to off flavors such as bitterness or a metallic flavor formed at the needed functional use levels. They are typically more expensive than sodium bicarbonate, and in the case of potassium bicarbonate, require a 19% increase in use level to get the same effect, due to molecular weight differences. Further, recent technical breakthroughs (such as potassium chloride) come with substantial expense to achieve a flavor that is acceptable to consumers.

Two of the most commonly used leavening acids are sodium based – sodium acid pyrophosphate (SAPP) and sodium aluminum phosphate (SALP). Lower sodium replacements are available for SAPP, although the ingredients are typically more expensive. There is no simple replacement available at this time for SALP, which is critical in baking applications requiring relatively slow rates of reaction. This challenge is being overcome, but the timeline for additional, necessary research is uncertain.

Additionally, there is usually an impact of some level to the overall yield per batch when the targeted sodium is through the leavening system of items such as cookies, wafers, or crackers, increasing the expense of production. In addition, not enough of these substitute ingredients are currently available in the marketplace to meet large scale sodium reduction demands, and as demand for these substitutes increases, their manufacturers will require time to increase the needed scale of production. Furthermore, most sodium substitutes that may work in bakery products are prohibitively expensive in large-scale, wholesale productions. In the short-term, increased demand for these substitutes could further raise prices for lower sodium products. In the long-term, such a price increase could drive consumers to non-reduced sodium products, undermining FDA's public health goals. For these and other reasons, some substitutes are not as effective in their functional roles and may be prohibitively expensive to be viable for large-scale, wholesale production alternatives.

E. Consumer Acceptance of the Names of Salt Substitutes

Relatedly, consumers are increasingly concerned about the name of their ingredients, particularly names they are not familiar with. Consumers prefer “clean” labels with ingredients that are easy to recognize. One “salt” that bakers can use in moderation to replace some amounts of sodium chloride (aka “salt”) is potassium chloride, but consumers might not recognize by its name that potassium chloride is a salt. FDA's common and usual name regulations require sodium chloride to be declared as “salt” in the ingredient statement. Manufacturers are more likely to use ingredients if they are permitted to use names that consumers recognize. FDA's common or usual name regulations require the name of an ingredient (or food) to identify in simple and direct terms the basic nature of the ingredient and to use uniform names among similar products. We recommend that FDA consider allowing salt compounds used the same

way as sodium chloride to include “salt” as part of the name, such as “potassium salt.”⁸ Allowing the use of the term “salt” will indicate to consumers the purpose of the ingredient and will be in line with FDA’s common or usual name requirements that the name identify the basic nature of the ingredient and be uniform among similar products.

F. Expense

Sodium reduction comes with significant expense and has the potential to further raise food prices. As sodium is removed, more expensive ingredients are often added to foods in its place. As explained above, sodium substitutes may have adverse impacts on yield and the cost of substitute products may cause significant product price increases for consumers.

The cost of sodium reduction includes costs from product research and development, product consumer acceptance testing, production of new food labels, and changes to marketing plans. These types of overhead costs will be difficult for companies to recapture in the marketplace, even for meeting long term targets. Smaller to mid-sized companies may find it more difficult to pass on these additional costs to consumers, resulting in additional economic stress and potential reduction in work force. We know from consumer research that after taste, price is the most important driver of consumer purchasing decisions.⁹ If these higher prices cause consumers to buy fewer lower sodium foods, the potential impact of an overall sodium reduction effort is likely to be minimized.

IV. FDA’s Voluntary Sodium Reduction Goals Must Recognize the Limitations of Consumer Preference and Expectation and Avoid Unintended Consequences

We agree that population-level sodium intake reduction should occur at a pace such that consumer preferences and expectations for saltiness in foods can adjust over time. As FDA noted and numerous studies have shown, consumer preference for higher sodium levels can be modified, but such changes will require gradual, step-wise reductions in sodium concentrations in food products.¹⁰ As noted in our previous comments, achieving a meaningful change in consumer preference is particularly challenging for bakery products. Consumers expect their trusted bakery products to be wholesome, safe, high quality, and to have a consistent taste, with expected shelf life at a reasonable price. Changes in sodium or salt concentration that significantly alter taste, texture, appearance, shelf life, or price are not likely to be acceptable to consumers.

⁸ See Petition, Docket No. FDA-2016-P-1826 (June 27, 2016) (requesting that FDA issues guidance recognizing ‘potassium salt’ as an additional common or usual name for potassium chloride).

