Sodium Reduction: FDA’s Voluntary Initiative

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Food and Drug Administration
What did FDA Announce?

• Draft, voluntary guidance on sodium reduction targets
  – Gradual approach:
    • Short-term targets (2 years, goal=3,000 mg/day)
    • Long-term targets (10 years, goal=2,300 mg/day)
  – Targets for 150 categories of food that are sales weighted to focus on dominant sellers in each category
  – Applies to food manufacturers, restaurants and food service operations
• Draft targets serve as a basis for continued dialogue
  – Additional data and information will help refine
Why Focus on Sodium?

• Americans consume almost 50 percent more sodium than what most experts recommend
  – Current intake is about 3,400 mg/day
  – Recommendation is 2,300 mg/day
• Expert bodies agree on the need to reduce sodium consumption to 2,300 mg/day for public health gains
  – Institute of Medicine
  – Evidence used for 2015-2020 Dietary Guidelines for Americans
  – Healthy People 2020
Scientific Evidence

• Totality of evidence supports sodium reduction from current levels
  – Diverse and strong body of evidence, including clinical trials, support link between sodium consumption and blood pressure
  – High blood pressure is a major risk factor for heart disease and stroke
• Sodium reduction could prevent hundreds of thousands of premature deaths and illnesses over a decade
Why are Targets Needed?

• Most sodium comes from salt added to processed and restaurant foods
• It is difficult to meet recommended sodium intake with current food supply
• Overall sodium content of food supply remains high, despite industry efforts
• Variability in sodium across similar foods in food supply shows that reductions are possible

Mattes and Donnelly, 1991
## Example of Variability: Cream Cheese

<table>
<thead>
<tr>
<th>Country</th>
<th>Sodium (mg/100g)</th>
<th>Short-Term Mean Target (mg/100g)</th>
<th>Long-Term Mean Target (mg/100g)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>403</td>
<td>380</td>
<td>340</td>
</tr>
<tr>
<td>U.K.</td>
<td>300</td>
<td></td>
<td></td>
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<tr>
<td>Ireland</td>
<td>300</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>348</td>
<td></td>
<td></td>
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<tr>
<td>New Zealand</td>
<td>348</td>
<td></td>
<td></td>
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<tr>
<td>Canada</td>
<td>400</td>
<td></td>
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<tr>
<td>Brazil</td>
<td>410</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Key Information Considered

• Survey of available food technology literature
  – Role of sodium (e.g., food safety, texture, fermentation)
  – Sodium reduction potential in food/food category
  – Comments

• Market surveys
  – Sodium content of high-selling products
  – Identified products in 2010 that had the lowest sodium concentrations

• Consultation with experts

• Reviewed other sodium reduction initiatives
3-Step Process to Set Targets

1. Developed 150 food categories

2. Determined baseline sodium concentrations (mg/100g)

3. Set quantitative goals (2 year and 10 year)
Step 1: Developed Food Categories

- Reviewed various food categorization systems
  - Government
  - Private-sector
  - Sodium reduction initiatives
- Captured USDA food codes
- Grouped foods with similar technical feasibility of sodium reduction using food technology literature/data
- Assessed contribution to sodium intake
- Revised based on technical input
- Includes
  - Processed foods (e.g., breads, marinated meats)
  - Foods prepared at retail (e.g., sandwiches, salads, mixed ingredient entrees)
  - Those available at both (e.g., pizza, soups)
Contribution of Foods to U.S. Sodium Intake by Sodium Guidance Targeted Foods

- Mixed Ingredient Dishes: 16%
- Other Combination Foods: 10%
- Breads, Baked Goods: 10%
- Meats: 9%
- Vegetables: 4%
- Soups: 4%
- Salads: 3%
- Sauces, Condiments: 3%
- Salty Snacks: 3%
- Fish, Seafood: 2%
- Cheeses: 2%
- Cereals: 2%
- Fats, Oils, Dressings: 1%
- Nuts, Seeds: 1%
- Toddler Foods: 0.1%
- Not Targeted: 11%
- Sandwiches: 19%

FDA Analysis, 2016
Step 2: Determined Baseline Sodium Concentrations

- Baseline concentrations
  - Point of reference for reduction goals
  - Expressed as the concentration of sodium in a food product (mg/100g)
  - Different amounts of data and levels of detail available for packaged and restaurant foods (e.g. sandwich data better for restaurants)

- Sources of data used combine the following
  - Sodium data from food package labels (2010) or restaurant menu data (2010-11)
  - Sales data (2010)

- Processed food/restaurant data are weighted by sales data
Step 3: Set Quantitative Goals

• Assessed options for types of goals – selected hybrid of sales-weighted mean and upper bound

• Target mean levels: apply to average sodium levels of foods in a category, not individual products

• Recommended upper bounds: apply to all individual products and discourage products with excessive sodium
Sales Weighting

• Focus is on:
  – Manufacturers whose products make up a significant proportion of national sales in one or more categories
  – Restaurant and similar retail food chains that are national or regional in scope
• Intended to provide more weight to commonly consumed products—the dominant sellers in each category
• More reflective of the sodium intake from the U.S. food supply (10% of products account for top 80% of sales)
• Company could assess own portfolio of products against category targets by determining sales-weighted mean for products in a category
Calculating Upper Bounds

What was taken into account?

