DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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Miles V. McEvoy
Deputy Administrator
National Organic Program
United States Department of Agriculture
Room 2646-South (Stop 0268)
1400 Independence Avenue SW
Washington, DC 20250-0268

Dear Mr. McEvoy,

This letter is in response to the questions submitted by your office on March 31, 2010, regarding clarification of the Food and Drug Administration Fortification Policy Title 21 of the Code of Federal Regulations 104.20.

The responses to your questions are provided below. Should you have additional questions or need further clarification, please contact Essie Yamini in my office at (301) 436-1450.

Sincerely,

Mary L. Roos
for

Barbara O. Schneeman, Ph.D.
Director
Office of Nutrition, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition
Food and Drug Administration

The Food and Drug Administration response to the questions submitted by the National Organic Program, USDA on March 31, 2010

1. Does FDA recognize or define "accessory nutrients"?

The term "accessory nutrients," used by USDA, means "nutrients not specifically classified as a vitamin or mineral but found to promote optimal health."[1] Examples of such nutrients include "omega-3 fatty acids, inositol, choline, camitine, [sic] and taurine." Id. The term "accessory nutrients" is not defined by FDA and is not a term that describes the nutrients that are the subject of FDA's fortification policy.

FDA considers only "essential nutrients"[2] to be within the scope of its fortification policy (21 CFR 104.20). When this policy was established in January 1980 (45 FR 6314; January 25, 1980), the essential vitamins and minerals listed under paragraph 104.20(d)(3) were the same as those listed in 21 CFR 101.9(c)(7)(iv)[3] (the list of essential vitamins and minerals are currently codified in 21 CFR 101.9(c)(8)(iv)). When FDA established the fortification policy in 1980, it anticipated that additional essential nutrients would be added to the list in § 101.9 and thus would be eligible for the rational fortification of food (Section 104.20(a) states that "it is reasonable to anticipate that the Reference Daily Intakes (RDI's) as delineated in 101.9 of this chapter and in paragraph (d) of this section will be amended from time to time to list additional nutrients and/or to change levels of specific RDI's as improved knowledge about human nutrient requirement and allowances develops."). FDA has modified the list of essential vitamins and minerals since 1980 and this list now includes vitamin K, manganese, selenium, chromium, molybdenum and chloride. These additional essential nutrients are considered "nutrients" under the fortification policy that may be rationally added to food under the circumstances set forth in such policy.

However, in order to add such nutrients to foods under the fortification policy, the addition would need to be consistent with the circumstances identified in the policy, i.e., to correct a dietary insufficiency, restore nutrients to certain levels, maintain a balanced nutrient profile, improve the quality of a replacement food, or be added as permitted or required by another FDA regulation. For example, under 104.20(f), a nutrient subject to the fortification policy could be added provided there is an FDA regulation that either permits or requires such nutrient addition. FDA considers the type of regulation to which § 104.20(f) refers as one that describes the circumstances under which an essential nutrient may be used in food "based upon the best available

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[1] USDA references the term "accessory nutrients" in the April 26, 2010 Action Memorandum from Miles McEvoy, Deputy Administrator, National Organic Program to the Chairman of the National Organic Standards Board.

[2] The term "essential nutrient" under the fortification policy refers to the vitamins and minerals in the list of Reference Daily Intakes (RDIs) in the current 21 CFR 101.9(c)(8)(iv) that are essential for human nutrition, in addition to protein and potassium that have Daily Reference Values (DRV). Potassium is considered an essential nutrient even though currently there is no RDI, nor was there a U.S. RDA in 1980 when FDA established the fortification policy (45 FR 6314 at 6319; January 25, 1980)

[3] *See* 38 FR 2125; January 19, 1973.

scientific data on food consumption patterns, nutritional needs, and dietary habits of the general population ...." (45 FR at 6317). Such regulations are those pertaining to a common or usual name (21 CFR part 102), standard of identity (21 CFR parts 130-169), or nutritional quality guideline (21 CFR 104.47).[4] There must also be a safe and lawful source of the essential nutrient (e.g., the substance must be an approved food additive or GRAS under the conditions of its intended use) and there should be no determination by the agency, 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.

