FDA Regulation of Salt and Sodium

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Presentation

- Regulatory Status of salt/sodium
- Nutrition labeling and claims for salt and sodium
- Current activities at FDA regarding salt and sodium

Generally Recognized as Safe

The Federal Food, Drug and Cosmetic Act states that an intentional ingredient of food is a "food additive" unless…

"…the substance is generally recognized as safe (GRAS) among experts qualified by scientific training and experience to evaluate its safety ("qualified experts") under the conditions of its intended use…"

The criteria for qualifying the use of a substance as GRAS is codified in 21 CFR 170.30.

Regulatory Status of Salt in the U.S.

- **Salt was part of the original 1959 GRAS list and is currently listed at the beginning of 21 CFR 182.1**

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  "It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use."

Salt's History as GRAS

- **Congressional record from the Food Additives Amendment discussions shows that salt was frequently the example given for what is GRAS.**
- **1978, FASEB Scientific Committee on GRAS Substances (SCOGS) Report:**
  - "The evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in the manner now practiced."
- **1982 FDA "Policy Notice"**
  - FDA would not classify salt as a food additive and deferred any decisions on GRAS status
  - Outlined FDA's goal of reducing sodium intake through labeling approaches.

Mandatory Label Requirements for foods, including dietary supplements

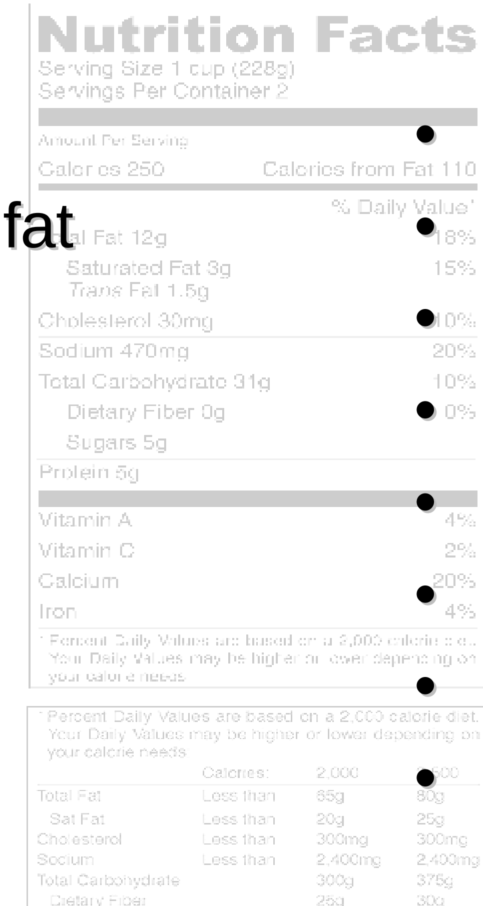
- The label must contain:
  - Identity of food
  - **List of ingredients**
  - Amount of food in package
  - Name and place of business
  - Nutrition information (unless exempt)
  - Information disclosing material facts about the food
  - Allergen labeling

Nutrition Labeling

- Nutrition Labeling and Education Act (NLEA) - 1990
  - Made nutrition information mandatory on most packaged foods (1994) (21 CFR 101.9)
  - Specified format and content for nutrition labeling (Nutrition Facts Label) (21 CFR 101.9)
  - Allowed nutrient content claims (21 CFR 101.13) and health claims (21 CFR 101.14) on foods

Mandatory Nutrients

- Calories
- Calories from fat
- Total fat
- Saturated fat
- *Trans* fat
- Cholesterol
- Sodium



- Total Carbohydrate
- Dietary Fiber
- Sugars
- Protein
- Vitamin A
- Vitamin C
- Calcium
- Iron

Nutrition Facts Label

- Daily Value – 2,400 mg/day

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 250	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 1.5g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Types of Claims Related to Health and Nutrition in Food Labeling

- Nutrient Content Claims
  - A claim on the label or in labeling of foods that expressly or implicitly characterizes the level of a nutrient in the food –premarket review or FDAMA notifications
- Health Claims, including qualified health claims
  - Characterizes a relationship between a food or food component and a disease or health-related condition – premarket review or FDAMA notifications

Nutrient Content Claims

- Expressed nutrient content claims
  - Describe the level of a nutrient or dietary substance
  - Compare the level of nutrient or dietary substance to another food
- Implied nutrient content claims
  - Claims that a food may be useful in maintaining healthful dietary practices (*e.g. Healthy)*

Nutrient Content Claims for Sodium
21 CFR 101.61

- Free
  - < 0.5 mg per RACC and labeled serving
  - For meals and main dishes: < 5 mg per labeled serving
  - “Salt free” must meet criteria for “sodium free”
- Very Low Sodium
  - ≤ 35 mg per RACC and per 50 g if reference amount is small
  - For meals and main dishes: ≤ 35 mg per 100g
- Low
  - ≤ 140 mg per RACC and per 50 g if reference amount is small
  - For meals and main dishes: ≤ 140mg per 100g

