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GENERAL MILLS

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

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Comments Re:

Docket No. FDA-2014-D-0055; Voluntary Sodium Reduction Goals; Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Draft Guidance for Industry (June 2, 2016)

Dear Sir or Madam:

General Mills (GMI) is a major packaged-food manufacturer engaged for over 150 years in the development and production of food products including ready-to-eat-cereals, yogurts, vegetables, soups, snacks, flour, cake and other dessert mixes, refrigerated dough and numerous other products. Our company's purpose is simple but powerful: we serve the world by making food people love. Embedded in this purpose is a deep respect and sense of service to our consumers and a commitment to understanding their needs and expectations. To help meet our consumers' health and nutrition needs, we have been committed to nutrition labeling for nearly 50 years, and today we provide information for over 4000 retail and food service nutrition labels.

We have long supported the Food and Drug Administration's (FDA) science-based nutrition labeling practices and have acted in accordance with the Agency's various regulations. Like the Agency, General Mills agrees with the importance of helping consumers maintain healthy dietary practices. We believe that any regulations or guidance be supported by the most current scientific evidence and dietary recommendations, and be based on transparent and robust methodology that allows the goals and objectives to be accurately measured and achieved.

We are aligned with the Agency's broad sodium reduction approach that encompasses both retail packaged and restaurant/away-from-home foods, as successful sodium reduction must be universally addressed in products across the food supply.

Executive Summary

GMI provides the following major points and recommendations on categories, baselines and short term targets for the Agency's consideration:

- General Mills has achieved significant sodium reduction across our portfolio.
- GMI supports FDA's use of 2010 product sodium and sales data for the baseline.
- The Agency should provide clarity and transparency on the methodology used to:
 - Develop the composition of categories and baseline values.
 - Model the effectiveness of the targets in achieving mean population sodium intake goals.
 - Track category sodium targets and population intake goals.
- Extend short term targets from 2 years to 4 years, with reporting progress at 5 years:
 - Allows time for reformulations, market penetration and consumer adaptation.
 - In some categories, GMI products do not yet meet targets; however, the baselines and targets seem reasonable if given 4 years to achieve.
 - In categories that are not appropriately defined, the short term reduction goals are not reasonable or feasible.
 - In categories where the Agency makes revisions, baselines need to be reevaluated.
- Re-issue draft guidance and allow time for the food industry to address changes.
- The Agency will need to consider a process to address marketplace shifts and dynamics, in particular, the ready-to-eat (RTE) soups and bars categories.
- We have specific recommendations and revisions for several key categories (see Appendix 2 for a detailed summary):
 - Divide category 79 (Frozen and Refrigerated Dough and Batter), into 2 sub-categories
 - Divide category 80 (Bakery Dry Mixes) into 2 sub-categories
 - Divide category 129 (Grain-based Meals/Entrees, Dry-Mix), into 2 sub-categories OR include 2 sets of target means
 - Merge the 2, ready-to-eat cereal categories (54 and 55) into 1 category
 - Expand the definition of categories 30b (Mashed Potatoes, Dry Mix) and 57 (Cereal and Granola Bars)

Background: General Mills Sodium Reduction Initiative

In 2010, General Mills (GMI) publicly pledged to reduce sodium by 20 percent in 10 key US retail product categories, using 2008 data as the baseline. As announced in December 2015, we met or exceeded our goal in seven of these 10 categories and made significant progress in the other three (see Table 1 below). This industry-leading effort includes sodium reductions in over 350 products – more than one-third of our US retail sales volume. Since we have just completed this significant undertaking, we appreciate the Agency's willingness to recognize sodium reduction achievements made during this timeframe.

Table 1. General Mills Sodium Reduction by Category

PRODUCT CATEGORY	FINAL WEIGHTED SODIUM REDUCTION PERCENTAGES*	GOAL ATTAINED
Savory Snacks	35%	YES
Frozen Pizza	29%	YES
Canned Vegetables	28%	YES
Variety Baking Mixes	24%	YES
Dinner Mixes	21%	YES
Refrigerated Dough	21%	YES
Side Dishes	20%	YES
Ready to Serve Soup	19%	NO
Mexican Dinners	19%	NO
Cereal	18%	NO

* 2015 results based on sales weighted sodium values per category, calculated using labeled sodium values and weighted product ship volumes, compared to 2008 baseline data.

When we established our 2015 target, we knew it would be challenging given the many roles sodium plays in our products. The approach we used was to gradually reduce sodium over several years using small, incremental changes and giving consumers time to adapt their palates to the lower sodium levels. Taste is the main driver of food purchases – and we believe making small changes over time is the best way to deliver the great taste consumers expect, while also supporting our commitment to the goal of reducing sodium intake in the food supply.

GMI used 2008 sales weighted averages as baselines, and to measure progress and results. Our decision to use sales weighted averages is similar to the approach proposed by the Agency. If unweighted means were used, sodium reduction goals could be met by reducing only low volume products. Using weighted means helped ensure that higher volume products would deliver sodium reductions to meet the 20% reduction goals, and our efforts would make a meaningful difference.

FDA’s Proposed Voluntary Sodium Reduction Initiative

FDA has requested comments on their approach and methodology related to categories, baseline means and short term targets, and has articulated the specific questions below which we will address in our comments.¹ Because categories, baseline means and short term targets are inextricably correlated we have chosen to comment in a holistic manner, versus addressing each question separately.

1. Are there categories where foods have been grouped together that should be separated on the basis of different manufacturing methods or technical effects relating to the potential for sodium reduction? Conversely, are there categories which could be merged due to similar sodium functionality and potential for reduction? Are there foods that contribute to sodium intake that we have not effectively captured? Are the categories amenable for use by restaurant chains and if not, how should they be modified to make them amenable for use by restaurant chains?

¹ Federal Register Vol 81, No. 106 (Food and Drug Administration, 2016, p. 35366).

2. Are the baseline sodium concentration values reasonably representative of the state of the food supply in 2010? For categories that do not appear representative, what food products are not adequately represented? Are there situations in which our method of quantification could lead to unrepresentative baseline values?
3. Are there categories for which the 2-year target concentration goals are infeasible? If so, why are these targets not feasible, e.g., for technical reasons? What goals would be feasible in the short-term (2-year), and why? For reference, a supplementary memorandum to the docket is provided to further describe the type of information needed, “Target Development Example: Supplementary Memorandum to the Draft Guidance” (Ref. 7).
4. Are the short-term (2-year) timeframes for these goals achievable? If the timeframes are not achievable, what timeframes would be challenging, but still achievable?

Per the Agency’s request, these comments will be specific to short term targets; feedback on long term targets will be provided in separate comments due on December 2, 2016.

FDA’s Overall Approach to Category, Baseline and Short Term Targets

FDA’s sodium reduction initiative is built on 150 food categories and their corresponding 2010 sales weighted baseline means. Short and long term targets, as well as upper bounds, are derived from the category baselines. As the foundation of the initiative, the importance of ensuring accurate and representative 2010 baseline values cannot be over-stated.

We appreciate FDA’s collaboration and will be providing detailed feedback and recommendations on categories, baselines, short term targets and challenges meeting the goals in our comments.² However, the Agency has not provided adequate transparency on the specific products included in categories, making it difficult to completely assess the baseline means and subsequent feasibility of the targets, and fully respond to their request for comments. If industry is unable to fully identify the composition of the categories and corresponding baselines, and/or if the baselines don’t represent the marketplace, measuring progress against the targets will be misaligned with the Agency’s data.

In addition, the absence of Walmart and club store sales information in the development of weighted baselines and subsequent targets is a significant deficit in the Agency’s methodology. It is difficult to have an accurate representation of the marketplace without inclusion of sales data from these leading grocery providers. Moving forward, it will be important for FDA to identify a process that will capture all important grocery providers.

² As FDA stated in their draft guidance, “In particular, we are interested in comments on collecting and organizing these data into food categories, our methods for quantifying sodium content, refinements to the specific mean and upper bound targets based on adjustments of our category structures and data, and any challenges of implementing the voluntary goals. Please provide the reasoning behind your comments, including, where available, any data you may have.” Federal Register Vol 81, No. 106 (Food and Drug Administration, 2016, p. 35366.

GMI supports using 2010 sales data for determining baseline means, as most sodium reduction work done by companies would be included in sales data post-2010, and thus would “count” toward the short term targets. The marketplace has shifted considerably in some categories since 2010, which will be discussed in detail in our comments.

Several Categories and Baselines Will Need to be Modified

In their Supplementary Memo, FDA stated that their approach to develop categories that:³

- Have similar functional roles for sodium containing ingredients
- Have similar sodium concentrations (within a range for the food category)
- Be compatible with existing industry and regulatory categories, and government databases
- Have similar technical potential for sodium reduction

FDA further stated, “The first two criteria reflect the recognition that reduction goals would be more achievable and meaningful if foods with similar ingredients and sodium content (within reason), based on both USDA nutrient data and label data, were grouped together.”

The Agency followed this protocol in many categories, grouping homogeneous foods with similar sodium concentrations, and creating additional categories based on obvious product and/or sodium differences. However, FDA has proposed some categories that are very diverse and heterogeneous and the category descriptions include an extensive array of dissimilar products. The histograms do not fully reflect the number of products expected in the category, and leading products that should impact the baseline do not seem to be fully represented.⁴ Finally, the diversity of products creates an unreasonably wide range of sodium concentrations.

It is imperative that the categories and corresponding baseline values be comprised of homogeneous foods with reasonable sodium concentration ranges for progress against the short term goals to be meaningful and appropriately measured. When categories are too diverse and sodium concentrations too wide, there is little incentive for products at the high end of the range to reduce sodium because targets are not achievable.

GMI recommends revising overly diverse categories to be more homogeneous. This will tighten sodium concentration ranges and make short term targets more realistic and feasible. FDA will need to recalculate baselines for the revised categories. Examples of categories that we recommend be revised are:

- Frozen/refrigerated dough and batter (#79)
- Bakery dry mixes (#81)
- Grain-based meals/entrees, dry-mix (#129)

While some categories are too diverse, other categories could be combined because products are homogenous, the functional role of sodium is similar and the concentration ranges are reasonable.

³ FDA’s Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance. June 1, 2016.

⁴ FDA’s Sodium in the U.S. Food Supply for Products in 2010, available at www.regulations.gov/document?D=FDA-2014-D-0055-0351.

Combining categories and revising the description will encompass the array of products available in the marketplace. FDA will need to recalculate baselines for the combined category. One example of a category that could be combined is RTE cereal, categories #53 and 54.

Extend Short Term Targets from 2 to 4 Years

FDA's voluntary sodium reduction initiative will have significant implications, including concurrent reformulations of hundreds of products to meet short term targets. Successfully achieving sodium reduction is challenging and complex. Sodium plays a multifunctional role in foods (safety, shelf life, texture, appearance, and flavor), is ubiquitous in foods and many ingredients, and an equivalent replacement does not exist. Additionally, sodium reduction is not a "one size fits all" approach and products must be addressed individually. Finally, gradual, step-wise reductions are required to allow time for consumer tastes to adapt and for this initiative to be successful.

GMI meets or is close to meeting short term targets in several categories. However, in other categories, many products will require significant reformulation. A key insight from our sodium reduction commitment is that sodium cannot be reduced a full 15% in one reformulation in most products and still be acceptable to consumers. A step-wise series of reformulations over 2-4 years is often required, with each reduction helping the consumer adapt to the lower sodium product. In addition, some products will require new technologies, not yet available, to achieve the short term goals. Reporting progress at 5 years is needed as some products, such as seasonal packs of vegetables and soups, take additional time to enter the food supply and be available for consumers to purchase.

Therefore, for the Agency's initiative to be achievable and successful, we recommend extending the short term targets from 2 to 4 years, with reporting progress at 5 years.