As other essential vitamins and minerals are added to § 101.9 (c)(8)(iv), those nutrients can also be recognized for rational addition under the fortification policy. However, omega-3 fatty acids, inositol, choline, carnitine, and taurine that USDA identifies as "accessory nutrients" are not essential nutrients listed under 101.9(c)(8)(iv) or that FDA otherwise considers to be essential nutrients (e.g., protein and potassium) under the fortification policy, and therefore, are not within the scope of FDA's fortification policy.[5]

2. *How does FDA enforce or use the guidance at 21CFR 104.20 at present? Can carbonated or non-carbonated drinks, including water, be fortified with nutrients? Can "energy bars" be fortified?*

FDA fortification policy (21 CFR 104.20) is expressed as a series of recommendations which manufacturers are urged to follow if they elect to add nutrients (see response to question 1 above) to a food for human consumption. The principles of rational fortification expressed in the fortification policy are: to correct

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[4] In the final 1980 fortification policy, §104.20(f) was substituted for proposed 100.1(g)(2) that was intended to permit the addition of nutrients to a food or class of foods "when necessary to comply with a standard of identity, a nutritional quality guideline, a common or usual name regulation, or any other Federal regulation." (45 FR at 6317 January 25, 1980). The language "any other Federal regulation" in § 104.20(f) referred to a type of regulation enumerated in the list provided; one that is related to the rational addition of an "essential nutrient" consistent with the purposes of the fortification policy. The standards of identity for enriched cereal-grain products, for example, require fortification at specified levels with thiamin, riboflavin, niacin, iron and folic acid.

[5] We note that choline and inositol are on the list of nutrients under section 412 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(i)) that are required to be in infant formula. At the time the January 1980 fortification policy was established, the Infant Formula Act of 1980 had not yet been enacted; it was enacted on September 29, 1980. To date, the agency has not considered infant formula to be within the scope of the fortification policy given the specific statutory requirements pertaining to the required nutrients and nutrient levels for such food under section 412 of the act and regulatory requirements in 21 CFR part 107 pertaining to required and essential nutrients for such formula. These nutrient specifications for infant formula are separate from the fortification policy for foods for the general population and include minimum amounts for 29 nutrients and maximum amounts for 9 of those nutrients. Other substances that may be added to infant formula as a food additive or GRAS substance are not those required by section 412 (i) of the Act or 21 CFR part 107. In addition, the essential nutrients subject to the fortification policy are set for children 4 years and above and not for those younger than 4 years. Thus, the nutrients under the fortification policy are not applicable for addition to foods geared toward children less than 4 years, including infants.

dietary insufficiency and for a public health purpose (e.g., iodized salt), for nutrient restoration, under a nutrient-to-caloric balance concept, to prevent nutrient inferiority in a food, and as permitted or required by another applicable FDA regulation.[6] For example, if a nutrient is to be appropriately added to a food for purposes of correcting a dietary insufficiency, sufficient scientific information should be available to identify a public health nutritional problem and the affected population groups, and that the food is suitable to act as a vehicle for the added nutrients (21 CFR §104.20 (b)(1)).

The fortification policy discourages indiscriminate addition of nutrients to foods and FDA stated in this policy that it does not consider it appropriate to fortify certain classes of food such as fresh produce, meat, poultry or fish products, sugars or snack foods such as candies and carbonated beverages.

Although this policy is primarily used as guidance, the provisions of the fortification policy have been incorporated into two labeling regulations which have the force and effect of law: 21 CFR 101.54(e) Nutrient content claims for "More" and 21 CFR 101.65(d) Nutrient content claim for "Healthy."[7] Consequently, FDA may issue a warning letter and take enforcement action if a manufacturer markets a food bearing one of these nutrient content claims and the food contains a nutrient addition that is inconsistent with the fortification policy.

