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June 8, 2012

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Via Certified Mail

U.S. Department of Agriculture
Food Safety and Inspection Service
FSIS Docket Clerk
Room 2534, South Agriculture Building
1400 Independence Avenue, S.W.
Washington, D.C. 20250-3700

Re: Petition for FSIS to Permit the Labeling of an Oat Fiber Ingredient Used as a Binder in Meat and Poultry Products As "Oat Fiber"

SunOpta Inc. ("SunOpta") submits this Petition to request the Administrator of the Food Safety and Inspection Service ("FSIS") to determine that the proper nomenclature for an oat fiber ingredient is "oat fiber" when the ingredient is used as a binder in meat and poultry products. This Petition is submitted pursuant to the FSIS Petition Regulations at 9 C.F.R. § 392.

On several occasions SunOpta has requested clarification from FSIS regarding the labeling of oat fiber when used as a binder in the production of standardized and non-standardized meat and poultry products.[1] SunOpta's oat fiber ingredients are composed almost entirely of fiber (93-97%).[2] In its responses to SunOpta, FSIS has stated that the proper nomenclature for an oat fiber ingredient used as a binder in meat and poultry products is "isolated oat product" or "modified oat product." FSIS explained that in light of its policy to not permit fortification of meat and poultry products, the term "fiber" cannot be used "per se as a direct food additive to meat and poultry products"[3] because (1) the Food and Drug

[1] *See* Letter from Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff to Mark Kirschbaum, SunOpta Ingredients (Nov. 8, 2006) ("November 8, 2006 Response Letter"); Letter from Robert C. Post, Branch Chief, Food Standards and Ingredients Branch, Product Assessment Division, Regulatory Programs to Daniel A. Kracov, Patton, Boggs & Blow (Sep. 15, 1993) ("September 15, 1993 Response Letter"); Letter from Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff to Mark Kirschbaum, SunOpta Ingredients (May 2, 2007).

[2] *See* SunOpta Canadian Harvest® Oat Fiber Brochure, p. 2, *available at* http://www.sunopta.com/ingredients/files/overviews/sunopta_ch_oat_fibers.pdf.

[3] September 15, 1993 Response Letter.

Administration ("FDA") has not defined the term "fiber," (2) "the term 'fiber' is very general and has been used to describe substances from nylon to a variety of grain products," and (3) fiber "connotes dietary implications and could be misconstrued to represent a fiber fortification claim."[4]

As discussed below, FSIS' rationale for its labeling guidance for oat fiber ingredients that are used as a binder in meat and poultry products is misguided. FSIS regulations require an ingredient to be labeled by its common or usual name: "Oat fiber" is the common and usual name of this ingredient. Also, "oat fiber" is not general because it includes the qualifying word "oat." Lastly, properly labeling this ingredient in a product's ingredient list is not a dietary or fortification claim because it is not a statement about a particular benefit of the product.

I. Definition of "Oat Fiber"

While the FDA has not established a definition for "fiber,"[5] the terms "fiber" and "oat fiber" are used in ingredient lists for FDA-regulated foods and processed foods. In fact, a review of the three GRAS Notifications that have been submitted to FDA for oat fiber ingredients state the common or usual name of the ingredient is "oat fiber."[6] FSIS should permit meat and poultry products to also use the common name of this ingredient when it is used as a binder in meat and poultry products. Such an approach would be consistent with the FSIS labeling regulations which require a product's "list of ingredients . . . show the common or usual names of the ingredients . . . ."[7] In addition, labeling this ingredient "oat fiber" is more specific than just "fiber" because it includes the qualifying word "oat."

Research also suggests that consumers have an interest in the proper labeling of fiber in food.[8] However, the current FSIS policy that requires oat fiber to be labeled as "isolated oat product" or "modified oat product" has led to confusion in the marketplace about this

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[4] November 8, 2006 Response Letter.

[5] *See, e.g.*, Food Labeling: Revision of Reference Values and Mandatory Nutrients, 72 Fed. Reg. 62149, 62166 (Nov. 2, 2007).

[6] *See* GRAS Notice 261, p. 6 (Aug. 13, 2008); GRAS Notice 342, p. 2 (May 19, 2010); GRAS Notice 366, p. 4 (Dec. 9, 2010).

[7] 9 C.F.R. § 317.2(f)(1).

[8] *See* Dietary Fibre – Codex Definition and Methods of Analysis, FOSS, p. 4 (May 2011); Dietary Fiber I, Technical Bulletin, AIB International, p. 5 (Jan. 2009).

ingredient, likely because it is not being labeled by its common or usual name. For example, when Taco Bell faced public scrutiny over the composition of its taco meat in early 2011, numerous commentators took issue that the company's taco meat contains "isolated oat product." One person went so far as to post on an online message board that Taco Bell's meat "is mostly comprised of something called 'Isolated Oat Product'. Not to mention, 'fillers' and 'extenders' – which sound a bit more benign than 'Oat Product'. But, I confess I'm having tremendous difficulty imagining what any of these things actually are."[9] There is also the potential that, in light of the confusion surrounding the terms "isolated oat product" and "modified oat product," labeling oat fiber something other than its common or usual name could lead to the meat or poultry product being misbranded.[10]

II. Fortification Claims; Dietary Implications

FSIS has also stated that "fiber" is not a permissible ingredient name in meat and poultry products because it can be misconstrued to represent a fiber fortification claim, which is not currently permitted for meat and poultry products,[11] and it may have dietary implications. As an initial matter, the use of oat fiber as a binder in meat and poultry products is not fortification of the product. "Fortification" has been defined by the World Health Organization ("WHO") and the Food and Agricultural Organization of the United Nations ("FAO") as "the practice of deliberately increasing the content of an essential micronutrient, *i.e.*, vitamins and minerals (including trace elements) in a food irrespective of whether the nutrients were originally in the food before processing or not, *so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health.*"[12] SunOpta's oat fiber ingredients are used as a binder in meat and poultry

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[9] *See* Brothers All :: Forum, Topic: Isolated Oat Product, *available at* http://forum.clonecommandos.net/index.php?topic=2599.0.

[10] 9 C.F.R. § 301.2.

[11] FSIS has stated publicly that it "does not permit the addition of nutrient additives (e.g., vitamins and minerals) to meat and poultry. FSIS continues to believe that the 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." FSIS Statement of Interim Labeling Guidance, The Labeling of Factual Statements on Nutrients in Meat and Poultry Products, p. 1, *available at* http://www.fsis.usda.gov/PDF/Nutrients_Meat_&_Poultry.pdf.

[12] Guidelines on Food Fortification with Micronutrients, WHO, p. xxvii (2006), *available at* http://www.who.int/nutrition/publications/guide_food_fortification_micronutrients.pdf (emphasis added).

products; they are not added to increase a product's nutrient content or provide a public health benefit. Accordingly, the use of an oat fiber ingredient as a binder is not fortification of the product.

Moreover, properly listing an ingredient by its common or usual name is not a "claim," whether for fortification or dietary purposes. "Claims" are statements about the benefits of a particular aspect of the food. For example, nutrient content claims are addressed at Parts 317.354 and 381.454 of the FSIS regulations,[13] and FDA addresses fiber claims at Parts 101.76, 101.77, and 101.81 of its regulations.[14] Permitted fiber claims include more than just the name of the ingredient. They address specific *statements* about a particular benefit of the food, such as "good source of fiber," "high in fiber," and "more fiber than."[15] The truthful labeling of an ingredient on a product's ingredient list is simply not a claim.[16]

III. Conclusion

SunOpta requests that FSIS determine that the proper nomenclature for an oat fiber ingredient is "oat fiber" when it is used as a binder in meat and poultry products.

Respectfully submitted,

Robert G. Hibbert

cc: R. Edelstein, FSIS
R. Murphy-Jenkins, FSIS

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[13] 9 C.F.R. §§ 317.354, 381.454.

[14] 21 C.F.R. §§ 101.76, 101.77, 101.81.

[15] 9 C.F.R. §§ 317.354, 381.454.

[16] *See, e.g.*, 21 C.F.R. § 101.13. Of course, we would be happy to discuss fiber fortification claims for FSIS-regulated products in a separate forum.

References

1. 9 C.F.R. § 392.
2. Letter from Robert C. Post, Branch Chief, Food Standards and Ingredients Branch, Product Assessment Division, Regulatory Programs to Daniel A. Kracov, Patton, Boggs & Blow (Sep. 15, 1993).
3. Letter from Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff to Mark Kirschbaum, SunOpta Ingredients (Nov. 8, 2006).
4. Letter from Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff to Mark Kirschbaum, SunOpta Ingredients (May 2, 2007).
5. SunOpta Canadian Harvest® Oat Fiber Brochure.
6. Food Labeling: Revision of Reference Values and Mandatory Nutrients, 72 Fed. Reg. 62149 (Nov. 2, 2007).
7. GRAS Notice 261 (Aug. 13, 2008).
8. GRAS Notice 342 (May 19, 2010).
9. GRAS Notice 366 (Dec. 9, 2010).
10. 9 C.F.R. § 317.2.
11. Dietary Fibre – Codex Definition and Methods of Analysis, FOSS (May 2011).
12. Dietary Fiber I, Technical Bulletin, AIB International (Jan. 2009).
13. Brothers All :: Forum, Topic: Isolated Oat Product.
14. 9 C.F.R. § 301.2.
15. FSIS Statement of Interim Labeling Guidance, The Labeling of Factual Statements on Nutrients in Meat and Poultry Products.
16. Guidelines on Food Fortification with Micronutrients, WHO (2006).
17. 9 C.F.R. § 317.354.
18. 9 C.F.R. § 381.454.
19. 21 C.F.R. § 101.76.
20. 21 C.F.R. § 101.77.
21. 21 C.F.R. § 101.81.
22. 21 C.F.R. § 101.13.

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9 C.F.R. § 392

hour per program employee in fiscal year 2008.

[71 FR 2142, Jan. 13, 2006]

§ 391.4 Laboratory services rate.

The rate for laboratory services provided pursuant to §§ 350.7, 351.9, 352.5, 354.101, 355.12, and 362.5 is $67.83 per hour per program employee in fiscal year 2006, $69.31 per hour per program employee in fiscal year 2007, and $70.82 per hour per program employee in fiscal year 2008.

[71 FR 2142, Jan. 13, 2006]

§ 391.5 Laboratory accreditation fees.

(a) The annual fee for the initial accreditation and maintenance of accreditation provided pursuant to §§ 318.21 and 381.153 shall be $4,000.00 for fiscal year 2006; $4,500.00 for fiscal year 2007; and $4,500.00 for fiscal year 2008.

(b) Laboratories that request special onsite inspections shall pay FSIS the actual cost of reasonable travel and other expenses necessary to perform the unscheduled or non-routine onsite inspections.

[58 FR 65269, Dec. 13, 1993 as amended at 59 FR 66449, Dec 27, 1994; 64 FR 19868, Apr. 23, 1999; 71 FR 2143, Jan. 13, 2006]

PART 392—PETITIONS FOR RULEMAKING

Sec.

AUTHORITY: 5 U.S.C. 553(e), 7 CFR 1.28.

SOURCE: 74 FR 16107, Apr. 9, 2009, unless otherwise noted.

§ 392.1 Scope and purpose.

This part contains provisions governing the submission of petitions for rulemaking to the Food Safety and Inspection Service (FSIS). The provisions in this part apply to all rulemaking petitions submitted to FSIS, except to the extent that other parts or sections of this chapter prescribe procedures for submitting a request to amend a particular regulation.

§ 392.2 Definition of petition.

For purposes of this part, a "petition" is a written request to issue, amend, or repeal a regulation administered by FSIS. A request to issue, amend, or repeal a document that interprets a regulation administered by FSIS may also be submitted by petition.

§ 392.3 Required information.

To be considered by FSIS, a petition must contain the following information:

(a) The name, address, telephone number, and e-mail address (if available) of the person who is submitting the petition;

(b) A full statement of the action requested by the petitioner, including the exact wording and citation of the existing regulation, if any, and the proposed regulation or amendment requested;

(c) A full statement of the factual and legal basis on which the petitioner relies for the action requested in the petition, including all relevant information and views on which the petitioner relies, as well as information known to the petitioner that is unfavorable to the petitioner's position. The statement should identify the problem that the requested action is intended to address and explain why the requested action is necessary to address the problem.

§ 392.4 Supporting documentation.

(a) Information referred to or relied on in support of a petition should be included in full and should not be incorporated by reference. A copy of any article or other source cited in a petition should be submitted with the petition.

(b) Sources of information that are appropriate to use in support of a petition include, but are not limited to:

(1) professional journal articles,
(2) research reports,
(3) official government statistics,
(4) official government reports,
(5) industry data, and
(6) scientific textbooks.

(c) If an original research report is used to support a petition, the information should be presented in a form that

would be acceptable for publication in a peer reviewed scientific or technical journal.

(d) If quantitative data are used to support a petition, the presentation of the data should include a complete statistical analysis using conventional statistical methods.

§ 392.5 Filing procedures.

(a) Any interested person may file a petition with FSIS. For purposes of this part, an "interested person" is any individual, partnership, corporation, association, or public or private organization.

(b) To file a petition with FSIS, a person should submit the petition to the FSIS Docket Clerk, Department of Agriculture, Food Safety and Inspection Service, Room 2534 South Building, 1400 Independence Ave., SW., Washington, DC 20250–3700.

(c) Once a petition is submitted in accordance with this part, it will be filed by the FSIS Docket Clerk, stamped with the date of filing, and assigned a petition number. Once a petition has been filed, FSIS will notify the petitioner in writing and provide the petitioner with the number assigned to the petition and the Agency contact for the petition. The petition number should be referenced by the petitioner in all contacts with the Agency regarding the petition.

(d) If a petitioner elects to withdraw a petition submitted in accordance with this part, the petitioner should inform FSIS in writing. Once a petition has been withdrawn, the petitioner may re-submit the petition at any time.

§ 392.6 Public display.

(a) All rulemaking petitions filed with FSIS, along with any documentation submitted in support of a petition, will be available for public inspection in the FSIS docket room and will be posted on the FSIS Web site at *http://www.fsis.usda.gov/*.

(b) If FSIS cannot readily determine whether information submitted in support of a petition is privileged or confidential business information, FSIS will request that the petitioner submit a written statement that certifies that the petition does not contain confidential information that should not be put on public display. If the petitioner fails to submit the certification within a time specified by FSIS, the Agency will consider the information to be confidential.

(c) If FSIS determines that a petition, or any documentation submitted in support of a petition, contains information that is exempt from public disclosure under the Freedom of Information Act (5 U.S.C. 552 *et seq.*) or any other applicable laws or regulations, and that the information would provide the basis for granting the petition, FSIS will inform the petitioner in writing. FSIS will provide the petitioner an opportunity to withdraw the petition or supporting documentation, or modify the supporting documentation to permit public disclosure.

§ 392.7 Comments.

(a) Any interested person may submit written comments on a petition filed with FSIS.

