# Sodium Reduction: FDA's Voluntary Initiative

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# 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?

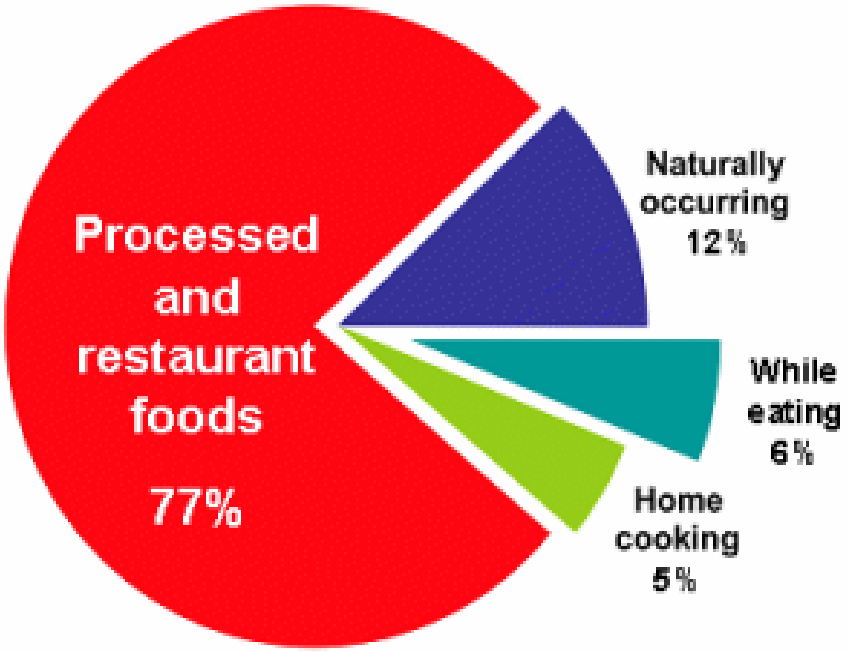
- Americans consume almost 50 percent more sodium than what most experts recommend
  - Current intake is about 3,400 mg/day
  - Recommendation is 2,300 mg/day
- Expert bodies agree on the need to reduce sodium consumption to 2,300 mg/day for public health gains
  - Institute of Medicine
  - Evidence 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 anc 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

