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FDA Issues Draft Guidance on Voluntary Sodium Reduction Targets

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Food & Drug

On June 1, 2016, the FDA announced draft guidance on voluntary sodium reduction targets that could have a substantial effect on food manufacturers and restaurants.[1] The Draft Guidance proposes short-term and long-term targets for various categories of commercially processed, packaged, and prepared foods, as well as recommended upper bounds for sodium in each food category. Although voluntary for industry participants, the new sodium targets may have a significant impact on food product formulations.

FDA is accepting comments on the Draft Guidance, with final guidance expected to issue next year. This client alert summarizes the key provisions of the Draft Guidance that may warrant industry attention.

FDA Draft Guidance

High levels of sodium consumption have long been of concern to the FDA.[2] FDA states in the Draft Guidance that "[d]ecreasing population sodium intake is expected to reduce the rate of hypertension, a major risk factor for heart disease and stroke, the first and fifth leading causes of death in the U.S."[3] In discussing the science supporting the disease risk reduction benefits of lowering sodium intake, FDA acknowledges that not all studies have found that a higher sodium intake is associated with a higher risk of cardiovascular disease and that a lower sodium intake is associated with a lower risk.[4] The agency concludes, however, that overall, the science supporting the relationship between sodium reduction and health is clear, particularly given that Americans consume on average 3,400 mg of sodium per day, which FDA notes is nearly 50% more than the 2,300 mg limit recommended by federal guidelines.[5]

In the Draft Guidance, FDA focuses specifically on sodium from processed and commercially prepared foods, which the agency states account for approximately 75% of dietary sodium

[1] *See* U.S. Food & Drug Admin., *Draft Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods* (June 2016) [hereinafter *Draft Guidance*], available here; *see also* 81 Fed. Reg. 35363 (June 2, 2016).
[2] *See, e.g.*, Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information, 76 Fed. Reg. 57050 (Sept. 15, 2011); *Sodium in Your Diet: Use the Nutrition Facts Label and Reduce Your Intake*, U.S. Food & Drug Admin., available here.
[3] *Draft Guidance* at 4.
[4] U.S. Food & Drug Admin., *Sodium Reduction*, available here.
[5] *Id.*

intake.[6] The Draft Guidance "aims to help Americans achieve the Dietary Guidelines-recommended sodium levels by encouraging food manufacturers, restaurants, and food service operations to reduce sodium in foods."[7] FDA emphasizes that its approach is consistent with and supports ongoing voluntary efforts in the food industry to achieve gradual sodium reduction in the U.S. food supply.

The proposed sodium targets, although voluntary, cover a significant portion of the food industry. The Draft Guidance broadly applies to processed foods, foods sold to other manufacturers or to restaurants, and to restaurant foods sold directly to consumers. The Draft Guidance is not intended to cover foods that contain only naturally occurring sodium, such as milk, or salt products consumers add directly to their food.[8]

The Draft Guidance sets forth a table of sodium targets for processed, packaged, and prepared foods, organized by category. The targets include both short-term (2-year) and long-term (10-year) goals for sodium reduction for each food category, which include targets for food product average sodium concentrations as well as upper bounds for sodium concentrations. For example, in the Popcorn category, which has a baseline average sodium concentration of 1214 mg per 100 g, FDA has proposed short-term reductions to 1020 mg average concentration, with an upper bound of 1460 mg. FDA proposes long-term targets of 750 mg average concentration and an upper bound of 1150 mg.[9]

The FDA explains that the targets were developed based on "the distribution of sodium in current packaged products and menu items, as well as by publicly available data and information about the formulation of sodium-reduced foods," with a particular focus on foods making up the top 80% of sales by volume in each category.[10] The proposed targets generally impose significant reductions across the categories of food products and menu items that include added sodium. However, the FDA did not suggest targets for foods that it identified as "not contribut[ing] meaningfully to overall sodium intake (e.g., salted dried fish and organ meat)" due to either low levels of consumption or low levels of sodium in comparison to other categories.[11]

Of note, the Draft Guidance highlights the FDA's encouragement for compliance by "food manufacturers whose products make up a significant proportion of national sales in one or more categories and restaurant chains that are national or regional in scope."[12] Such food manufacturers should take this encouragement into account, as the FDA states that it and other agencies will continue to monitor sodium in the food supply.[13]

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[6] *Draft Guidance* at 3.
[7] *Id.*; *see also* U.S. Dept. of Health & Hum. Serv. and U.S. Dept. of Agric., 2015 – 2020 Dietary Guidelines for Americans (8th ed. Dec. 2015), available here.
[8] *Draft Guidance* at 5.
[9] *See id.* App. Table 1 (providing baseline targets based on data from 2010).
[10] *Draft Guidance* at 10, 12 (noting that nutrition data came from Nutrition Facts Panels and restaurant nutrition information); *see also* U.S. Food & Drug Admin., *Memo: FDA's Voluntary Sodium Reduction Goals Supplementary Memorandum to the Draft Guidance* (2016).
[11] *Id.* at 11.
[12] *Draft Guidance* at 10.
[13] *Draft Guidance* at 7.

FDA Final Guidance

The FDA will accept comments on the Draft Guidance in two phases. Stakeholders have 90 days to submit comments concerning the FDA's system of categorization, use of baseline sodium values, proposed short-term targets, and proposed 2-year timeframe for these targets. Stakeholders have 150 days to submit comments on the proposed long-term targets, the proposed 10-year timeframe, necessary technological or research needs to assist industry with meeting these targets, and concerns regarding the FDA's standard of identity regulations and permissibility of alternative ingredients.

Industry stakeholders should review the sodium concentration of their products and consider the feasibility of achieving the FDA's short-term and long-term targets. For those considering the submission of comments to the FDA, the 90-day window for comments on categorization and short-term targets will be especially critical.

FDA Denies CSPI Citizen Petition on Sodium

Also on June 1, the FDA formally denied the citizen petition filed by the Center for Science in the Public Interest (CSPI) asking the FDA to revoke the generally recognized as safe (GRAS) status of salt, mandate reductions of sodium in all processed foods, reduce the Daily Value (DV) for sodium to 1,500 mg, and take other actions regarding sodium. In its letter to CSPI denying the petition, the FDA referenced its release of the Draft Guidance and stated that, when final, voluntary guidelines should help address the concerns raised in CSPI's petition.[14] The agency stated further, "[w]e believe that this is the most effective and appropriate approach at this time based on the scientific and technical information currently available to us about the feasibility of sodium reduction across the entire breadth of the complex and heterogeneous U.S. food supply."[15]

Covington will closely monitor developments on this issue and would be pleased to answer questions regarding the likely impact of FDA's proposed voluntary sodium reduction targets on industry interests.

[14] Letter from Steven Musser, Ph.D., CFSAN Deputy Director for Scientific Operations, to Michael F. Jacobson, Ph.D., Executive Director, CSPI (June 1, 2006), at 6.
[15] *Id*. at 6-7.

Covington is experienced in advising clients on legal matters related to conventional foods and dietary supplements and is available to provide individualized compliance counseling concerning these issues. If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drug & Device Practice Group:

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