Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Steven B. Steinborn
Veronica Colas

Date: June 7, 2016

Re: **FDA Issues Draft Guidance on Voluntary Sodium Reductions**

The Food and Drug Administration (FDA) is asking the food industry to voluntarily reduce the sodium content of foods by about one-third over a ten year period, with the goal of reducing sodium intake to 2,300 milligrams (mg) per day. 1/ FDA's draft guidance sets short-term (two year) and long-term (ten year) sodium reduction targets for about 150 subcategories of both packaged and restaurant foods. The target dates would be two and ten years, respectively, from the date a final guidance document is issued.

The draft guidance identifies baseline sodium levels that represent "the current state of the market" and target mean (average) goals for each category, both based on a sales-weighted average. Significantly, in addition to the "mean" goals for each category, the draft guidance also sets "upper bound" sodium levels for all categories, both in the short- and long-term. While the target mean represents FDA's goal "for each food category as a whole, not necessarily for an individual manufacturer," the upper bound "could be applied to every individual product in a category." FDA encourages food companies to consider the following two questions related to these goals:

1. Are each of my products below the highest level recommended for its category?; and
2. Do my products help achieve the overall mean goals for their respective categories?

The proposal raises a number of significant questions, highlighted at the end of this memorandum. Below, we summarize the key elements of the draft guidance. We encourage food companies to review both the draft guidance and the spreadsheet that specifies the goals for each food category. Comments related to the food categories, baseline sodium levels, and short-term goals are due August 31 and comments related to the long-term goals and changes that would be needed to the standard of identity regulations are due October 31.

Background

FDA began the present dialogue on sodium reductions in 2011, when the agency and the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) opened parallel dockets for public comment, seeking input on technical challenges and opportunities for sodium

1/ FDA Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (June 2016), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm494732.htm. Appendix Table 1 and the summary explanation of Table 1 can be accessed from this link.

reductions, potential unintended consequences of reduction, and other issues. 2/ FDA and FSIS also held a public meeting in November 2011 to discuss the issues raised in the request for comment. Commenters stressed the need for gradual change that allows time for consumer tastes to adjust and takes into account technical and regulatory constraints, food safety issues, and the potential costs (both health-related and monetary) of sodium reductions.

Separately, in 2005, the Center for Science in the Public Interest (CSPI) submitted a citizen petition asking FDA to take action to reduce sodium in the food supply by revoking salt's status as a generally recognized as safe (GRAS) ingredient and regulating it as a food additive, and by requiring warning labels on certain retail packages of salt. CSPI filed suit in October 2015 seeking to compel the FDA to act on its citizen petition. FDA has now formally denied CSPI's petition, concurrent with its issuance of the draft guidance.

Justification for Setting Voluntary Sodium Reduction Targets

As justification for establishing voluntary sodium reduction targets, FDA relies on the following information about current sodium consumption and the U.S. food supply:

- Average sodium intake in the U.S. is approximately 3,400 mg per day;
- The current Dietary Guidelines for Americans recommend consuming no more than 2,300 mg of sodium per day;
- About 75 percent of sodium in the diet is added during food manufacturing and commercial food preparation; and
- The 2010 Institute of Medicine (IOM) report, "Strategies to Reduce Sodium Intake in the United States," cites the food supply as an obstacle to consumers meeting dietary recommendations for sodium. Despite public health efforts, including voluntary industry reductions and education campaigns, there has been no overall reduction of the level of sodium in the food supply.