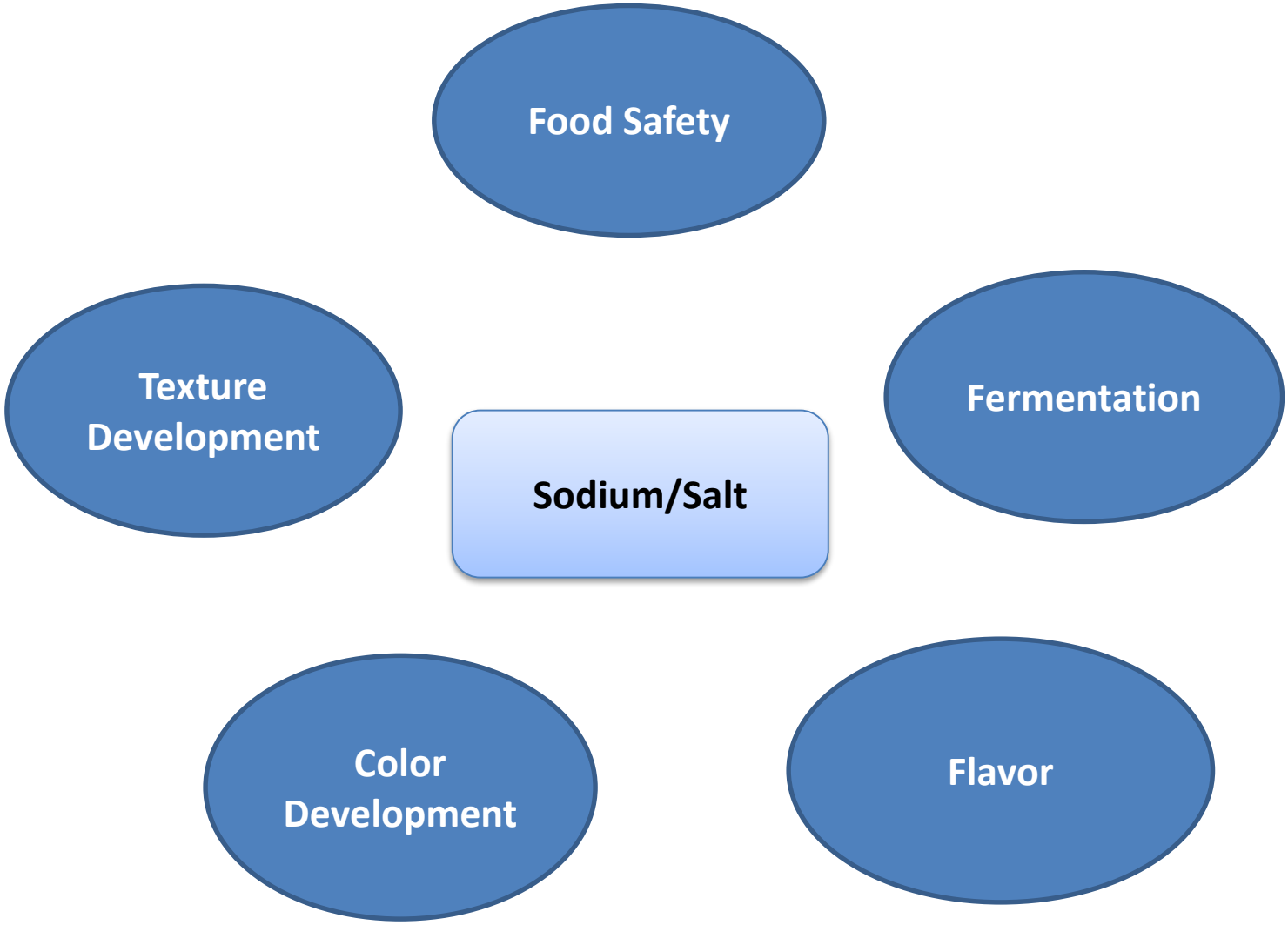



Mattes and Donnelly, 1991

# Example of Variability:
## Cream Cheese

| Country | Sodium (mg/100g) | Short-Term Mean Target (mg/100g) | Long-Term Mean Target (mg/100g) |
|---|---|---|---|
| U.S. | 403 | 380 | 340 |
| U.K. | 300 | | |
| Ireland | 300 | | |
| Australia | 348 | | |
| New Zealand | 348 | | |
| Canada | 400 | | |
| Brazil | 410 | | |

Spreadable


Food Safety
Texture Development
Fermentation
Sodium/Salt
Color Development
Flavor