Upper Bounds

GMI has concerns regarding the Agency's approach in providing Upper Bound levels for individual products and the potential for unintended consequences it brings to the marketplace and the Agency's initiative. Success of the initiative will be measured based on category progress toward meeting the short and long term mean goals. Having some products target the Upper Bound while others are working to achieve the category mean has the potential to create an uneven playing field in the marketplace, which conflicts with the Agency's stated intention to, "...promote a level playing field among industry sectors."⁵ More importantly, it weakens advancement of the Agency's initiative since larger, nationally distributed products working toward the category mean will be at a disadvantage compared to smaller, regional products working to meet the higher Upper Bound sodium level. This will be especially true in categories like tortillas and snack foods where regional brands have significant presence in the marketplace. In summary, the objectives of FDA's initiative may be better served by eliminating the Upper Bounds, and having all products in a category focused on achieving the same short term means.

⁵ U.S. Food & Drug Admin., Memo: FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance, p. 3, (2016).

FDA's Modeling Evaluation to Achieve the 2- and 10-year Targets: Methodology Issues

We appreciate the Agency's efforts to evaluate how the sodium reduction initiative's short and long term targets would impact mean population sodium intake. To do this evaluation, the Agency used national food intake data from the 2007-2008 and 2009-2010 National Health and Examination Surveys (NHANES) (detailed in Sections 5.4 and 5.5 of the Draft Guidance document).⁶ However, we believe there are some methodological issues that the Agency must address and a summary is provided below; for more details, please see Appendix 1.

1. Lack of transparency of the data used to evaluate the feasibility of achieving the mean population sodium goals including issues related to:
 - The use of a proprietary database for modeled baseline sodium intake values.
 - Only partial information is provided on how the Agency mapped the FNDDS 5.0 food codes to their sodium reduction target categories.⁷ For example, no information was provided on how broad FNDDS food codes that would belong in multiple sodium reduction categories, such as "Cheese, not further specified," were proportionally assigned to the appropriate categories.
 - The agency did not provide an estimate of the percentage of the population meeting or exceeding the adequate intake for sodium; therefore, it is not known how these draft sodium category targets would impact the **percentage** of the population achieving the recommended sodium intake level.
 - The methods section of the draft industry guidance was not congruent with the mapping information provided in the sodium docket. For example, FDA stated that they used SR codes to proportionally assign FNDDS codes to multiple sodium reduction categories. However, this was not done. This has significant implications for estimating the effectiveness of the sodium targets in achieving the mean population sodium goals and for tracking the success of FDA's sodium reduction initiative.
2. The Agency's mapping of the FNDDS 5.0 food codes to the sodium reduction categories. Some of the FDA sodium reduction categories contained no food codes (and therefore, these food categories would not contribute to the modeled reduction in sodium intake) while other categories contained unrepresentative foods. For example, category 129, Grain-based Meals/Entrees, Dry-Mix contained only 3 FNDDS 5.0 food codes and all were instant white rice, which do not represent the diverse set of products contained within this category.
3. Tracking of the sodium content of products as well as the population dietary patterns/sodium intake will be critical to assessing the effectiveness of the Agency's sodium reduction initiative. Due to possible shifts in dietary intake patterns and discretionary salt use, mean population sodium intake may not decrease despite efforts by the food industry to reduce the sodium content of their products. The Agency has not detailed how What We Eat in America/NHANES

⁶ FDA's Voluntary Sodium Reduction Goals: Supplementary Memorandum to the Draft Guidance. June 1, 2016.

⁷ FDA's FNDDS Mapping File Request 082516, available at <https://www.regulations.gov/document?D=FDA-2014-D-0055-0410>.

data will be used to track food intake patterns and sodium intake, or how the Agency will overcome the limitations of the mapping of FNDDS food codes to the sodium reduction categories (see previous comment).

In summary, these methodological issues must be resolved to ensure the integrity of FDA's approach; without resolution the viability of FDA's approach is compromised.

The Dynamic and Evolving Marketplace: Category Considerations

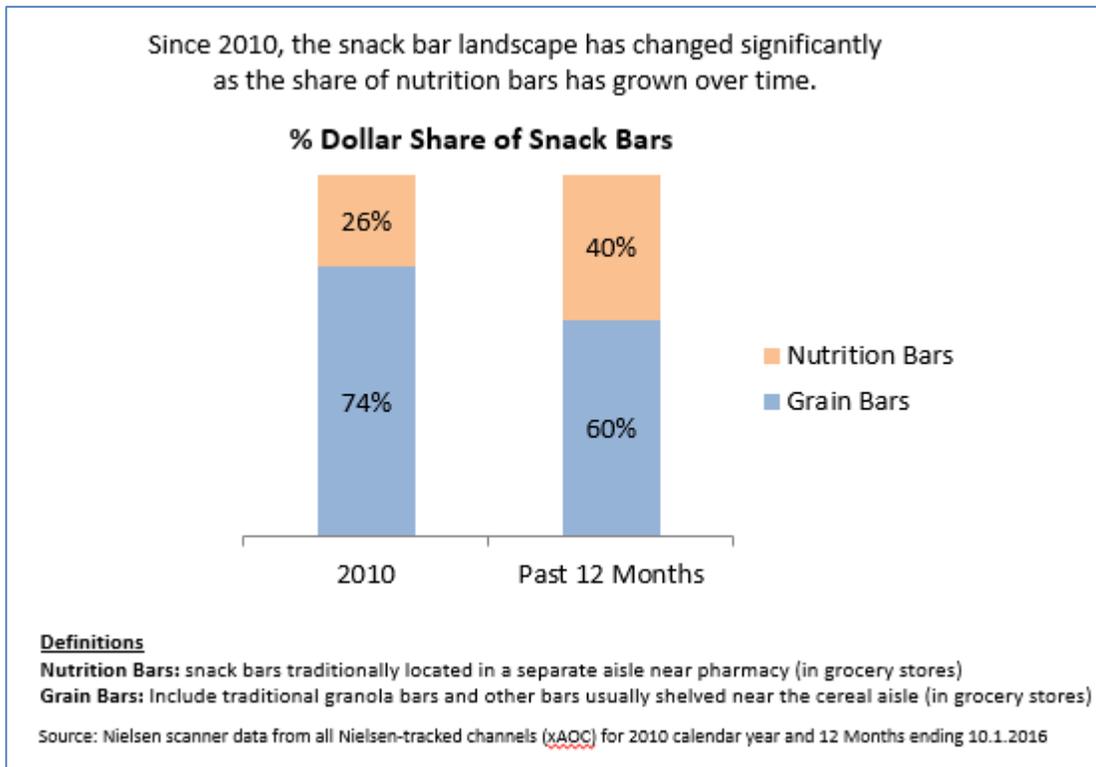
The number and variety of products available to consumers in the marketplace has dramatically evolved and expanded in the past decade. The pace and degree of change is predicted to increase, as consumers' tastes become more global, their concept of health and wellness evolves, and the food industry responds to their changing tastes and preferences. Consumer buying patterns will continue to be primarily driven by taste and will significantly impact the composition of the marketplace. GMI has questions and concerns regarding how the Agency will address this changing marketplace and the impact on baseline sodium means and subsequent sodium reduction targets. Following are specific examples to illustrate the marketplace shifts in two categories; one created by product innovation and the other caused by consumer buying patterns: Bars and RTE Soup.

Bars

The bars market in 2010 consisted largely of traditional "grain" bars and are the products FDA describes for category 57: bars made from cereal and/or granola, including a combination of cereal/granola ingredients primarily offered to consumers as individually wrapped rectangles. In 2010, there were fewer brands and product offerings and the category was more homogeneous compared to today.

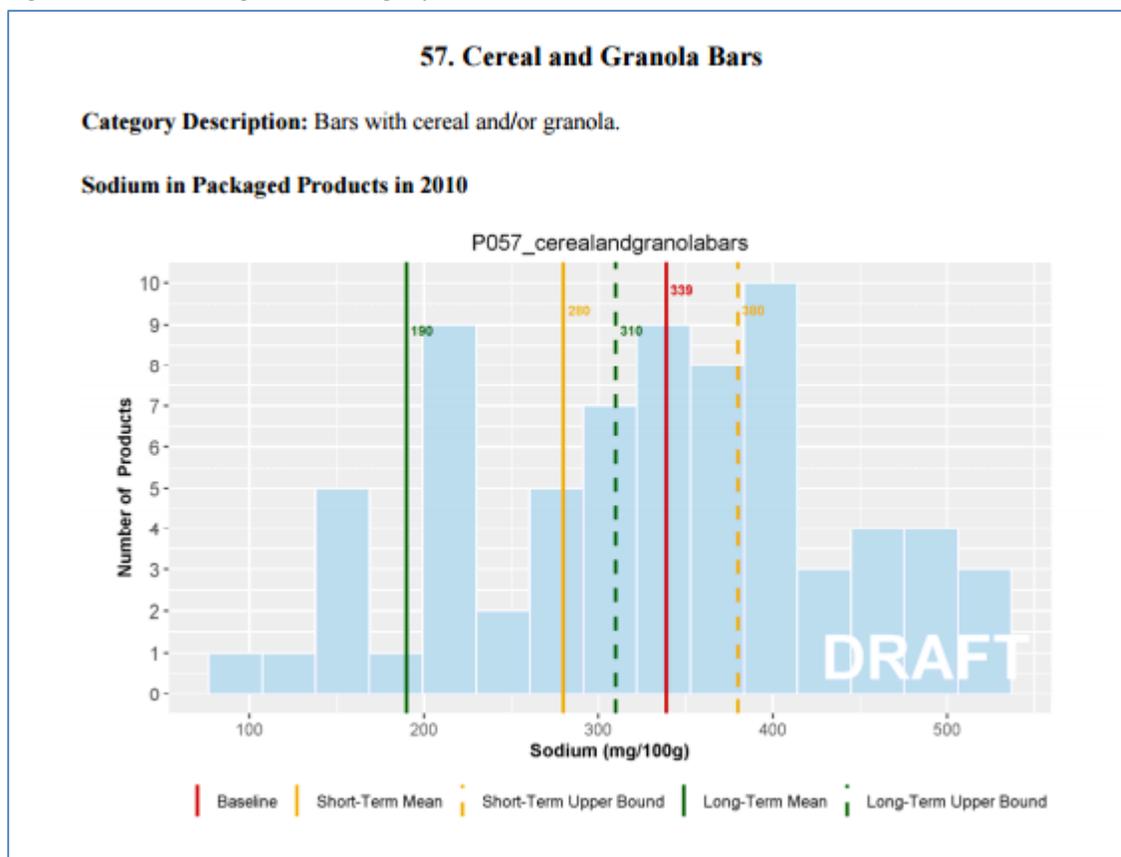
The landscape in the bars category has dramatically shifted since 2010 and no longer resembles the 2010 category. Product offerings have expanded to include not only cereal and granola bars, but products that are markedly different in composition, such as nut bars, fruit bars, meat/jerky bars, protein bars, energy bars, weight management bars and more (some are classified as "nutrition" bars). In addition to changes in composition, the "bars" category now offers products in a variety of formats, including bites, clusters, and sandwich-type products. The evolution of this category will continue, and we expect it to look much different in the future. Food technology and innovation has introduced entirely new bar platforms that are not accounted for in the 2010 sodium baselines. Products that were driving the 2010 sodium baseline may no longer be category leaders now or in the future, replaced by new products. Figure 1 illustrates the dramatic evolution in the bars category since 2010.

Figure 1. The evolution of the bars category: 2010 – 2016.



While FDA’s category #57 describes a similar group of products, the 2010 histogram reveals a relatively wide sodium range: 50mg – 550mg/100g. A significant number of products would require greater than 15% sodium reduction to meet the short term goal (280mg/100g). The largest group of products in the histogram contains 400mg of sodium/100g (see Figure 2). These products would require sodium reductions in the range of 30% to reach short term targets, which is neither reasonable nor achievable.