The agency also cites information about the correlation between excess sodium consumption and health outcomes, and the potential benefits of reducing sodium consumption, including the following:

- Research shows that excess sodium consumption contributes to hypertension. Dietary reduction of sodium can lower blood pressure, as has been demonstrated in the Dietary Approaches to Stop Hypertension (DASH)-Sodium trial;
- Citing the 2010 IOM report, FDA states that "Many expert advisory panels have concluded that scientific evidence supports the value to public health of reducing sodium intake in the general population";
- The 2013 IOM report, "Sodium Intake in Populations: Assessment of Evidence" found that sodium intakes are too high, confirmed a positive relationship between higher levels of sodium intake and the risk of heart disease, and found "substantial evidence of population benefit and no evidence of harm associated with reductions in sodium intake down to 2,300 mg/day";
- A number of members of the committee that authored the 2013 IOM report issued a publication explaining that reduction in sodium intake is expected to have significant benefit;
- The 2015 Dietary Guidelines Advisory Committee Sodium Working Group concluded that higher levels of sodium are associated with increased blood pressure and risk of cardiovascular disease;
- Researchers have estimated the benefits of sodium reduction; and
- Other voluntary or mandatory initiatives provide examples of a path forward to reduce sodium.

2/ 76 Fed. Reg. 57050 (Sept. 15, 2011).

Key Elements of the Draft Guidance

The guidance consists of: (1) approximately 150 food categories, including both packaged and restaurant foods, (2) baseline average sodium concentrations, based on 2010 levels, for each category, (3) short-term (two year) target means and upper bounds for each category; and (4) long-term target means and upper bounds for each category. We summarize FDA's discussion of how each of these elements was developed, below. Appendix A provides examples of the food categories, baseline levels, and goal levels.

Food Categories

FDA organized packaged and restaurant foods into various categories by reviewing a number of food categorization systems. The agency considered factors such as contribution to sodium intake (and did not suggest targets for certain categories that do not contribute meaningfully to overall sodium intake); the amount of sodium in the food; technical potential for reducing sodium; and compatibility with existing industry and regulatory categories. The agency also grouped together foods with similar sodium concentrations or similar functional roles for sodium-containing ingredients.

Baseline Levels

The baseline levels represent FDA's tentative assessment of the "state of the market" for the sodium concentration (in mg per 100 grams) in each food category in 2010. The data is based on product labels and menu nutrition information, as well as sales volume data, focusing on foods making up the top 80 percent of sales by volume in each category. The baselines are sales-weighted averages, so products with higher sales volume are given extra weight within a category. FDA developed two separate baselines for packaged and restaurant versions of a food when both were represented in a category. Because FDA used 2010 data to set the baseline levels, companies that have made reductions in sodium between 2010 and the date the final guidance is issued will essentially get "credit" for those reductions that have already taken place. (In contrast, if FDA were to use 2016 data as the baseline, the already reduced levels would be the starting point and companies would not get credit for those reductions.)

Sodium Reduction Goals

FDA next developed two types of sodium reduction goals: (1) targets (means), defined as the goal sodium level for the category, calculated as the sales-weighted average sodium level, in mg per 100 g; and (2) upper bounds, defined as the goal upper bound sodium content of an individual food in a food category, also in mg per 100 g. The draft guidance sets both short-term and long-term goals for the target means and upper bounds.

In setting the goals, FDA started with a default reduction percentage (not specified in the draft guidance), which the agency then modified based on information available for the specific food category, such as the functions of sodium-containing ingredients in the category, and the distribution of sodium concentrations in products in that category. FDA states that it aimed to maintain concentrations of sodium needed for food safety functions, such as antimicrobial functionality. The short-term targets are intended to be feasible "using existing technology" and are "within the range of currently available commercially products." FDA does not expect that technological advances would be needed to achieve the two-year targets, but innovation "may" be necessary to reach the ten-year targets.

The long-term targets are intended to line up with a population-wide reduction in sodium consumption to 2,300 mg per day. The target mean sodium concentrations are intended to

represent FDA's "goals for the category as a whole" and are not necessarily to be applied to an individual food. Instead, these benchmarks will be used to assess overall progress by the food industry, although FDA suggests individual food companies may want to use the target means to set priorities for where to focus their voluntary reformulation efforts. In contrast, the upper bounds are intended to be applied to individual products. FDA suggests that companies determine whether each of their products is below the "highest level recommended for its category." The agency states that many products are already meeting short- and long-term targets.