Nutrient Content Claims for Sodium 21 CFR 101.61

- Reduced (lower, fewer):
  - At least 25% reduction for the nutrient per RACC compared to an appropriate reference food
  - For meals and main dishes, at least 25% reduction per 100 g of food compared to and appropriate reference food.
- No salt added/Unsalted
  - Declaration: "This is not a sodium free food" if food is not sodium free
- Salt Free
  - Must meet criteria for "sodium free"

Nutrient Content Claims for Sodium 21 CFR 101.61

- Lite in sodium/Light in sodium
  - 50% reduction in sodium
- Lightly Salted
  - 50% less sodium than normally added to reference food
  - If not low in sodium, so labeled on the information panel.

Nutrient Content Claims

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  - Compare the level of nutrient or dietary substance to another food
- Implied nutrient content claims
  - Claims that a food may be useful in maintaining healthful dietary practices (*e.g. Healthy)*

Criteria for use of "Healthy"

	Individual Food* (RACC is ≥ 30 g)	Seafood/Game Meat	Main Dish/Meal Product
Total Fat	3 g or less /RACC (low)	Less than 5 g per RACC & 100g	3 g or less/100g & no more than 30% of calories (low)
Saturated Fat	1 g or less/RACC & 15% or less calories (low)	Less than 2 g per RACC and 100g	1 g or less/100 g & <10% of calories (low)
Sodium	480 mg or less/RACC & /labeled serving	480 mg or less/RACC & /labeled serving*	600 mg or less per labeled serving
Cholesterol	60 mg or less/RACC & /labeled serving	Less than 95 mg/RACC & 100g	90 mg or less per labeled serving
Beneficial Nutrients	At least 10% RDI or DRV per RACC for one or more of vitamins A, C, iron, calcium, protein, or fiber‡		Main dish: 2 nutrients; Meal: 3 nutrients

*For foods with a RACC of 30 g or less or 2 tablespoons or less, the criteria refer to the amount per 50 g of food.
‡Except raw fruits and vegetables; frozen or canned single ingredient/mixture fruits and vegs, except that ingredients whose addition does not change the nutrient profile of the fruit or veg may be added; enriched cereal-grain products that conform to a standard of identity.
RACC = Reference amount customarily consumed, which is the basis of serving size on food labels.

Health claims related to sodium and blood pressure

- Authorized Health Claims
  - Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
- FDAMA Claims (Authoritative statements)
  - Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke.

Implied Health Claims

- Statements, symbols, vignettes or other forms of communication that suggest a relationship between the presence or level of a substance in the food and a disease or health-related condition.
  - Examples: third party references, terms or symbols such as "heart" (AHA)

Use of disclosure and disqualifying statements with claims

- Requirement for disclosure levels with nutrient content claims.
  - If a product exceeds certain levels for fat, saturated fat, cholesterol, or sodium
  - "See nutrition information for _____ content."
- For use of health claims, a product must meet certain criteria, including:
  - Food contains, without fortification, 10% or more of the DV for one or more of vitamin A, vitamin C, iron, calcium, OR fiber
  - Food contains less than a specified level for total fat, saturated fat, cholesterol, and sodium.

Minimum levels for disclosure or disqualifying requirements on claims

	Individual food*	Main Dish product	Meal Product
	per RACC	per labeled serving	
Fat, g	13.0	19.5	26.0
Saturated fat, g	4.0	6.0	8.0
Cholesterol, mg	60	90	120
Sodium, mg	**480**	**720**	**960**

Current Activity

- Public Hearing held November 29, 2007
  - The purpose of the hearing was for FDA to share its current framework of policies regarding salt and sodium and solicit information and comments from interested persons on this current framework and on potential future approaches.
  - Questions 1-4: Salt reduction/regulatory status of salt
  - Questions 5-7: Effectiveness of Labeling
  - Comment period re-opened until August 11, 2008

Current Activity

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

RIN 0910–ZA30

[Docket No. 2006N–0168]

Food Labeling: Revision of Reference Values and Mandatory Nutrients

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

Current Activities

- ANPRM for the revision of the Daily Values
  - Should the DRV for sodium be based on the UL for sodium (2,300 mg/day) as suggested by the Dietary Guidelines for Americans or should it be based on the AI (1,500 mg/d using the population-coverage approach)?
  - If the UL should be used, should it be adjusted using the same approach (population-weighted or population-coverage) as the other DRIs?

Summary

- Salt is regulated as a GRAS ingredient per 21 CFR 182.1
- FDA has commented previously on salt's GRAS status and has chosen labeling, rather than ingredient regulation to encourage lower sodium intakes.
- Sodium is part of the mandatory elements for nutrition labeling.
- Nutrient content claims and health claims related to sodium can be made voluntarily on food products consistent with regulations; sodium content is included in disclosure & disqualifying criteria.