



# FDA Issues Sodium Reduction Final Guidance

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**On October 13, 2021, the U.S. Food and Drug Administration (FDA) issued final guidance titled “*Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods.*” The guidance provides voluntary, short-term (2.5-year) reduction targets for certain foods as an initial step to reduce the amount of sodium in the U.S. food supply.**

## Background and Final Guidance

FDA began discussing sodium reductions in 2011 together with the U.S. Department of Agriculture’s (USDA’s) Food Safety and Inspection Service (FSIS) when the agencies solicited comments and hosted a public meeting. FDA published draft guidance<sup>1</sup> in 2016 that proposed short-term (2-year) and long-term (10-year) targets for sodium reduction in commercially processed, packaged, and prepared foods. The recently-published final guidance<sup>2</sup> builds on the 2016 draft to set short-term targets to be achieved for the mean and upper bound sodium concentrations for a variety of food categories, which are based on sodium levels in the food supply in 2010.

The average sodium intake in the U.S. is approximately 3,400 mg/day, and FDA states 70% of this intake comes from sodium added during commercial food preparation. The 2020–2025 Dietary Guidelines for Americans recommend limiting sodium consumption to 2,300 mg/day. The targets in the final guidance seek to reduce U.S. average sodium intake by 12% to 3,000 mg/day through encouraging food manufacturers, restaurants, and food service operators to gradually reduce added sodium in their products over time. FDA targeted an average intake of 3,000 mg/day because it recognizes that the shift to reduced sodium intake must be broad and take place over time to be effective in the long term and give industry time to reformulate and innovate. FDA characterizes these initial targets as only the first step of a long-term plan to achieve the recommended limit of 2,300 mg/day.

The final guidance document includes the following three tables:

- Table 1. Voluntary Sodium Reduction Goals: Downloadable spreadsheet that contains a table with food categories and descriptions, baseline levels, target means, and upper bound concentrations for each of the target categories.

- **Table 2. Non-Target Categories:** Identifies categories for which FDA did not develop goals, including foods that do not contain meaningful amounts of added sodium or are rarely consumed. The table includes some dairy products like yogurt, milk, and ice cream; various forms of fruits and vegetables, ready-to-eat cereals like granola and muesli; ground meat and poultry; and a variety of candy and chocolate items.
- **Table 3. Definitions:** Defines terms specific to this guidance document.

In Table 1, the short-term goals to be achieved over 2.5 years include target mean concentrations and upper bound concentrations of sodium for 163 food categories. The food categories are grouped into 16 general product categories, with the “bakery,” “sauces, gravies, dips, condiments, and seasonings,” and “meat and poultry” sections containing the bulk of the individual food categories. As with the draft guidance, FDA considered several factors in developing the reduction targets, specifically accounting for the various functions of sodium in food, which include taste, texture, and microbial safety and stability. The targets account for reductions in sodium that is added by food industry only, not naturally-occurring sodium or salt added by consumers. The guidance provides details on the information in Table 1 and how FDA intends industry to use each element. Table A, below, shows a selection of food categories and data elements that illustrate the following components:

- **Foods and Food Categories:** The final food categories were chosen based on their contribution to sodium intake in the U.S., the amount of added sodium they contain, and the function of the sodium in the food, among other considerations.
- **Baseline information:** Table 1 includes information from FDA’s 2010 baseline surveys including the sample size of packaged products, number of restaurants surveyed, and sales weighted mean (corresponding with the short-term target sales weighted mean). FDA determined the values using label, menu, and nutrition data from the 2010 survey. FDA plans to use these baseline sodium concentrations for each food category to track sodium reduction progress. The values are weighted in favor of foods in the category that have a higher sales volume to ensure that more widely-consumed products would have an increased influence on the final sodium concentration for the category.
- **Target mean concentration:** The desired average sodium concentration for the food category as a whole. The mean is also weighted by relative sales volume such that more popular products have a larger effect on the category average. The guidance notes that the concentrations will be used to represent voluntary industry efforts, and industry may choose to assess the sales-weighted status of their products in a given category to inform reformulation decisions.
- **Upper bound concentration:** The goal for the highest sodium concentration for any product in that food category. These numbers are generally higher than the target mean concentrations to reflect the current distribution of sodium concentrations in a category. The guidance emphasizes that these concentrations are goals and are not maximum allowable levels for sodium. FDA intends for industry to compare products in a category to the upper bound concentration and aim to achieve a concentration below this level.

## Departures from 2016 Guidance

FDA received 200 comments on its 2016 draft guidance pertaining to both its short- and long-term reduction goals. FDA states the final guidance takes these comments into account by improving the targets to better reflect baseline data, clarify food categories, enhance the utility

and readability of the table, and provide more detailed food category descriptions. In particular, the final guidance reduction targets differ from those in the 2016 draft guidance in a few notable ways.