Figure 2. FDA Histogram – Category 57.



The Agency must consider how to account for sodium reduction progress given the dramatic changes that have occurred in the bars category. There are hundreds of additional products in the marketplace today compared to 2010 and are not represented in the present model. We recommend that the Agency expand their current description of category 57 to reflect the marketplace and address baseline means accordingly (see Appendix 2).

RTE Soup

In contrast to bars, the RTE soup landscape itself has not dramatically changed, but shifts in consumer buying patterns have impacted our current mean compared to the 2010 baseline. Progresso RTE Soups were part of GMI’s sodium reduction commitment, and were on track to achieve the 20% reduction goal. However, when we did our final assessment in 2015, the marketplace had shifted and our sales weighted mean increased. While individual products achieved significant sodium reductions, consumer buying patterns shifted to higher sodium soups (versus lower sodium soups), and subsequently the weighted mean increased. Progresso RTE soups nearly met our 20% reduction goal, achieving a respectable 19% sodium reduction, but the example serves to illustrate how consumer buying patterns can have unintended consequences on the weighted mean.

Moving forward, consumer taste preferences will be a critical factor in our ability to achieve the short term targets, given that we have just completed significant sodium reductions. A 4-year time frame is

needed because of the increased difficulty to achieve acceptable sodium reductions in this savory category.

In summary, the food marketplace is dynamic and evolving. Consumer buying patterns will shift to reflect food and taste trends, new health and nutrition recommendations, and food technology/innovation advancements. Sales weighted means will shift along with marketplace shifts and product sodium reductions may not have the same impact on the mean. These changes are inevitable and must be considered in conjunction with sodium reduction and tracking efforts that measure progress of this voluntary initiative. A collaborative effort between the food industry and FDA is necessary to develop a process that can address this important issue.

Specific Recommendations for Category Revisions

The following GMI comments specifically address the Agency's questions below for Categories 30b, 79, 80 and 129.

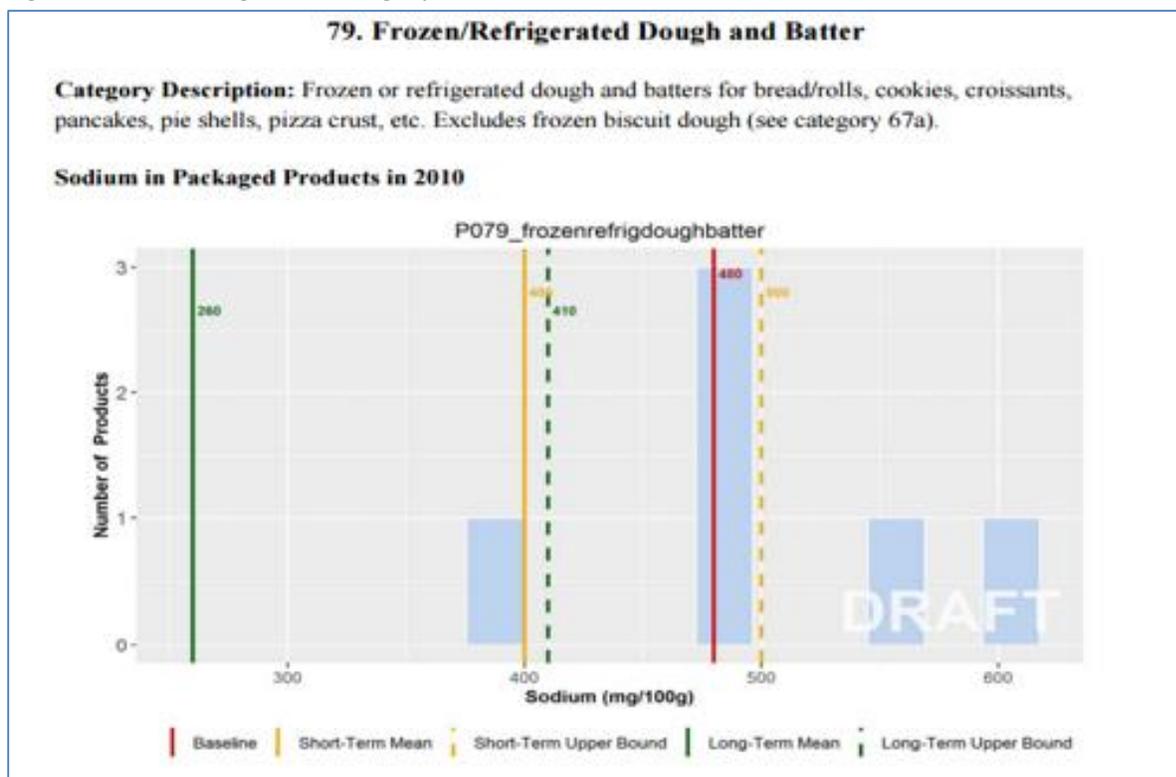
Category 30.b. Mashed Potatoes, Dry-Mix

The dry-mix potatoes market includes a variety of both mashed potato and casserole-style potato products (e.g. scalloped and au gratin potatoes). The agency's current description only accounts for mashed potato products (with or without additions). GMI recommends that the Agency expand the definition of category 30b. to include dry-mix casserole potatoes as they are similar in composition and sodium concentration to dry-mix mashed potatoes. GMI provides specific recommendations for category description revisions in Appendix 2.

Category 79. Frozen/Refrigerated Dough and Batter

The description for proposed Category #79 includes an extremely diverse group of bakery products. However, FDA's histogram and corresponding baseline do not represent the large number and diversity of products in the marketplace (see Figure 3). There should be hundreds of products in this category, yet FDA's histogram shows only 6 products. Entire groups of important products expected to be in this category do not appear to be represented, such as canned dough. Because the proposed category is too diverse and the baseline is not representative of the category, sodium reduction efforts by industry will not be reasonable or achievable.

Figure 3. FDA Histogram – Category 79.



GMI is providing recommendations to better define and align this category and to help make sodium reduction targets more reasonable for bakery products. They build on FDA’s proposed categories and are based on the sodium content differences inherent to the leavening systems used in bakery products. We recommend that bakery doughs and products be subdivided into non-yeast leavened products, and yeast leavened and unleavened products. Additionally, to group homogeneous products and leverage the Agency’s already proposed categories, GMI recommends moving refrigerated biscuit dough and cookie dough from category 79 to Frozen Biscuits (category 67a) and Cookies (category 77) respectively. Figure 4 further illustrates this recommendation.

- Refrigerated biscuit dough is not inherently different in sodium content from frozen biscuit dough, which FDA has already included in category 67a; thus it was logical to keep all biscuit dough (refrigerated and frozen) together.
- Similarly, cookie dough is similar in sodium concentration to RTE cookies, and thus it made sense to keep these like products together in category 77.

Figure 4. Broad recommendations for Category #79 revisions.



The Sodium Content of Bakery Products is Driven by Leavening Ingredients

The sodium content of bakery products is driven by the leavening ingredients required to make the product. For simplicity and purposes of sodium reduction, bakery products can be divided into 2 basic leavening categories/systems:

- Yeast leavened and unleavened products
- Non-yeast leavened products

Yeast leavened products rely on the fermentation of yeast and sugar resulting in the production of gases that provide dough development and flavor characteristics. Salt is included for flavor and helps with dough development. Unleavened products contain some salt for flavor, and rely on steam generated by baking to expand dough volume; while these products do not contain leavening agents, their sodium content is similar to yeast-leavened products, and thus could be categorized with yeast-leavened products for this initiative.

In contrast, non-yeast leavened products contain sodium from salt and from required leavening ingredients, typically baking soda and baking powder:

- Baking soda = sodium bicarbonate
- Baking powder = sodium bicarbonate + acid salts which are typically monocalcium phosphate + sodium aluminum sulfate

Salt provides flavor and aids in dough development, while the reaction of the acid salts with sodium bicarbonate releases carbon dioxide gas that produces the traditional characteristic flaky, tender, or cake-like texture of biscuits, cakes, muffins and other non-yeast leavened products.

In refrigerated canned doughs which are all non-yeast leavened, sodium also helps control water activity necessary in preventing spoilage of refrigerated dough products. When sodium content in canned dough is significantly reduced, water activity increases and ultimately leads to increased can pressure and package structure failure due to the following issues:

- Growth of Lactic acid bacteria (inherent to flour)
- Decrease in Dough pH
- Decrease in CO₂ solubility

The physical properties of non-yeast leavened products must be maintained when undergoing reformulation; sodium reduction in non-yeast leavened products is extremely challenging as technical solutions do not currently exist that provide the same physical, functional, shelf-life, taste and value as sodium-based leavening agents. Table 2 below summarizes the differences in yeast leavened and non-yeast leavened systems.

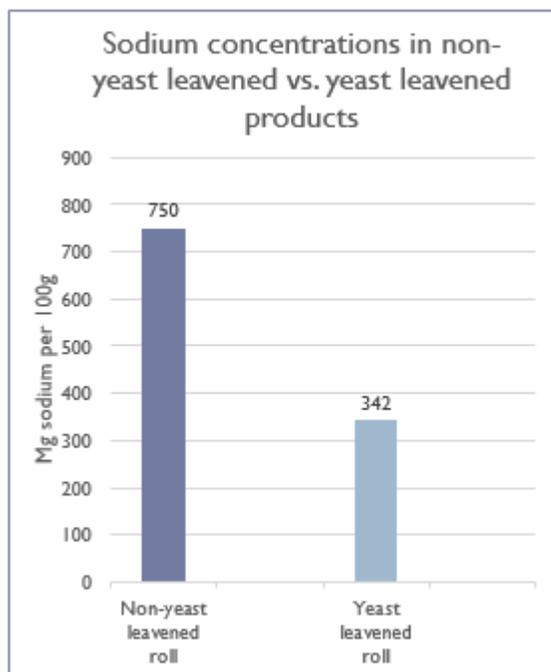
Table 2. Differences in yeast leavened/unleavened and non-yeasted leavened systems.

Leavening Process	Leavening Ingredients	Role of sodium	Products Examples
Yeast leavened and unleavened	Yeast and sugar	Flavor, dough development	Yeast breads and pastries Pie crust, puff pastries
Non-yeast leavened	Acid salts + sodium bicarbonate	Leavening, flavor, dough development, and water activity control (to prevent can failure)	All canned dough Biscuits, waffles, pancakes Cakes, brownies, muffins, cookies

FDA has recognized and accounted for leavening agents' effects on sodium levels in some products, as they have proposed distinct categories for "Frozen Biscuits" and "Prepared Biscuits" (categories 67a and 67b) that are separate from other bakery products/doughs. However, the Agency has also categorized together a diverse group of yeast leavened, unleavened and non-yeast leavened products in category 79's description. The products described have, by nature of their different leavening systems, very different sodium concentrations.

Figure 5 illustrates the differences in sodium between a non-yeast leavened dinner roll (leavened with sodium bicarbonate) compared to a yeast-leavened roll. However, the Agency's proposed category 79 includes both of these products. It is neither realistic nor feasible to require non-yeast leavened products to achieve the same sodium reduction targets as yeast leavened products, as their sodium levels are inherently and significantly higher.

Figure 5. Sodium content differences in non-yeast leavened vs. yeast leavened products.