# 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

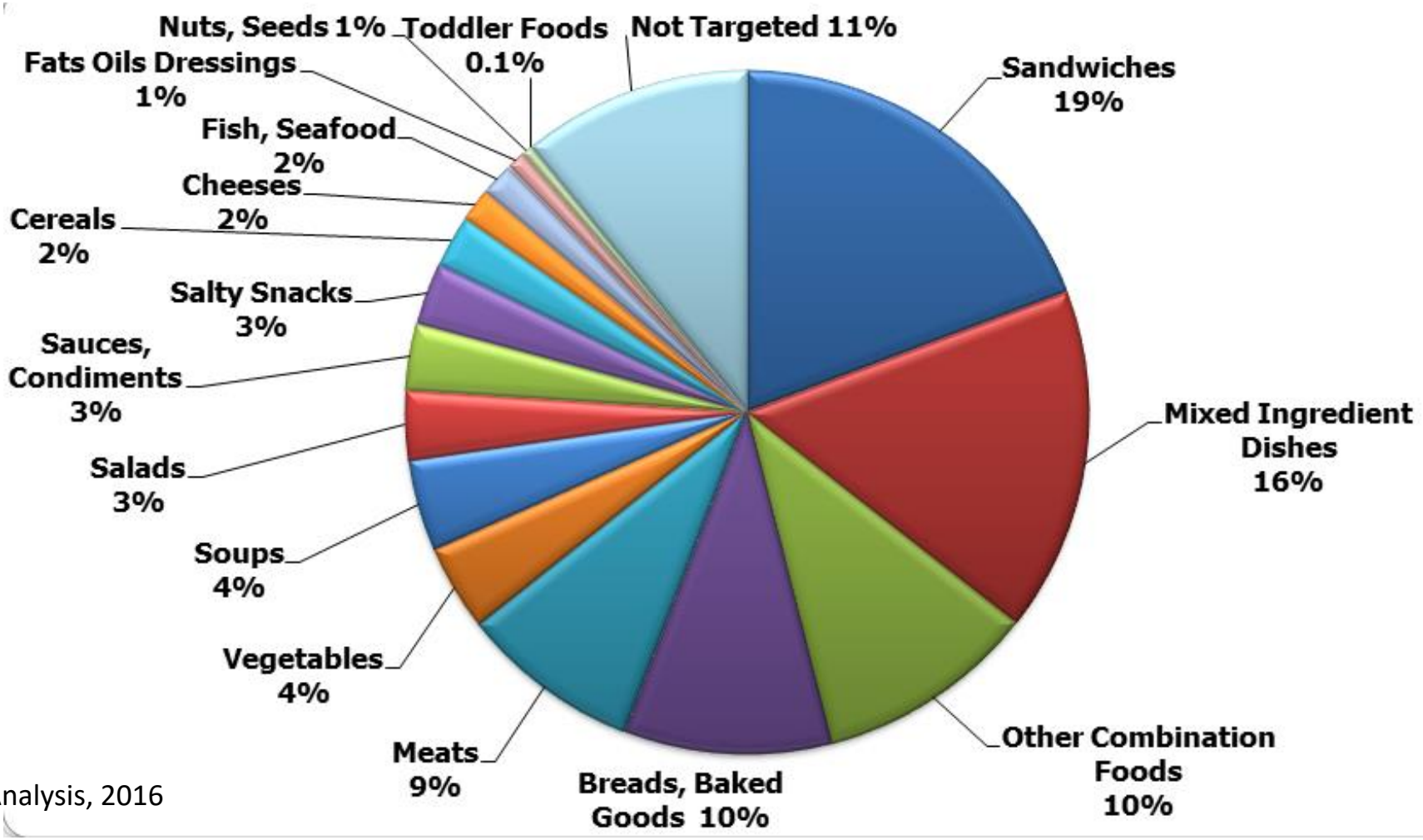
# 3-Step Process to Set Targets

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




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)

| Nutrition Facts | Serving Size | Calories | Calories from Fat | Total Fat (g) | % Daily Value** | Saturated Fat (g) | % Daily Value** | *Trans* Fat (g) | Cholesterol (mg) | % Daily Value** | Sodium (mg) | % Daily Value** | Carbohydrates (g) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sandwiches** | | | | | | | | | | | | | |
| Hamburger | 3.5 oz (100 g) | 250 | 80 | 9 | 13 | 3.5 | 16 | 0.5 | 25 | 9 | 520 | 22 | 31 |
| Cheeseburger | 4 oz (114 g) | 300 | 110 | 12 | 19 | 6 | 28 | 0.5 | 40 | 13 | 750 | 31 | 33 |
| Double Cheeseburger | 5.8 oz (165 g) | 440 | 210 | 23 | 35 | 11 | 54 | 1.5 | 80 | 26 | 1160 | 48 | 34 |

**Nutrition Facts**
8 servings per container
**Serving size** **2/3 cup (55g)**

**Amount per serving**
**Calories** **230**

| | % Daily Value* |
|---|---|
| **Total Fat** 8g | **10%** |
| Saturated Fat 1g | **5%** |
| *Trans* Fat 0g | |
| **Cholesterol** 0mg | **0%** |
| **Sodium** 160mg | **7%** |
| **Total Carbohydrate** 37g | **13%** |
| Dietary Fiber 4g | **14%** |
| Total Sugars 12g | |
| Includes 10g Added Sugars | **20%** |
| **Protein** 3g | |
| Vitamin D 2mcg | 10% |
| Calcium 260mg | 20% |
| Iron 8mg | 45% |
| Potassium 235mg | 6% |

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

- 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?***

| | | | | | |
|---|---|---|---|---|---|
| **General Calculation** | **Percentile of 2010 baseline distribution** | **+** | **Percentage of target mean** | **÷ 2** |
| **Short-term Upper Bound** | **80th percentile of baseline distribution** | **+** | **130% of Short-term mean** | **÷ 2** |
| **Long-term Upper Bound** | **60th percentile of baseline distribution** | **+** | **130% of long-term mean** | **÷ 2** |

