January 13, 2025

Submitted electronically via regulations.gov

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

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Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry (Edition 2); Availability; Docket No. FDA-2014-D-0055

Dear Sir or Madam:

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) draft guidance for industry entitled "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Edition 2)." As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

FMI shares FDA's public health goal of reducing sodium content in foods. Many FMI members have made longstanding public commitments to reducing sodium, and have made significant progress in those efforts, long before FDA published its Phase I or draft Phase II targets.

As an overarching comment, FMI appreciates FDA's statements in the draft guidance regarding the importance of gradual reductions in sodium, which continues to be a critical theme for sodium reduction in foods. A gradual approach is necessary to maintain consumer acceptance and provide time for technology to develop and advance, while also taking into account the significant resources and time needed – typically between 1.5 and 3 years for a single product – for product reformulation. In its notice, FDA states, "[o]ur goal is to further encourage gradual, efficient reduction of overall sodium content using effective and sustainable strategies that maintain other measures of nutritional quality." Further, FDA has indicated that the Phase II goals are "intended to balance the need for broad and gradual reductions in sodium and what is publicly known about technical and market constraints on sodium reduction and reformulation." The agency also recognizes the role of sodium in foods for microbial safety, stability, and various other functions. FMI appreciates FDA's thoughtful consideration of these important aspects, as they remain key factors in our ability to reduce sodium in foods.

FMI also strongly supports the decision to continue to pursue voluntary sodium targets, as opposed to a mandatory approach, as well as FDA's comments in its Federal Register notice[1] that any future guidance on long-term sodium reductions, would be issued in draft form, rather than final. We appreciate the opportunity to provide additional comments on the long-term targets, once FDA publishes a future draft guidance. This approach appropriately recognizes the need for a robust evaluation of the impact of the previous phase(s) of targets – not only on the sodium content of foods but also on population-wide intake of sodium – before finalizing additional phases of targets. It also is consistent with the FY 2024 consolidated appropriations bill language directing FDA not to finalize long-term targets until an assessment of the impacts of the short-term targets has been completed,[2] as well as the similar language currently being considered for inclusion in the FY 2025 agriculture appropriations bill. More broadly, we support FDA's decision to apply a gradual, phased approach on continued reduction targets toward FDA's eventual population intake goal of 2,300mg/day. We are supportive of this iterative process. Compared with FDA's previous stated approach to issue consider "short-" and "long-term" targets, an iterative approach better allows FDA and industry to continuously evaluate comments, set targets, evaluate progress, and adjust as needed based on remaining technical barriers and changes in consumer demand.

Below we provide a top-line summary of our comments, followed by our more detailed comments.

Executive Summary

1. FDA's Evaluation of Progress Toward Phase I Targets:
    a. FDA's evaluation of progress toward the Phase I Targets should be updated to account for 2023 and 2024 product nutrition data. FMI recommends that before finalizing the Phase II goals, FDA should evaluate and publish its findings on the impact of the Phase I goals. The Phase II goals should be informed by this assessment.
    b. FMI asks FDA to conduct and publish an assessment of whether the targets are impacting consumer intake of sodium, before proceeding with further targets.
2. Timeframe for Implementation of Phase II Targets: A 3-year timeframe is not sufficient to achieve the Phase II targets. Given the need for between 18 and 36 months to complete a *single* product reformulation, as well as the need to develop new

[1] 89 Fed. Reg. 66727, 66729 (Aug. 16, 2024) ("We note that we do not intend to finalize the draft long-term (10-year) sodium reduction goals that were included in the 2016 draft of the first edition of the guidance that we announced in the Federal Register of June 2, 2016 (81 FR 35363). We plan to announce any future sodium reduction goals via draft guidance").