(b) Comments on a petition should be submitted within 60 days of the posting date of the petition and should identify the number assigned to the petition to which the comments refer.

(c) FSIS will consider all timely comments on a petition that are submitted in accordance with this section as part of its review of the petition.

(d) All comments on a petition will become part of the petition file and will be available for public inspection in the FSIS docket room and posted on the FSIS Web site at *http://www.fsis.usda.gov/*.

(e) Any interested person who wishes to suggest an alternative action to the action requested by the petition should submit a separate petition that complies with these regulations and not submit the alternative as a comment on the petition.

(f) If FSIS determines that a comment received on a petition is in fact a request for an alternative action, the Agency will inform the commenter in writing. The Agency will take no further action on the requested alternative action unless the commenter submits an appropriate petition for rulemaking.

§ 392.8 Expedited review.

(a) A petition will receive expedited review by FSIS if the requested action is intended to enhance the public health by removing or reducing foodborne pathogens or other potential food safety hazards that might be present in or on meat, poultry, or egg products.

(b) For a petition to be considered for expedited review, the petitioner must submit scientific information that demonstrates that the requested action will reduce or remove foodborne pathogens or other potential food safety hazards that are likely to be present in or on meat, poultry, or egg products, and how it will do so.

(c) If FSIS determines that a petition warrants expedited review, FSIS will review the petition ahead of other pending petitions.

§ 392.9 Availability of additional guidance.

Information related to the submission and processing of petitions for rulemaking may be found on the FSIS Web site at *http://www/fsis.usda.gov/*.

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Letter from Robert C. Post, Branch Chief, Food Standards and Ingredients Branch, Product Assessment Division, Regulatory Programs to Daniel A. Kracov, Patton, Boggs & Blow (Sep. 15, 1993)

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

SEP 15 1993

write Regulatory V request or letter regulatory interpretation for opinion

Mr. Daniel A. Kracov
Patton, Boggs & Blow
2550 M Street, N.W.
Washington, D.C. 20037

Dear Mr. Kracov:

This is in response to your letter of August 31, 1993, on behalf of your client Opta Food Ingredients, Inc., which requested written confirmation of the correct ingredient statement nomenclature for a product which you identify as "oat fiber," produced from oat hulls, when it is incorporated into low-fat beef patties. You state that the product identified was formerly manufactured by D.D. Williamson and Company under the name "BETTER BASICS Advanced Oat Fiber."

"Isolated oat product" is the correct declaration for the product which you describe. "Isolated oat product" may be used in a non-standardized meat product, such as low-fat meat patties, and is permitted in products covered by Policy Memo 121A (copy enclosed). The terms "fiber" or "oat fiber" can not be used. The federal meat and poultry regulations currently do not provide for the use of the term "fiber" per se as a direct food additive to meat and poultry products.

Includes Poultry

Please feel free to contact me or Ms. Anita Manka at Area Code (202) 254-2588, if you need additional information.

Sincerely,

USI

Robert C. Post, Branch Chief
Food Standards and Ingredients Branch
Product Assessment Division
Regulatory programs

Enclosure

FSIS FORM 2650-8 (6/86)

1-800

Bill Jones

Letter from Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff to Mark Kirschbaum, SunOpta Ingredients (Nov. 8, 2006)

United States Department of Agriculture | Food Safety and Inspection Service | Office of Policy, Program and Employee Development | Washington, D.C. 20250

Mr. Mark Kirschbaum
SunOpta Ingredients
25 Wiggins Avenue
Bedford, MA 01730

NOV 8 2006

Dear Mr. Kirschbaum:

This letter is in response to your letter of September 5, 2006, in regard to the correct labeling of your "fiber" products that are used in the production of standardized and non-standardized meat and poultry products that are under the jurisdiction of the Food Safety and Inspection Service (FSIS).

With regard to naming an ingredient, the source of the ingredient and the process used to manufacture it must be considered, along with its relationship to similar ingredients with previously established identities and uses. FSIS does not permit the use of the term "fiber" as nomenclature for ingredients used in meat or poultry food products because the Food and Drug Administration (FDA) has not yet defined the term "fiber" as it applies to ingredients and additives. The term "fiber" is very general and has been used to describe substances from nylon to a variety of grain products. Furthermore, the word "fiber" connotes dietary implications and could be misconstrued to represent a fiber fortification claim. Fortification of meat and poultry products (i.e., dietary fiber fortification) is not permitted at this time. Because of the lack of a regulatory definition and the ambiguity of its meaning, the policy of the Agency has been not to approve the use of the designation of "fiber" for ingredients on meat and poultry food product labels.

Therefore, regarding the declaration of "fiber" ingredients, we recommend a descriptive naming approach. FSIS has approved labels bearing the terms "isolated" and "product" (e.g., "isolated oat product") to identify isolates from plant sources that contain various amounts of carbohydrate, protein, and fat (e.g., "isolated carrot product," "isolated soy product," and "isolated pea product"). In addition, FSIS has previously established, in consultation with FDA, that the use of the term "modified," is an acceptable term in lieu of the term "isolated," (e.g., "modified carrot product"). Therefore, SunOpta may descriptively label their "fiber" products in a similar manner (e.g., "isolated soy product," and "isolated wheat product") when used in the production of meat and poultry products.

If you have any questions, please contact Mr. Jeff Canavan, Food Technologist, or me at Area Code (202) 205-0279.

Sincerely,

Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

Letter from Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff to Mark Kirschbaum, SunOpta Ingredients (May 2, 2007)

United States Department of Agriculture | Food Safety and Inspection Service | Office of Policy, Program and Employee Development | Washington, D.C. 20250

Mr. Mark Kirschbaum
SunOpta Ingredients
25 Wiggins Avenue
Bedford, MA 01730

MAY 0 2 2007

Dear Mr. Kirschbaum:

This letter is in response to your letter of February 26, 2007, regarding the use of SunOpta's "isolated soy product" in the production of meat and poultry products regulated by the Food Safety and Inspection Service (FSIS). Specifically, you are requesting clarification on: (1) the labeling of the subject ingredient in meat and poultry products that have a food standard of identity; (2) the level of use in meat and poultry products; and (3) whether the ingredient is regulated by the level of protein in the ingredient or by the volume of the ingredient in the finished food.

Soy okara is the pulp derived from soybeans after mechanically grinding the soybeans for soy milk. The product is approximately 56 percent fiber, 28 percent protein, and 9 percent fat. The product is currently labeled as "isolated soy product" when used to formulate non-standardized meat and poultry products. In regard to the product name, FSIS continues to recommend a descriptive naming approach when used to formulate meat and poultry products. FSIS has approved labels bearing the terms "isolated" and "product" (e.g., "isolated oat product") to identify isolates from plant sources that contain various amounts of carbohydrate, protein, and fat (e.g., "isolated carrot product," "isolated soy product," and "isolated pea product"). In addition, FSIS has previously established, in consultation with FDA, that the use of the term "modified," is an acceptable term in lieu of the term "isolated," (e.g., "modified carrot product"). Therefore, FSIS believes the subject ingredient is appropriately labeled as "isolated soy product" or "modified soy product."

On April 29, 2003, FSIS published in the *Federal Register* a direct final rule titled, "Use of Any Safe and Suitable Binder or Antimicrobial Agent in Meat and Poultry Products With Standards of Identity or Composition." The rule amended FSIS regulations to permit the use of any safe and suitable binder or antimicrobial agent in the production of meat and poultry products that are subject to a standard of identity or composition that provides for the use of such ingredients (e.g. certain types of sausages and chili con carne). Prior to the publication of this rule, only those binders and antimicrobial agents listed in 9 CFR 424.21(c) could be used to formulate meat and poultry products with a standard of identity. The direct final rule provided meat and poultry establishments with greater flexibility in formulating their products.

Because of the direct final rule described above, the use of SunOpta's "isolated soy product" may be used in non-standardized and standardized meat and poultry product where binders are permitted. When used to formulate standardized meat and poultry, the level of use will be regulated similarly to soy flour and soy protein concentrate listed in 9 CFR 424.21(c)

(i.e., 3.5 percent in sausages, 8 percent in chili con carne; and up to 12 percent in spaghetti with meat balls and similar products. The level of use is based on the weight of the product formulation (e.g., the use of the isolated soy protein product cannot exceed 3.5 percent of the weight of the total formulation of a hot dog).

If you have any questions, please contact Mr. Jeff Canavan, Food Technologist, or me at Area Code (202) 205-0279.

Sincerely,

for Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

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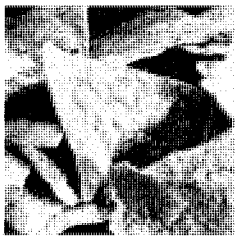
SunOpta Canadian Harvest® Oat Fiber Brochure

SunOpta™
Ingredients Group

Canadian Harvest® Oat Fibers



SunOpta Ingredients Group is the **world's largest producer of oat fiber** for the food industry. With over 20 years of technical and operations know-how, SunOpta's fiber experts are ready to support your next product development effort. From concept to commercial launch, your SunOpta team stands ready to help.

Canadian Harvest® Oat Fibers are very versatile ingredients that can enhance food and beverage products by providing **additional nutritional and functional benefits**.

Oat fiber is an ideal choice for:

- Increasing **fiber** content for digestive health
- Reducing **calorie** content for weight management
- Enhancing **texture**
- Adding **strength and flexibility** to fragile baked goods or snacks
- Improving **moisture** retention
- Extending **shelf life**
- Optimizing processing **yields**

Consumer perception of "oat fiber" on an ingredient statement is very positive. Both "oat" and "fiber" elicit an impression of health, nutrition and well-being. The appeal of this ingredient as "**good-for-you**" covers all age brackets and consumer segments.

Your SunOpta Sales and Technical team can help you select the right Canadian Harvest® Oat Fibers for your product application. Our series of natural oat fibers are each designed for specific food or beverage categories and cover a broad spectrum of retail and food service products including:

Baked Goods – Breads, Cookies and Crackers, Ice Cream Cones
Snacks – Tortilla Chips, Taco Shells, Pretzels and Extruded Snacks
Cereal Products – Flakes, Extruded Shapes, Breakfast Bars
Meat Products – Ground Meat, Pizza Toppings, Sausages, Emulsified Meats, Meat Analogs
Other Applications – Tortillas and Wraps, Pasta, Breading, Energy/Sports Bars, Nutritional Beverages and Tablets
Pet Food – Treats, Dry Kibble, Canned, Pouched

Naturally Sustainable – Oat crops are not irrigated and the SunOpta Environmental Team has decreased water use by 25% in the last 3 years as part of their water conservation efforts.

Ingredients for Success

100 Apollo Drive
Chelmsford, MA USA 01824
T: 800 353 6782 F: 781 276 5125

ALL CANADIAN HARVEST® OAT FIBERS ARE KOSHER-CERTIFIED

Canadian Harvest™ Oat Fibers

SERIES	200	240	300	610	640	680	770/780
Description	• Low water absorption • Good for low moisture foods, fiber enrichment and whole grain products • Lowest cost	• Low water absorption • Good for low moisture foods, fiber enrichment and white bread products	• Versatile, all-purpose fiber	• Versatile, all-purpose fiber	• Moderate water absorption • Good for white baked products	• Moderate water absorption • Good for increasing fiber and reducing breakage in crunchy snacks	• Highest water and oil holding capacity • Improves product strength and yields • Mimics natural texture in certain
Grind Size	Medium 150 Fine 58	Fine 58	Medium 150 Fine 58 Ultra Fine 48 Micro Fine 33	Fine 58	Fine 58	Fine 58	Fine 58
Color	Light Tan	Light Tan	Light Cream	Creamy White	White to Creamy White	Light Tan	Medium Tan/ Light Cream
Fiber content							
Total % *(as is basis)*	• 89	• 89	• 91	• 92	• 92	• 92	• 93
Total % *(dry basis)*	• 93	• 93	• 95	• 96	• 96	• 96	• 97
Soluble %	• < 5.0	• < 5.0	• < 5.0	• < 5.0	• < 5.0	• < 5.0	• < 2.0
Water Holding % *(range reflects differences in grind size)*	250 to 280	280	370 to 420	450	470	454	590
Kosher	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Natural[1]	Yes	Yes	Yes	Yes	Yes	Yes	Yes – 770 No – 780
Non-GMO	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Organic Compliant[2]	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Flavor	Bland	Bland	Bland	Bland	Bland	Bland	Bland
Applications and Uses	• Baked Goods • Cereals • Cookies • Crackers • Extruded Snacks • Nutrition Bars • Nutrition Supplements • Pasta • Pet Food • Tablets • Whole Grain Breads	• Baked Goods • Cereals • Cookies • Crackers • Extruded Snacks • Nutrition Bars • Pasta • White Bread	• Breading • Breads • Cereals • Cookies • Extruded Snacks • Fried Snacks • Muffins • Nutrition Bars • Pasta • Powdered Drinks and Beverages • Tortillas	• Baked Goods • Bakery Mixes • Beverages • Breads • Extruded Products • Meat • Nutrition Bars • Pasta • Pizza Toppings • Smoothies • Tortillas	• Bakery Mixes • Breads • Crackers • Pasta • Tortillas	• Cereals • Crackers • Extruded Snacks • Snacks	• Baked Goods • Extruded Products • Ice Cream Cones • Meat (Taco Meat, Pizza Toppings, Sausages) • Microwave Cookies • Taco Shells • Tortilla Chips

1 FDA, NLEA 1993; oat fiber is derived from natural oat hulls

2 Refers to a product which has not been irradiated, is completely Non-GMO, was not grown with the application of sewage sludge and was not produced with the use of solvents

122011

SUNOPTA INGREDIENTS GROUP
100 Apollo Drive, Chelmsford, MA USA 01824
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Fax: 781 276 5125, email: ingredients@sunopta.com
www.sunopta.com/ingredients

Food Labeling: Revision of Reference Values and Mandatory Nutrients, 72 Fed. Reg. 62149 (Nov. 2, 2007)

Authority: 26 U.S.C. 3304(a)(9)(B); Secretary's Order No. 3–2007, April 3, 2007 (72 FR 15907).

§ 616.5 [Removed]

2. Remove § 616.5.

3. Revise paragraph (e) of § 616.6 to read as follows:

§ 616.6 Definitions.

* * * * *

(e) *Paying State.* A single State against which the claimant files a Combined-Wage Claim, if the claimant has wages and employment in that State's base period(s) and the claimant qualifies for unemployment benefits under the unemployment compensation law of that State using combined wages and employment.

* * * * *

4. Add paragraph (f) to § 616.7 to read as follows:

§ 617.7 Election to file a Combined-Wage Claim.

* * * * *

(f) If a State denies a Combined-Wage Claim, it must inform the claimant of the option to file in another State in which the State finds that claimant has wages and employment during that State's base period(s).

§ 616.8 [Amended]

5. In § 616.8(a) remove the words ", even if the Combined-Wage Claimant has no earnings in covered employment in that State".

Signed at Washington, DC, this 29th day of October 2007.