# Target Table

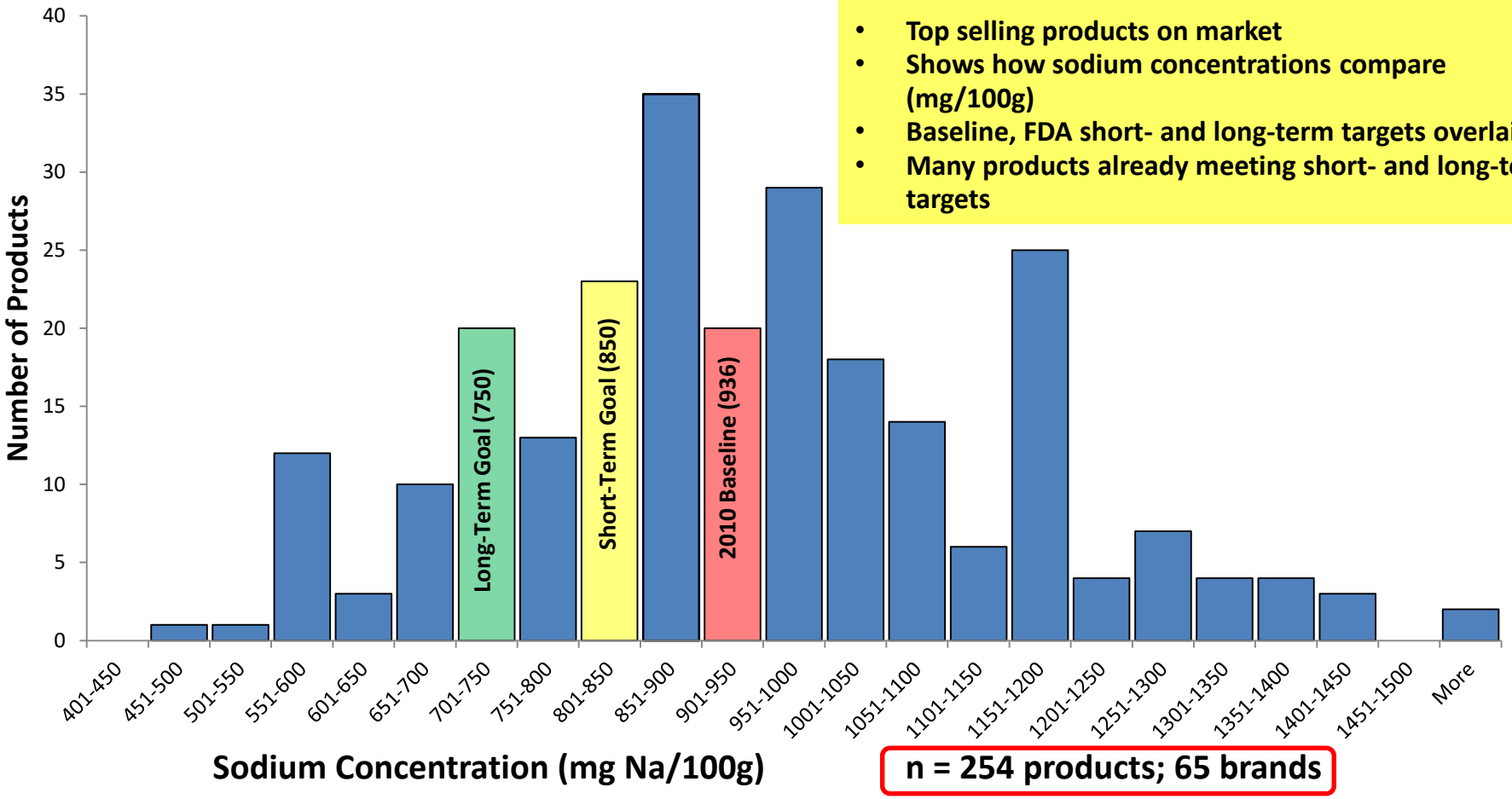
**Table 1. Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods**