[2] H.R. 4366 Consolidated Appropriations Act, 2024, section 763, available at https://www.congress.gov/bill/118th-congress/house-bill/4366.

technologies to achieve further sodium reductions in certain categories, we request the Phase II targets be considered effective 5 years after the final guidance is issued

3. Comments on Phase II Targets:
    a. Feasibility: Technology does not exist today to achieve the level of sodium reduction envisioned by the Phase II targets, especially in such a short time. Beyond the reductions the industry has already achieved, it will be difficult to do more without new tools, particularly in the bakery category, certain dairy categories, and certain meat categories, among others.
    b. Methodology: FMI requests clarification on how FDA determined the percent reduction in sodium from baseline for each category, including the rationale for some categories having steeper reductions than others (including in some instances where the particular category has a relatively small contribution to daily sodium intake), as well as the rationale for the upper bound targets.
    c. Other Nutritional Standards: FDA should consider how the sodium targets intersect with other FDA nutritional policies, including the low sodium definition.
    d. Comments on Phase II targets for specific categories.
4. Salt Substitutes in Standardized Foods. FMI urges FDA to finalize its proposed rule allowing salt substitutes in standardized foods, as sodium reduction is stalled in these categories without the ability to use salt substitutes in product reformulation efforts.
5. Consumer Education. Reducing sodium consumption is multi-faceted and ultimately will require more than reformulation of products. Consumer education is critical to ensure that consumers are mindful about sodium consumption and the role of sodium within a healthy dietary pattern. We ask FDA to include a discussion of this in the final guidance, and to also commit to providing this type of consumer education as a companion effort to the voluntary sodium reduction targets.

Detailed Comments

1. *FDA's Evaluation of Progress Toward the Phase I Targets*

a. FDA's evaluation of progress toward the Phase I Targets should be updated to account for 2023 and 2024 data.

We understand that in its "Sodium Reduction in the U.S. Food Supply 2010-2022: A Preliminary Assessment of Progress", the agency relied upon public information (e.g., product labels and menus in the marketplace), rather than analytical testing of food products; and further that the data relied upon is from 2010-2022, but does not reflect 2023 or early 2024 data. We also understand that this assessment is considered preliminary in nature, and that the agency intends to update the assessment once data from 2023 and 2024 becomes available, repeating the assessment roughly every 3 years.

FMI strongly supports FDA's plan to update the assessment to include 2023 and 2024 data. Because the target completion date for the Phase I targets was April 2024, we suspect that the preliminary assessment does not reflect the vast majority of sodium reductions that were undertaken in direct response to the Phase I targets published by FDA in October 2021. Given the time needed to reformulate and commercialize a food product, we anticipate that the very earliest any products that were reformulated in response to the final guidance would have been on the marketplace in 2023. This means, in effect, that the targets in the draft guidance are based on insufficient data that does not reflect industry's full efforts to meet the targets established as part of Phase I.

FMI recommends that before finalizing the Phase II goals, FDA should evaluate and publish its findings on the impact of the Phase I goals. The Phase II goals should be informed by this assessment.

As the Agency has pointed out, industry has made significant progress on reducing sodium and achieving FDA's Phase I voluntary targets. Specifically, FDA noted in its preliminary assessment that, "overall, 40% of food categories has already achieved Phase I sodium targets or were within 10% of meeting the targets." The decreases in sodium content for many categories observed between 2010-2022 show that industry's commitment to sodium reduction began long before the Phase I targets were issued. Notably, this progress was achieved in the face of significant headwinds, as FDA finalized the Phase I targets in October 2021, when the world was still in the midst of the Covid 19 pandemic.

As FDA conducts the assessment of the updated data through 2024, we ask the agency to keep a few key points in mind:

- <u>The data from 2023 and 2024 may not reflect all reformulations undertaken in response to the Phase I targets</u>. In particular, products reformulated to meet the Phase I targets may not yet have made their way into distribution by April 2024, depending on existing inventory levels. Further, the product labels may not always reflect reductions in sodium that have been made to the formulation. Where a product has been reformulated to achieve a small reduction in sodium content that is within the allowance for reasonable deficiencies of sodium under labeled amounts within good manufacturing practice,[3] and there are no other changes in the ingredient labeling, the label may not immediately be updated to reflect the slightly lower sodium content.

