AMERICAN FROZEN FOOD INSTITUTE

Issue Brief: Fortification

The Food and Drug Administration (FDA) and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) both have implemented policies discouraging fortification of foods except in specified circumstances. Although there are legal limitations on the binding nature of the agencies' policies, fortification of foods is primarily enforced through voluntary compliance. AFFI members should consult with legal counsel when considering fortification of foods in a manner that would not be consistent with the fortification policy.

Legal Framework

FDA

FDA's fortification policy, codified in 21 C.F.R. § 104.20, establishes specific guidelines for the fortification of food products with additional nutrients. Fortification with specified nutrients is permitted under specified conditions related to:

- Correcting a dietary insufficiency recognized by the scientific community to exist and known to result in nutritional deficiency disease; 1/
- Restore nutrients to a level representative of the food prior to storage, handling, and processing; 2
- To balance vitamin, mineral, and protein content in proportion to the total caloric content of the food; 3/
- To avoid nutrition inferiority for a food that replaces a traditional food in the diet; 4/ or
- As permitted or required by applicable FDA regulations. 5/

FDA's policy also provides further parameters on when it is appropriate to add a nutrient to a food, such as when it is stable in the food under customary storage, distribution and use conditions, is physiologically available from the food, and there is a reasonable assurance that the level of the nutrient will not result in excessive intake. 6/ Certain permissible labeling claims also are set forth in the policy. 7/

FDA only supports fortification for certain types of foods. The policy states:

1/ 21 C.F.R. § 104.20(b).
2/ *Id.* § 104.20(c).
3/ *Id.* § 104.20(d).
4/ *Id.* § 104.20(e).
5/ *Id.* § 104.20(f).
6/ *Id.* § 104.20(g).
7/ *Id.* § 104.20(h) (e.g., "fully restored with vitamins and minerals," "vitamins and minerals are added in proportion to caloric content").

The Food and Drug Administration does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. 8/

Additionally, manufacturers who elect to fortify foods are urged by FDA to follow the policy's principles when adding nutrients to food.

The fortification policy was codified in the Federal Register as "a series of guidelines," but was not subject to notice and comment rulemaking under the Administrative Procedure Act (APA). 9/ FDA has recognized, therefore, that "the fortification policy is only a guideline," unless it has been subjected to notice and comment rulemaking. 10/ This means that the policy is non-binding except where it is given binding effect through incorporation into a specific nutrient content claim regulation.

FDA has incorporated the fortification policy into its regulations for claims using the terms "more," "fortified," "enriched," "added," "extra," and "plus;" as well as its regulations for "high potency" claims. 11/ Also, the addition of any nutrients added to meet the "healthy" definition must be in accordance with the fortification policy for certain foods. 12/ In contrast, the fortification policy is not binding for a product that makes a "good source" claim because the policy has not been incorporated by reference into that regulation.

FSIS

FSIS does not permit the addition of nutrient additives (e.g., vitamins and minerals) to meat and poultry, in accordance with FDA's fortification policy. 13/ FSIS's position is:

[T]he indiscriminate addition of nutrients to meat and poultry is not in the best interest of consumers since, to-date, there is no demonstrated need or consensus in the scientific community that the fortification of meat and poultry is necessary. 14/

8/ *Id.* § 104.20(a).
9/ 45 Fed. Reg. 6314 (Jan. 25, 1980).
10/ 58 Fed. Reg. 2302, 2363 (Jan. 6, 1993).
11/ 21 C.F.R. § 101.54(e)(1)(ii); (f)(1)(3).
12/ 21 C.F.R. § 101.65(d)(2)(iv). These foods are: (1) raw, single-ingredient seafood or game meat, (2) a meal product or main dish product (as defined in FDA's nutrition labeling regulations), and (3) any other food that is not (i) a raw fruit or vegetable, (ii) a single-ingredient or a mixture of frozen or canned fruits and vegetables, or (iii) an enriched cereal grain product that conforms to a standard of identity in 21 CFR Parts 136, 137, or 139.
13/ FSIS Statement of Interim Labeling Guidance: The Labeling of Factual Statements on Nutrients in Meat and Poultry Products (Sept. 10, 2009), *available at* http://www.fsis.usda.gov/wps/wcm/connect/cc1d1275-4538-4d0e-9e1d-fe380a8818b8/Nutrients_Meat___Poultry.pdf?MOD=AJPERES. This is a longstanding agency position. *See* 70 Fed. Reg. 33803, 33805-06 (June 10, 2005).
14/ *Id.*

However, FSIS will not object if a food fortified under FDA's jurisdiction is added to meat and poultry products in a dual jurisdiction establishment (e.g., enriched spaghetti noodles are added to meatball sauce). The agency expects that any claims regarding fortification of such dual jurisdiction products will specifically identify the food that is the source of the fortified nutrient (e.g., "enriched pasta is a good source of calcium").

Similarly, FSIS does not object to fortification of a food produced under FDA's jurisdiction that contains a substance not specified in FDA's fortification policy (e.g., Lycopene, Omega-3 Fatty Acids, Lutein) that is added to a meat or poultry product, so long as the safety of the use of the substance in meat and poultry products has been established. Again, any claims would need to identify the food that is the source of the nutrient (e.g., "250 mg Omega-3 Fatty Acids per serving from the Flax seed in crust"). In fact, FSIS takes the position that it would be misleading not to disclose the source of the nutrient in these situations, as it could create the impression that the meat or poultry is the source of the nutrient, which would not be correct. 15/

Recent Developments

FDA has sent several Warning Letters in recent years interpreting the fortification policy as applying to both express and implied fortification claims. 16/ There also have been class action lawsuits alleging that foods were fortified in violation of FDA's policy. 17/ Companies that fortify products in a manner inconsistent with the Fortification Policy, therefore, face potential class action litigation and regulatory liability.

Issues to Watch

- Continued enforcement by FDA, expanding the scope of claims that the agency considers legally bound by the policy
- Continued scrutiny of fortification claims and fortified products by the class action bar and consumer groups

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15/ To the extent that the feeding practices of the animal producer are the reason the substance is present (e.g., flax seed fed to cattle introduced Omega-3 fatty acids into the meat tissue), the source of the substance would not need to be declared. However, FSIS takes the position that the presence of the substance should be declared (e.g., "X mg of Omega-3 fatty acids per serving").

16/ *See, e.g.*, FDA Warning Letter to The Hershey Company (Feb. 14, 2012) (objecting to product labels bearing the claims "plus" and "fortification" that FDA contended did not comply with the fortification policy because they are syrups); FDA Warning Letter to Dr. Pepper Snapple Group (Aug. 30, 2010) (taking the position that "enhanced" is a synonym for "more" and the product, as a carbonated beverage, was not fortified in a manner consistent with fortification policy).

17/ *See, e.g.*, *Green v. Dr. Pepper Snapple Group* (C.D. Cal. No. 12-CV-09567) (alleging the fortification of a carbonated beverage, 7UP Antioxidant, was inconsistent with FDA's fortification policy and therefore misleading); *Ackerman v. Coca-Cola Company* (E.D.N.Y. No. 09-CV-00395) (challenging the representation of Vitamin Water as a nutrient-enhanced water beverage).

AFFI Action Items

- Monitor FDA, FSIS, and class action litigation filings to identify potential priorities and areas of focus for enforcement

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