| Food Category ID | Food Category Name[1] | Food Category Description | 2010 Baselines[2] | | Short-Term Goals (2 years) | | Long-Term Goals (10 years) | |
|---|---|---|---|---|---|---|---|---|
| | | | Sales-Weighted Mean[3] | | Sales-Weighted Target Mean[4*] | Upper Bound[5**] | Sales-Weighted Target Mean[4*] | Upper Bound[5**] |
| | | | P | R | both | both | both | both |
| **Snacks** | | | | | | | | |
| 109 | Unflavored Potato and Vegetable Chips | 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). | 585 | 624 | 500 | 650 | 250 | 480 |
| 110 | Flavored Potato and Vegetable Chips | Salted potato and other vegetable chips with additional flavor seasonings, e.g. barbeque or sour cream. Includes both reformed chips/crisps and sliced chips. | 774 | | 630 | 830 | 380 | 630 |
| 111 | Unflavored Grain Chips | Salted corn, wheat, multigrain, and rice chips, e.g. salted tortilla chips. Excludes grain chips with other seasoning in addition to salt (see 112). | 438 | 448 | 390 | 510 | 300 | 410 |

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

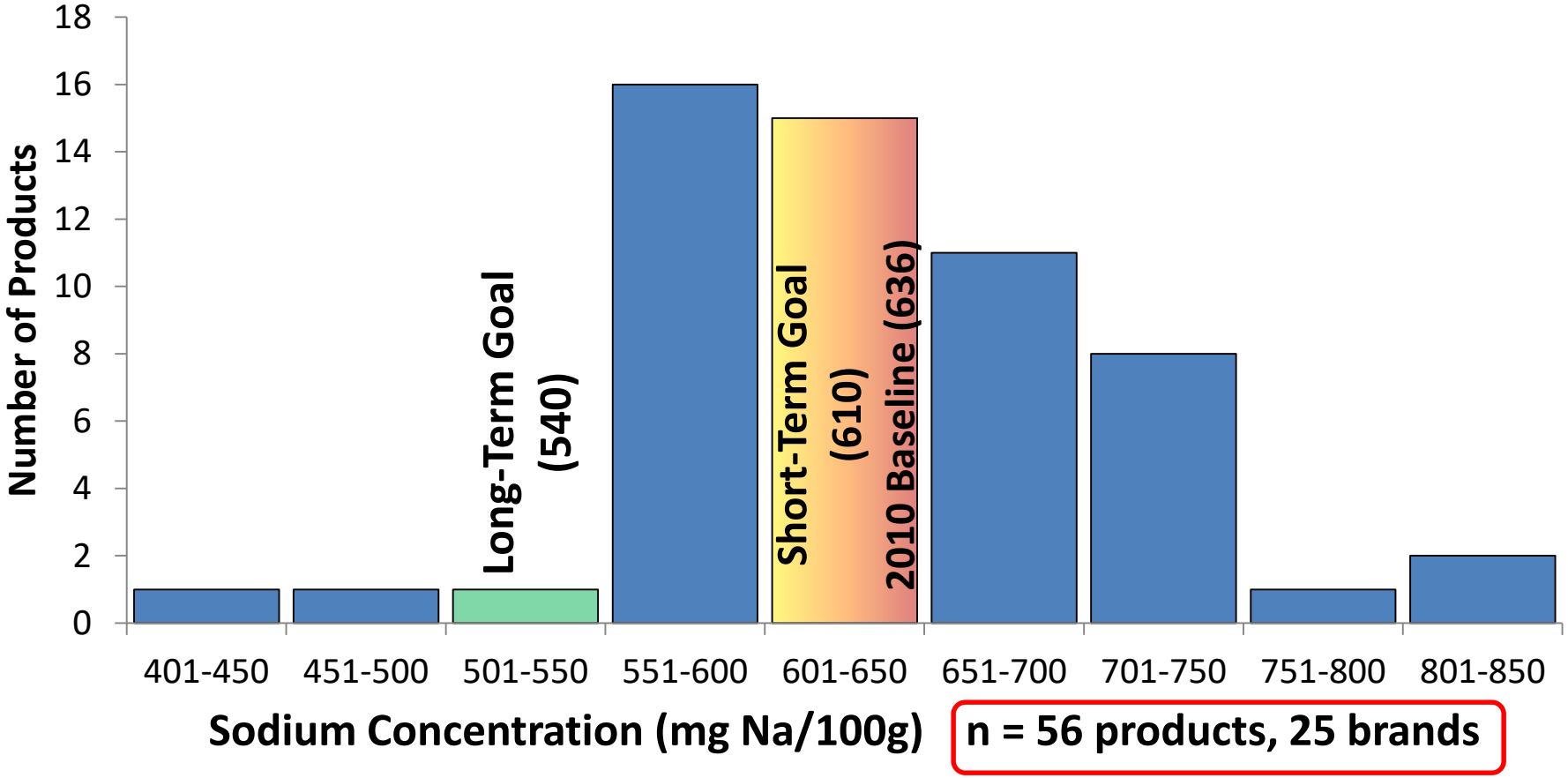



- Top selling products on market
- Shows how sodium concentrations compare (mg/100g)
- Baseline, FDA short- and long-term targets overlaid
- Many products already meeting short- and long-term targets