- The final guidance seeks to achieve the reduction targets over 2.5 years, rather than the 2 years proposed in the draft guidance.
- While the 2016 proposed guidance provided long-term (10-year) reduction targets, FDA declined to finalize these at this time, stating that it would work to finalize its long-term goals within the next couple of years through stakeholder collaboration. The agency noted it plans to actively engage with industry to learn more about sodium reduction efforts.
- The final guidance sought to separate foods into more precise categories, resulting in 163 categories, more than the 150 categories in the draft guidance.
  - In some cases, FDA separated high-sodium products into their own category, e.g., separating “bouillon” from “dry seasoning and dry sauce mixes” and splitting up “salted butter” from “regular and lightly-salted butter.”
  - In other cases, separate categories seek to provide more clarity and specificity for industry (e.g., separating “canned” and “frozen” vegetables into four categories accounting for shelf-stable, breaded, and non-breaded products; accounting for differences in in-shell and not-in-shell nuts and seeds; and separating a general “condiments” category into separate categories for hot sauce; mustard and Worcestershire sauce; mayonnaise and tartar sauce; and ketchup, barbeque, cocktail, and steak sauce).
  - The final guidance includes some distinctly new categories, e.g., “plant-based products marketed as cheese alternatives.”
  - FDA merged other categories in the final guidance where data indicated similar concentrations in products. For example, the “ready-to-eat cereal, flakes” category merged with the “ready-to-eat cereal, puffed” category, and the “whole muscle pork” and “whole muscle beef” categories merged into a single “whole muscle meat” category.
- While both the draft and final guidance account for different sodium targets for packaged and restaurant products, the final guidance clearly indicates “P” for “packaged” and “R” for “restaurant” next to product names to better direct industry to the relevant category.
  - This clarification allows for better comparison of the reduction goals between the restaurant and food manufacturing industries. In particular, it appears that FDA has given slightly more aggressive mean reduction targets for restaurant foods than for packaged foods. The average reduction in mean sodium content for restaurant food categories was 15%, higher than the average reduction in mean sodium content for packaged and other non-restaurant food categories at 12.7%. This indicates that FDA has identified more opportunities to reduce added sodium content in restaurant foods.

When FDA issued the draft guidance in 2016, we prepared a chart that identified the 2-year and 10-year goals for various food categories. Table A, below, identifies the 2-year sales targeted means and upper bound levels found in the 2016 draft guidance with the 2.5-year sales weighted means and upper bound levels in the final guidance. The Table identifies any adjustments made

by FDA in response to the comments. We also are providing two additional tables that identify the 20 foods with the highest percent reduction in mean sodium content for restaurant foods (Table B) and non-restaurant foods (Table C). Note these tables were created by Hogan Lovells and do not appear in the final guidance.

## **Next steps**

Compliance with the guidance is voluntary for industry. Consumer groups and the class action bar will likely use the guidance to put additional pressure on industry to work towards lowering added sodium content. In addition, FDA plans to monitor and evaluate progress on the sodium reduction goals and continue discussions with stakeholders to develop guidance for its long-term (10-year) sodium reduction goals. In particular, FDA will monitor levels of sodium in the food supply as a whole, progress in particular categories, and levels of other nutrients to ensure that sodium reduction is not achieved by increasing nutrients with negative health consequences.

FDA specified it plans to work towards finalizing guidance for its long-term (10-year) reduction targets over the next few years but did not give a definite timeline.

We will continue to monitor and report on any updates FDA provides regarding progress on the reduction targets and the long-term guidance.

<p align="center"><b>Table A: Comparison of 2016 2-Year Targets and 2021 2.5 Year Targets for Select Foods</b></p> <p align="center"><i>All levels are listed in mg per 100 g.</i></p> <p align="center"><i>This chart is intended for use only as an example; the full FDA Appendix Table 1 should be consulted.</i></p> <p align="center"><i>Chart created by Hogan Lovells.</i></p>						
<b>Food Category ID 2021 Guidance</b> <i>P=Packaged</i> <i>R=Restaurant</i>	<b>Food Category Name*</b>	<b>2010 Baseline Sales Weighted Mean*</b>	<b>2016 2-Year Target Sales Weighted Mean</b>	<b>2021 2.5-Year Target Sales Weighted Mean</b>	<b>2016 2-Year Upper Bound</b>	<b>2021 2.5-Year Upper Bound</b>
11	Parmesan and Other Hard Cheese	1554	1480	1500	1800	1820
23 - R	Fried Potatoes without Toppings	377	310	300	490	470
36	Nut/Seed Butters and Pastes	454	400	400	500	490
66 - R	White Bread	522	440	430	570	560
67 - R	Wheat and Mixed Grain Bread	472	420	380	540	490
83 - P	Cookies	359	300	300	430	410
92 - P	Cooked Sausage	930	850	840	1090	1040
98 - R	Boneless, Breaded/Battered Poultry	727	660	560	860	740
100 - P	Cured/Smoked Pork and Canadian Bacon	1176	970	1030	1220	1360
132	Frozen Meals and Sides	328	280	270	390	380
111 - P	Unflavored Potato and Vegetable Chips	596	500	510	650	650
112	Flavored Potato and Vegetable Chips	758	630	640	830	820
116	Popcorn	861	680	730	960	990
117	Pretzels	1247	1020	1040	1460	1480
158 - P	Pizza: Without Meat/Poultry or Seafood – Frozen	494	420	400	570	550
<p>* Where category names or baseline means differed between the 2016 draft guidance and the 2021 final guidance documents, this chart reflects the values from the 2021 final guidance.</p>						