⁹ E.g., Int’l Food Information Council Foundation, *2011 Food & Health Survey* (May 5, 2011), <http://www.foodinsight.org/Content/3840/2011%20IFIC%20FDTN%20Food%20and%20Health%20Survey.pdf>

¹⁰ See Institute of Medicine (IOM), *Strategies to Reduce Sodium Intake in the United States*, Washington DC: The National Academies Press (2010).

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For some bakery products in particular, limitations in consumer preference and expectation may create adverse and unintended consequences. The U.S. Dietary Guidelines for Americans recommends a consumption, on average, of six ounces of grains per day, three ounces of which should be whole grains.¹¹ Whole grain breads, however, have a bitter flavor that is moderated by sodium and sugar. Reductions in sodium may put this balance in flavor at risk, which may lead to reduced consumer acceptance and reduced consumption of whole grain products. Additionally, enriched grain-based food products have a significant impact on overall health and disease prevention. For example, following an FDA mandate that enriched grains be fortified with twice as much folic acid, the United States has seen a significant reduction in the incidence of neural tube defects.¹² It is critical that consumers continue to prefer and accept such enriched grain-based food, and reductions in sodium may have an unintended consequence of causing consumers to consume less of these important grain products.

ABA believes that reasonable, incremental reductions that gradually lower sodium levels can meet consumer expectations and preferences in many products, and ABA intends to continue to invest the time and resources necessary to achieve such an end. Aggressive sodium reductions may lead to product reformulations that decrease consumer preference for such products, a result that is not feasible for continued industry efforts to reduce sodium in food products and may create unintended consequences for consumption of certain foods. It is critical that FDA's sodium reduction targets are both reasonable and gradual. Particularly for the FDA's draft long term sodium reduction goals, sodium reductions may not be feasible or desirable based on rates of consumer preference changes.

V. FDA's Guidance Should Extend the Long-Term Target Date

The draft guidance proposes a long-term target date of ten years for industry members to reformulate products in order to meet the FDA's targets, but as explained above, we are concerned about the feasibility of meeting this timeframe. While ABA members have made consistent progress toward reducing sodium in bakery products, a significant amount of additional resources will be required to properly analyze current formulations, reformulate those products that do not currently meet the short-term mean and upper limit targets and update packaging. Due to the sheer number of products in our members' portfolios, significant resources will need to be allocated to appropriate design work on the reformulation, which will take time to reallocate from other resources.

Further, any reformulations must undergo consumer preference and expectation testing, due to the significant concerns discussed above. Particularly for products facing feasibility challenges for the proposed short term targets, achieving the long-term targets will be significantly more difficult. As products are reformulated over the long term, each reformulations must undergo consumer preference and expectation testing, due to the significant

¹¹ *Dietary Guidelines 2015-2020*, Centers for Disease Control & Prevention (2015), <https://health.gov/dietaryguidelines/2015/guidelines/>.

¹² *Morbidity & Mortality Weekly Report, Spina Bifida and Anencephaly Before and After Folic Acid Mandate --- United States, 1995--1996 and 1999--2000*, Centers for Disease Control & Prevention (May 7, 2004), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5317a3.htm>.

concerns discussed above. This iterative process will take a significant amount of time, but must be employed in order to ensure consumer acceptance of reduced sodium products. Additionally, ABA members must also assess market penetration effects from revised formulations, which must also be repeated as members take steps to meet the long term targets.

Aside from the concerns identified above, ABA members believe that many of the long-term targets may be achievable if given enough time to conduct the necessary analyses, reformulations, and testing. For some products, however, it will not be feasible to achieve the long-term targets without the development of new technologies. It is unclear whether this technology can be developed in the next ten years. The industry has put significant resources into sodium reduction for the past few decades, with excellent progress in some areas such as developing sodium free chemical leavening agents, and salt substitutes that work in breads and rolls (although these cost significantly more than salt).

ABA respectfully asks FDA to extend the long-term target date, and recommends FDA reevaluate what should be an appropriate long term target date in five years. By this time, the DRI will have been established and validated, and industry will be able to better assess the technology and cost impact of achieving the DRI in various product categories.

VI. Conclusion

ABA appreciates the opportunity to provide this input to FDA as the Agency considers the substance and form of its guidance on sodium reduction targets. ABA respectfully requests that FDA issue a revised draft guidance so that FDA can incorporate stakeholder feedback and the IOM's recommendations for the sodium DRI. We look forward to continuing to partner with the FDA throughout this process. Should there be any questions or if additional information is needed, the contact regarding ABA's comments is Lee Sanders, Senior Vice President, Government Relations and Public Affairs. Ms. Sanders can be reached at lsanders@americanbakers.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Lee Sanders", with a stylized, flowing script.

Lee Sanders
Senior Vice President
Government Relations & Public Affairs