Emily Stover DeRocco,

Assistant Secretary for Employment and Training.

[FR Doc. E7–21513 Filed 11–1–07; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

RIN 0910–ZA30

[Docket No. 2006N–0168]

Food Labeling: Revision of Reference Values and Mandatory Nutrients

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on what new reference values the agency should use to calculate the percent daily value (DV) in the Nutrition Facts and Supplement Facts labels and what factors the agency should consider in establishing such new reference values. In addition, FDA requests comments on whether it should require that certain nutrients be added or removed from the Nutrition Facts and Supplement Facts labels. Comments on what factors should be considered to update the agency's reference values will inform any FDA rulemaking that may result from this ANPRM.

DATES: Submit written or electronic comments by January 31, 2008.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0168, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula R. Trumbo, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2579, or e-mail: *Paula.Trumbo@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background[1]

On November 8, 1990, the Nutrition Labeling and Education Act (NLEA) of 1990 (Public Law No. 101–535) was signed into law (the 1990 amendments) amending the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments made the most significant changes in the act and had a direct bearing on FDA's revision of nutrition labeling in 1993. The 1990 amendments added section 403(q) (21 U.S.C. 403(q)) to the act which specified, in part, that: (1) With certain exceptions, a food is to be considered misbranded unless its label or labeling bears nutrition labeling; (2) certain nutrients and food components are to be included in

[1] A list of the acronyms cited in this ANPRM are defined in Appendix A.

of foods for these four groups. Therefore, the IOM Committee recommended that separate DVs for foods manufactured specifically for these four groups be used for that specific life-stage group.

See discussion in section I.B.1 of this document on requirements for foods that are represented or purported to be for the use of infants (up to 12 months of age) or children 1 to 4 years of age, and pregnant women or lactating women.

• *The Supplement Facts label should use the same DVs as the Nutrition Facts label.* The IOM Committee recommended that all other guiding principles should apply to dietary supplement labeling. The IOM Committee came up with this recommendation because the Supplement Facts label requires the inclusion of the percent DVs for the nutrients that are mandated for conventional food (21 U.S.C. 321(ff)). Therefore, the comparisons that are shown for the Nutrition Facts label in tables 11a and 11b of this document are the same for the Supplement Facts label.

• *Absolute amounts should be included in the Nutrition Facts and Supplement Facts labels for all nutrients.* The IOM Committee concluded that including absolute amounts (e.g., mg/serving) would assist consumers who want nutrient information but are yet unable to understand the percent DVs. Furthermore, absolute amounts for macronutrients are already required on the Nutrition and Supplement Facts labels. Therefore, the IOM Committee stated that adding absolute amounts for micronutrients would make the labeling consistent. The IOM Committee also recommended that the units used for vitamin A (IU), vitamin D (IU), vitamin E (IU), folate (µg), copper (mg), sodium (mg), potassium (mg) and chloride (mg) be changed to be consistent with the units in the new DRI reports (vitamin A (µg Retinol Activity Equivalents), vitamin D (µg), vitamin E (mg α-tocopherol), folate (µg dietary folate equivalents), copper (µg), sodium (g), potassium (g), and chloride (g)).

F. IOM Report on the Definition of Fiber

1. Definitions

Because there is not a formal definition for dietary fiber, dietary fiber is the material isolated using AOAC INTERNATIONAL Enzymatic-Gravimetric Method 985.29 (Ref. 12). This method includes lignin and nonstarch polysaccharides and some resistant starch, inulin, chitin, chitosan, chondroitin sulfate, and noncarbohydrate material. This method does not include oligosaccharides, polydextrose, or resistant maltodextrins. Currently, dietary fiber is indented under "Total Carbohydrates" in the Nutrition Facts label (§ 101.9(c)(6)(i)).

In 2001 the IOM Panel on the Definition of Dietary Fiber (the IOM Panel) responded to FDA's request to provide definitions for dietary fiber based on its role in human physiology and health. The IOM Panel developed two categories of definitions of fiber: "Dietary Fiber" and "Functional Fiber" (Ref. 12). See table 13 of this document from the IOM Report on the Definition of Dietary Fiber, which lists the characteristics of dietary fiber currently determined by FDA and by the IOM definitions for dietary and functional fibers.

TABLE 13.—CHARACTERISTICS OF VARIOUS DIETARY FIBER DEFINITIONS[1]

Reference	Nondigestible Animal CHOs[2]	CHOs Not Recovered by Alcohol Precipitation[3]	Nondigestible Mono- and Disaccharides	Lignin	Resistant Starch	Intact, Naturally Occurring Food Sources Only	Resistant to Human Enzymes	Specifies Physiological Effect
U.S. Food and Drug Administration (USFDA), 1987[4]	Yes	Some inulin	No	Yes	Some	No	No	No
Institute of Medicine (IOM) (Proposed), 2001								
Dietary Fiber	No	Yes	No	Yes	Some	Yes	Yes	No
Added Fiber	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes

[1]All definitions are assumed to include nonstarch polysaccharides.
[2]CHO = carbohydrate.
[3]Includes inulin, oligosaccharides (3–10 degrees of polymerization), fructans, polydextrose, methylcellulose, resistant maltodextrins, and other related compounds.
[4]Method-based definition.
Source: Adapted from the IOM, "Dietary Reference Intakes: Proposed Definition of Dietary Fiber," Washington, DC: National Academy Press, 2001.

a. *The IOM Panel defined "Dietary Fiber" as nondigestible carbohydrates and lignin that are intrinsic and intact in plants.* Nondigestible means that the material is not digested and absorbed in the human small intestine. Fractions of plant foods are still considered "Dietary Fiber" if the plants' cells and their three dimensional interrelationships remain largely intact. Examples of "Dietary Fiber" include cereal brans; resistant starch that is naturally occurring; naturally occurring oligosaccharides such as raffinose, stachyose, verbacose; and low molecular weight fructans. The known physiological benefits of foods containing "Dietary Fiber," such as attenuation of postprandial blood glucose and cholesterol levels and improved laxation, are recognized.

b. *The IOM Panel defined "Functional Fiber" as isolated, nondigestible carbohydrates that have beneficial physiological effects in humans.* "Functional Fibers" can be isolated or extracted nondigestible carbohydrates, using chemical, enzymatic, or aqueous procedures or synthetically manufactured. Provided that one or more beneficial physiological effects are demonstrated in humans, examples of "Functional Fiber" would include isolated nondigestible animal carbohydrates, pectins or gums, resistant starch formed during processing, and synthetic fibers such as resistant maltodextrin and fructooligosaccharides. At this time, current FDA regulations have not established formal criteria for establishing the beneficial physiological effects of potential "Functional Fibers."

c. *The IOM Panel defined "Total Fiber" as the sum of "Dietary Fiber"*

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August 13, 2008

Gary L. Yingling
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gary.yingling@klgates.com

Dr. Laura Tarantino, Director
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notification for Grain Millers, Inc.'s Oat Fiber

Dear Dr. Tarantino:

Pursuant to the regulatory and scientific procedures established in proposed 21 C.F.R. § 170.36, Grain Millers, Inc. has determined that its Oat Fiber, an insoluble fiber processed from oat hulls, is a Generally Recognized as Safe ("GRAS") substance for its intended use and is, therefore, exempt from the requirement for premarket approval.

We are hereby submitting, in triplicate, a GRAS notification, in accordance with proposed 21 C.F.R. § 170.36, informing FDA of the view of Grain Millers, Inc. that the Oat Fiber is GRAS through scientific procedures for use as an ingredient in food systems as a source of dietary fiber and at levels consistent with current Good Manufacturing Practices (cGMP).

If you have questions or require additional information, please contact me at (202) 778-9124.

Sincerely Yours,

Gary L. Yingling

Enclosures

DC-1198278 v6

000002

GRAS Notification
Oat Fiber

Grain Millers, Inc.
315 Madison Street
Eugene, OR 97402

August 13, 2008

GRAS Notification for Oat Fiber

1.1 Name and Address of Notifier

Grain Millers, Inc.
315 Madison Street
Eugene, OR 97402

1.2 Common or Usual Name of Substance

Oat Fiber

1.3 Applicable Conditions of Use

Oat Fiber is intended for the addition to food at levels consistent with current Good Manufacturing Practices (cGMP) and is self-limiting for technological reasons. Such technological reasons may include taste, color and rheological impacts. And although Grain Millers' clinical trials were successfully completed with no adverse events at a level of incorporation of seven (7) grams per fifty (50) gram serving, we estimate that in most food applications, oat fiber is formulated to provide a dietary fiber range of between 2.5-5.0 grams per serving.

1.4 Basis for GRAS Determination

Grain Millers Inc. has determined that Oat Fiber is GRAS for use as an ingredient in foods on the basis of scientific procedures.

1.5 Availability of Information for FDA Review

The data and information that are the basis for Grain Millers' GRAS determination are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at the offices of Grain Millers, Inc., 315 Madison St., Eugene, OR 97402 or will be sent to FDA upon request.

2. Manufacturing Process

2.1 Raw materials

The origin of the fiber source consists of pre-qualified, cleaned oat hulls. The pre-qualification consists of pre-selection of the oat hull for color, odor, moisture content, multiple residue analysis (MRA not to exceed Food Chemical Codex's maximum levels for human consumption), mycotoxins (not to exceed USDA's and FDA's maximum threshold), and heavy metals (not to exceed Food Chemical Codex's maximum levels for arsenic, cadmium, mercury, chromium and lead).

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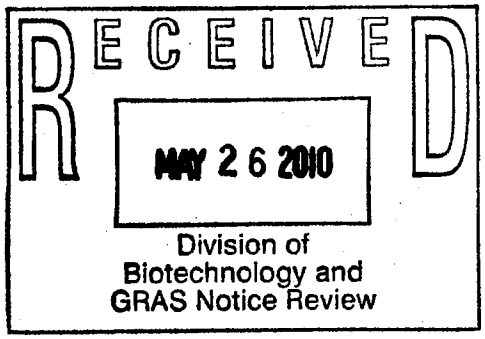
May 21, 2010



Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notice for Oat Hull Fiber

Dear Sirs:

On Behalf of our client, JP Rettenmaier USA LP, we are hereby submitting the enclosed GRAS Notice for the use of Oat Hull Fiber as an ingredient in comminuted meat and both whole muscle and comminuted poultry products. In compliance with 21 C.F.R. 170.36(b) (proposed), we are enclosing 3 copies of this Notice.

Should you have any questions regarding this submission, please do not hesitate to contact me.

Sincerely,

(b) (6)

Mark L. Itzkoff

MLI:akp
Enclosure

000002

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May 19, 2010

GRAS NOTIFICATION

I. Claim of GRAS Status

A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1)

J. Rettenmaier USA LP has determined that oat hull fiber (Vitacel® Isolated Oat Product) is Generally Recognized As Safe (GRAS) for use as an ingredient in comminuted meat and in both whole muscle and comminuted poultry products, consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as described in the following sections, under the conditions of its intended use in selected food. Therefore, the use of Isolated Oat Product is exempt from the requirement of premarket approval.

Signed,

(b) (6)

5/19/10

Mark L. Itzkoff Date

Counsel for

J. Rettenmaier USA LP
16369 US 131 Hwy
Schoolcraft, MI 49087
USA

B. Name and Address of Notifier:

Curtis Rath
J. Rettenmaier USA LP
16369 US 131 Hwy
Schoolcraft, MI 49087
USA

Telephone: 269-679-2490
Fax: 269-679-2364
Email: crath@jrsusa.com

C. Common or usual name of the notified substance:

Oat Fiber; Isolated Oat Product

D. Conditions of use:

Isolated Oat Product containing 85% oat fiber is intended for use as a food ingredient in meat (sausage) and poultry (comminuted and whole muscle products) at levels consistent with current Good Manufacturing Practice and is self limiting for technological reasons. Use of Isolated Oat Product improves the texture, controls moisture migration, and improves stability of the food product. The intended use of Vitacel® Isolated Oat Product (containing 85% fiber) in above mentioned food categories is estimated to result in a maximum daily (90^{th} percentile) intake of 5.78 g oat fiber/person.

E. Basis for GRAS Determination:

In accordance with 21 CFR 170.30, the intended use of Isolated Oat Product has been determined to be generally recognized as safe (GRAS) based on scientific procedures. A comprehensive search of the scientific literature on oat hull fiber and other related fiber was also utilized for this review. Oat hulls are a component of whole grain oats that contain a high level of insoluble fiber in the form of celluloses and hemicelluloses. Vitacel® Isolated Oat Product contains approximately 85% dietary fiber.

Oats have been used as human food since ancient times, particularly in Scottish culinary traditions. Oatmeal along with its fiber portion has been consumed for centuries. Available information suggest that in spite of differences in the proportionality of the oat kernel components among the parts of the kernel, the oat kernel components are common throughout various parts of the kernel, including the oat groat, bran, and hull. The similarity of the composition of the oat hull with that of other edible oat tissues (groat and bran) and the safety data of oat groat and bran tissues along with human and animal studies of oat hull fiber supports the safety of oat hull fiber for use as a food ingredient. Sufficient qualitative and quantitative scientific evidence, including human and animal data are available to determine safety-in-use for oat hull fiber. The safety determination of Isolated Oat Product is

GRAS ASSOCIATES, LLC

20482 Jacklight Lane
Bend, OR 97702-3074
541-678-5522
mcquate@gras-associates.com

December 9, 2010

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety (HFS-200)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Attention: Dr. Robert L. Martin

Re: GRAS Notification – Oat Hull Fiber

Dear Dr. Martin:

On behalf of Z Trim Holdings, Inc. of Mundelein, IL, we are submitting for FDA review a GRAS notification for Oat Hull Fiber. The attached documentation contains the specific information that addresses the safe human food uses for the subject notified substance as discussed in the GRAS guidance document.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me via telephone or email.

We look forward to your feedback.

Sincerely,

(b) (6)

Robert S. McQuate, Ph.D.
CEO & Co-Founder
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074
541-678-5522
mcquate@gras-associates.com
www.gras-associates.com

Enclosure: GRAS Notification – Oat Hull Fiber (four copies)

000003

GRAS ASSOCIATES, LLC

GRAS ASSESSMENT

OAT HULL FIBER - OAT Z TRIM®

Food Usage Conditions for General Recognition of Safety

For

Z TRIM HOLDINGS, INC.
Mundelein, IL

Evaluation By

Richard C. Kraska, Ph.D., DABT
Robert S. McQuate, Ph.D.
Madhusudan G. Soni, Ph.D., FACN

December 8, 2010

TABLE OF CONTENTS

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I. GRAS EXEMPTION CLAIM

A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36(c)(1)[1]

Oat Z Trim® products, meeting the specifications for Z Trim Holdings, Inc. (ZTH) as described below, have been determined to be Generally Recognized As Safe (GRAS) in accordance with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination was made by experts qualified by scientific training and experience; it is based on scientific procedures as described in the following sections; and the evaluation accurately reflects the conditions of the intended use of this ingredient in foods.