- <u>Industry had requested more than 2.5 years to implement the Phase I targets</u>. FDA initially proposed a 2-year timeframe for the short-term (Phase I) sodium reductions, and industry responded in turn by requesting at least 4 years, with an additional year for the reformulated products to become visible in the marketplace and noting that the draft

[3] 21 CFR 101.9(g)(6) ("Reasonable deficiencies of calories, total sugars, added sugars, total fat, saturated fat, trans fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice").

targets would require longer for certain categories. While we appreciated the slightly longer timeframe of 2.5 years provided by FDA in the final guidance, the time available to meet the Phase I targets was still significantly shorter than the period industry had forecasted would be necessary – and as noted above the supply chain disruptions caused by the COVID-19 pandemic meant that the actual time needed was even longer than industry had originally predicted. As noted above, a single reformulation can take between 18 months and 36 months, and given the personnel resources and testing needed for each recipe, it is not feasible for companies to conduct all reformulations together at the same time for all covered product categories. Any evaluation of the progress made in 2022-2024 must take this into account.

- The reductions since 2010 reflect 12 years – or as of 2024, 14 years – of time to reformulate; additional reductions of the same magnitude cannot be accomplished in a few years' time. We were pleased to see that many categories of foods have lower average sodium levels than in 2010. We recognize, however, that this represents a 12-year period. Once FDA updates the data to reflect 2023 and 2024 information, the progress report will reflect a 14-year period. It is important to recognize that sodium reduction efforts naturally started with the "lowest hanging fruit" – i.e., categories where sodium could be reduced (either through lowering the amount of salt, or replacing it in part with potassium chloride, spices, or other ingredients), and only taste would be impacted. With those low hanging reformulations accomplished, the next phases of sodium reduction – i.e., those where sodium is serving a more complex role in the formulation or there would be more significant impacts on flavor or taste – will be more challenging. We ask FDA to keep in mind that additional reductions of the magnitude seen over a 12- or 14- year timeframe cannot simply be repeated in the 3-year timeframe proposed for the Phase II targets. This is both because of the short time period, and also because the marginal ability to decrease sodium further is much lower with the second round of reformulations.

- During the 2010-2024 timeframe, industry has not had the ability to use salt substitutes in certain standardized foods. As discussed elsewhere in these comments, FDA has not yet finalized its proposed rule to allow the use of salt substitutes in standardized foods. As a result, industry lacked a critical tool to reduce sodium in standardized foods. We urge FDA to finalize this proposed rule as soon as feasible so that companies may begin reformulating standardized foods by using salt substitutes. The positive potential impact of this action would extend beyond the FDA target categories that apply directly to standardized foods (e.g., cheeses, etc.) since products in other FDA target categories often include foods subject to a standard of identity as ingredients. These ingredients can often be significant contributors to overall sodium values in other target categories such as sauces, dips, sandwiches, mixed ingredient dishes, and other combination foods.

FMI also would like to offer comments on some of the specific findings of the progress report.

- Soups: We suspect that FDA's 2022 baseline for the ready-to-eat (RTE) soup category (category #39) may be incorrect. Given the significant work to reduce sodium in this category over the period between 2010 and 2022, we expect that sodium content of this category, on average, would have decreased. We ask FDA to revisit its calculation for this category to confirm the accuracy of the new 2022 baseline number.

- Sauces/gravies/condiments/seasonings: This broad category showed an increase in average sodium content between 2010 and 2022. We note that the items in this category are consumed in small amounts, meaning their contribution to overall sodium intake is likely proportionally smaller. The Phase I targets for these categories were very strict, and as a result it was a category where sodium reduction was particularly difficult. Indeed, this is one of the categories where industry had commented that the draft Phase I short-term targets would not be achievable, even with four years' time. We ask FDA to consider if any of the sub-categories should be considered "non-target categories" since they are consumed in small amounts and contribute less to the overall sodium intake.