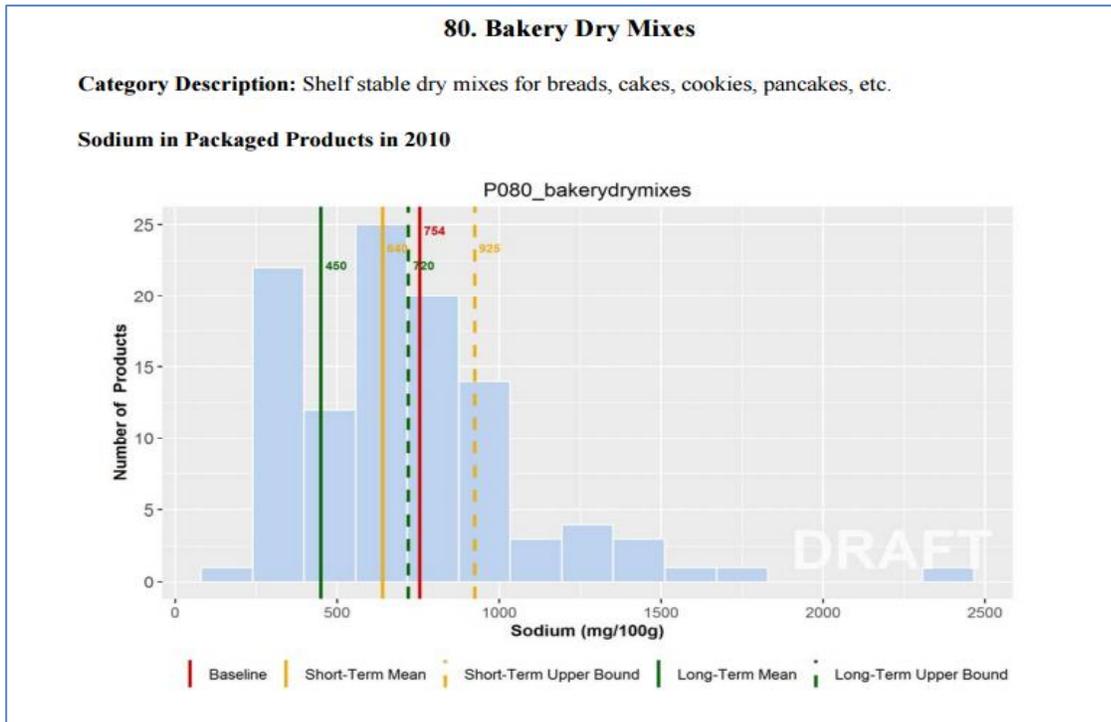
In summary, to better define category 79 into more homogeneous products with reasonable sodium concentrations based on leavening systems, GMI recommends subdividing the category:

- Divide category 79 into 2 categories:
 - 79a: Frozen/Refrigerated Dough and Batter: non-yeast leavened products, including all canned, refrigerated dough except biscuits, pancakes
 - 79b: Frozen/Refrigerated Dough and Batter: yeast leavened and unleavened products, including yeast breads and pastries, pie crust and puff pastries
- Reevaluate the baselines, based on the new sub-categories
- Leverage the Agency's already proposed Frozen Biscuit (67a) and Cookies (77) categories, and move refrigerated biscuit dough and cookie dough from 79 into 67a and 77 respectively
 - Refrigerated biscuit dough is not inherently different in sodium content from frozen biscuit dough, which FDA has already included in 67a; thus it was logical to keep all biscuit dough (refrigerated and frozen) together.
 - Similarly, cookie dough is similar in sodium concentration to RTE cookies, and thus it made sense to keep these like products together in category 77.

Category specific comments: Category 80: Bakery Dry Mixes

GMI recommends similar changes to FDA’s proposed category 80, “Bakery Dry Mixes.” While the leavening systems are similar across this category, the diversity of bakery mixes is driving the wide range in sodium concentrations (50mg-1500mg/100g) seen in FDA’s histogram below (Figure 6). For example, FDA’s proposed category 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/pancake mixes to have the same targets as sweet bakery mixes; GMI’s recommendation is to subdivide this category into 2 categories: dessert baking mixes and variety/pancake baking mixes.

Figure 6. FDA Histogram – Category 80.



In summary, GMI's recommended changes to categories 79 and 80 are below and in greater detail in Appendix 2:

- Category 79 changes:
 - Divide into 2 categories:
 - 79a Frozen/Refrigerated Dough and Batter – non-yeast leavened
 - Description: Frozen or refrigerated dough and batters for non-yeast leavened bread/rolls, pancakes, pizza crust, etc. Includes canned/pressurized dough. Excludes frozen and refrigerated biscuit dough.
 - 79b Frozen/Refrigerated Dough and Batter – yeast leavened and unleavened
 - Description: Frozen or refrigerated dough and batters for yeast leavened bread/rolls, croissants, pie crust and shells, pizza crust, etc. Excludes canned/pressurized doughs, and frozen and refrigerated biscuits dough.
 - Reevaluate the baseline of the new sub-categories (79a and 79b).
 - Move refrigerated biscuit dough to 67a (frozen biscuits and biscuit dough)
 - 67a. Frozen Biscuits
 - Description: Frozen biscuits and frozen and refrigerated biscuit dough. Includes frozen biscuits with cheese and other additions.
 - Reevaluate the category baseline.
 - Move refrigerated cookie dough to 77 (RTE cookies)
 - 77. Cookies.
 - Description: Ready-to-eat cookies and refrigerated/frozen cookie dough. Includes sandwich cookies with filling, wafers, refrigerated cookie dough tubes and pucks, and animal crackers.
 - Reevaluate the category baseline.
- Category 80 changes:
 - Divide into 2 sub-categories:
 - 80a. Dessert Baking Mixes
 - Description: shelf stable dry mixes for bread, cakes, cookies, brownies and other products.
 - Reevaluate the baseline of the expanded category
 - 80b. Variety/Pancake Baking Mixes
 - Description: shelf stable dry mixes for biscuits, pancakes and a variety of other products.
 - Reevaluate the category baseline.

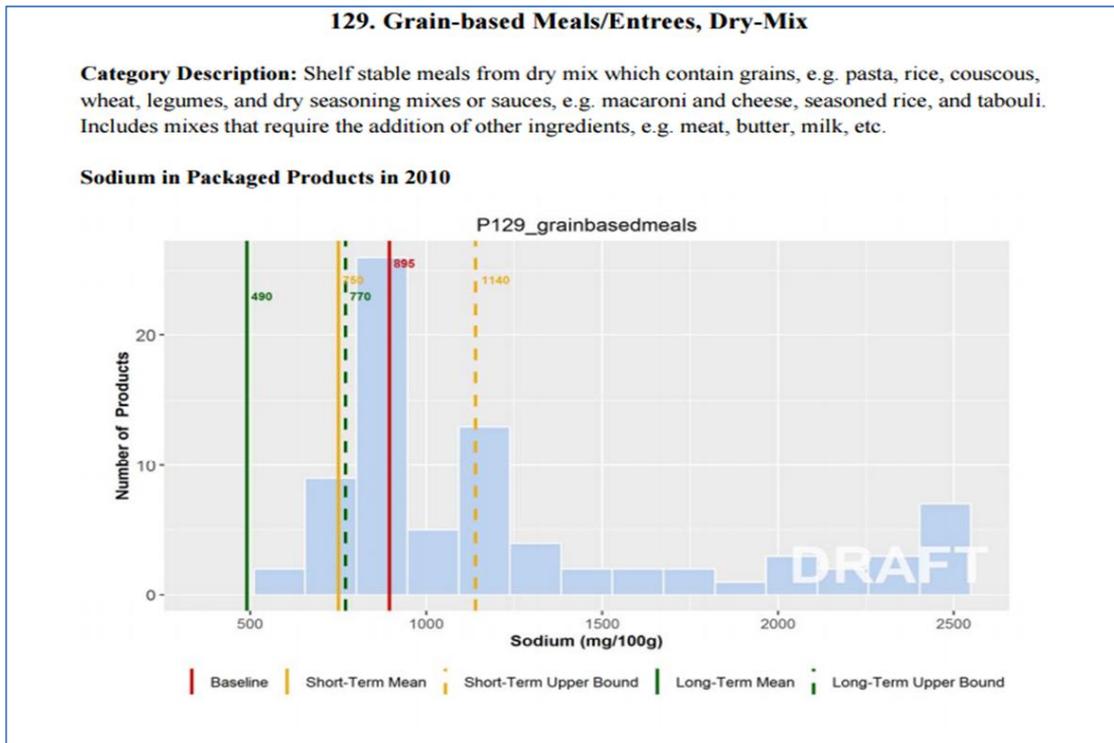
Tortillas are an example of another bakery product where sodium reduction challenges are interrelated and include multiple considerations. For product texture and appearance, tortillas contain both leavening and salt. Sodium bicarbonate is the traditional leavener used and there is not an equal technical solution. Sodium contributes to dough structure, strength and elasticity, so reductions in salt make it difficult to control size and maintain a consistent appearance. Salt also has an important role in reducing undesirable tortilla stickiness. Finally, salt contributes flavor to these basic and products. Industry could achieve the short term targets if given 4 years, but not in 2 years.

Category specific comments: Category 129: Grain-based Meal/Entrees, Dry-Mix

While the products in proposed category 129 may appear to be very similar, they are actually very diverse and represent a wide assortment of products including main courses, entrees, side dishes and salads. Product examples include seasoned rice and pasta side dishes and salads, macaroni and cheese, and pasta based dinner kits requiring the addition of meat. Additionally, FDA’s histogram appears to exclude leading products that would affect the baseline mean. The Helper brand (including Hamburger, Tuna and Chicken Helpers) is a category leader in the grain-based dinner kit category for products requiring the addition of meat/protein and other ingredients, and does not appear to be fully represented.

The wide array of products included in category 129’s description is not aligned with the Agency’s stated objectives for category development. FDA was inconsistent in their approach to this category, as the majority of the other 150 categories are much less diverse, with more homogeneous products and tighter sodium concentration ranges. Sodium concentration ranges in proposed category 129 are extremely wide (500 – 2500mg), making targets unreasonable and unachievable for some products, while other products will have to make little to no sodium reductions to meet goals. FDA’s histogram below (Figure 7) illustrates the wide sodium concentration ranges.

Figure 7. FDA Histogram – Category 129.

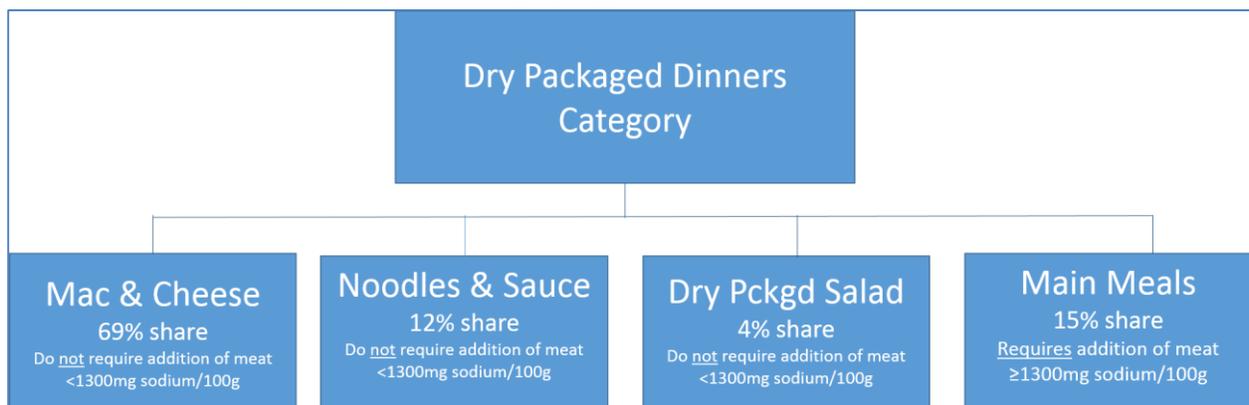


As discussed above, the sodium concentrations in proposed category 129 are so wide they actually serve as a disincentive to industry for making sodium reductions. Targets are unachievable for a significant number of products at the higher end of the range. If FDA’s short term goal is 15% reduction and the specific short term target is 750mg, the majority of products in FDA’s histogram would be required to

make well over a 15% reduction to meet the short term target. In fact, many products would be required to reduce sodium by over 50% to meet the short term targets. Sodium reductions of this magnitude are not feasible or achievable in a short timeframe, and will result in fewer products fulfilling the Agency’s voluntary initiative. In contrast, products at the low end of the range are close to meeting or already meet the targets and will have no incentive to make further sodium reductions.