Signed:

(b) (6)

12-9-2010

Robert S. McQuate, Ph.D.
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074

Date

B. Name & Address of Notifier

Z Trim Holdings, Inc.
1011 Campus Drive
Mundelein, IL 60060

As the notifier, ZTH accepts responsibility for the GRAS determination that has been made for Oat Z Trim® and as described in the subject notification. Consequently, the Oat Z Trim® preparations meeting the conditions described herein are exempt from premarket approval requirements for food ingredients.

C. Common Name & Identity of the Notified Substance

The common name of the notified substance is oat fiber or oat hull fiber.

[1] See 62 FR 18938 (17 April 1997) which is accessible at http://www.gpo.gov/fdsys/pkg/FR-1997-04-17/html/97-97-9706.htm.

10

9 C.F.R. § 317.2

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15580, Oct. 3, 1970, unless otherwise noted.

Subpart A—General

§ 317.1 Labels required; supervision by Program employee.

(a) When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in § 317.2 except that the following do not have to bear such a label.

(1) Wrappings of dressed carcasses and primal parts in an unprocessed state, bearing the official inspection legend, if such wrappings are intended solely to protect the product against soiling or excessive drying during transportation or storage, and the wrappings bear no information except company brand names, trade marks, or code numbers which do not include any information required by § 317.2;

(2) Uncolored transparent coverings, such as cellophane, which bear no written, printed, or graphic matter and which enclose any unpackaged or packaged product bearing all markings required by part 316 of this subchapter which are clearly legible through such coverings;

(3) Animal and transparent artificial casings bearing only the markings required by part 316 of this subchapter;

(4) Stockinettes used as "operative devices", such as those applied to cured meats in preparation for smoking, whether or not such stockinettes are removed following completion of the operations for which they were applied;

(5) Containers such as boil-in bags, trays of frozen dinners, and pie pans which bear no information except company brand names, trademarks, code numbers, directions for preparation and serving suggestions, and which are enclosed in a consumer size container that bears a label as described in § 317.2;

(6) Containers of products passed for cooking or refrigeration and moved from an official establishment under § 311.1 of this subchapter.

(b) Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear all features required on a label for an immediate container.

(c) No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee.

§ 317.2 Labels: definition; required features.

(a) A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.

(b) Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. In order to meet this requirement, such information must appear on the principal display panel except as otherwise permitted in this part. Except as provided in § 317.7, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(c) Labels of all products shall show the following information on the principal display panel (except as otherwise permitted in this part), in accordance with the requirements of this part or, if applicable, part 319 of this subchapter:

(1) The name of the product, which in the case of a product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in part 319 of this subchapter, shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation, as prescribed in paragraph (e) of this section;

(2) If the product is fabricated from two or more ingredients, the word "ingredients" followed by a list of the ingredients as prescribed in paragraph (f) of this section;

(3) The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section;

(4) An accurate statement of the net quantity of contents, as prescribed in paragraph (h) of this section;

(5) An official inspection legend and, except as otherwise provided in paragraph (i) of this section, the number of the official establishment, in the form required by part 312 of this subchapter;

(6) Any other information required by the regulations in this part or part 319 of this subchapter.

(d) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part and part 319 of this subchapter with clarity and conspicuousness and without obscuring of such information by designs or vignettes or crowding. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. The principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is at least the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area that is 40 percent of the product of the height of the container times the circumference of the container, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: *Provided, however*, That if there is immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in paragraphs (c) (2), (3), and (5), such panel shall be known as the "20 percent panel" and such information may be shown on that panel in lieu of showing it on the principal display panel.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

(e) Any descriptive designation used as a product name for a product which has no common or usual name shall clearly and completely identify the product. Product which has been prepared by salting, smoking, drying, cooking, chopping, or otherwise shall be so described on the label unless the name of the product implies, or the manner of packaging shows that the product was subjected to such preparation. The unqualified terms "meat," "meat byproduct," "meat food product," and terms common to the meat industry but not common to consumers such as "picnic," "butt," "cala," "square," "loaf," "spread," "delight," "roll," "plate," "luncheon," and "daisy" shall not be used as names of a product unless accompanied with terms descriptive of the product or with a list of ingredients, as deemed necessary in any specific case by the Administrator in order to assure that the label will not be false or misleading.

(f)(1) The list of ingredients shall show the common or usual names of the ingredients arranged in the descending order of predominance, except as otherwise provided in this paragraph.

(i) The terms spice, natural flavor, natural flavoring, flavor and flavoring may be used in the following manner:

(A) The term "spice" means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(B) The term "natural flavor," "natural flavoring," "flavor" or "flavoring" means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powered onion, powdered garlic, and powdered celery.

(ii) The term "corn syrup" may be used to designate either corn syrup or corn syrup solids.

(iii) The term "animal and vegetable fats" or "vegetable and animal fats" may be used to designate the ingredients of mixtures of such edible fats in product designated "compound" or "shortening." "Animal fats" as used herein means fat derived from inspected and passed cattle, sheep, swine, or goats.

(iv) When a product is coated with pork fat, gelatin, or other approved substance and a specific declaration of such coating appears contiguous to the name of the product, the ingredient statement need not make reference to the ingredients of such coating.

(v) When two meat ingredients comprise at least 70 percent of the meat and meat byproduct ingredients of a formula and when neither of the two meat ingredients is less than 30 percent by weight of the total meat and meat byproducts used, such meat ingredients may be interchanged in the formula without a change being made in the ingredients statement on labeling materials: *Provided*, That the word "and" in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(vi)(A) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided*, That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as "Contains _____ percent of _____," "Less than _____percent of _____." The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(B) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with §318.7(c)(4) and part 319 of this subchapter, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(2) On containers of frozen dinners, entrees, pizzas, and similar consumer

packaged products in cartons the ingredient statement may be placed on the front riser panel: *Provided*, That the words "see ingredients" followed immediately by an arrow is placed on the principal display panel immediately above the location of such statement without intervening print or designs.

(3) The ingredient statement may be placed on the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container.

(4) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(g)(1) The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as "Prepared for * * *". The place of business of the manufacturer, packer, or distributor shall be shown on the label by city, State, and postal ZIP code when such business is listed in a telephone or city directory, and if not listed in such directory, then the place of business shall be shown by street address, city, State, and postal ZIP code.

(2) The name and place of business of the manufacturer, packer, or distributor may be shown:

(i) On the principal display panel, or

(ii) On the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container, or

(iii) On the front riser panel of frozen food cartons, or

(iv) On the information panel.

(h)(1) The statement of net quantity of contents shall appear on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph.

(2) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in §317.19. The statement shall not include any term qualifying a unit of weight, measure, or count such as "jumbo quart," "full gallon," "giant quart," "when packed," "minimum," or words of similar importance.

(3) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel in lines generally parallel to the base: *Provided*, That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph (h). In any case, the statement may appear in more than one line. The terms "net weight" or "net wt." shall be used when stating the net quantity of contents in terms of weight, and the term "net contents" or "content" when stating the net quantity of contents in terms of fluid measure.

(4) Except as provided in §317.7, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semisolid viscous or a mixture of solid and liquid. For example, a declaration of ¾-pound avoirdupois weight shall be expressed as "Net Wt. 12 oz." except as provided for in paragraph (h)(5) of this section for random weight packages; a declaration of 1½ pounds avoirdupois weight shall be expressed as "Net Wt. 24 oz. (1 lb. 8 oz.)," "Net Wt. 24 oz. (1½ lb.)," or "Net Wt. 24 oz. (1.5 lbs.)."

(5) On packages containing 1 pound or 1 pint and less than 4 pounds or 1 gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parentheses) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in

the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart, except that on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. Paragraph (h)(9) of this section permits certain exceptions from the provisions of this paragraph for margarine packages, random weight consumer size packages, and packages of less than ½ ounce net weight. Pargraph (h)(12) of this section permits certain exceptions from the provision of this paragraph for multi-unit packages.

(6) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel of the package and shall be uniform of all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on packages, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on packages, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenths inch in height on packages, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on packages, the principal display panel of which has an area of more than 100 but not more than 400 square inches.

(v) Not less than one-half inch in height on packages, the principal display panel of which has an area of more than 400 square inches.

(7) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). Heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter "o" or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(8) The statement shall appear as a distinct item on the principal display panel and shall be separated by a space at least equal to the height of the lettering used in the statement from other printed label information appearing above or below the statement and by a space at least equal to twice the width of the letter "N" of the style of type used in the quantity of contents statement from other printed label information appearing to the left or right of the statement. It shall not include any term qualifying a unit of weight, measure, or count such as, "jumbo quart," "full gallon," "giant quart," "when packed," "Minimum" or words of similar import.

(9) The following exemptions from the requirements contained in this paragraph (h) are hereby established:

(i) Individually wrapped, random weight consumer size packages shipped in bulk containers (as specified in paragraph (h)(11) of this section) and meat products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined under §317.19 need not bear a net weight statement when shipped from an official establishment, provided that a net weight shipping statement which meets the requirements of paragraph (h)(2) of this section is applied to their shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement on random weight consumer size packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on

the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (h)(2) of this section;

(iii) Individually wrapped and labeled packages of less than ½ ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(iv) Margarine in 1 pound rectangular packages (except packages containing whipped or soft margarine or packages that contain more than four sticks) is exempt from the requirements of paragraphs (h) (3) and (5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel and that the statement be expressed both in ounces and in pounds, if the statement appears as "1 pound" or "one pound" in a conspicuous manner on the principal display panel.

(v) Sliced shingle packed bacon in rectangular packages is exempt from the requirements of paragraphs (h)(3) and (h)(5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel, and that the statement be expressed both in ounces and in pounds, if the statement appears in a conspicuous manner on the principal display panel.

(10) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(11) As used in this section, a "random weight consumer size package" is one which is one of a lot, shipment or delivery of packages of the same product with varying weights and with no fixed weight pattern.

(12) On a multiunit retail package, a statement of the net quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and in parentheses, the total net quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (h)(5) of this section. For the purposes of this section, "multiunit retail package" means a package containing two or more individually packaged units of the identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (h) (2), (3), (6), and (8) of this section.

(i) The official establishment number of the official establishment in which the product was processed under inspection shall be placed as follows:

(1) Within the official inspection legend in the form required by part 312 of this subchapter; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix "EST"; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling material in the container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as "EST. No. on Metal Clip" or "Est. No. on Pan", if shown in

a prominent and legible manner in a size sufficient to insure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix "EST".

(j) Labels of any product within any of the following paragraphs shall show the information required by such paragraph for such product:

(1) A label for product which is an imitation of another food shall bear the word "imitation" immediately preceding the name of the food imitated and in the same size and style of lettering as in that name and immediately thereafter the word "ingredients:" and the names of the ingredients arranged in the order of their predominance.

(2) If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR part 125) established pursuant to sections 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

(3) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of a meat food product, as permitted in part 318 of this subchapter, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as "Artificial Smoke Flavoring Added" or "Smoke Flavoring Added," as may be applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring so added as an ingredient in the formula of the meat food product.

(4) When any other artificial flavoring is permitted under part 318 of this subchapter to be added to a product, the ingredient statement shall identify it as "Artificial Flavoring."

(5) When artificial coloring is added to edible fats as permitted under part 318 of this subchapter such substance shall be declared on the label in a prominent manner and contiguous to the name of the product by the words "Artificially colored" or "Artificial coloring added" or "With added artificial coloring." When natural coloring such as annatto is added to edible fats as permitted under part 318 of this subchapter, such substance shall be declared on the label in the same manner by a phrase such as "Colored with annatto."

(6) When product is placed in a casing to which artificial coloring is applied as permitted under part 318 of this subchapter, there shall appear on the label, in a prominent manner and contiguous to the name of the product, the words, "Artificially colored."

(7) If a casing is removed from product at an official establishment and there is evidence of artificial coloring on the surface of the product, there shall appear on the label, in a prominent manner and contiguous to the name of product, the words "Artificially colored."

(8) When a casing is colored prior to its use as a covering for product and the color is not transferred to the product enclosed in the casing, no reference to color need appear on the label but no such casing may be used if it is misleading or deceptive with respect to color, quality, or kind of product, or otherwise.

(9) Product which bears or contains any other artificial coloring, as permitted under part 318 of this subchapter, shall bear a label stating that fact on the immediate container or if there is none, on the product.

(10) When an antioxidant is added to product as permitted under part 318 of this subchapter, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement identifying the officially approved specific antioxidant by its common name or abbreviation thereof and the purpose for which it is added, such as, "BHA, BHT, and Propylgallate added to help protect flavor."

(11) Containers of meat packed in borax or other preservative for export to a foreign country which permits the use of such preservative shall, at the time of packing, be marked "for export," followed on the next line by the words "packed in preservative," or such equivalent statement as may be approved for this purpose by the Administrator and directly beneath this there shall appear the word "establishment"

or abbreviation thereof, followed by the number of the establishment at which the product is packed. The complete statement shall be applied in a conspicuous location and in letters not less than 1 inch in height.

(12) Containers of other product packed in, bearing, or containing any chemical preservative shall bear a label stating that fact.

(13)(i) On the label of any "Mechanically Separated (Species)" described in §319.5(a) of this subchapter, the name of such product shall be followed immediately by the phrase "for processing" unless such product has a protein content of not less than 14 percent and a fat content of not more than 30 percent.

(ii) When any "Mechanically Separated (Species)" described in §319.5 of this subchapter is used as an ingredient in the preparation of a meat food product and such "Mechanically Separated (Species)" contributes 20 mg or more of calcium to a serving of such meat food product, the label of such meat food product shall state the calcium content of such meat food product, determined and expressed as the percentage of the U.S. Recommended Daily Allowance (U.S. RDA) in a serving in accordance with 21 CFR 101.9(b)(1), (c)(7) (i) and (iv), and (e), as part of any nutrition information included on such label, or if such meat food product does not bear nutrition labeling information, as part of a prominent statement in immediate conjunction with the list of ingredients, as follows: "A _____ serving contains ___% of the U.S. RDA of calcium", with the blanks to be filled in, respectively, with the quantity of such product that constitutes a serving and the amount of calcium provided by such serving: *Provided*, That, calcium content need not be stated where (*a*) the percent of the U.S. RDA of calcium to be declared would not differ from the percent of the U.S. RDA that would be declared if the meat food product contained only hand deboned ingredients or (*b*) the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more if the meat food product contained only hand deboned ingredients.

(k) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: "Keep Refrigerated," "Keep Frozen," "Perishable Keep Under Refrigeration," or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution and thawed prior to or during display for sale at retail shall bear the statement on the shipping container: "Keep Frozen." The consumer-size containers for such products shall bear the statement "Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated." For all perishable canned products the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be in upper case letters at least one-half inch in height.

(l) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, other equine that do not meet the requirements contained in §318.17, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations For Fully-Cooked Patties in §318.23, except as exempted under paragraph (l)(4) of this section.