- Sales weighted average: In some cases, we observed that the average sodium content for a category is impacted more by the sales volume of one or more particular products, or by the mix of the category (e.g., new products now included in the category), rather than being driven solely by the overall levels of sodium. For instance, if within a particular category one item became particularly popular, it could pull up the average sodium content, even if other significant market leaders reduced sodium by 10%. We therefore ask that FDA consider establishing a process to address marketplace shifts and dynamics as part of its evaluation of industry's progress in implementing the sodium guidance. Marketplace shifts can have a significant impact on average sodium content, and this is particularly true for Phase II targets and beyond, because changes in consumer buying patterns and product innovations could expand with the longer timeframe.

b. FMI urges FDA to evaluate population-wide sodium intake before proceeding with further sodium reduction targets.

In addition to updating its progress assessment to include 2023 and 2024 data, FMI strongly encourages the agency to evaluate population-wide sodium intake following implementation of the Phase I targets. Specifically, we ask FDA to conduct an assessment of whether the targets are actually impacting consumer intake of sodium, before proceeding with finalizing further targets. To some extent this could be assessed by monitoring sales in the marketplace of reduced sodium items, but this would not address the amount of sodium intake in the overall diet for an individual.

Without data on consumer intake of sodium, we cannot know whether consumers are choosing the newly reformulated lower-sodium products in a way that positively impacts their overall sodium intake, nor can we know whether consumers are replacing the sodium removed from these products with other foods – such as higher-sodium restaurant or packaged food items –

or adding additional salt at the table. Accordingly, this data is needed to know whether reductions in the sodium content of foods, translate into reduced sodium intake across the population.

Relatedly, we encourage FDA to invest in research into how consumers respond to lower sodium products, including whether consumers provided a lower sodium food item have a lower overall sodium intake level, both on a short-term and longer-term basis.

2. ***Timeframe for Phase II Targets*. A 3-year timeframe is not sufficient to achieve the Phase II targets. Given the need for between 18 and 36 months to complete a *single* product reformulation, as well as the need to develop new technologies to achieve further sodium reductions in certain categories, we request that the Phase II targets be considered effective 5 years after the final guidance is issued.**

We appreciate that FDA has proposed a 3-year timeframe for the Phase II targets, which is slightly longer than the 2.5 year period for the Phase I targets. Nevertheless, the draft Phase II targets are not achievable in a 3-year timeframe. For many categories, the targets are significantly lower than the 2022 baseline and cannot be achieved without new technologies, which will take time to develop. Even for those categories where reformulations could in theory be accomplished using existing technologies, a 5-year period is needed to develop, test, and commercialize the massive amount of reformulation envisioned by the targets. As noted, a single reformulation takes an average of 18 months to 3 years, and that is assuming that the technology exists to accomplish the reduction without sacrificing quality, safety, and other important organoleptic properties such as texture and flavor.

The reformulations conducted by industry to date to reduce sodium have focused on "low hanging fruit" – for example, the use of existing technologies and ingredients (particularly potassium chloride and spices), and in product matrices where sodium is primarily being used for flavor/taste, rather than serving another functional element (e.g., texture, leavening, dough strengthening). When sodium performs a technical function in the product, reformulation is much more challenging and new technologies or ingredients may need to be developed. Further, items that were recently reformulated in response to the Phase I targets are just now hitting store shelves, and it is important from a commercialization perspective to evaluate whether consumers accept these products and allow consumers' palettes to adjust before doing further reformulations. There also are sustainability considerations to keep in mind, as discarding significant packaging and ingredient inventory due to a slight reduction in sodium, is not a practice that would be beneficial with respect to sustainability. All of these factors result in the need for a longer timeframe to reformulate products to meet the Phase II targets.