**n = 254 products; 65 brands**

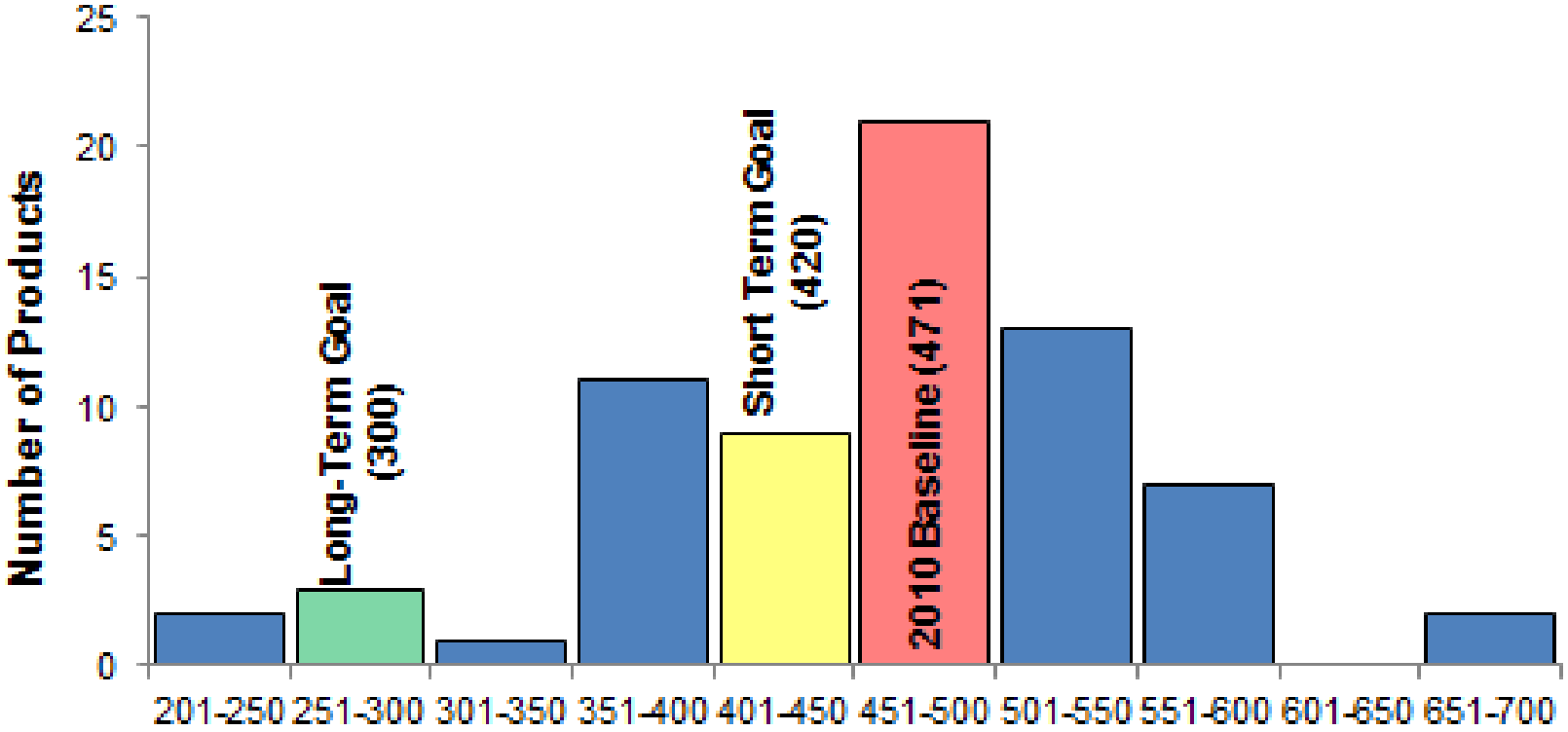
Note: Data on the number of products was obtained from Nielsen. Sodium concentration values were calculated from sodium values on nutrition labels obtained from Gladson and Mintel.