In reviewing FDA’s histogram and taking into account our understanding of this category, there is a natural “break point” in product sodium concentrations at 1300mg of sodium/100g. This “break point” is driven by added ingredients required to make the products. Products that require the addition of meat and significant quantities of other ingredients (milk, water) have higher sodium concentrations ($\geq 1300\text{mg}/100\text{g}$) because these added ingredients significantly dilute the sodium concentration of the prepared product.⁸ Nielsen segmentation data in Figure 8 below recognizes the distinction among these types of products and aligns with distinguishing between products that require the addition of meat.⁹

Figure 8. Nielsen Dry Package Dinners Category segmentation.



Macaroni & Cheese is its own sub-category, and comprises two-thirds of entire category sales

“Noodles & Sauce” are separate, and includes side dish noodles

“Dry Packaged Salad” includes pasta salad dry mixes.

“Main Meals” are dry mix products that require the addition of meat; General Mills’ Hamburger Helper, Chicken Helper and Tuna Helper brands are category leaders in this segment

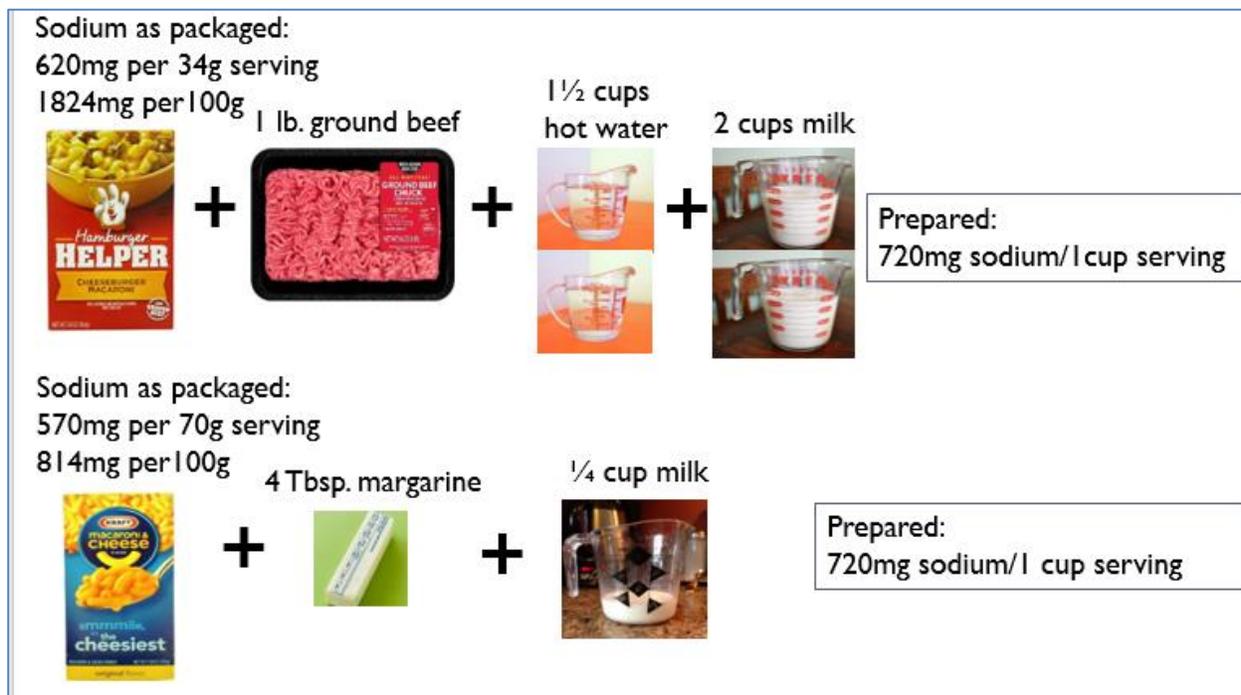
Products in the “Mac & Cheese,” “Noodles & Sauce,” and “Dry Packaged Salad” segments are relatively homogeneous and coincide with sodium concentrations <1300mg/100. Products in these (3) sub-segments are distinct from the “Main Meals” sub-category in that they do not require significant additions of meat/protein and other ingredients to prepare. In contrast, products in the “Main Meals” segment (“Helpers”) coincide with sodium concentrations $\geq 1300\text{mg}/100\text{g}$, and require significant

⁸ GMI recognizes that many products provide multiple recipe options for consumers; some options may require the addition of meat while others do not. The primary recipe should be used to determine whether meat is a required additional ingredient. The primary recipe is generally the first recipe given, and is the recipe on which the Nutrition Facts panel is based

⁹ Nielsen XAOC, 52 weeks ending 10/01/16.

additions of meat/protein and other ingredients which significantly dilute the sodium in the prepared product. The comparison in Figure 9 illustrates the dilution effect of required added ingredients.

Figure 9. Comparison illustrating the dilution effects of required ingredients.



The sodium concentration in the product requiring the addition of meat and other ingredients is significantly diluted, equalizing the sodium concentration per serving. The differing dilution factors between these 2 types of products has not been considered in proposed category 129, but is critical for the Agency to take into account so that sodium reduction targets are reasonable and achievable for both types of products.

If this category remains as proposed, the Hamburger Helper product requires nearly a 60% reduction to meet short term targets, while the Macaroni & Cheese product requires an 8% reduction, yet both deliver the same sodium content as prepared.¹⁰

The Agency has recognized the dilution effect in other categories, specifically:

- Soup: separate categories for canned, condensed soup (#33) and canned, ready-to-eat (RTE) soup (#34).
 - Condensed soup requires the consumer addition of ingredients (liquid), RTE soups do not require the consumer addition of ingredients. FDA’s baseline means and targets reflect this as the sodium mean and targets for condensed soups are significantly higher

¹⁰ Interestingly, if this Hamburger Helper product was prepared and sold in a super market deli or restaurant, it would nearly meet the short term target for category #132, “Grain-based Dishes” (prepared noodle and pasta dishes). If this product was prepared, frozen and sold in category #128, “Frozen Meals/Entrees,” it would require a 20% reduction to meet the short term target.

(roughly twice as high) as those of RTE soup where the sodium concentration has already been diluted with additional ingredients.

- Cooked cereal: separate categories for prepared, cooked cereal (56a) and dry mix instant cereal (56b).
 - Dry mix instant cereal requires the consumer addition of ingredients (liquids), prepared, cooked cereal does not require the consumer addition of ingredients – it already includes the required liquids. Again, the Agency has recognized the dilution effect of the liquid to the sodium concentration of the product as the means and targets for dry mix, instant cereal is significantly higher than the means/targets for prepared cooked cereal where the sodium concentration has been diluted with water.

GMI proposes two options that will address the above concerns about the overly diverse category and wide sodium concentration ranges. Both approaches are based on the above rationale and both will help make sodium reduction goals more reasonable, helping to ensure success for the Agency and Industry (details also provided in Appendix 2).

- ***Option 1.*** Divide the category into 2 sub-categories, each with their own distinct baselines and targets. Dividing the category will make products within the new sub-categories more homogenous, better align the baseline mean with the marketplace, and tighten the range of sodium concentration ranges. FDA will need to reevaluate baselines for both of the new sub-categories. Recommended descriptions for these revised sub-categories follows:
 - Category 129.a: Grain-based Meals/Entrees, Dry-mix, **requiring** the addition of meat/protein
 - Description: Shelf stable meals/products from dry mix which contain grains, e.g., pasta, rice, and dry seasoning mix and/or wet pouch seasoning/sauce that ***require the addition of meat/protein and significant amounts of other added ingredients*** to make the primary recipe (e.g., milk, water, butter, vegetables). Examples include dry pasta or rice dinner kits requiring the addition of hamburger, chicken or tuna.
 - Category 129.b: Grain-based Meals/Entrees, Dry-mix, **not requiring** the addition of meat/protein
 - Description: Shelf stable meals/products which contain grains, e.g., pasta, rice, and dry seasoning mix and/or wet pouch seasoning/sauce that require the addition of added ingredients to make the primary recipe (e.g. milk, water, butter, vegetables). Examples include macaroni and cheese, seasoned rice and tabouli. Excludes products requiring the addition of meat/protein.
- ***Option 2.*** Maintain the category as a single category, but include 2 separate targets based on sodium concentrations using 1300mg/100g as the break point. The revised recommendation category descriptions follow:
 - Category 129. Grain-based Meals/Entrees, Dry-Mix.
 - Description: Shelf stable meals from dry mix which contain grains, e.g. pasta, rice, couscous, wheat, legumes, and dry seasoning mixes or sauces, e.g.

macaroni and cheese, seasoned rice, and tabouli. Includes mixes that require the addition of other ingredients, e.g. meat, butter, milk, etc.

- FDA will need to determine baseline and targets for products <1300mg sodium/100g.
- FDA will need to determine baseline and targets for products ≥1300mg sodium/100g.

For simplicity and consistency reasons, GMI recommends that Mexican dinner kits be exempt from entrée sub-categories. The individual components of these kits (e.g., salsa, taco sauce, taco seasoning mix, hard and/or soft shells/tortillas) are already covered in other FDA categories. Additionally, sodium reduction efforts would be completed on the components, not the kit. It may also be sensible for the Agency to take the same approach with other “kit” products, e.g., Asian kits, lunch box kits, etc.

Recommendation for Combining RTE Cereal, Categories 54 and 55

While some categories are too diverse, there are other categories, such as ready-to-eat (RTE) cereal, that could be combined as products are homogenous, sodium’s functional role in the products is similar and sodium concentration ranges are still reasonable in the combined categories. Combining categories would increase clarity of what products are included and better account for the range of products available in the marketplace.

GMI recommends combining FDA’s two proposed RTE cereal categories (#54 RTE Cereal, Flakes and #55 RTE Cereal, Puffed) into one comprehensive category for the following reasons: sodium’s functional role in all cereal is broadly similar, one category adequately represents all homogeneous and heterogeneous component products, and sodium concentration ranges of a single combined category are reasonable. The RTE cereal marketplace is large, dynamic and evolving. FDA’s current approach does not encompass the array of products available in the marketplace, as many are not “flakes” or “puffs,” but a different process altogether (e.g. latticed) or a combination of technologies and components, e.g. clusters or particulates. FDA’s histograms (Figures 10 and 11) indicate the ranges of sodium concentration would be reasonable, as the “Puffed” cereal range would be addressed in the current “Flakes” histogram.

Figure 10. FDA Histogram – Category 54.