3. ***Comments on Proposed Phase II Targets***

    a. **Feasibility: Technology does not exist today to achieve the level of sodium reduction envisioned by the Phase II targets, especially in such a short**

time. Beyond the reductions the industry has already achieved, it will be difficult to do more without new tools.

FDA states in the draft guidance that the Phase II targets should be feasible based on current products in marketplace: "In setting these target means, FDA has taken into account concentrations necessary to achieve important food safety functions (e.g., antimicrobial) and functionality roles. The Phase II targets are intended to be feasible using existing technology and are within the range of currently available top-selling commercial products." As previewed above, we do not agree that the Phase II targets are broadly feasible using existing technologies, particularly in the timeframe proposed. Beyond the reductions in sodium the industry has already achieved, it will be difficult to do more without new tools. Further, we disagree that in all cases, the agency has fully accounted for the concentrations necessary to achieve food safety and other functions.

To provide a few examples, sodium chloride plays a critical and multi-functional role in cheesemaking, including rind formation for brine-salted cheeses, inhibiting the growth of microorganisms, ripening, contributing to the texture of the final cheese by affecting how the fats and proteins break down within the cheese as it ages, water binding, and enhancing the flavor and taste of the cheese. In certain meat products like sausage and bacon, further reductions are challenging with current technologies, as sodium chloride is used for its binding abilities, preservation, and other functions. In products that require sodium as a moisture retention agent, it can be challenging to find another alternative that serves the same function. We request clarification on how FDA is assessing feasibility. The existence of a single product within a category that meets the Phase II targets does not signal that the levels are feasible for the category as a whole. Rather, we anticipate that FDA would want to see that significant top-selling products in each category have achieved a target in order to consider it feasible. Moreover, simply because industry meets the Phase I target for a particular category, or has reduced average sodium content since 2010, does not necessarily mean a further reduction is possible, particularly without losing consumer acceptance or making unacceptable sacrifices in texture, quality, functionality, etc.

b. Methodology: FMI requests clarification on how FDA determined the percent reduction in sodium from baseline for each category, including the rationale for some categories having steeper reductions than others; as well as the rationale for the upper bound targets.

FMI would like to better understand how FDA determined the percent reductions for each category, particularly because some categories have steeper reductions than others. It is important for FDA to articulate the methodology it is using to set the Phase II targets. As part of that, we would like to understand how or whether the following considerations were factored in:

- progress toward the Phase I targets to date;
- the relative caloric contribution of a particular category;

- the relative contribution to sodium intake of a particular category (taking into account frequency and amount of consumption);
- the extent to which categories with major established manufacturers may have been treated differently;
- feasibility (including how this is assessed, as discussed above);
- the function of sodium in the category beyond flavor/taste; and
- any other factors.

We ask that FDA provide specific examples of how the methodology was applied in particular categories.

We also ask that FDA address why certain categories have a particularly steep reduction target compared to other categories, particularly for categories that only make a small contribution to overall sodium intake, such as bakery dry mixes and hot sauces. In these categories, sodium reduction is particularly challenging and yet would not seem to provide a commensurate benefit to reducing intake for the consumer.

In this vein, we want to call FDA's attention to a recent analysis of sodium content and sodium intake contributions of both store-bought and restaurant-prepared foods, based on National Health and Nutrition Examination Survey (NHANES) data.[4] This analysis found:

- Sodium reductions targeting top sodium contributors, such as lunch-meat sandwiches and restaurant-prepared pizza, would most effectively reduce sodium intake in the United States.
- Foods obtained from stores and restaurants contributed 62% and 26% of the sodium in the US diet for those 2 years of age and older, respectively.
- Ten categories contributed 52% of total sodium, including sandwiches, tortilla products, pizza, poultry products, soups, breads and rolls, fried rice/lo mein/stir fry, poultry mixed dishes, fried potatoes/vegetables (does not include potato chips), and fish/seafood.
- Meeting FDA targets for the largest sodium contributors, namely mixed dishes such as lunchmeat sandwiches, pizza with meat, burgers, and tacos/burritos, had the greatest projected impact on sodium intake reduction.

