FDA Fortification Policy and Infant Formula Regulation

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Food Fortification Policy (21 CFR 104.20)

- FDA published fortification policy guidelines in 1980 (45 FR 6314, January 25, 1980)

- The objective was to establish a uniform set of principles that would serve as a model for the rational addition of essential vitamins and minerals and protein

Fortification Policy

- Discourages indiscriminate addition of nutrients to foods

- 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 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…

- This list in 101.9 (c)(8)(iv) has been modified since 1980 and now includes 6 more vitamins and minerals (vitamin K, manganese, selenium, chromium, molybdenum and chloride)

- As other essential vitamins and minerals are added to 101.9 (c)(8)(iv), they can also be recognized for rational addition under the fortification policy

Nutrients…

There must be a safe and lawful source of the nutrient

- The nutrient must be an approved food additive or GRAS under the conditions of its intended use
- There should be no determination by the FDA, in a regulation or as a matter of policy, that fortification by that nutrient is inappropriate
- 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 *(21 CFR 172.345);* vitamin D (*21 CFR 172.380; 184.1950))*

Principles of fortification policy

A nutrient(s) may appropriately be added to a food:

- to correct a dietary insufficiency and for a public health purpose *(21 CFR 104.20(b))*
  - recognized by the scientific community to exist and known to result in nutritional deficiency disease;
- to restore nutrients *(21 CFR 104.20(c))*
  - to levels representative of the food prior to storage, handling, and processing;

Principles.. (Cont'd)

- to maintain a balanced nutrient profile in proportion to the caloric value of a food *(21 CFR 104.20(d));*
- to improve the quality of a replacement food so as to avoid nutritional inferiority relative to the food that it replaces *(21 CFR 104.20(e));*
- as permitted or required by applicable FDA regulations *(21 CFR 104.20(f))*

What other regulations are mentioned under 104.20 (f)?

- Standards of identity *(21 CFR parts 130-169))*
- Nutritional quality guidelines *(e.g., 21 CFR 104.47)*
- Common or usual name regulations *(21 CFR part 102)*

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
- Suitable for its intended purposes and meets requirements for the safety of substances in food

Enforcement

- The provisions of the fortification policy have been incorporated into two labeling regulations which have the force and effect of law:
  - Nutrient content claims for “More” *(21 CFR 101.54(e))*
  - Nutrient content claim for “Healthy” *(21 CFR 101.65(d))*

Infant Formula Regulation (21 CFR 107)

- Not under the scope of fortification policy
- Specific statutory requirements pertaining to the required nutrients and nutrient levels (under section 412 of the FD&C Act and regulatory requirements in 21 CFR 107)

Nutrient requirements for infant formula

- Provides sole source of nutrition during a vulnerable period
- Must contain appropriate amounts of all essential nutrients
- Minimum levels for 29 nutrients and maximums for 9 of the 29 under 21 CFR 107.100
- Adulterated if it does not provide all nutrients as required under 21 CFR 107.100

FDA CFSAN

Premarket notification requirements for infant formula manufacturers

- Must provide a 90-day notification before marketing a new infant formula or formula with a major change

- Premarket notification must contain:
  - Quantitative formulation
  - Description of the changes made
  - Assurances that the formula will not be marketed unless it meets nutrient requirements and quality factors and is manufactured with good manufacturing practices and quality control procedures

FDA CFSAN

FDA compliance tools for infant formulas

- FDA plant inspections
  - Yearly inspections at all infant formula facilities
    - **Good manufacturing practices**
    - **Quality control procedures**
    - **Records and reports**

- Mandatory recalls of adulterated products

Questions