<table>
<thead>
<tr>
<th>General Calculation</th>
<th>Percentile of 2010 baseline distribution</th>
<th>+</th>
<th>Percentage of target mean</th>
<th>÷ 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short-term Upper Bound</td>
<td>80th percentile of baseline distribution</td>
<td>+</td>
<td>130% of Short-term mean</td>
<td>÷ 2</td>
</tr>
<tr>
<td>Long-term Upper Bound</td>
<td>60th percentile of baseline distribution</td>
<td>+</td>
<td>130% of long-term mean</td>
<td>÷ 2</td>
</tr>
</tbody>
</table>
# Target Table

**Table 1. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods**

<table>
<thead>
<tr>
<th>Food Category ID</th>
<th>Food Category Name</th>
<th>Food Category Description</th>
<th>2010 Baselines</th>
<th>Short-Term Goals (2 years)</th>
<th>Long-Term Goals (10 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sales-Weighted Mean</td>
<td>Sales-Weighted Target Mean</td>
<td>Sales-Weighted Target Mean</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Upper Bound</td>
<td>Upper Bound</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>P</td>
<td>R</td>
<td>both</td>
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<td>R</td>
<td>both</td>
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<td>both</td>
<td>both</td>
<td>both</td>
</tr>
<tr>
<td><strong>Snacks</strong></td>
<td></td>
<td></td>
<td></td>
<td>Upper Bound</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>109</td>
<td>Unflavored Potato and Vegetable Chips</td>
<td>Salted potato and other vegetable chips. Includes both reformed chips/crisps and sliced chips. Excludes chips with other seasonings in addition to salt (see 110).</td>
<td>585</td>
<td>624</td>
<td>500</td>
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<td>650</td>
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<td></td>
<td>250</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>480</td>
</tr>
<tr>
<td>110</td>
<td>Flavored Potato and Vegetable Chips</td>
<td>Salted potato and other vegetable chips with additional flavor seasonings, e.g. barbeque or sour cream. Includes both reformed chips/crisps and sliced chips.</td>
<td>774</td>
<td>630</td>
<td>830</td>
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<td>380</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>630</td>
</tr>
<tr>
<td>111</td>
<td>Unflavored Grain Chips</td>
<td>Salted corn, wheat, multigrain, and rice chips, e.g. salted tortilla chips. Excludes grain chips with other seasoning in addition to salt (see 112).</td>
<td>438</td>
<td>448</td>
<td>390</td>
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<td>510</td>
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<td>410</td>
</tr>
</tbody>
</table>

P = Packaged; R = Restaurant; both = P and R; (baseline values are based on data available for P and R)

All values are in milligrams (mg) per 100 grams (g)
Sample Category: Precooked Sausage

- Top selling products on market
- Shows how sodium concentrations compare (mg/100g)
- Baseline, FDA short- and long-term targets overlaid
- Many products already meeting short- and long-term targets

Note: Data on the number of products was obtained from Nielsen. Sodium concentration values were calculated from sodium values on nutrition labels obtained from Gladson and Mintel.
Sample Category: Monterey Jack and Other Semi-Soft Cheese

Number of Products

Sodium Concentration (mg Na/100g) n = 56 products, 25 brands

Long-Term Goal (540)
Short-Term Goal (610)
2010 Baseline (636)

Note: Data on the number of products was obtained from Nielsen. Sodium concentration values were calculated from sodium values on nutrition labels obtained from Gladson and Mintel.
Sample Category:
Wheat and Mixed Grain Bread

Sodium Concentration (mg Na/100g)

Note: Data on the number of products was obtained from Nielsen. Sodium concentration values were calculated from sodium values on nutrition labels obtained from Gladson and Mintel.
Monitoring Plans

FDA:

- Industry progress in achieving the targets for each food category

USDA, CDC:

- Sentinel surveillance of specific foods over time that have high sodium levels or are significant contributors to sodium intake
- Sodium intake through dietary recalls (USDA - What We Eat in America/NHANES) and through urinary data (CDC - NHANES)
Stakeholder Participation Important

All parties must work together to see success
Comments

• Separate comment periods for short- and long-term targets
  – 90 days on issues outlined in the Notice of Availability regarding the short-term targets
  – 150 days on issues outlined in the Notice of Availability regarding the long-term targets
  – Link to docket:
    https://www.regulations.gov/#!docketDetail;D=FDA-2014-D-0055
Specific Feedback Requested...

Categories
• Have we miscategorized products?
• Should categories be separated or merged?
• amenable for use by restaurant chains?

Baselines
• Are they representative of the state of the food supply in 2010 for each category?
• Can our methods for quantifying sodium content be improved and if so, how?

Please submit comments to the docket!
Specific Feedback Requested...

Targets

• Can our methods for developing mean and recommended upper bound targets be improved and if so, how?
• Are they feasible for 2 years and if not, why?
• Are they feasible for 10 years and if not, why?
• What timelines are appropriate for each food category?
• Are there research needs or technological advances that could enhance the ability to meet these goals?

Please submit comments to the docket!
Specific Feedback Requested...

Reformulation

• What are the possible innovations in the area of sodium reduction?
• Are there any unintended consequences associated with their use?

Other Considerations

• What amendments to FDA’s standard of identity regulations are needed to facilitate sodium reduction?
• Are there other information gaps that we are overlooking?

Please submit comments to the docket!
Documentation on Methodology

in the Docket

Reference 07 (to NOA) - Supplementary Target Development Example

- https://www.regulations.gov/#!documentDetail;D=FDA-2014-D-0055-0221

Reference 17 (to Draft Guidance) - Supplementary Materials Packet: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry; Availability

- https://www.regulations.gov/#!documentDetail;D=FDA-2014-D-0055-0011
For More Information

FDA Website: www.fda.gov/SodiumReduction

• Draft Guidance
• Notice of Availability (includes issues for comment)
• Draft sodium reduction targets (available in Excel or Word format)
• At a Glance fact sheet
• FAQ

Email: SodiumReduction@fda.hhs.gov