We believe that future sodium reduction targets should indeed take into account the category's contribution to overall sodium intake.

We also note that it does not seem logical to expect those categories where sodium has decreased between 2010 and 2022 to achieve steeper reductions during Phase II solely based on the reductions done to date. Such an approach would set up negative incentives for implementing the sodium reduction targets, where categories that have not implemented the

[4] Debra R. Keast and Patricia M. Guenther, Sodium Content and Sodium Intake Contributions of Store-Bought and Restaurant-Prepared Foods in Their As-Eaten Form: National Health and Nutrition Examination Survey, 2009-2008, CURRENT DEVELOPMENTS IN NUTRITION 8:104455, https://www.sciencedirect.com/science/article/pii/S2475299124023898

Phase I sodium targets are asked to do less, and categories where sodium has been reduced are asked to do more. Further, simply because sodium has been reduced in a category does not signal that a further reduction is possible, particularly without impacting consumer acceptance or functionality. We therefore ask FDA to avoid "penalizing" those categories where reductions have already been made, on that basis alone.

Further, FMI requests clarification on the rationale for the upper bound targets. There are a number of categories where the Phase II upper bound target is lower than or nearly identical to the category sales weighted mean baseline. FDA explains that the upper bound target represents FDA's goal for the highest sodium concentration for any product in that food category. Since the upper bound is meant to apply to individual products, it is illogical to have category upper bounds that are lower than the baseline. Setting the upper bounds this low raises significant questions of feasibility. We greatly appreciate FDA's continued recognition in the draft guidance that, "The upper bound sodium concentrations are goals and do not represent maximum allowable levels for sodium." It is unclear, however, why upper bound targets need to be included or how the agency expects companies to use the upper bound targets in evaluating sodium reduction efforts. FMI requests that FDA consider whether the goals of the guidance could be achieved just as effectively with the use of only the sales weighted mean targets.

We also request clarification on the basis for proposing different targets for certain packaged foods, as compared to restaurant-type foods within the same food category. For example, the upper-bound target for pizza with meat/poultry/seafood is 550 mg per 100 g for packaged foods, but 600 mg per 100 g for restaurant foods. There also are differences in the sodium targets for packaged vs. restaurant foods in the fried potatoes, breaded vegetables, soups, and numerous other categories. We ask FDA to address the justification for the increasing divergence in the sodium content between packaged foods and restaurant type foods.

Further, we note that some packaged food categories are lumped together in broad categories with large baseline sample sizes, whereas restaurant categories have greater specificity. For example, category 132 Frozen Meals and Sides (a packaged food category) could presumably match up with multiple restaurant categories including 143-R Meat/Poultry-based Dishes, 147-R Grain-based Dishes, and 149-R Combination Meals/Platters, all of which have higher targets than the presumable packaged food comparator. Sandwich-type foods offer another example. We ask that FDA provide more detailed information on how it sets restaurant targets relative to comparable packaged foods ones and consider categorizing with greater specificity to better align targets for both sectors.

Relatedly, we note that retailers may pack and/or distribute restaurant-type foods (e.g., in the hot foods, deli, or baked goods sections of a store), and it is unclear whether these foods should be subject to the packaged or restaurant food targets under the draft guidance. We ask FDA to clarify whether such products should be subject to the restaurant food targets, particularly given the similarities to restaurant foods in terms of how the items are prepared and consumed.