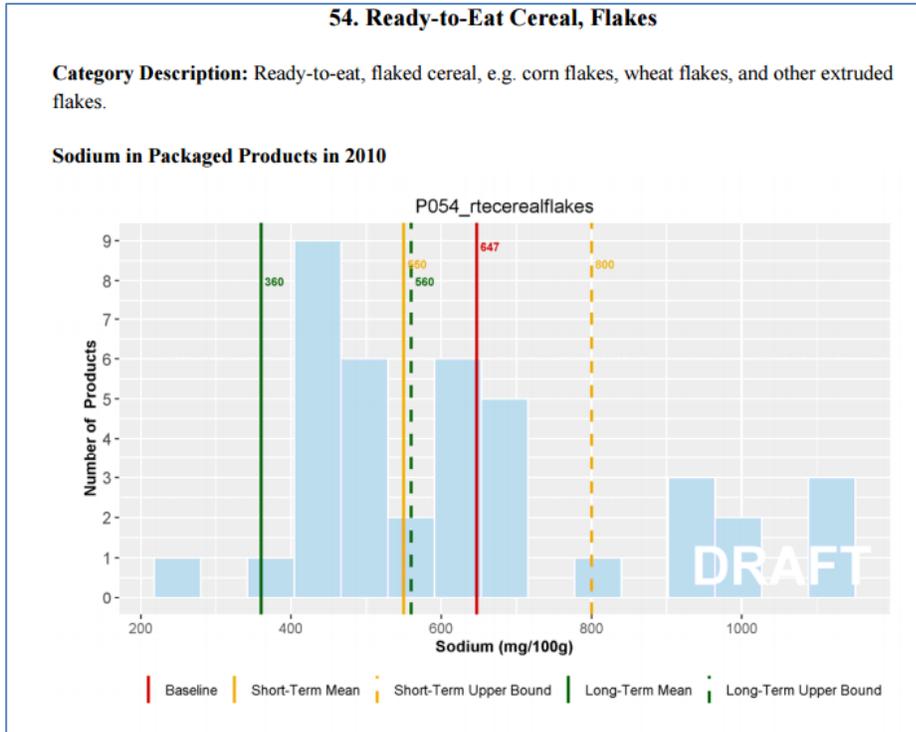
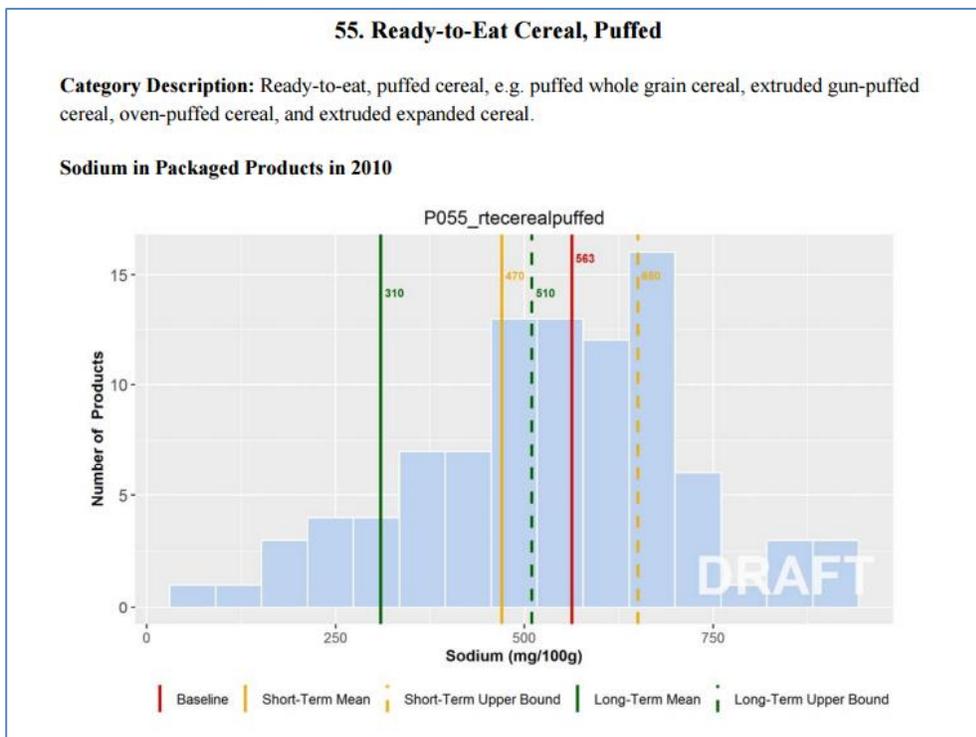


Figure 11. FDA Histogram – Category 55.



Salt and sodium play a number of important roles in cereal manufacturing beyond providing the traditional “salty” taste. These roles are described in detail below and include: functionality, food safety, shelf-life/stability, and simple consumer labeling.

Functionality

- Salt is a flavor modulator, promoting brown and toasted grain flavors.
- Salt has a direct role in masking bitterness from whole grains and balancing overall flavor (the umami aspect of salt)
- Non-salt sodium contributors (e.g. sodium bicarbonate) are present in some cereal formulas and have a functional impact on overall eating experience.
- The cooking process is very important to flavor development in some flaked and puffed cereals. Subsequent to cooking, there is an important toasting step; reducing sodium has a significant impact on the level of “cook” and “toast” that can be achieved when making the cereal.

Food safety, shelf-life and stability

- Salt aids in inhibiting microbial growth in some of our cereal processes.
- The browning reactions play a crucial role in shelf life stability of RTE cereals. As mentioned above, sodium from salt and other water soluble salts helps in browning reactions that aid in the shelf-life and stability of RTE cereals. There has been a direct correlation in some cereals between sodium reduction and a decrease in shelf-life.

Consumer Perspectives

- While products in some categories have been successful in reducing sodium by replacing sodium salts with potassium salts, many salt substitutes and salt enhancers have not been effective from a flavor and stability perspective in cereal. Additionally, these substitutes and enhancers usually do not lend themselves to labeling as “pantry friendly” ingredients.
- The RTE cereal category is somewhat uniquely challenged with balancing sodium and sugar reduction. The Agency should acknowledge the interaction that reducing sodium *and* sugar will have on cereal products. Reducing sodium beyond a certain threshold may limit the ability to achieve and maintain sugar reduction.

GMI recommends merging the 2 cereal categories into 1 category and the description for this new, combined RTE cereal category be (details also provided in Appendix 2):

- Category 54: Ready-to-Eat Cereal
 - Description: All RTE cereals including puffed, flaked, extruded, latticed and multi-component cereals containing particulates, clusters and combinations of these components.
 - FDA will need to recalculate the baseline for the revised category.

Conclusion:

General Mills appreciates the opportunity to provide these comments and looks forward to engaging with the Agency on potential next steps for this voluntary initiative. We look forward to collaborating with FDA in achieving gradual, successful and realistic sodium reductions in the food supply while advancing public health goals for consumers.

Respectfully submitted,

A handwritten signature in black ink that reads "Kathryn L. Wiemer MS, RD". The signature is written in a cursive style.

Kathryn L. Wiemer, MS, RD
Senior Fellow
General Mills Bell Institute of Health and Nutrition

A handwritten signature in black ink that reads "Amy Loew MS, RD". The signature is written in a cursive style.

Amy Loew, MS, RD
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General Mills Bell Institute of Health and Nutrition

Appendix 1.

Methodological Comments – Baseline Categories

FDA's goal for their sodium reduction targets is to reach a population mean intake for sodium of 3,000 mg/day through their 2-year sodium reduction targets and 2,300 mg/day by through their 10-year sodium reduction targets. FDA undertook two modeling exercises (Sections 5.4 and 5.5 of the Draft Guidance document) to evaluate if these FDA sodium initiative draft categories would be effective in helping the population achieve this intake level based on current food intake patterns from the National Nutrition and Health Examination Survey (NHANES), which represents the typical eating habits of U.S. residents on any given day. This modeling work using food intake data is critical to three important components of the sodium reduction initiative: 1) understanding it's public health impact, 2) estimating the efficacy of the sodium targets to lower population sodium intake, and 3) the ability to track progress not only in the sodium content of products but in sodium consumption in the population which may, or may not, align.

Public Health Impact

In order for sodium reduction in a particular food category to have a public health impact, the food category needs two qualities: 1) to be a significant source of sodium and 2) to be consumed frequently in the population. FDA did not provide any category specific results from their modeling exercise, limiting the ability to determine which categories may have the greatest impact on sodium intake. However, we were able to assess the contribution of each FDA sodium reduction target category to total sodium intake using the information provided in the sodium docket on mapping the FNDDS 5.0 food codes to the categories and NHANES 2009-2010 data. We found that several of the FDA categories may not, in fact, have a significant impact on achieving population-level sodium intakes. Approximately 1/3 of the food categories (i.e. 52 categories) contributed 75% of the baseline total sodium intake in NHANES 2009-2010. 111 categories contributed less than 1% to the overall population sodium intake, and 80 categories contributed less than 0.5%, meaning that many of the sodium reduction target categories make a minimal contribution to overall sodium intake (see Appendix 1, Table 1). Therefore, extra attention should be paid to the appropriate development of sodium reduction target categories that contribute proportionally more sodium to the diet. The top 5 FDA sodium initiative target categories contributing to sodium intake in NHANES 2009-2010 were Grain-Based Dishes (contributed 7.0% to total sodium intake), Meat/Poultry-Based Dishes (5.8% of total sodium intake), Pizza: with Meat/Seafood, Frozen and Not-Frozen (4.3% of total sodium intake), White Bread (3.6% of total sodium intake), and Canned, Ready-to-Eat Soup (3.4% of total sodium intake). The bottom 5 categories (other than those with that contain no food codes as detailed below) were Olives with Additions (0.005%), Canned Meat (0.003%), Frozen/Refrigerated Dough and Batter (0.002%), Canned Anchovies (0.0007%), and Baby/Toddler Snacks: Cookies/Biscuits (0.0005%).

Furthermore, the FDA completed their modeling exercise looking at the mean sodium intake for the population that would be achieved if the 2-year and 10-year sodium targets for each food category were achieved. However, the mean population intake does not provide information on what percentage of the population is above this target value. If the distribution of sodium intake in the population was normal, achieving a population mean intake for sodium of 2,300 mg/day would mean that 50% of the

population would still be consuming more than the target amount of sodium. While it was stated in the Draft Guidance that the percentage of the population above the AI (AI for sodium is 1,500 mg/day) for sodium was done, these results were not provided in the Draft Guidance. Therefore, there is currently no estimate provided by the FDA on how these draft sodium category targets would improve the percentage of the population achieving the recommended sodium intake level.

FDA Modeling of Estimated Efficacy of Sodium Category Targets

While FDA undertook both a preliminary and detailed modeling exercise to investigate the impact of their sodium targets and showed that achieving the 10 year targets could lead to a mean population sodium intake of approximately 2,300 mg/day, the modeling did not reflect any possible changes in product selection, food patterns, or discretionary salt use that may occur. In addition, the modeling assumed universal adoption of the sodium target goals by industry. While these issues were highlighted by the FDA, it is worth noting that their modeling of the sodium intakes achieved with the sodium targets would represent a best case scenario of sodium reduction, rather than a conservative estimation. And because FDA used a proprietary database, this limits the ability to verify the findings of the FDA.

In addition to the conceptual issues with the modeling, we have several methodological concerns, specifically regarding the categorization of the FNDDS 5.0 food codes into the sodium target categories. Based on the mapping file provided in the sodium docket, we found that several categories that were not reflective of the products that would actually be contained in the FDA target categories. Multiple FDA sodium target categories contained no FNDDS food codes including 37 Frozen Soups, 38 Refrigerated Soups, 52 Dry Seasonings and Dry Sauce Mix, 53 Batters and Coatings, 80 Bakery Dry Mix, 86 Uncooked Sausage, 102 Canned Poultry, 110 Flavored Potato and Other Vegetable Chips, 120 Dry/Cured Meat-based Sandwiches, 131 Combination Meals/Platters, 136 Seafood-based Dishes with Breading, 140 Lettuce/Green Salads: Without Additions – With Dressing, 142 Grain/Vegetable-Based Salads (see Appendix 1, Table 2). None of these categories, therefore, were modeling as having a sodium reduction and had no impact on the achievement of the population sodium goals. Other categories contain food codes but these foods may be completely unrepresentative of the products that would fit into this category. For example, category #79, Frozen and Refrigerated Dough/Batter only contained two food codes both of which were cookie dough; category #80 Bakery Dry Mix contained no entries; and category #129 Grain-based Meals/Entrees, Dry-Mix included only three food codes all of which were instant white rice which is not representative of the top-selling products in this diverse category. We acknowledge that many of the foods that would be contained in these three categories were captured in other food categories; for example, cakes made from a bakery dry mix would be captured within the Cake category. However, we are not able to know how this would impact the achievement of the population-level sodium target. Overall, there are concerns related to both the importance of certain categories in achieving the target population sodium intake and in how sodium population-level intake will be tracked using NHANES data in the future.