(l)(i) Safe handling instructions shall accompany every meat or meat product, specified in this paragraph (l) destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under

the heading "Safe Handling Instructions" which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (l)(2) and (l)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) The labels of the meat and meat products specified in this paragraph (l) shall include the following rationale statement as part of the safe handling instructions, "This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions." This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Meat and meat products, specified in this paragraph (l), shall bear the labeling statements:

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions, may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Meat or meat products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (l)(1) through (l)(3) of this section.

(m)(1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

[35 FR 15580, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 317.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

Dietary Fibre – Codex Definition and Methods of Analysis, FOSS (May 2011)

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Dietary Fibre – Codex Definition and methods of analysis

By Dr. Jürgen Möller

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Dedicated Analytical Solutions

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Dietary Fibre
– Codex Definition and methods of analysis

By Jürgen Möller

Introduction

For more than 30 years, Foss has been supplying a solution for the determination of dietary fibre, the Fibertec E, following the AOAC methods 985.29 and 991.43. Market developments have placed new demands on the analytical method for the determination of dietary fibres - especially with respect to resistant starch and low molecular weight carbohydrates. Recently an integrated method, AOAC 2009.01, which is compatible with the latest Codex definition of dietary fibre has been published.
Originally, dietary fibre was only the natural, edible carbohydrates that were not digested in the small intestine. Numerous studies revealed that these carbohydrates had a positive contribution to intestinal functions, preventing constipation, slowing down the speed of digestion and enhancing fermentation in the colon – promoting the growth of beneficial Bacteria (prebiotic effect).

Fibres in human milk protect babies against allergies and diabetes. Dietary fibres were also shown to contribute to the prevention of heart disease, diabetes, some forms of cancer and the improvement of both short and long-term memory functions. The World Health Organization (WHO) recommends a dietary fibre intake of at least 25g per day .The average intake is only 12-18g in the USA and 15-20g in Europe, but 40-60 g in Africa. One consequence of this imbalance in dietary fibre intake is obesity.

Obesity, heart disease, stroke, type 2 diabetes and cancer are the leading causes of preventable death which cost societies and governments trillions of dollars every year. A focal point in improving nutrition and health is the consumption of dietary fibre. While a billion people are starving or being undernourished, another billion are overweight. A situation that was already bad in 2005 is expected to get even worse by 2015. The prevalence of obesity and overweight is increasing rapidly.

Codex definition

The Codex Alimentarius Comission is an international network established in 1963. It is a cooperation between FAO (Food & Agriculture Organisation of the United Nations) and WHO (World Health Organisation), which is also acknowledged by WTO (World Trade Organisation).

The Codex agrees on standards and guidelines in the food/feed/agri sectors that are valid for all nations. The focus is on import/export inspection and certification, codes of conduct, arbitration in cases of conflict, etc but also on methods of analysis.

Dietary fibre denotes carbohydrate polymers(1) with 10 or more monomeric units(2), which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:

- Edible carbohydrate polymers naturally occurring in the food consumed.
- Carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological benefit to health, as demonstrated by generally accepted scientific evidence to competent authorities.
- Synthetic carbohydrate polymers that have been shown to have a physiological benefit to health, as demonstrated by generally accepted scientific evidence to competent authorities.

NOTES:

(1) Includes also lignin and other compounds if quantified by AOAC 991.43.

(2) Decision on whether to include carbohydrates with a degree of polymerization from DP 3 to 9 should be left to national authorities.

After years of discussion the Codex finally agreed in 2009 on a definition of dietary fibre: A number of countries, e.g. Thailand and Brazil have decided to stay with DP10, whilst the European Union has decided to include DP 3-9. Naturally this leads to some analytical challenges and to challenges in international trade.

Methods of analysis

The standard method AOAC 985.29 for the determination of total dietary fibre (TDF) is based on an older definition of DF: Carbohydrates of food that are not resorbed in the small intestine and partly in the colon, comprising mainly non-starch polysaccharides (cellulose, hemicellulose, pektin) as well as resistant starch and lignin.

Samples are incubated at ~ 95oC for 30 min in a phosphate buffer(pH 8.2) solution containing alfa-amylase. The pH is then adjusted to 7.5 and 100µL protease are added. After incubation at 60oC for 30 min the pH is adjusted to 4.5.

Before the last incubation at 60oC for 30 min, 200µL amyloglucosidase are added. Available carbohydrates have now been solubilised and the total dietary fibre content can be obtained after ethanol precipitation, filtration, and drying. Duplicate samples are always processed, allowing the subtraction of protein and ash for the calculation of the TDF content.

Some years later the method was modified by the standard AOAC 991.43 for the determination of soluble and insoluble DF.

For more than 20 years these methods have been the dominating analytical protocols for the determination of dietary fibre. The problem is that they only determine high-molecular-weight dietary fibre (HMWDF) fractions and parts of the resistant starch. Low-molecular-weight dietary fibre (LMWDF) like non-digestible oligosaccharides, i.e. fructo-oligosaccharides, resistant maltodextrins and galacto-oligosaccharides as well as soluble non-starch-polysaccharides have also shown to have some prebiotic effects. Not being fully resorbed in the small intestine allows them to benefit the host by stimulating the growth and/or activity of beneficial bacteria in the colon. LMWDF are increasingly being used in the food industry, and additional analytical methods have been developed to determine them.

AOAC 985.29 Total Dietary Fibre in Foods
AOAC 991.43 Total, Soluble, and Insoluble Dietary Fibre in Foods
AOAC 2001.03 Dietary Fibre Containing Supplemented Resistant Maltodextrin (RMD)
AOAC 2002.02 Resistant Starch in Starch and Plant Materials
AOAC 2001.02 Determination of Trans-Galactooligosaccharides (TGOS)
AOAC 997.08 Fructans in Food Products
AOAC 999.03 Measurement of Total Fructan in Foods
AOAC2000.11 Polydextrose in food

Codex definition method

Incubation in maleate buffer, pH 6.0, 37oC for 16 h, containing pancreatic a-amylase + amyloglucosidase.

pH adjustment to ~ 8.0 and incubation at 100oC for 20 min

Addition of protease and incubation at 60oC for 30 min

Stop of enzymatic reactions by adding HCl (adjustment to pH ~ 4.5).

Ethanol precipitation, filtration, washing and drying.

In the AOAC 2009.01/ AACC 32-45.01 method, duplicate test portions are incubated with pancreatic -amylase and amyloglucosidase (AMG) for 16 hours at 37 °C in sealed bottles in a shaking water batch that is mixed with sufficient vigour to maintain a continuous suspension. During this step, non-resistant starch is solubilised and hydrolysed to glucose and maltose by the combined action of the two enzymes.

The reaction is terminated by pH adjustment and temporary heating. Protein in the sample is digested with protease. For the measurement of high-molecular-weight dietary fibre (HMWDF), ethanol is added, and the insoluble and precipitable soluble dietary fibre is captured, washed with ethanol and acetone, dried, and weighed. One of the duplicate residues is analysed for protein, while the other is analysed for ash. Non-precipitable dietary fibre in the filtrate is recovered by concentrating, then desalting through ion exchange resins, and concentrating and quantitating by LC.

	AOAC 991.43	AOAC 2009.01
b-Glucan	98.0	96.0
Casein	0	0
Pectin	86.5	87.0
Wheat Starch	0.1	0.1
Larch Arabinogalactan	83.5	84.0
High Amylose Maize Starch	29.3	46.5
Green Banana	7.5	37.6

Conclusions

In view of global obesity and overweight problems, the labeling and analysis of food for dietary fibre is of interest. Depending on regulation and customer/client demands, several methods will be used in parallel: AOAC 985.29 for the determination of total dietary fibre; AOAC 991.43 for insoluble and soluble dietary fibre; and the new AOAC 2009.01 and AACC 32-45.01 methods following the new Codex definition - as well as methods for specific components.

AOAC 2009.01 facilitates the measurement of Total Dietary Fibre (TDF), including resistant starch. This may lead to different results, particularly for samples with higher resistant starch contents (see table above).

Fibertec E has participated in the validation of AOAC methods 985.29, 991.43 and 2009.01 and may thus be used for the determination of dietary fibre also according to the new Codex definition. Fibertec E allows the collection of filtrates from individual samples for the determination of low molecular weight fractions by liquid chromatography.

Taking into account the time and resource demands for all dietary fibre determinations, faster and more automated methods are of interest.

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TECHNICAL BULLETIN

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DIETARY FIBER I

Rajen Mehta, Ph.D.
SunOpta

INTRODUCTION

The beneficial effects of dietary fiber (DF) have been known since ancient times, but became more clearly understood only between the 1950s and 1970s (Kritchevsky, 1988; Dreher, 1987; DeVries and Rader, 2005). Ancient Greek physician Hippocrates, who famously said, "let food be thy medicine, and medicine be thy food," is known to have recommended the positive effects of whole-grain bread in the bowel. In the United States, Sylvester Graham talked about the beneficial effects of bran early in the 19th century, and the Kellogg brothers, Dr. John Harvey Kellogg and William K. Kellogg, did the same late in the 19th century.

The term *dietary fiber* was first used by E.H. Hippsley in 1953 (Kritchevsky, 1988; Dreher, 1987; DeVries and Rader, 2005). This was a key turning point because prior to that, crude fiber (CF) was commonly measured as a component of food that was resistant to digestion. CF is still used in animal nutrition and in some countries for human nutrition; however, most scientists will agree that DF is a more relevant measure of the food components resistant to digestion. Analytically, CF is the residue remaining after food has been first treated to fat solvent extraction and then hot acid and alkali treatment, whereas enzymatic procedures simulating human digestive systems are the basis of DF assays. Between the 1950s and the 1970s, D.P. Burkitt, A.R.P. Walker, H. Trowell, T.L. Cleave, and coworkers developed the hypothesis about DF's positive role on health, based on high-fiber diets of native populations in South Africa (DeVries and Rader, 2005; Dreher, 1987). It was hypothesized that increased DF consumption would lead to reductions in diverticular disease, diabetes, cancer, heart disease, and a range of other diseases.

IMPORTANT FIBER DEFINITIONS, ANALYSES, AND CLAIMS

DeVries and coworkers (2005) and Nelson (2001) have reviewed the important definitions, fiber types, and analytical procedures for dietary fiber. These and other sources (Codex Committee on Nutrition and Foods, 2004) have been used to compile Tables 1, 2, 3, and 4. The American Association of Cereal Chemists (AACC) and Codex definitions of fiber (Table 1) are most widely accepted. The Institute of Medicine definition, on the other hand, has been a little controversial.

The commercially important fibers are listed in Table 2. Insoluble, soluble, and viscous soluble fibers have different effects on the characteristics of bakery products and have differing health effects. The choice of fiber will also tremendously affect processing. In addition, the raw-material source and its processing can significantly affect its properties. Several companies have introduced blends of insoluble and soluble fiber to allow bakers to easily use a one-bag system, yet utilize the positives associated with both types of fibers.

Dietary fiber methods (Table 3) simulate human digestive behavior and attempt to quantify food components that are not digested. Thus, after extracting and removing the fat, enzymes are used to break down foods. The portion remaining is measured using

gravimetric (weighing), spectrophotometric, and/or chromatographic techniques.

It is important for the baker and food scientist to be cognizant of the type and source of fiber used in a bakery product, as listed in Table 3. One important reason, besides its functionality, is that the methods commonly used by analytical labs (AOAC International method 991.43, also known as AACC method 32-07) do not quantitate some soluble fibers, such as inulin, polydextrose, fructo-oligosaccharides, resistant maltodextrin, and all resistant starches except RS3 types. There are different methods that analyze for these types of resistant starch. Thus, it is important to have an analytical lab analyze for these types of fibers. There is a new method being developed by a committee at AACC that should allow all the fibers to be analyzed by one method; however, it will be at least a year before it is approved for regular use.

The types of resistant starches are listed in Table 4 (Gordon, 2008; Maningat, 2008; Nelson, 2001). These are becoming commercially important and each has its own unique benefits and challenges for both formulation and health.

Table 1. Important Fiber Definitions.

American Association of Cereal Chemists (AACC, 2000)
"Dietary fiber is the edible parts of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Dietary fiber includes polysaccharides, oligosaccharides, lignin, and associated plants substances. Dietary fibers promote beneficial physiological effects including laxation, and/or blood cholesterol attenuation, and/or blood glucose attenuation."

Institute of Medicine (IOM, 2002)
"Dietary fiber consists of non-digestible carbohydrates and lignin that are intrinsic and intact in plants. Functional fiber consists of isolated, non-digestible carbohydrates that have beneficial physiological effects in humans. Total fiber is the sum of dietary fiber and functional fiber."

Codex Alimentarius Commission (CAC, 2006)
"Dietary fibre means carbohydrate polymers* with a degree of polymerisation not lower than 3, which are neither digested nor absorbed in the small intestine. A degree of polymerisation not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average degree of polymerisation of a mixture. Dietary fibre consists of one or more of:

- edible carbohydrate polymers naturally occurring in the food as consumed,
- carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic, or chemical means,
- synthetic carbohydrate polymers.

Dietary fibre generally has properties such as:

- Decrease intestinal transit time and increase stool bulk
- Fermentable by colonic microflora
- Reduce blood total and/or LDL cholesterol levels
- Reduce post-prandial blood glucose and/or insulin levels."

*"When from plant origin, dietary fibre may include fractions of lignin and/or other compounds when associated with polysaccharides in plant cell walls and if these compounds are quantified by the AOAC gravimetric analytical method for dietary fibre analysis. Fractions of lignin and/or other compounds (e.g. proteic fractions, phenolic compounds, waxes, saponins, phytates, cutin, phytosterols) intimately associated with plant polysaccharides are often extracted with the polysaccharides in the AOAC 991.43 method. These substances are included in the definition of fibre insofar as they are actually associated with the poly- or oligo-saccharidic fraction of fibre. However, when extracted or even re-introduced into a food containing non-digestible polysaccharides, they cannot be defined as dietary fibre. When combined with polysaccharides, these associated substances may provide additional beneficial effects."

Table 2. Commercially Important Fibers.

Fiber Types	Mostly Insoluble	Mostly Soluble — Low Viscosity	Mostly Soluble — High Viscosity	Insoluble & Soluble
Cereal-Based				
Oats	X			
Wheat	X			
Soy	X			
Barley				X
Brans (wheat, corn)	X			
Brans (oat, rice)				X
Oat Beta-Glucan			X	
Barley Beta-Glucan			X	
Rye	X			
Flax			X	
Plant-Based				
Cellulose	X			
Inulin (various sources)		X		
Cottonseed	X			
Bamboo	X			
Gums*			X	
Peas				X
Konjac			X	
Psyllium			X	
Sugarbeet				X
Potato	X			
Fruits and Vegetables				
Citrus				X
Apple				X
Prunes, Dates, Figs, Raisins				X
Other				
Polydextrose		X		
Resistant Starches and Maltodextrins	X			
Modified Cellulose			X	

*Gums can be extracted from plants (e.g., gum acacia, gum karaya, tragacanth), seeds (e.g., guar, locust bean gum), seaweeds (e.g., carrageenan, alginates), microbially fermented gums (e.g., xanthan, gellan)

Table 3. Analytical Methods for Fibers.