Participation by the Food Industry

FDA states that change in sodium levels is "contingent upon broad participation by, and evenly distributed impact upon, the food industry." At the same time, the draft guidance focuses on the need for sodium reductions by the largest food companies, stating,

> the great majority of food consumption in the U.S. comes from a fairly small number of products and menu items and … many of these products are produced by a limited number of companies. It is possible that reformulation by these companies could lead to increased demand for lower-sodium versions of ingredients.

FDA therefore "specifically encourages attention" to the draft guidance by:

1. manufacturers whose products make up a significant proportion of national sales in one or more food categories and
2. restaurant and similar retail food chains that are national or regional in scope.

The agency also stresses the need to minimize the impact on low-market share products in each food category, and recognizes that small businesses may not have the same resources as larger companies to reach the goals. However, FDA anticipates that in time and with the spread of innovations, the goals will "ultimately be within reach for all firms."

Companies should understand that the framework FDA has set out for voluntary reductions is similar to what we expect FDA would have done if they had taken a mandatory approach or reconsidered the GRAS status of salt and issued a food additive regulation for salt. As noted, FDA's rejection of the CSPI petition requesting that FDA revoke the GRAS status of salt is significant, as it means that FDA is committed to a voluntary approach for the foreseeable future. The draft guidance also does not contain a "trigger provision" whereby the standards become mandatory if there is not sufficient participation.

Questions in Federal Register Notice

FDA poses a number of questions in the *Federal Register* notice announcing the availability of the draft guidance. 3/ The questions are grouped into the following broad categories, with comments on categories 1-4 due August 31 and comments on categories 5-8 due October 31.

1. **Appropriateness of food categories**. Should any be merged or separated? Are they appropriate for use by restaurant chains?

2. **Baseline sodium levels**. Are they reasonably representative?

3. **Two-year targets**. Are they feasible? If not, why not? What goals would be feasible in the short-term?

3/ 81 Fed. Reg. 35363 (June 2, 2016).

4. **Two-year timeframe**. Are the goals achievable within this timeframe? If not, what timeframe would be challenging but still achievable?

5. **Ten-year targets**. Are they feasible? If not, why not? What goals would be feasible in the long-term?

6. **Ten-year timeframe**. Are the goals achievable within this timeframe? If not, what timeframe would be challenging but still achievable?

7. **Technological innovation**. What specific research needs or technological advances could enhance ability to meet the goals? What are possible innovations in the area of sodium reduction and are there any unintended consequences associated with their use?

8. **Changes to standards of identity**. What changes are needed to facilitate sodium reduction by permitting alternative ingredients to be used in standardized foods?

It is critically important to respond to the agency's questions, as the final guidance will establish the benchmarks against which the industry will be evaluated. If there are any incorrect assumptions or flaws in FDA's analysis, companies and trade associations should point them out at this juncture.

Issues to Consider

The draft guidance raises a number of significant issues worth considering, beyond those raised by FDA in the *Federal Register* notice. We highlight a few of these issues below.

1. **Comment period**. Food companies and trade associations should consider requesting an extension of the two comment periods.

2. **Time needed for reformulation**. FDA states that food manufacturers and ingredient suppliers estimate the average time for product reformulation as two years from the start of the project to market. Is that assumption accurate? Does it sufficiently account for consumer acceptance and other challenges to achieving sodium reduction levels?

3. **Conflicting regulatory priorities**. Are FDA's expectations of the food industry realistic given the many conflicting regulatory priorities facing food companies in the coming years, including regulatory changes requiring reformulation and changes to product labels, such as the new Nutrition Facts panel revisions and FDA's determination that partially hydrogenated oils (PHOs) are no longer GRAS?