Further, when considering the disparate targets for restaurant and packaged foods, we ask FDA to be mindful of placing a disproportionate burden on packaged foods, as compared to restaurant food items. We would encourage the agency to conduct outreach and education to restaurant industry members with respect to the sodium guidance to ensure they are aware of the draft guidance and have the tools they need to take initial steps towards implementing the guidance once it is finalized. It is important that the agency avoid inadvertently creating a situation where two segments of the food supply are held to very different standards.

c. Other Nutritional Standards: FDA should consider how the sodium targets intersect with other FDA nutritional policies, including the low sodium definition.

While we recognize the sodium reduction targets are voluntary, we encourage FDA to consider how the targets intersect with other FDA nutritional policies and ensure there is a robust basis for each of the targets. For example:

- The upper bound target for unflavored tortilla chips is 129 mg per 30 g reference amount customarily consumed (RACC) (430 mg per 100 g) with a sales weighted mean target of 95 mg per 30 g RACC (340 mg per 100 mg). The sales weighted mean target is only 11 mg higher than the criteria for a "low sodium" claim for a small RACC snack food of 84 mg/30g RACC (140 mg/50g product) 21 CFR 101.61(b)(4). This means that FDA is effectively recommending that, on average, all unflavored tortilla chips should be close to low sodium. Long-term, is it FDA's goal for all tortilla chips on the market to not only meet, but to fall well under, the low sodium criteria? This raises concerns about the ability of consumers to choose for themselves among a variety of products with different sodium levels to meet their preference.

It is also important for FDA to recognize the significant resources needed to implement the many agency nutritional regulations and guidance documents being issued in a short timeframe – including the revised definition of healthy, the planned proposed rule on front-of-package nutrition labeling, the existing draft guidance on plant-based food labeling and final guidance on labeling of plant-based milk alternatives, the forthcoming final guidance on dietary guidance statements, potential action related to added sugars reduction, potential guidance on the labeling of foods sold on e-commerce platforms, as well as the sodium reduction guidance. Many of the same individuals within food companies are responsible for implementing all of these initiatives across affected products. When a significant number of regulatory requirements and guidance documents are implemented in a similar timeframe, the mandatory requirements, by necessity, must take priority. This is not due to a lack of desire to implement the voluntary initiatives but rather to competing priorities. We ask FDA to take these competing regulatory priorities into account when determining the final timeframe for implementing the Phase II targets.

d. Comments on Phase II targets for specific categories.

- Bakery.

- For the White Bread category (66P), FDA observed a modest decrease in sodium in 2022 as compared to the 2010 baseline of -6.9%, yet FDA has proposed significant decreases to the Phase II sales weighted mean and upper bound targets, of -22% and 14.5%, respectively. The White Bread category raises significant technical challenges for sodium reduction due to the functional need of sodium-containing ingredients. We ask FDA to revisit the feasibility of the Phase II targets in light of the functional purpose of sodium in these products.
- Similar issues arise within the Bakery categories of Rye Bread, Garlic and Cheese Breads, Crackers, Cake, Doughnut, Cookies, Sweet Rolls/Pastries/Pies, and Bakery Dry Mixes where multiple sources of sodium can play a critical role to enable proper leavening, dough strength and texture. For example, alternative leavening agents to sodium bicarbonate (baking soda) often have bitter flavors and require multi-factorial solutions to balance overall taste and consumer acceptability, making reductions in this category extremely complex. The Phase II targets for these categories are also aggressive given the technical challenges, the level of progress shown in the FDA nutrition labeling monitoring, and the fact that many of these products are meant for indulgence and occasional consumption, rather than being mainstays in the everyday diet.
- The table below lists categories where the large decreases in the Phase II sales weighted mean (SWM) and upper bound targets, are not in line with the modest sodium reduction between 2010 and 2022, particularly given the technical challenges in reducing sodium in baked goods. Although the data from 2010-2022 does not reflect the 2023-2024 reformulations, as discussed above, it could evidence the significant challenges in reformulations in these categories. FDA should revisit the proposed targets with the benefit of the 2023-2024 data.