Dietary Fiber Description	AOAC Method Number	Comments
		More Frequently Used Methods
Total Dietary Fiber	991.43 & 985.29	These methods analyze foods for insoluble and soluble fiber sequentially, and then add up the individual values. They do not quantitate soluble fibers such as inulin, polydextrose, fructo-oligosaccharides, resistant maltodextrin and all resistant starches except RS3 types. They do quantitate RS3 resistant starches and lignin and associated substances. 991.43 is now more commonly used in the U.S. because it does not use phosphate buffer and is faster.
Beta-D-Glucans	992.28 & 995.16	Some beta-glucans are bound by insoluble fiber and thus all soluble fiber in oats and by-products is not beta-glucan and vice versa; it is more accurate to analyze for beta-D-glucan for coronary heart disease claim (21CFR 101.81).
Resistant Starch	2002.02	This analyzes for RS2 and RS3 resistant starches only. It does not analyze for RS1 and RS4 resistant starches.
Fructans	999.03 & 997.08	Analyzes for inulin and other fructans such as fructo-oligosaccharides and oligo-fructans.
TDF (with resistant maltodextrins)	2001.03	Analyzes for TDF including resistant maltodextrins.
Trans-Galacto-Oligosaccharides	2001.02	Analyzes for TGOS only.
		Less Frequently Used Methods
Total Dietary Fiber	994.13	Expensive and thus few users. Information on individual fiber components obtained.
Total Dietary Fiber	992.46 & 993.21	Less frequently or not used.
Insoluble Fiber	991.42	Used in conjunction with 993.19 soluble fiber method.
Soluble Fiber	993.19	Used in conjunction with 991.42 insoluble fiber method.

Table 4. Resistant Starches.

RS Type	Description of Starch	Natural Occurrence
RS1	Physically entrapped and inaccessible	Partially milled grains, seeds, and legumes
RS2	Raw granules	Native potato starch
RS3	Retrograded, nongranular, crystalline	Ready-to-eat breakfast cereals
RS4	Chemically cross-linked	Cross-linked starches

FIBER'S EFFECT ON HEALTH AND DISEASE

Dietary fiber is viewed positively by consumers. The interest and confidence that fiber is healthy and good for you has been steadily increasing over the last several years (Mehta, 2005; Datamonitor, 2009) (Figure 1). Most Americans (93%) believe that certain foods reduce disease or other health concerns. Consequently, one-third of consumers agree that it is worth paying a slight premium for foods with extra nutritional benefits. Consumers agree that fiber is one of the most important nutrients for health. As a result, new product introductions with fiber have been increasing steadily over the years (Datamonitor, 2009) (Figure 2).

Obesity continues to increase dramatically in the United States and worldwide. In 2007, only one U.S. state (Colorado) had a prevalence of obesity less than 20%. Thirty states had a prevalence equal to or greater than 25% (CDC, 2008). Obesity and excess body weight contribute to a wide range of diseases, and consequently there is a concern it may soon become the number one cause of death in the United States. Dietary fiber consumption has been associated with weight loss and the prevention and reduction in risk of diseases such as cancer and heart disease (Mehta, 2005). Dietary fiber provided by a mixed diet is 66% to 75% insoluble and 25% to 33% soluble. Amongst other benefits, insoluble fiber promotes gastrointestinal health, and soluble fiber reduces the risk of heart disease.

The United States has one of the lowest consumptions of dietary fiber (10 g to 15 g per day) versus the recommended Daily Value (DV) of 25 g for a 2,000-calorie diet. To make a fiber nutrient content claim of "high," "rich," or "excellent source" in the United States, a food must contain 5 g of fiber (20% of the DV) per serving. To make a "good source," "contains," or "provides" claim, the food should contain 2.5 g or more of fiber (10% of the DV). If the food is not low in total fat, the label must state total fat in conjunction with the fiber claim. Heart-healthy claims are allowed with the use of beta-glucan from oat and barley (0.75 g beta-glucan per serving, 21CFR 101.81), and with psyllium (1.7 g per serving).

In Canada, "a source of fiber," "high source of fiber," or "very high source of fiber" claim can be made with 2 g, 4 g, and 6 g total dietary fiber (TDF) per serving respectively. TDF is defined more fully in Table 1. For bakery products in Mexico, "a source of" or "contains" claim requires 1.5 g TDF/100 g and "rich in" requires 3 g/100 g. In Europe, 6 g TDF/100 g food allow a "high fiber" claim and 3 g allow "a source of" fiber claim. The European Union has recently developed suggestions (not regulations) allowing "contains" (3 g) or "rich in" (6 g) regardless of serving size.

Figure 1. Importance Attached by U.S. Consumers to Factors That Maintain a Healthy Diet. (Datamonitor, 2009)

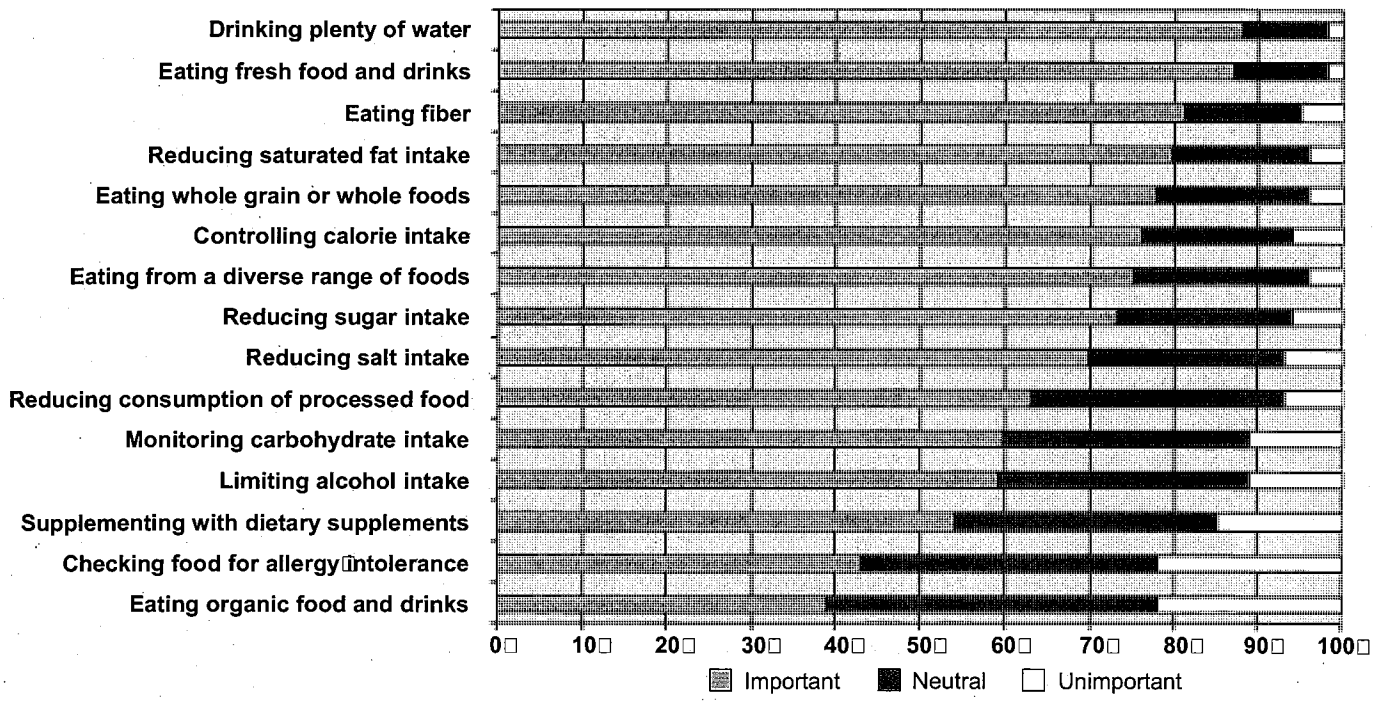
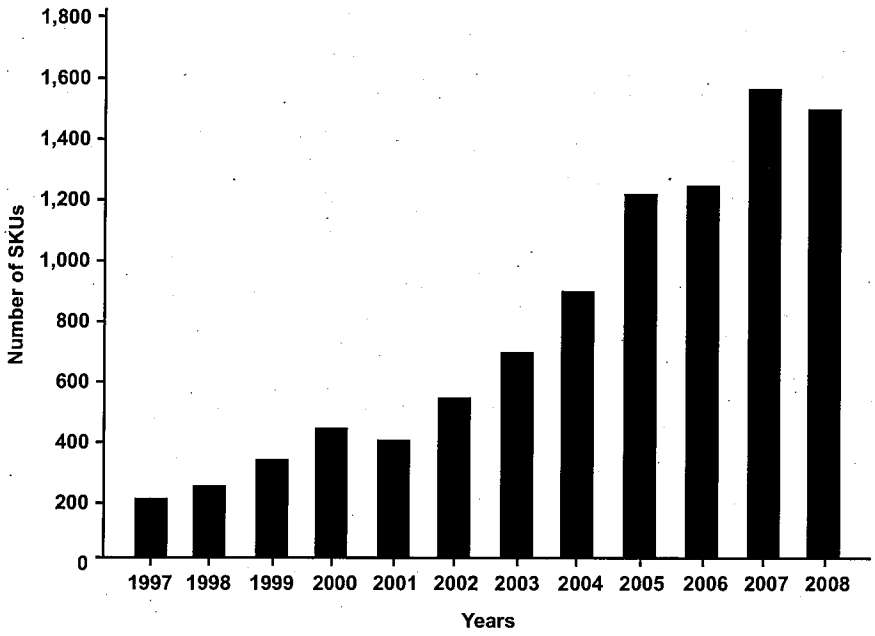


Figure 2. New Product Introductions in North America With a "High Fiber" Claim or Tag. (Datamonitor, 2009)



CONCLUSION

Consuming adequate quantities of dietary fiber can lead to improvements in gastrointestinal health, and reduction in susceptibility to diseases such as diverticular disease, heart disease, cancer, and diabetes. Increased consumption has also been associated with increased satiety and weight loss. In spite of these benefits, U.S. consumers' average intake of dietary fiber is 10 g to 15 g per day versus a recommended Daily Value of 25 g. A "good source" or "excellent source" of fiber claim or a heart-healthy claim can be made in bakery products when certain specific fiber addition requirements are met. By carefully selecting the appropriate type and amount of fiber, bakers can have a significant impact on the nutritional value of their bakery products.

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Brothers All :: Forum, Topic: Isolated Oat Product

Author | Topic: Isolated Oat Product (Read 1416 times)

Fenn Shysa
Captain
Posts: 416

Isolated Oat Product
« on: January 26, 2011, 12:01:13 PM »

[Maybe this should be filed under "What happned today" or "What I ate today"; but, I couldn't resist the title]

I read this story in the paper today about Taco bell cathching heat for its meat.
http://www.nypost.com/p/news/national/meat_filling_taco_bull_says_suit_77K5FOfkn3KFvXSHUOHU

Apparently, it is mostly comprised of something called "Isolated Oat Product". Not to mention, "fillers" and "extenders" - which sound a bit more benign than "Oat Product". But, I confess I'm having tremendous difficulty imagining what any of these things actually are.

I can envision "Oat"; and maybe "Oat Product". but, what in the world makes it isolated?

I hope I didn't ruin anybody's lunch plans

Logged

"I find your lack of faith distrubing."

Grunt Trooper
Forum Missionary
Commander
Posts: 1011

Re: Isolated Oat Product
« Reply #1 on: January 26, 2011, 01:40:35 PM »

I'll still go to taco bell, but I just won't get their nasty beef
I heard about this and just laughed, because not even a week ago my mom was commenting on how different their beef was tasting. We don't go very often so we all just put it off as coincidence or something.

Logged

WWTDD: What would the Doctor do?

Mia Ge'tal'mesh
Master Assassin
Commander
Posts: 1092

Re: Isolated Oat Product
« Reply #2 on: January 27, 2011, 04:18:41 AM »

Ehh, everything's bad for you in some kinda way. lolz That's weird, but it's not gonna stop me from getting a chalupa or two from there.

Logged

"To say nothing is true, is to realize that the foundations of society are fragile and that we must be the shepherds of our own civilization. To say everything is permitted, is to understand that we are the architects of

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9 C.F.R. § 301.2

therefor, take reasonable samples of the inventory.

[63 FR 72354, Dec. 31, 1998, as amended at 69 FR 254, Jan. 5, 2004]

PART 301—TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

Sec.
301.1 General.
301.2 Definitions.

AUTHORITY: 21 U.S.C. 601–695; 7 U.S.C. 138–138i, 450, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

§ 301.1 General.

For purposes of this chapter and unless otherwise specifically provided by regulation or required in the context of particular regulations:

(a) Terms have the meanings set forth in this part;

(b) The singular form also imports the plural, and the masculine form also imports the feminine and vice versa.

[69 FR 254, Jan. 5, 2004]

§ 301.2 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

The Act. The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 21 U.S.C., sec. 601 *et seq.*).

Adulterated. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(iv) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: *Provided,* That an article which is not deemed adulterated under paragraphs (aa)(2) (ii), (iii), or (iv) of this section shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to

increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or,

(9) If it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise adulterated.

Anesthesia. Loss of sensation or feeling.

Animal food. Any article intended for use as food for dogs, cats, or other animals derived wholly, or in part, from the carcass or parts or products of the carcass of any livestock, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Livestock or poultry feeds manufactured from processed livestock byproducts (such as meatmeal tankage, meat and bonemeal, bloodmeal, and feed grade animal fat).

Animal food manufacturer. Any person engaged in the business of manufacturing or processing animal food.

Artificial coloring. A coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

Artificial flavoring. A flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

Biological residue. Any substance, including metabolites, remaining in livestock at time of slaughter or in any of its tissues after slaughter as the result of treatment or exposure of the livestock to a pesticide, organic or inorganic compound, hormone, hormonelike substance, growth promoter, antibiotic, anthelmintic, tranquilizer, or other therapeutic or prophylactic agent.

Capable of use as human food. This term applies to any carcass, or part or product of a carcass, of any livestock, unless it is denatured or otherwise identified as required by the applicable provisions of §§ 314.3, 314.10, 325.11, and 325.13 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., hoofs or horns in their natural state.

Captive bolt. A stunning instrument which when activated drives a bolt out of a barrel for a limited distance.

Carbon dioxide. A gaseous form of the chemical formula CO_2.

Carbon dioxide concentration. Ratio of carbon dioxide gas and atmospheric air.

Carcass. All parts, including viscera, of any slaughtered livestock.

Chemical preservative. Any chemical that, when added to a meat or meat food product, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices or substances added to meat and meat food products by exposure to wood smoke.

