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


- 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

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

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