# FDA Food Fortification Policy: Principles and Considerations

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# Overview

- History of U.S. fortification
- Guiding U.S. principles for fortification
- Considerations in addressing a public health need: folic acid as an example

# History of U.S. Fortification

- In the first half of the 20th century, fortification in the U.S. addressed classical nutritional deficiencies, e.g.,
  - Iodization of salt to reduce the risk of goiter
  - Fortification of milk with vitamin D to reduce the risk of rickets

# History…

- In the 1940s and 1950s, FDA specified levels of iron, niacin, thiamin and riboflavin in standards of identity for enriched staple foods (e.g., enriched- flour, bread)

- More recently (1998), folic acid was added to these enriched products to reduce the risk of neural tube defects

# Guiding U.S. Principles for Fortification

- FDA fortification policy entitled “Nutritional Quality of Foods; Addition of Nutrients” published in 1980 *(21 CFR 104.20; FR, vol 45, January 25, 1980, 6314)*

- Food standard regulations

# Standardized Foods: Vehicles of Fortification

- Food standards are the mandatory requirements that determine what a food product must contain to be marketed under a certain name in interstate commerce (21 CFR parts 131 to 169)

- On occasion, food standards have served as a means to improve the overall nutritional quality of the food supply and to meet a demonstrated public health need

# Examples of Standardized Foods: Nutrient Levels for Enriched Cereal Grains

| Enriched Grain Products | Thiamin Mg/lb | Riboflavin Mg/lb | Niacin Mg/lb | Iron Mg/lb | Folic acid Mg/lb |
|---|---|---|---|---|---|
| Breads, rolls, buns | 1.8 | 1.1 | 15 | 12.5 | 0.43 |
| Corn meal | 2 - 3 | 1.2 – 1.8 | 16 – 24 | 13 – 26 | 0.7 – 1.0 |
| Farina | 2 – 2.5 | 1.2 – 1.5 | 16 - 20 | >=13 | 0.7 – 0.87 |
| Flour | 2.9 | 1.8 | 24 | 20 | 0.7 |
| Macaroni and noodle | 4 – 5 | 1.7 – 2.2 | 27 - 34 | 13 – 16.5 | 0.9 – 1.2 |
| Rice | 2 – 4 | 1.2 – 2.4 | 16 – 32 | 13 – 26 | 0.7 – 1.4 |

# Standardized Foods: Additional Vehicles of Fortification

- "Margarine" is required to contain vitamin A and may contain vitamin D

- "Milk" may contain vitamin A and/or vitamin D. The name of the food is "Milk, vitamins A and D added"

# Food Fortification Policy (21 CFR 104.20)

- The objective is to establish a uniform set of principles/guidelines that would serve as a model for the rational addition of essential vitamins and minerals to foods

- Discourages indiscriminate addition of nutrients to foods

# Fortification Policy

- Does not consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods (e.g., candies or carbonated beverages)

# Nutrients Considered Under the Fortification Policy

- FDA considers only essential nutrients to be within the scope of its fortification policy
    - The term essential nutrient under the fortification policy refers to the vitamins and minerals that are essential for human nutrition (Reference Daily Intakes (RDIs) - codified in 21 CFR 101.9(c)(8)(iv)), as well as potassium and protein (Daily Reference Values (DRVs) (21 CFR 101.9(c)(9))

# Nutrients…

**There must be a safe and lawful source of the essential nutrient**

- The nutrient must be an approved food additive or Generally Recognized As Safe (GRAS) under conditions of its intended use
- There should be no determination by the FDA that fortification with that nutrient is inappropriate (e.g., by regulation)
- In addition, some nutrients are limited by food additive or GRAS regulation regarding the foods that may be fortified and to what level (e.g., folic acid (172.345); vitamin D (172.380; 184.1950)

# Principles: Reasons for Adding Essential Nutrients

- To correct a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease and/or for a public health purpose
- To restore nutrients to levels representative of the food prior to storage, handling, and processing
- To maintain a balanced nutrient profile in proportion to the caloric value of a food (e.g., meal replacement products)
- To avoid nutritional inferiority in foods that replace traditional foods (21 CFR*101.3(e)(2)).*

# Principles (contd.)

- A nutrient added to a food is appropriate only when the nutrient is:
  - Stable under customary conditions of storage, distribution, and use
  - Physiologically available from the food
  - Present at a level at which there is a reasonable assurance that over-consumption will not occur, considering cumulative amounts from other sources in the diet

# Fortification to Address a Public Health Need: Folic Acid as an Example

- Considerations:
  - Assessment of public health needs
  - Selection of appropriate vehicle(s) for fortification
  - Dietary modeling to evaluate fortification levels for the target population while maintaining a safe level of intake for the non-target population
  - Assessment of the impact of fortification

# Folic Acid Fortification: Assessment of Need

- Target population: women of childbearing age

- 1992 U.S. Public Health Service recommendation:
  - All women of childbearing age capable of becoming pregnant should consume 400 mcg folic acid per day for prevention of neural tube defects
    - Keep total intake at less than 1 mg per day

# Folic Acid Fortification: Goal and Food Vehicle

- Aim: to increase folic acid intakes in the target population, while maintaining safe intakes for all age and sex groups

- Rationale for fortifying enriched cereal grain products:
  - Most women consume
  - Would not require change in dietary patterns

# Folic Acid Fortification: Dietary Modeling

- General approach
  - Estimated distributions of “current” total daily folate intake from a national food consumption survey for 8 age and sex groups
    - Included intake from dietary supplements
  - Projected increases in intake for various food fortification scenarios
    - Enriched cereal grains – at 70, 140, 350 µg folic acid per 100 g
    - Breakfast cereals– at 100 or 400 µg folic acid per serving

# FDA Regulatory Decision-Making

- Mandated folic acid fortification of enriched cereal grain products
  - < Based on a fortification level of ~ 140 µg/100g
- Under food additive regulation, FDA permitted folic acid fortification in these additional food categories:
  - < Breakfast cereals, corn grits, meal replacement products, infant formula, foods for special dietary use

# Folic Acid Fortification: Assessment of Impact

- Increase in folic acid intake and folate status (serum and RBC folate levels) since fortification

- Reduction in prevalence of neural tube defect


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# Thank you

**http://www.fda.gov/Food/default.htm**