4. **Need for technological advances**.
    a. FDA assumes that short-term reductions will not require technological advances. Is that assumption correct? Specific examples of where technological innovation would be required to meet short-term goals would be particularly persuasive.
    b. FDA states that the amount of a sodium-containing ingredient needed to achieve various technical effects (including flavor) in foods could decrease over time, due to advances in food technology such as flavor science, food preservation, and changes in consumer preferences. Is that assumption accurate?
    c. Is ten years a realistic timeframe for the long-term targets, particularly given that FDA expects these reductions to require technical innovation?
    d. There are various technological advances that have been seen in the past decade. To what extent are these advances accessible to food companies in meeting sodium reduction goals?

5. **Restaurant and packaged foods**. Did FDA provide sufficient justification for allowing the target levels for restaurant and packaged foods to converge, despite recognizing that the baseline levels are different?

6. **Likelihood of success**.
    a. Does industry or agency precedent call into question the likelihood that the targets can be achieved? 4/ Are there examples of failed efforts to reduce sodium content that might inform FDA's understanding of the challenges the food industry faces?
    b. What efforts can industry point to in striving to reach meaningful sodium reduction levels over the past decade and to what extent do such efforts suggest that significant barriers exist to obtaining the kind of voluntary reductions FDA believes are possible?

7. **Overall approach**. FDA has carved out a significant role for the federal government in encouraging substantial changes in the formulation of foods and consumers' dietary behaviors. Has FDA identified sufficient justifications for its proposed approach? What assumptions or assertions are made and has FDA presented a compelling case for why such assumptions or assertions are valid?

8. **Legal authority**. Does the agency have legal authority to set voluntary standards and limits for the amount of sodium in foods, outside of its food additive authority, which is not cited in the draft guidance?

* * *

Should you have any questions, or wish to discuss these issues further, please contact us.

4/ For instance, FDA's original "healthy" claim criteria established a tiered approach for sodium content, with the first tier effective in 1994 and the second, more restrictive tier (reflecting a 25 percent reduction) to become effective in 1998. In 2005, FDA eliminated the more restrictive sodium requirements, based on comments documenting substantial technical difficulties in finding suitable alternatives for sodium and demonstrating the lack of consumer acceptance of "healthy" products made with lower sodium.

Appendix A
Examples of Sodium Reduction Goals for Specific Food Categories

All sodium levels are listed in mg per 100 g
All baseline levels are based on packaged foods unless otherwise specified
Targets are for both restaurant and packaged foods
These are intended only as examples; the full FDA Appendix Table 1 should be consulted

Category Name	2010 Baseline Mean	Short Term Target Mean	Short Term Upper Bound	Long Term Target Mean	Long Term Upper Bound
Parmesan and Other Hard Cheese	1554	1480	1800	1320	1690
Frozen Vegetables and Legumes	195	150	260	80	180
Fried Potatoes without Toppings	385 (based on restaurant data)	310	490	190	340
Nuts and Seeds	413	350	490	200	330
Nut/Seed Butters and Pastes	447	400	500	300	430
White Bread	523	440	570	300	460
Wheat and Mixed Grain Bread	471	420	540	300	410
Cookies	360	300	430	220	330
Precooked sausage	936	850	1090	750	950
Uncooked bacon	581	530	680	450	600
Boneless, Breaded/Battered Poultry	707	660	860	500	670
Cured/Smoked Pork and Canadian Bacon	1065	970	1220	800	1070
Frozen Meals/Entrees	332	280	390	180	290
Unflavored Potato and Vegetable Chips	585	500	650	250	480
Flavored Potato and Vegetable Chips	774	630	830	380	630
Puffed Corn Snacks	1075	870	1190	550	900
Popcorn	846	680	960	400	720
Pretzels	1214	1020	1460	750	1150
Snack Mixes	953	860	1130	700	930
Pizza: Without Meat/Poultry or Seafood – Frozen	508	420	570	260	420