FDA Sodium Reduction Guidance Category	Change in Baseline	Change in SWM Target	Change in UB
Bakery			
66P White Bread	-6.9%	-22%	-14.5%
68P Garlic and Cheese Breads	5%	-20%	-10%
79P Crackers	-9.2%	-19.7%	-14.9%
81P Cake	-4.5%	-14.3%	-7.7%
83P Cookies	-8.1%	-20%	-14.6%
84P Sweet Rolls, Pastries, Pies	-5.6%	-17.2%	-8.1%
88 Bakery Dry Mixes	5.2%	-19.4%	-6.1%
132 Frozen Meals and Sides	2.1%	-22.2%	-13.2%

135 Refrigerated Meals and Sides	3.4%	-18.9%	-6.3%
56P Vegetable/fruit-based dips and spreads	-2.6%	-31%	-11.7%
118 Snack Bars	-0.6%	-17.9%	-10.3%

- Snack Bars. FDA has established a single category for "snack bars" that includes essentially all bars. The category covers "cereal bars, granola bars, rice snack bars, fruit and grain bars, protein bars, and breakfast bars", as well as smaller bite-sized products with the same composition as a larger snack bar. By comparison, there are 15 separate categories covering cheese. We ask FDA to explore whether separate categories would be justified for snack bars given the wide range of products currently captured by this category. Given the very different eating occasions and ingredients in various types of bars, we suspect that multiple categories would be better tailored to the different types of sodium uses in this category.
- Soups.
    - Dry Soup Mixes: FDA has established sodium concentration targets for dry soup mixes on an "as-packaged" basis. Dry soups vary due to the wide range of characteristics of the mixes and required dilution. In general, dry mixes used to prepare thicker and chunkier soups require less water to prepare while dry mixes used to prepare broth-based soups generally require a higher ratio of water to dry mix. Some dry soups contain vegetables and/or grains which may contribute to a lower sodium concentration "as-packaged" compared to other products that mainly contain flavoring and starch. Since consumers enjoy a bowl of soup regardless of how (can, pouch, packet) it originates, we ask FDA to explore establishing sodium targets for dry soup mixes on an "as-prepared" basis. Establishing sodium concentration "as-prepared" for consumption allows an equitable assessment for all soups.
    - Bouillon: We ask FDA to categorize the bouillons category (43) as a non-target category. This would align with FDA's classification of "liquid/paste bouillon" as a non-target category. Regardless of the format, bouillon is used to prepare a liquid broth. This aligns with the FDA's definition of RACCs for "Dry Soup Mixes and Bouillons", where the RACC is defined as the amount to make 245g, Further, seasoned salt is also classified as a non-target category. Occasionally powdered bouillon is used to season dishes before cooking. When seasoned salt is replaced with powdered bouillons to season dishes, sodium consumption can be reduced by approximately 40% on a gram-to-gram basis. Since the FDA's voluntary sodium reduction goals aim to help Americans reduce sodium intake, categorizing bouillons (dehydrated bouillon cubes and powders) as a non-target category would be appropriate.
- Sauces, Gravies, Dips, Condiments, and Seasonings. As mentioned above, we ask FDA to consider if any of the sub-categories should be considered "non-target categories" since they are consumed in small amounts and contribute less to the overall sodium intake.

4. **<u>Salt Substitutes in Standardized Foods</u>. FMI urges FDA to finalize its proposed rule allowing salt substitutes in standardized foods, as sodium reduction is stalled in these categories without the ability to use salt substitutes in product reformulation efforts.**

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FMI greatly appreciates the opportunity to provide comment on the agency's Phase II voluntary sodium reduction targets. We look forward to further dialogue and collaboration with the agency and would be pleased to provide any further information that would be helpful to the agency.

Sincerely,

Dana Graber
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FMI – The Food Industry Association

Erin McCarthy
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