Additionally, there were several other shortcomings to the reporting of the modeling done by FDA. First, while FDA did provide results of their modeling in Table 1 of the Draft Guidance document, they did not

provide detailed category-specific baseline contribution to sodium intake and the corresponding reductions in sodium intake were not shown, making it challenging to understand the relative contribution of each category to sodium intake and their contribution to achieving the 2,300 mg/d level. Second, there were several data reporting errors in Table 1, *Mean modeled sodium intake from food and water with 2010 sales-weighted mean baseline sodium concentrations replaced by short-term and long-term sodium concentration targets in 2018 and 2026, respectively*, including having two 9-13 year age groups with different data being reported, an n value of 3 for females 19+, and a modeled sodium intake value of 141559 mg/day for females age 2-3 years. Third, several foods in the FNDDS 5.0 database contain brand-specific nutrition information (e.g. ready-to-eat cereal and cereal and granola bars). However, since FDA merged their proprietary sodium database and NHANES food intake data and used the broad sodium content values for the food categories from their proprietary database rather than the sodium information in the FNDDS 5.0, they may have used less representative data and reduced the accuracy of their results.

Tracking

Because shifts in population food intake patterns may occur, it is important to track not only changes in the sodium content of packaged and restaurant foods but also the overall population sodium intake. It has been shown that sodium intakes have been consistent over several decades^{11,12} and it is possible that changing the sodium content of some packaged and restaurant foods may result in shifts to other products and/or changes in discretionary salt use. Therefore, it is critical to track population sodium intakes using food intake data from a representative sample of the US population. In order to track the effectiveness of the voluntary targets the following data should be tracked: 1) if products are meeting their category targets tracked using the FDA proprietary data; 2) if the mean population sodium intake decreasing towards the goal of 2300 mg/day tracked using WWEIA/NHANES data; and 3) if sodium intake patterns are shifting tracked using WWEIA/NHANES data. This last piece of data may be difficult to track due to the issues previously addressed in the way FDA mapped food intake data according to the Sodium Reduction Target Food Categories; however all three pieces of tracking information would be critical to understand how effective their initiative was, if any delay in reaching their population-level sodium intake goals are due to compliance issues from the food industry or due to shifting food intake patterns, and if any of the categories/targets need to be adjusted.

¹¹ Bernstein AM, Willett WC. Trends in 24-h urinary sodium excretion in the United States, 1957-2003: a systematic review. *American Journal of Clinical Nutrition* 2010; 92: 1172-1180.

¹² Rehm CD, Penalvo JL, Afshin A, Mozaffarian D. Dietary Intake Among US Adults, 1999-2012. *JAMA* 2016; 315(23): 2542-2553.

Appendix 1, Table 1: Percent Contribution of Sodium Reduction Initiative Targets to Total Sodium Intake in Total Population Age 1 Year and Older in NHANES 2009-2010.¹³

Category Number	Category Name	Number of Individuals Consuming Foods in this Category	Percent of the Population Consuming Foods in this Category	%Contribution to Total Sodium Intake	Cumulative % contribution to Total Sodium Intake
132	Grain-based Dishes	3044	30.9%	7.0%	7.0%
135	Meat/Poultry-based Dishes	1772	21.0%	5.8%	12.8%
145.a and 145.b	Pizza: With Meat/Poultry or Seafood - Frozen/ Not Frozen	927	9.7%	4.3%	17.1%
58	White Bread	3164	34.6%	3.6%	20.7%
34	Canned, Ready-to-Eat Soup	1099	10.2%	3.4%	24.1%
133	Vegetable-based Dishes	2053	22.9%	2.7%	26.8%
147	Tacos, Burritos, and Enchiladas	786	7.7%	2.4%	29.2%
134	Egg-based Dishes	1896	18.5%	2.0%	31.2%
59	Wheat and Mixed Grain Bread	1974	22.9%	2.0%	33.2%
85	Frankfurters, Hot Dogs, and Bologna	737	7.2%	1.7%	34.9%
81	Deli Meats - Ham	599	6.9%	1.7%	36.6%
17	Salad Dressing	1444	19.6%	1.7%	38.2%
47	Condiments	2152	23.7%	1.5%	39.8%
95	Reformed/ Restructured, Breaded/ Battered Chicken	678	6.5%	1.5%	41.2%
146.a and 146.b	Pizza: Without Meat/Poultry or Seafood - Frozen/ Not Frozen	400	4.1%	1.4%	42.6%
84	Deli Meats - Loaves/Mixtures	425	5.6%	1.3%	43.9%
3	Processed Cheese/Cheese Food (Semi-soft)	768	9.7%	1.2%	45.1%
11	Cheddar and Colby Cheese (Hard)	1457	16.0%	1.2%	46.3%
105	Non-Breaded Fish and Other Seafood	486	5.9%	1.1%	47.4%
72	Crackers	1364	15.3%	1.1%	48.5%
55	Ready-to-Eat Cereal, Puffed	1705	16.9%	1.1%	49.6%
87	Precooked Sausage	615	6.0%	1.1%	50.7%
98	Whole Muscle Beef	856	8.7%	1.1%	51.7%

¹³ NHANES 2009-10 (Day 1) data used including total population 1+ years of age.

Category Number	Category Name	Number of Individuals Consuming Foods in this Category	Percent of the Population Consuming Foods in this Category	%Contribution to Total Sodium Intake	Cumulative % contribution to Total Sodium Intake
93.a and 93.b	Boneless, Non-Breaded/Battered, Uncooked or Precooked Poultry	602	7.3%	1.1%	52.8%
127	Hamburgers/ Ground Meat Sandwiches: With Cheese	333	3.3%	1.0%	53.8%
78.a and 78.b	Frozen/ Refrigerated or Prepared Breakfast Bakery Products	703	6.9%	1.0%	54.8%
29	Potato Side Dishes	599	7.3%	0.9%	55.8%
77	Cookies	2115	22.1%	0.9%	56.7%
106	Breaded Fish and Other Seafood	408	4.5%	0.9%	57.6%
26	Fried Potatoes without Toppings	1307	13.2%	0.9%	58.5%
99	Reformed/ Shaped Beef	739	7.9%	0.9%	59.4%
88.a and 88.b	Uncooked or Cooked Bacon	591	6.4%	0.9%	60.4%
92	Bone-in, Breaded/Battered Poultry	559	4.7%	0.9%	61.2%
139	Lettuce/Green Salads: With Additions - Without Dressing	458	5.6%	0.9%	62.1%
70	Tortillas and Wraps	671	5.8%	0.9%	63.0%
74	Cake	839	8.9%	0.9%	63.8%
51	Vegetable/fruit-based Dips	980	9.8%	0.8%	64.7%
119	Poultry/Fish-based Sandwiches	237	2.3%	0.8%	65.5%
137	Seafood-based Dishes - Without Breading	177	2.1%	0.8%	66.3%
94	Boneless, Breaded/Battered Poultry	340	3.6%	0.8%	67.2%
96	Cured/Smoked Pork and Canadian Bacon	206	2.3%	0.8%	67.9%
97	Whole Muscle Pork	577	6.3%	0.8%	68.7%
109	Unflavored Potato and Vegetable Chips	1168	13.4%	0.7%	69.4%

Category Number	Category Name	Number of Individuals Consuming Foods in this Category	Percent of the Population Consuming Foods in this Category	%Contribution to Total Sodium Intake	Cumulative % contribution to Total Sodium Intake
56.a and 56.b	Prepared Cooked or Dry Mix Instant Cereal	708	7.8%	0.7%	70.1%
63	Bagels and Soft Pretzels	357	5.1%	0.7%	70.8%
91	Bone-in, Non-Breaded/Battered Poultry	629	5.8%	0.7%	71.5%
28	Hash Browns and Home Fries	332	4.1%	0.7%	72.1%
30.a and 30.b	Mashed Potatoes, Prepared/ Dry Mix	495	5.3%	0.6%	72.8%
130	Canned Meals	459	4.0%	0.6%	73.4%
67.a and 67.b	Frozen or Prepared Biscuits	303	3.3%	0.6%	74.0%
54	Ready-to-Eat Cereal, Flakes	794	8.2%	0.6%	74.6%
115	Popcorn	583	6.3%	0.6%	75.1%
116	Pretzels	291	4.3%	0.5%	75.7%
23	Pickled Vegetables	366	5.4%	0.5%	76.2%
75	Pastries, Pie, and Cobbler	506	5.6%	0.5%	76.7%
82	Deli Meats - Beef	108	1.5%	0.5%	77.2%
143	Filled Dough Appetizers	226	2.5%	0.5%	77.7%
89	Salami and Pepperoni	123	1.7%	0.5%	78.2%
121	Deli Meat-based Sandwiches	84	1.0%	0.5%	78.6%
39	Soy Sauce	145	1.9%	0.4%	79.0%
33	Canned, Condensed Soup	122	1.5%	0.4%	79.5%
111	Unflavored Grain Chips	826	9.1%	0.4%	79.9%
4	Monterey Jack and Other Semi-soft Cheese	325	4.1%	0.4%	80.3%
18	Frozen Vegetables and Legumes	378	4.7%	0.4%	80.7%
31	Nuts and Seeds	508	7.2%	0.4%	81.1%
19	Canned Vegetables	484	5.3%	0.4%	81.5%
8	Pasta Filata Cheese (Soft)	464	5.0%	0.4%	81.8%
128	Frozen Meals/Entrees	111	1.5%	0.4%	82.2%
123	Breakfast Sandwiches on Biscuits	80	0.9%	0.4%	82.6%

Category Number	Category Name	Number of Individuals Consuming Foods in this Category	Percent of the Population Consuming Foods in this Category	%Contribution to Total Sodium Intake	Cumulative % contribution to Total Sodium Intake
10	Cottage and Other Soft Cheese	253	2.3%	0.3%	82.9%
32	Nut/Seed Butters and Pastes	724	9.1%	0.3%	83.2%
113	Puffed Corn Snacks	429	3.7%	0.3%	83.6%
138	Lettuce/Green Salads: With Additions - With Dressing	238	2.8%	0.3%	83.9%
65	Sweet Rolls	513	4.4%	0.3%	84.2%
126	Hamburgers/ Ground Meat Sandwiches: Without Cheese	138	1.4%	0.3%	84.5%
69	Muffins	177	2.4%	0.3%	84.8%
60	Garlic and Cheese Bread	218	2.6%	0.3%	85.1%
68	Cornbread	157	1.7%	0.3%	85.4%
76	Donuts	341	3.4%	0.3%	85.7%
124	Breakfast Sandwiches Not on Biscuits	86	1.0%	0.3%	85.9%
48	Cheese-based Dips	58	0.9%	0.3%	86.2%
46	Gravy	293	3.0%	0.3%	86.5%
14	Butter	938	11.8%	0.3%	86.7%
40	Asian-style Sauce	112	1.2%	0.2%	86.9%
15	Margarine and Vegetable Oil Spreads	913	11.2%	0.2%	87.2%
24	Vegetable Juice	78	1.2%	0.2%	87.4%
83	Deli Meats -Turkey/Chicken	103	1.2%	0.2%	87.6%
61	Rye Bread	113	1.8%	0.2%	87.8%
16	Mayonnaise and Other Sandwich Spreads	837	10.0%	0.2%	88.0%
122	Hot Dogs on Buns and Corn Dogs	88	1.0%	0.2%	88.2%
57	Cereal and Granola Bars	404	6.1%	0.2%	88.4%
112	Flavored Grain Chips	210	2.2%	0.2%	88.6%
144	Cheese-based Appetizers	41	0.6%	0.2%	88.7%
118	Beef/Pork-based Sandwiches	50	0.6%	0.1%	88.9%
104	Meat Substitutes and Analogues	51	0.9%	0.1%	89.0%
27	Fried Potatoes with Toppings	34	0.3%	0.1%	89.2%