<b>Table B – Restaurant Food Categories, 20 Highest Target % Reduction in Mean Sodium from 2010 Baseline Levels</b>		
<b>Final Guidance Food Category ID</b> <i>P=Packaged</i> <i>R=Restaurant</i>	<b>Food Category Name</b>	<b>Target % Reduction*</b>
52 - R	Gravy	<b>33.1</b>
27 - R	Potato Side Dishes	<b>28.9</b>
48 - R	Mexican-style Sauce	<b>27.8</b>
31 - R	Olives without Additions	<b>27.1</b>
29 - R	Pickles	<b>24.2</b>
98 - R	Poultry - Breaded	<b>23.0</b>
44 - R	Tomato-based Sauce	<b>22.5</b>
74 - R	Biscuits	<b>21.8</b>
72 - R	English Muffins	<b>21.4</b>
159 - R	Tacos and Burritos	<b>21.2</b>
73 - R	Croissants	<b>21.1</b>
131 - R	Breakfast Sandwiches Not on Biscuits	<b>20.9</b>
23 - R	Fried Potatoes without Toppings	<b>20.4</b>
80 - R	Cheesecake	<b>20.2</b>
93 - R	Bacon	<b>20.0</b>
127 - R	Hamburgers without Cheese	<b>19.9</b>
67 - R	Wheat and Mixed Grain Bread	<b>19.5</b>
128 - R	Hamburgers with Cheese	<b>19.4</b>
155 - R	Filled Dough Appetizers	<b>19.3</b>
53 - R	Cheese-based Dips and Spreads	<b>18.6</b>
<p>*Values calculated by Hogan Lovells using Voluntary Sodium Reduction Goals Final Guidance Table 1 (Oct. 2021).                      Percent Reduction in Mean Sodium = (2010 Baseline Sales Weighted Mean) – (Short Term Targets Sales Weighted Mean)/(2010 Baseline Sales Weighted Mean) * 100.                      Refer to Final Guidance for food category descriptions, baseline sales weighted mean, and short term targets sales weighted mean.</p>		

<b>Table C: Non-Restaurant Food Categories, 20 Highest Target % Reduction in Mean Sodium from 2010 Baseline Levels</b>		
<b>Final Guidance Food Category ID</b> <i>P=Packaged</i> <i>R=Restaurant</i>	<b>Food Category Name[1]</b>	<b>Target % Reduction*</b>
94 - P	Bacon Bits	<b>27.3</b>
65 - P	Cooked Cereal	<b>25.9</b>
49 - P	Asian-style Sauce <sup>7</sup>	<b>25.3</b>
20	Vegetables - Not Breaded	<b>25.2</b>
161	Toddler Meals	<b>23.7</b>
77 - P	Tortillas	<b>23.1</b>
115	Puffed Snacks	<b>20.2</b>
139	Shelf Stable Meals	<b>19.4</b>
106	Meat Substitutes	<b>19.2</b>
158 - P	Pizza without Meat/Poultry/Seafood	<b>19.0</b>
47	Pesto Sauce	<b>18.5</b>
64	Instant Cereal	<b>18.4</b>
78	Hard Taco Shells	<b>17.8</b>
132	Frozen Meals and Sides	<b>17.7</b>
99 - P	Poultry - Reformulated Nuggets and Patties	<b>17.6</b>
66 - P	White Bread	<b>17.3</b>
79	Crackers	<b>17.0</b>
117	Pretzels	<b>16.6</b>
18 - P	Salad Dressing <sup>7</sup>	<b>16.6</b>
63	Ready-to-Eat Cereal	<b>16.5</b>
<p>*Values calculated by Hogan Lovells using Voluntary Sodium Reduction Goals Final Guidance Table 1 (Oct. 2021).                      Percent Reduction in Mean Sodium = (2010 Baseline Sales Weighted Mean) – (Short Term Targets Sales Weighted Mean)/(2010 Baseline Sales Weighted Mean) * 100.                      Refer to Final Guidance for food category descriptions, baseline sales weighted mean, and short term targets sales weighted mean.</p>		

## References

- 1 Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry; Availability, 85 Fed. Reg. 35363 (June 2, 2016).
- 2 Guidance for Industry: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Oct. 2021), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-sodium-reduction-goals>. The Final Guidance, Table 1, and summary explanation of Table 1 can be accessed at this link.

## Contacts



**Martin Hahn**  
Partner, Washington, D.C.  
T +1 202 637 5926  
[martin.hahn@hoganlovells.com](mailto:martin.hahn@hoganlovells.com)



**Connie Potter**  
Associate, Washington, D.C.  
T +1 202 637 3661  
[connie.potter@hoganlovells.com](mailto:connie.potter@hoganlovells.com)

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