Other definitions, if any, that are applicable only for purposes of a specific part of the regulations in this subchapter, are set forth in such part.

Commerce. Commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

Consciousness. Responsiveness of the brain to the impressions made by the senses.

Cutting up. Any division of any carcass or part thereof, except that the trimming of carcasses or parts thereof to remove surface contaminants is not considered as cutting up.

Dead livestock. The body (cadaver) of livestock which has died otherwise than by slaughter.

Dying, diseased, or disabled livestock. Livestock which has or displays symptoms of having any of the following:

(1) Central nervous system disorder;

(2) Abnormal temperature (high or low);

(3) Difficult breathing;

(4) Abnormal swellings;

(5) Lack of muscular coordination;

(6) Inability to walk normally or stand;

(7) Any of the conditions for which livestock is required to be condemned

on ante-mortem inspection in accordance with the regulations in part 309 of this subchapter.

Edible. Intended for use as human food.

Experimental animal. Any animal used in any research investigation involving the feeding or other administration of, or subjection to, an experimental biological product, drug, or chemical or any nonexperimental biological product, drug, or chemical used in a manner for which it was not intended.

Exposure time. The period of time an animal is exposed to an anesthesia-producing carbon dioxide concentration.

Federal Food, Drug, and Cosmetic Act. The Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Firm. Any partnership, association, or other unincorporated business organization.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

Immediate container. The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Inedible. Adulterated, uninspected, or not intended for use as human food.

Inhumane slaughter or handling in connection with slaughter. Slaughter or handling in connection with slaughter not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901 through 1906, as amended by the Humane Methods of Slaughter Act of 1978, 92 Stat. 1069) and part 313 of this subchapter.

"Inspected and passed" or "U.S. Inspected and Passed" or "U.S. Inspected and Passed by Department of Agriculture" (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Labeling. All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

Livestock. Cattle, sheep, swine, goat, horse, mule, or other equine.

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

(2) [Reserved]

Meat broker. Any person engaged in the business of buying or selling carcasses, parts of carcasses, meat or meat food products of livestock on commission, or otherwise negotiating purchases or sales of such articles other than for his/her own account or as an employee of another person.

Meat byproduct. Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Meat food product. Any article capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, except those exempted from definition as a meat food product by the Administrator in specific cases or by the regulations in part 317 of this subchapter, upon a determination that they contain meat or other portions of such carcasses only in

a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to assure that the meat or other portions of such carcasses contained in such articles are not adulterated and that such articles are not represented as meat food products. This term, as applied to food products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Misbranded. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (vv)(7)(ii) of this section unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will

FSIS Statement of Interim Labeling Guidance, The Labeling of Factual Statements on Nutrients in Meat and Poultry Products

Food Safety and inspection Service (FSIS) Statement of Interim Labeling Guidance

The Labeling of Factual Statements on Nutrients in Meat and Poultry Products

[This is an interim policy statement and may be withdrawn or modified if information is received by FSIS that shows that significant consumer confusion exists in this subject area.]

This policy provides guidance on how factual statements can be declared for nutrients in a serving of meat or poultry product when the nutrients come from a food that is produced or fortified under the jurisdiction of the Food and Drug Administration (FDA) for the purpose of improving the overall nutritional profile of the finished food. Unapproved nutrient content claims (or implied claims) about specific nutrients, as well as the direct fortification of meat or poultry products, are not permitted.

FSIS has received an increasing number of requests to approve labels that make factual statements about the amount of various vitamins, minerals and other nutrients present in meat or poultry products. In accordance with FDA's fortification policy in Title 21 of the Code of Federal Regulations (CFR), Section 104.20, FSIS does not permit the addition of nutrient additives (e.g., vitamins and minerals) to meat and poultry. FSIS continues to believe that the 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.

FSIS does not object to the addition of foods that are fortified under FDA's jurisdiction to meat and poultry products in a Federal establishment (e.g., an enriched spaghetti noodle that is added to a sauce with meatballs in order to make "spaghetti with meatballs" which is under FSIS jurisdiction). If a company intends to make a nutrient content claim or factual statement on the level of the particular nutrient contributed by the FDA fortified food, FSIS expects that the statement will identify the food that is the source of the nutrient (e.g., "enriched pasta is a good source of Calcium, Vitamin D, and Magnesium"). Similarly, FSIS does not object to 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, and Lutein) being added to a meat or poultry product as long as the safety of the use of the substance in meat and poultry products has been established. If a company intends to make a factual statement on the presence or level of such a substance on the meat or poultry product label, the statement will also need to identify the food that is source of the nutrient (e.g., "250 mg Omega-3 Fatty Acids per serving from the Flax seed in crust" or "250 mg of Omega-3 Fatty Acids per serving from fish oil in breading"). This information on labeling is to inform consumers about what food component has been added to the meat or poultry product that is the source of the nutrient. Statements of this type would be misleading if the source of the nutrient is not disclosed because it would create the impression that the meat or poultry is the source of the substance, which would not be correct. In some situations, however, the feeding practices employed by the producer would be the reason the substance is present (e.g., feeding flax seed to cattle and swine can introduce Omega-3 fatty acids to the meat tissue). In this situation, because there is nothing added to the meat after the animal is slaughtered, the source of the source of the substance

would not need to be declared, although presence of the substance should be (e.g. □X mg of Omega-3 fatty acids per serving□).

The addition of an FDA regulated food (e.g., vegetable and fish oils such as menhaden oil, tuna oil, canola oil, or olive oil) to meat or poultry products cannot be done in a way that conflicts with a FSIS standard of identity or any other Federal regulation. For example, if a processor wished to add an FDA regulated seasoning that contains caffeine to meat or poultry, it would not be permitted to do so because under 21 CFR 182.1180, caffeine is only GRAS for addition to cola-type beverages. In regard to FSIS food standards of identity, standardized foods such as □Italian Sausage□(9 CFR 319.145) and □Ham, With Natural Juices□(9 CFR 319.104) do not provide for the addition of ingredients such as fish and vegetable oils. If a Federal establishment wishes to formulate a meat or poultry product with a food that is not provided for in the standard of identity, the common or usual name of the meat or poultry product will need to be modified to describe the new food so that consumers can distinguish it from the traditional product (e.g., □Ham with Natural Juices with Olive Oil□or □Italian Sausage with Menhaden Oil□).

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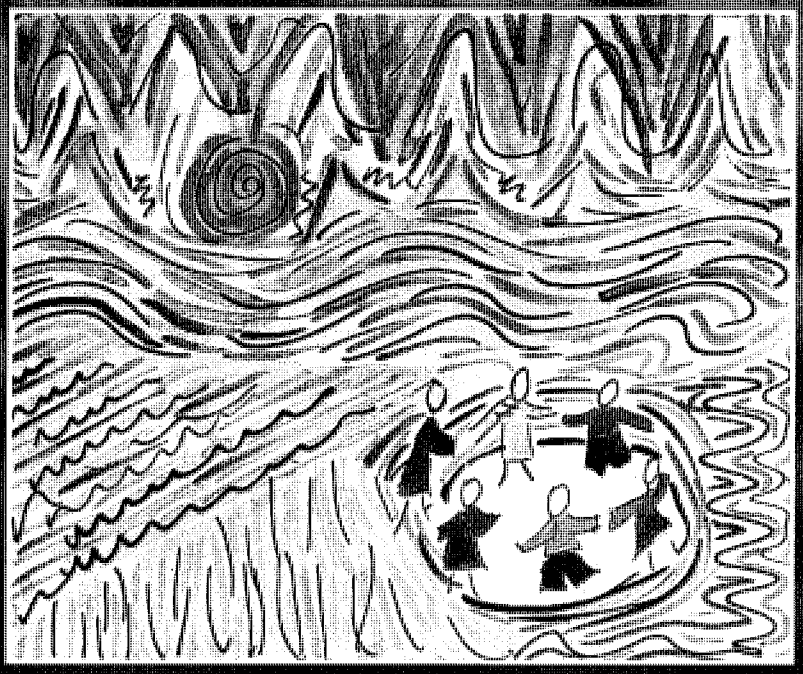
Guidelines on Food Fortification with Micronutrients, WHO (2006)



Guidelines on food fortification with micronutrients

Edited by Lindsay Allen, Bruno de Benoist, Omar Dary and Richard Hurrell

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and technological constraints, as the level that will provide the greatest number of at-risk individual with an adequate intake without causing an unacceptable risk of excess intakes in the whole population.

Food commodities are staple foods, condiments and milk.

Fortification is the practice of deliberately increasing the content of an essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food, so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health.

Legal Minimum level (LmL) is the minimum amount of micronutrient that a fortified food must contain according to national regulations and standards. This value is estimated by adding the intrinsic content of a micronutrient in the food to the selected level of fortification.

Market-driven fortification refers to the situation where the food manufacturer takes the initiative to add one or more micronutrients to processed foods, usually within regulatory limits, in order to increase sales and profitability.

Mass fortification refers to the addition of micronutrients to foods commonly consumed by the general public, such as cereals, condiments and milk.

Maximum Tolerable Level (MTL) is the maximum micronutrient content that a fortified food can present as it is established in food law, in order to minimize the risk of excess intake. It should coincide or be lower than the safety limit.

Minimum Fortification Level (mFL) is the level calculated by reducing the Feasible Fortification Level by three standards deviations (or coefficients of variation) of the fortification process, in order that the average coincides or is lower than the calculated Feasible Fortification Level.

Monitoring refers to the continuous collection and review of information on programme implementation activities for the purposes of identifying problems (such as non-compliance) and taking corrective actions so that the programme fulfils its stated objectives.

Nutritional equivalence is achieved when an essential nutrient is added to a product that is designed to resemble a common food in appearance, texture, flavour and odour in amounts such that the substitute product has a similar nutritive value, in terms of the amount and bioavailability of the added essential nutrient.

Nutrient Reference Values (NRVs) are dietary reference values defined by the Codex Alimentarius Commission with the aim of harmonizing the labelling of processed foods. It is a value applicable to all members of the family aged

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subpart for the mandatory nutrition labeling program.

[58 FR 664, Jan. 6, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 60 FR 189, Jan. 3, 1995]

EFFECTIVE DATE NOTE: At 75 FR 82165, Dec. 29, 2010, §317.345 was amended as follows, effective Jan. 1, 2012. At 76 FR 76890, Dec. 9, 2011, the effectiveness was delayed until Mar. 1, 2012.

a. Revise the section heading and paragraphs (a) and (c);

b. Amend paragraph (d) by removing "should" and adding, in its place, "for products covered in paragraphs (a)(1) and (a)(2) must";

c. Amend paragraph (e) by removing "its published form, the Agriculture Handbook No. 8 series" and by adding, in its place, "its released form, the USDA National Nutrient Database for Standard Reference", and by removing "(including ground beef)";

d. Amend paragraph (f) by adding "provided" after "nutrition information is"; and

e. Amend paragraph (g) by removing the phrase "(including ground beef)".

For the convenience of the user, the revised text is set forth as follows:

§317.345 Nutrition labeling of single-ingredient, raw meat products that are not ground or chopped products described in §317.301.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw meat products identified in §317.344, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under §317.400. If nutrition information is presented on the label, it must be provided in accordance with §317.309. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw meat products that are not ground or chopped meat products described in §317.301 and are not major cuts of single-ingredient, raw meat products identified in §317.344, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of §317.309.

(3) A retailer may provide nutrition information at the point-of-purchase by various methods, such as by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of §317.309 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of §317.309 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in §317.309(c)(8)) and footnote required by §317.309(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

* * * * *

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in §317.309(f).

* * * * *

§§ 317.346–317.353 [Reserved]

§317.354 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV) established for that nutrient (excluding total carbohydrate) in §317.309(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §317.313; and

(3) The product for which the claim is made is labeled in accordance with §317.309.

(b) *"High" claims.* (1) The terms "high," "rich in," or "excellent source of" may be used on the label or in labeling of products, except meal-type products as defined in §317.313(l), and main-dish products as defined in §317.313(m) provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l), and main-dish product as defined in §317.313(m) provided that:

(i) The product contains a food that meets the definition of "high" in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., "the serving of broccoli in this meal is high in vitamin C").

(c) *"Good Source" claims.* (1) The terms "good source," "contains," or "provides" may be used on the label or in labeling of products, except meal-type products as described in §317.313(l), and main-dish products as defined in §317.313(m) provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l), and main-dish product as defined in §317.313(m) provided that:

(i) The product contains a food that meets the definition of "good source" in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., "the serving of sweet potatoes in this meal is a good source of fiber").

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains "more" fiber, and the product is not "low" in total fat as defined in §317.362(b)(2) or, in the case of a meal-type product or a main-dish product, is not "low" in total fat as defined in §317.362(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., "contains 12 grams (g) of fat per serving"); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *"More" claims.* (1) A relative claim using the terms "more" and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in §317.313(l), and main-dish products as defined in §317.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in §317.313(j)(1); and

(ii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber than 'reference product'"); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving").

(2) A relative claim using the terms "more" and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in §317.313(l), and main-dish products as defined in §317.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in §317.313(j)(1); and

(ii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product'"), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product or a main-dish product per specified weight with that of the reference product that it replaces

is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz").

[60 FR 189, Jan. 3, 1995, as amended at 69 FR 58802, Oct. 1, 2004]

§ 317.355 [Reserved]

§ 317.356 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the terms "light" or "lite" to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *"Light" claims.* The terms "light" or "lite" may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l) and main-dish products as defined in § 317.313(m), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in § 317.313(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33⅓ percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 317.313(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 317.313(j)(1); and

(3) As required in § 317.313(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (e.g., "⅓ fewer calories and 50 percent less fat than the market leader"); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving"); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A "light" claim may not be made on a product for which the reference product meets the definition of "low fat" and "low calorie."

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms "light" or "lite" without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., "50 percent less sodium than the market leader"); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving").

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms "light in sodium" or "lite in sodium" if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that "light" or "lite" is presented in immediate proximity with

9 C.F.R. § 381.454

d. Amend paragraph (f) by adding "provided" after "nutrition information is".

For the convenience of the user, the revised text is set forth as follows:

§381.445 Nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped products described in §381.401.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw poultry products identified in §381.444, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under §381.500. If nutrition information is presented on the label, it must be provided in accordance with the provisions of §381.409. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw poultry products that are not ground or chopped poultry products described in §381.401 and are not major cuts of single-ingredient, raw poultry products identified in §381.444, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of §381.409.

(3) A retailer may provide nutrition information at the point-of-purchase by various methods, such as by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of §381.409 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of §381.409 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in §381.409(c)(8)) and footnote required by §381.409(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

* * * * *

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in §381.409(f).

* * * * *

§§381.446–381.453 [Reserved]

§381.454 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV), established for that nutrient (excluding total carbohydrate) in §381.409(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §381.413; and

(3) The product for which the claim is made is labeled in accordance with §381.409.