3. *For nonorganic food, under current regulations, can manufacturers use a nutrient not mentioned in 21 CFR 104.20 such as glucosamine or citrus bioflavonoids for fortification under 21 CFR 104.20 based on a self-affirmed GRAS status? If not, does listing in the GRAS Notifications Inventory constitute approval as per 21 CFR 104.20(f) as "nutrients covered in "this chapter".*

Consistent with what we explained previously, glucosamine and citrus bioflavonoids would not be essential nutrients that are subject to the FDA fortification policy. Therefore, a manufacturer's self-determination of GRAS or a GRAS notification for such substances is not relevant to whether these substances are within the scope of the fortification policy.

Even if a manufacturer self-determined as GRAS the addition to food of an essential nutrient that is within the scope of the fortification policy, or has submitted a GRAS

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[6] Because the fortification policy deals only with essential nutrients that are listed under § 101.9(c)(8)(iv), plus protein and potassium, these regulations are limited to those specifically pertaining to the use of such nutrients in accordance with the fortification policy and include regulations pertaining to a standard of identity, common or usual name and a nutritional quality guideline. In addition, FDA has identified by regulation certain nutrients (selenium, molybdenum, chromium and chloride) under the fortification policy that are optional when making a determination as to whether a particular food is nutritionally inferior to a food for which it substitutes and that it resembles ((60 FR 67164; December 28, 1995); (21 CFR 101.3 (e)(4)(ii)).

[7] The nutrients that may be in foods at levels that make the food eligible to bear the "more" or "healthy" nutrient content claim are not all considered to be an "essential nutrient" that are within the scope of the 1980 fortification policy (e.g., dietary fiber).

notification for such nutrient addition, the manufacturer would not be able to rely on 21 CFR 104.20(f) for the addition under the fortification policy. 21 CFR 104.20(f) is intended to allow the addition of an essential nutrient to a food or class of foods when such addition is permitted or required by regulation. First, neither a self-determination of GRAS or a GRAS notification submission is a regulation that would permit or require the addition of such a nutrient. Second, FDA considers nutrients added to food under the fortification policy to be consistent with a regulation that considers the "best available scientific data on food consumption patterns, nutritional needs, and dietary habits of the general population..." (45 FR at 6317), which includes standards of identity ((21 CFR parts 130-169)), nutritional quality guidelines (21 CFR 104.47), or common or usual name regulations (21 CFR part 102). These types of nutrient regulations address the permissible or required addition of essential nutrients to food (e.g., the addition of folic acid to enriched grain products). 21 CFR 104.20(a) otherwise outlines the conditions under which FDA believes fortification is appropriate. It focuses on the addition of essential nutrients to certain foods and specifically reference those nutrients with RDI's listed in § 101.9(c)(8)(iv) plus protein and potassium. It anticipates that these nutrients will change from time to time as they had since the fortification policy's initial drafting in 1980.

4. *Are DHA and ARA approved for use by FDA as GRAS for all foods, or certain foods - including in infant formula?*

Different sources of DHA (Docosahexaenoic acid) have been the subject of several GRAS notifications submitted to FDA (see e.g., GRN 41, 94, 137, and 319). DHA from algal oil is considered GRAS for use in several food categories. Certain sources of DHA are considered GRAS for different categories of infant formula. FDA responses to GRAS notifications do not constitute FDA approval.
Different sources of arachidonic acid (ARA) have been the subject of several GRAS notices (see e.g., GRN 41, 80, 94, and 326). These GRAS notifications are limited to the use of ARA from a certain source to categories of infant formula. FDA's responses to the GRAS notices mentioned above are available on FDA's Inventory of GRAS Notice Web site http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing).

FDA would not consider these substances or other substances that are not essential nutrients (those listed as RDI's in § 101.9(c)(8)(iv) plus protein and potassium) to be appropriate for fortification of foods under 104.20, and considers substances added to infant formula to be outside the scope of the fortification policy.