Category Number	Category Name	Number of Individuals Consuming Foods in this Category	Percent of the Population Consuming Foods in this Category	%Contribution to Total Sodium Intake	Cumulative % contribution to Total Sodium Intake
13	Parmesan and Other Hard Cheese	228	2.8%	0.1%	89.3%
21	Olives without Additions	133	2.0%	0.1%	89.4%
43	Tomato-based Sauce	123	1.5%	0.1%	89.5%
90	Jerky and Prosciutto	40	0.7%	0.1%	89.7%
35	Dry Mix Soup	50	0.4%	0.1%	89.8%
49	Cream-based Dips	87	1.3%	0.1%	89.9%
64	English Muffins	109	1.9%	0.1%	90.0%
117	Snack Mixes	81	0.9%	0.1%	90.1%
41	Mexican-style Sauce	162	1.2%	0.1%	90.2%
25	Battered/ Breaded Vegetables	102	1.2%	0.1%	90.3%
6	Cheese Spreads/Other Spreadable Cheese (Soft)	61	0.8%	0.1%	90.4%
5	Cream Cheese (Soft)	217	2.7%	0.1%	90.5%
12	Swiss and Swiss-type Cheese (Hard)	186	2.9%	0.1%	90.5%
107	Canned Fish and Seafood	40	0.5%	0.1%	90.6%
73	Cheesecake	58	0.8%	0.1%	90.7%
20	Sauerkraut	19	0.5%	0.1%	90.7%
50	Bean-based Dips	61	0.9%	0.1%	90.8%
71	Hard Taco Shells	114	0.8%	0.1%	90.8%
62	Breadcrumbs and Croutons	118	1.7%	0.1%	90.9%
9	Feta Cheese (Soft)	32	0.6%	0.0%	90.9%
101	Canned Sausage	20	0.1%	0.0%	91.0%
66	Croissants	60	0.6%	0.0%	91.0%
125	Vegetarian Sandwiches	13	0.2%	0.0%	91.0%
2	Gouda and Edam Cheese (Semi-soft)	16	0.3%	0.0%	91.1%
36	Shelf Stable Liquid Broth and Stock	20	0.2%	0.0%	91.1%
44	Cheese-based Sauce	42	0.4%	0.0%	91.1%
1	Blue/Blue-Veined Cheese (Semi-soft)	20	0.3%	0.0%	91.2%
7	Brie and Other Ripened Cheese (Soft)	42	0.5%	0.0%	91.2%

Category Number	Category Name	Number of Individuals Consuming Foods in this Category	Percent of the Population Consuming Foods in this Category	%Contribution to Total Sodium Intake	Cumulative % contribution to Total Sodium Intake
129	Grain-based Meals/Entrees, Dry- Mix	18	0.2%	0.0%	91.2%
42	Pesto	13	0.2%	0.0%	91.2%
141	Seafood/Meat-Based Salads	15	0.2%	0.0%	91.2%
45	Cream-based Sauce	23	0.2%	0.0%	91.2%
103	Bacon Bits/Pieces	30	0.4%	0.0%	91.2%
114	Puffed Rice Snacks	33	0.5%	0.0%	91.3%
148	Toddler Meals and Entrees	12	0.1%	0.0%	91.3%
22	Olives with Additions	5	0.1%	0.0%	91.3%
100	Canned Meat	2	0.0%	0.0%	91.3%
79	Frozen/ Refrigerated Dough and Batter	3	0.1%	0.0%	91.3%
108	Canned Anchovies	2	0.0%	0.0%	91.3%
149	Baby/Toddler Snacks: Cookies/ Biscuits	10	0.0%	0.0%	91.3%
37	Frozen Soup	0	0.0%	-	91.3%
38	Refrigerated Soup	0	0.0%	-	91.3%
52	Dry Seasoning and Dry Sauce Mixes	0	0.0%	-	91.3%
53	Batters and Coatings	0	0.0%	-	91.3%
80	Bakery Dry Mixes	0	0.0%	-	91.3%
86	Uncooked Sausage	0	0.0%	-	91.3%
102	Canned Poultry	0	0.0%	-	91.3%
110	Flavored Potato and Vegetable Chips	0	0.0%	-	91.3%
120	Dry/Cured Meat-based Sandwiches	0	0.0%	-	91.3%
131	Combination Meals/Platters	0	0.0%	-	91.3%
136	Seafood-based Dishes - With Breading	0	0.0%	-	91.3%
140	Lettuce/Green Salads: Without Additions - With Dressing	0	0.0%	-	91.3%
142	Grain/ Vegetable-Based Salads	0	0.0%	-	91.3%
	Total	9317	100%	100.0%	91.3%

Appendix 1, Table 2: Sample of Sodium Reduction Target Categories that Contain Unrepresentative Food Codes from FDA Mapping¹⁴

Sodium Reduction Category	FNDDS 5.0 Food Codes Assigned
37 Frozen Soups	No Food Codes Assigned
38 Refrigerated Soups	No Food Codes Assigned
52 Dry Seasonings and Dry Sauce Mix	No Food Codes Assigned
53 Batters and Coatings	No Food Codes Assigned
79 Frozen and Refrigerated Dough/Batter	53100070, Cake batter, raw, not chocolate 53200100, Cookie, batter or dough, raw, not chocolate
80 Bakery Dry Mix	No Food Codes Assigned
86 Uncooked Sausage	No Food Codes Assigned
102 Canned Poultry	No Food Codes Assigned
110 Flavored Potato and Other Vegetable Chips	No Food Codes Assigned
120 Dry/Cured Meat-based Sandwiches	No Food Codes Assigned
131 Combination Meals/Platters	No Food Codes Assigned
136 Seafood-based Dishes with Breading	No Food Codes Assigned
140 Lettuce/Green Salads: Without Additions – With Dressing	No Food Codes Assigned
142 Grain/Vegetable-Based Salads	No Food Codes Assigned
129 Grain-based Meals/Entrees, Dry-Mix	56205430, Rice, white, cooked, instant, fat added in cooking 56205440, Rice, white, cooked, converted, fat added in cooking 56205550, Rice, brown, cooked, instant, fat added in cooking

¹⁴ <https://www.regulations.gov/document?D=FDA-2014-D-0055-0410>

Appendix 2: General Mills detailed category descriptions

FDA Category #	FDA Category Name	FDA Category Description	General Mills' Recommended Changes to Category Description
30.b	Mashed Potatoes, Dry Mix	Dry mix mashed potatoes, with or without additions	Expand description: <ul style="list-style-type: none"> • Dry mix mashed potatoes and casserole-style potatoes, with or without additions. • Recalculate the baseline for the revised category.
54	Ready-to-Eat Cereal, Flakes.	Ready-to-eat, flaked cereal, e.g. corn flakes, wheat flakes, and other extruded flakes.	Merge 2 cereal categories into 1 category: Category 54: Ready-to-Eat Cereal <ul style="list-style-type: none"> • Description: All RTE cereals including puffed, flaked, extruded, latticed and multi-component cereals containing particulates, clusters and combinations of these components. • Recalculate the baseline for the revised category.
55	Ready-to-Eat Cereal, Puffed.	Ready-to-eat, puffed cereal, e.g. puffed whole grain cereal, extruded gun-puffed cereal, oven-puffed cereal and extruded expanded cereal.	
57.	Cereal and Granola Bars.	Bars with cereal and/or granola.	Expand description: <ul style="list-style-type: none"> • Expand category description to reflect the expanded marketplace • Recalculate the baseline for the revised category.
67.a	Frozen Biscuits	Frozen biscuits and biscuit dough. Includes frozen biscuits with cheese and other additions.	Expand description: <ul style="list-style-type: none"> • Frozen biscuits and frozen and refrigerated biscuit dough. Includes frozen biscuits with cheese and other additions. • Recalculate the baseline for the revised category.
77	Cookies	Ready-to-eat cookies. Includes sandwich cookies with filling, wafers, and animal crackers.	Expand description: <ul style="list-style-type: none"> • Ready-to-eat cookies and refrigerated/frozen cookie dough. Includes sandwich cookies with filling, wafers, refrigerated cookie dough tubes and pucks, and animal crackers. • Recalculate the baseline for the revised category.
79	Frozen/Refrigerated Dough and Batter	Description: Frozen or refrigerated dough and batters for bread/rolls, cookies, croissants, pancakes, pie shells, pizza crust, etc. Excludes frozen biscuit dough (see 67.a).	Divide into 2 sub-categories: <p>79a. Frozen/refrigerated Dough and Batter – non-yeast leavened</p> <ul style="list-style-type: none"> • Description: Frozen or refrigerated dough and batters for non-yeast leavened bread/rolls, pancakes, pizza crust, etc. Includes canned/pressurized dough. Excludes frozen and refrigerated biscuit dough. • Recalculate the baseline for the revised category. <p>79b. Frozen/Refrigerated Dough and Batter – yeast leavened and unleavened</p> <ul style="list-style-type: none"> • Description: Frozen or refrigerated dough and batters for yeast leavened bread/rolls, croissants, pie crust and shells, pizza crust, etc. Excludes canned/pressurized doughs and frozen and refrigerated biscuit dough. • Recalculate the baseline for the revised category.
80	Bakery Dry Mixes	Shelf stable dry mixes for bread, cakes, cookies, pancakes, etc.	Divide into 2 sub-categories: <p>80a. Dessert Baking Mixes</p> <ul style="list-style-type: none"> • Description: shelf stable dry mixes for bread, cakes, cookies, brownies and other products. • Recalculate the baseline for the revised category <p>80b. Variety/Pancake Baking Mixes</p> <ul style="list-style-type: none"> • Description: shelf stable dry mixes for biscuits, pancakes and other products. • Recalculate the baseline for the revised category

FDA Category #	FDA Category Name	FDA Category Description	General Mills' Recommended Changes to Category Description.
129	Grain-based Meals/Entrees, Dry-Mix	Shelf stable meals from dry mix which contain grains, e.g. pasta, rice, couscous, wheat, legumes, and dry seasoning mixes or sauces, e.g. macaroni and cheese, seasoned rice, and tabouli. Includes mixes that require the addition of other ingredients, e.g. meat, butter, milk, etc.	<p>Option 1: Divide into 2 sub-categories: Category 129.a: Grain-based Meals/Entrees, Dry-mix, requiring the addition of meat/protein</p> <ul style="list-style-type: none"> Description: Shelf stable meals/products from dry mix which contain include grains, e.g., pasta, rice, couscous, wheat, legumes and dry seasoning mix and/or wet pouch seasoning/sauce that require the addition of meat/protein and significant amounts of other added ingredients to make the primary recipe (e.g. milk, water, butter, vegetables). Examples include dry pasta or rice dinner kits requiring the addition of hamburger, chicken or tuna. Recalculate the baseline for the revised category. <p>Category 129.b: Grain-based Meals/Entrees, Dry-mix, not requiring the addition of meat/protein</p> <ul style="list-style-type: none"> Description: Shelf stable meals/products from dry mix which include grains, e.g., dry pasta, rice, couscous, wheat, legumes and dry seasoning mix and/or wet pouch seasoning/sauce that require the addition of added ingredients to make the primary recipe (e.g. milk, water, butter, vegetables). Examples include macaroni and cheese, seasoned rice, and tabouli. Excludes products requiring the addition of meat/protein. Recalculate the baseline for the revised category. <p>Option 2: Maintain the category as a single category, but include 2 separate targets based on sodium concentrations using 1300mg/100g as the break point.</p> <ul style="list-style-type: none"> FDA will need to determine baseline and targets for products <1300mg sodium/100g. FDA will need to determine baseline and targets for products ≥1300mg sodium/100g.