# Sample Category:
# Monterey Jack and Other Semi-Soft Cheese




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

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# Monitoring Plans

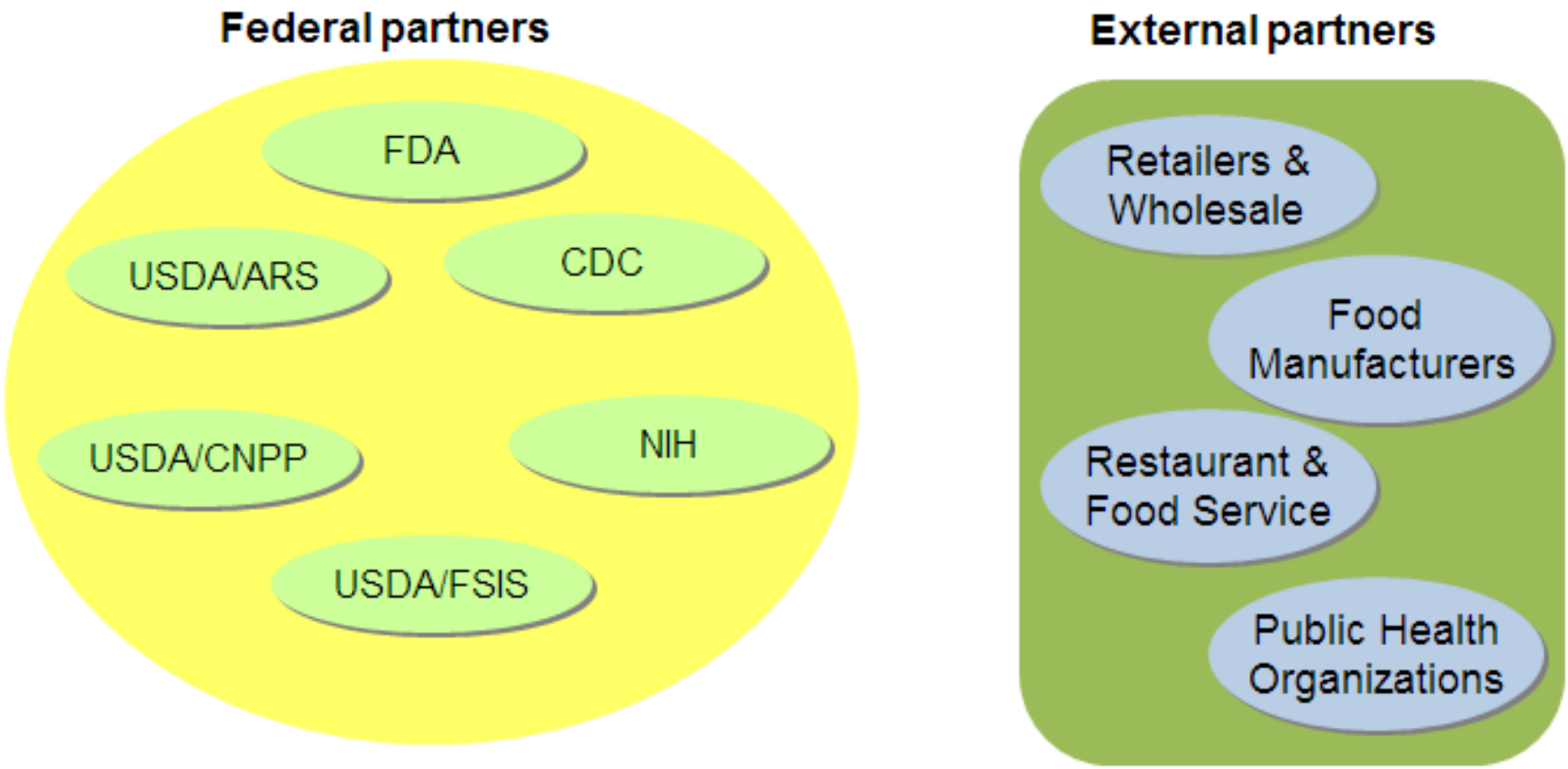
FDA:

- 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