(b) *"High" claims.* (1) The terms "high," "rich in," or "excellent source of" may be used on the label or in labeling of products, except meal-type products as defined in §381.413(l) and main-dish products as defined in §381.413(m), provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l) and main-dish product as defined in §381.413(m), provided that:

(i) The product contains a food that meets the definition of "high" in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., "the serving of broccoli in this meal is high in vitamin C").

(c) *"Good Source" claims.* (1) The terms "good source," "contains," or "provides" may be used on the label or in labeling of products, except meal-type products as described in §381.413(l) and main-dish products as defined in §317.313(m), provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type

product as defined in § 381.413(l) and main-dish product as defined in § 381.413(m), provided that:

(i) The product contains a food that meets the definition of "good source" in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., "the serving of sweet potatoes in this meal is a good source of fiber").

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains "more" fiber, and the product is not "low" in total fat as defined in § 381.462(b)(2) or, in the case of a meal-type product or in a main-dish product, is not "low" in total fat as defined in § 381.462(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., "contains 12 grams (g) of fat per serving"); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *"More" claims.* (1) A relative claim using the terms "more" and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber than 'reference product' "); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving").

(2) A relative claim using the terms "more" and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 381.413(l) and main-dish products as defined in § 381.413(m), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product' "), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product or in a main-dish product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz").

[60 FR 210, Jan. 3, 1995, as amended at 69 FR 58803, Oct. 1, 2004]

§ 381.455 [Reserved]

§ 381.456 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the terms "light" or "lite" to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

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(5) The claim may include information on the number of people in the United States who have coronary heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA), Government Printing Office.

(6) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," DHHS and USDA, Government Printing Office.

(7) The claim may state that individuals with elevated blood total- or LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- or LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(e) *Model health claims.*The following are model health claims that may be used in food labeling to describe the relationship between dietary saturated fat and cholesterol and risk of heart disease:

(1) While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease;

(2) Development of heart disease depends upon many factors, but its risk may be reduced by diets low in saturated fat and cholesterol and healthy lifestyles;

(3) Development of heart disease depends upon many factors, including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking, lack of exercise, and the type of dietary pattern. A healthful diet low in saturated fat, total fat, and cholesterol, as part of a healthy lifestyle, may lower blood cholesterol levels and may reduce the risk of heart disease;

(4) Many factors, such as a family history of the disease, increased blood- and LDL-cholesterol levels, high blood pressure, cigarette smoking, diabetes, and being overweight, contribute to developing heart disease. A diet low in saturated fat, cholesterol, and total fat may help reduce the risk of heart disease; and

(5) Diets low in saturated fat, cholesterol, and total fat may reduce the risk of heart disease. Heart disease is dependent upon many factors, including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity.

[58 FR 2757, Jan. 6, 1993]

§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.

(a) *Relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include: A family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The scientific evidence establishes that diets low in fat and high in fiber-containing grain products, fruits, and vegetables are associated with a reduced risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets low in fat and high in fiber-containing foods are associated with reduced risk of some types of cancer.

(b) *Significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in grain products, fruits, and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (five or more servings daily), and grain products (six or more servings daily).

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in fat and high in fiber-containing grain products, fruits, and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fiber-containing grain products, fruits, and vegetables "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer," or "some cancers";

(C) The claim is limited to grain products, fruits, and vegetables that contain dietary fiber;

(D) The claim indicates that development of cancer depends on many factors;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fiber-containing grain products, fruits, and vegetables;

(F) In specifying the dietary fiber component of the labeled food, the claim uses the term "fiber", "dietary fiber" or "total dietary fiber"; and

(G) The claim does not specify types of dietary fiber that may be related to risk of cancer.

(ii) *Nature of the food.* (A) The food shall be or shall contain a grain product, fruit, or vegetable.

(B) The food shall meet the nutrient content requirements of §101.62 for a "low fat" food.

(C) The food shall meet, without fortification, the nutrient content requirements of §101.54 for a "good source" of dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables, and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer causing chemicals, and dietary factors.

(3) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk:

(1) Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in grain products, fruits, and vegetables that contain dietary fiber may reduce your risk of some cancers.

[58 FR 2548, Jan. 6, 1993]

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21 C.F.R. § 101.77

§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

(a) *Relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(3) Populations with relatively low blood cholesterol levels tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fruits, vegetables, and grain products. Although the specific roles of these plant foods are not yet fully understood, many studies have shown that diets high in plant foods are associated with reduced risk of coronary heart disease. These studies correlate diets rich in fruits, vegetables, and grain products and nutrients from these diets, such as some types of fiber, with reduced coronary heart disease risk. Persons consuming these diets frequently have high intakes of dietary fiber, particularly soluble fibers. Currently, there is not scientific agreement as to whether a particular type of soluble fiber is beneficial, or whether the observed protective effects of fruits, vegetables, and grain products against heart disease are due to other components, or a combination of components, in these diets, including, but not necessarily limited to, some types of soluble fiber, other fiber components, other characteristics of the complex carbohydrate content of these foods, other nutrients in these foods, or displacement of saturated fat and cholesterol from the diet.

(b) *Significance of the relationship between diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events; such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals, including persons with blood cholesterol levels in the normal range. Additionally, consuming diets high in fruits, vegetables, and grain products, foods that contain soluble fiber, may be a useful adjunct to a low saturated fat and low cholesterol diet.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. Intakes of fiber-containing fruits, vegetables, and grain products are about half of recommended intake levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Recommended total dietary fiber intakes are about 25 grams (g) daily, of which about 25 percent (about 6 g) should be soluble fiber.

(4) Current dietary guidance recommendations encourage decreased consumption of dietary fat, especially saturated fat and cholesterol, and increased consumption of fiber-rich foods to help lower blood LDL-cholesterol levels. Results of numerous studies have shown that fiber-containing fruits, vegetables, and grain products can help lower blood LDL-cholesterol.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease;"

(C) The claim is limited to those fruits, vegetables, and grains that contain fiber;

(D) In specifying the dietary fiber, the claim uses the term "fiber," "dietary fiber," "some types of dietary fiber," "some dietary fibers," or "some fibers;" the term "soluble fiber" may be used in addition to these terms;

(E) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol;" and

(F) The claim indicates that development of heart disease depends on many factors; and

(G) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit, vegetable, or grain product.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food.

(C) The food contains, without fortification, at least 0.6 g of soluble fiber per reference amount customarily consumed;

(D) The content of soluble fiber shall be declared in the nutrition information panel, consistent with § 101.9(c)(6)(i)(A).

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of coronary heart disease, elevated blood-, total- and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber to heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in saturated fat and cholesterol and high in fruits,

vegetables, and grain products that contain fiber and coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term "total fat" in addition to the terms "saturated fat" and "cholesterol."

(5) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber:

(1) Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

(2) Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease.

[58 FR 2578, Jan. 6, 1993]

§ 101.78 Health claims: fruits and vegetables and cancer.

(a) *Relationship between substances in diets low in fat and high in fruits and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Although the specific roles of the numerous potentially protective substances in plant foods are not yet understood, many studies have shown that diets high in plant foods are associated with reduced risk of some types of cancers. These studies correlate diets rich in fruits and vegetables and nutrients from these diets, such as vitamin C, vitamin A, and dietary fiber, with reduced cancer risk. Persons consuming these diets frequently have high intakes of these nutrients. Currently, there is not scientific agreement as to whether the observed protective effects of fruits and vegetables against cancer are due to a combination of the nutrient components of diets rich in fruits and vegetables, including but not necessarily limited to dietary fiber, vitamin A (as beta-carotene) and vitamin C, to displacement of fat from such diets, or to intakes of other substances in these foods which are not nutrients but may be protective against cancer risk.

(b) *Significance of the relationship between consumption of diets low in fat and high in fruits and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in fruits and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These

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snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.

(ii) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.

(iii) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar used to sweeten this food, unlike other sugars, may reduce the risk of dental caries.

(iv) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar in [name of food], unlike other sugars, does not promote tooth decay.

(v) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Sucralose, the sweetening ingredient used to sweeten this food, unlike sugars, does not promote tooth decay.

(2) Example of the shortened claim for small packages:

(i) Does not promote tooth decay.

(ii) May reduce the risk of tooth decay.

(iii) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar does not promote tooth decay.

(iv) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar may reduce the risk of tooth decay.

[61 FR 43446, Aug. 23, 1996, as amended at 62 FR 63655, Dec. 2, 1997; 66 FR 66742, Dec. 27, 2001; 67 FR 71470, Dec. 2, 2002; 71 FR 15563, Mar. 29, 2006; 72 FR 52789, Sept. 17, 2007]

§ 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as whole oat products.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soluble fiber from certain foods to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories

from all fat. Recommended daily cholesterol intakes are 300 milligrams (mg) or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total- and LDL-cholesterol levels. Soluble fiber from certain foods, when included in a low saturated fat and cholesterol diet, also helps to lower blood total- and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met. The label and labeling of foods containing psyllium husk shall be consistent with the provisions of § 101.17(f).

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods "may" or "might" reduce the risk of heart disease.

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease";

(C) In specifying the substance, the claim uses the term "soluble fiber" qualified by the name of the eligible source of soluble fiber (provided in paragraph (c)(2)(ii)) of this section. Additionally, the claim may use the name of the food product that contains the eligible source of soluble fiber;

(D) In specifying the fat component, the claim uses the terms "saturated fat" and "cholesterol";

(E) The claim does not attribute any degree of risk reduction for CHD to diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section; and

(F) The claim does not imply that consumption of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section is the only recognized means of achieving a reduced risk of CHD.

(G) The claim specifies the daily dietary intake of the soluble fiber source that is necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of soluble fiber sources listed in paragraph (c)(2)(ii) of this section that have been associated with reduced risk coronary heart disease are:

(*1*) 3 g or more per day of β-glucan soluble fiber from either whole oats or barley, or a combination of whole oats and barley.

(*2*) 7 g or more per day of soluble fiber from psyllium seed husk.

(ii) *Nature of the substance—Eligible sources of soluble fiber.* (A) Beta (β) glucan soluble fiber from the whole oat and barley sources listed below. β-glucan soluble fiber will be determined by method No. 992.28 from the "Official Methods of Analysis of the AOAC INTERNATIONAL," 16th ed. (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

(*1*) *Oat bran.* Oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry weight basis (dwb)) β-glucan soluble fiber and a total dietary fiber content of 16 percent (dwb), and such that at least one-third of the total dietary fiber is soluble fiber;

(*2*) *Rolled oats.* Rolled oats, also known as oatmeal, produced from 100 percent dehulled, clean oat groats by steaming, cutting, rolling, and flaking, and provides at least 4 percent (dwb) of

β-glucan soluble fiber and a total dietary fiber content of at least 10 percent.

(*3*) *Whole oat flour.* Whole oat flour is produced from 100 percent dehulled, clean oat groats by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of β-glucan soluble fiber and a total dietary fiber content of at least 10 percent (dwb).

(*4*) *Oatrim.* The soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour, also known as oatrim. Oatrim is produced from either oat bran as defined in paragraph (c)(2)(ii)(A)(*1*) of this section or whole oat flour as defined in paragraph (c)(2)(ii)(A)(*3*) of this section by solubilization of the starch in the starting material with an alpha-amylase hydrolysis process, and then removal by centrifugation of the insoluble components consisting of a high portion of protein, lipid, insoluble dietary fiber, and the majority of the flavor and color components of the starting material. Oatrim shall have a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb).

(*5*) *Whole grain barley and dry milled barley.* Dehulled and hull-less whole grain barley with a β-glucan soluble fiber content of at least 4 percent (dwb) and a total dietary fiber content of at least 10 percent (dwb). Dry milled barley grain products include barley bran, barley flakes, barley grits, pearl barley, barley flour, barley meal, and sieved barley meal that are produced from clean, sound dehulled or hull-less barley grain using standard dry milling techniques, which may include steaming or tempering, and that contain at least 4 percent (dwb) of β-glucan soluble fiber and at least 8 percent (dwb) of total dietary fiber, except barley bran and sieved barley meal for which the minimum β-glucan soluble fiber content is 5.5 percent (dwb) and minimum total dietary fiber content is 15 percent (dwb). Dehulled barley, hull-less barley, barley bran, barley flakes, barley grits, pearl barley, and barley flour are as defined in the Barley Glossary (AACC Method 55–99), published in Approved Methods of the American Association of Cereal Chemists, 10th ed. (2000), pp. 1 and 2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Association of Cereal Chemists, Inc., 3340 Pilot Knob Rd., St. Paul, Minnesota, 55121, or may be examined at the Center for Food Safety and Applied Nutrition Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Barley meal is unsifted, ground barley grain not subjected to any processing to separate the bran, germ, and endosperm. Sieved barley meal is an endosperm cell wall-enriched fraction of ground barley separated from meal by sieving or by air classification.

(*6*) *Barley betafiber.* Barley betafiber is the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(*5*) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis.

(B)(*1*) Psyllium husk from the dried seed coat (epidermis) of the seed of *Plantago* (*P.*) ovata, known as blond psyllium or Indian psyllium, *P. indica,* or *P. psyllium.* To qualify for this claim, psyllium seed husk, also known as psyllium husk, shall have a purity of no less than 95 percent, such that it contains 3 percent or less protein, 4.5

percent or less of light extraneous matter, and 0.5 percent or less of heavy extraneous matter, but in no case may the combined extraneous matter exceed 4.9 percent, as determined by U.S. Pharmacopeia (USP) methods described in USP's "The National Formulary," USP 23, NF 18, p. 1341, (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

(*2*) FDA will determine the amount of soluble fiber that is provided by psyllium husk by using a modification of the Association of Official Analytical Chemists' International (AOAC's) method for soluble dietary fiber (991.43) described by Lee et al., "Determination of Soluble and Insoluble Dietary Fiber in Psyllium-containing Cereal Products," *Journal of the AOAC International*, 78 (No. 3):724–729, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall include:

(*1*) One or more of the whole oat or barley foods from paragraphs (c)(2)(ii)(A)(*1*), (*2*), (*3*), and (*5*) of this section, and the whole oat or barley foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product; or

(*2*) The food containing the oatrim from paragraph (c)(2)(ii)(A)(*4*) of this section or the barley betafiber from paragraph (c)(2)(ii)(A)(*6*) of this section shall contain at least 0.75 g of beta-glucan soluble fiber per reference amount customarily consumed of the food product; or

(*3*) Psyllium husk that complies with paragraph (c)(2)(ii)(B) of this section, and the psyllium food shall contain at least 1.7 g of soluble fiber per reference amount customarily consumed of the food product;

(B) The amount of soluble fiber shall be declared in the nutrition label, consistent with § 101.9(c)(6)(i)(A).

(C) The food shall meet the nutrient content requirement in § 101.62 for a "low saturated fat" and "low cholesterol" food; and

(D) The food shall meet the nutrient content requirement in § 101.62(b)(2) for a "low fat" food, unless the food exceeds this requirement due to fat content derived from whole oat sources listed in paragraph (c)(2)(ii)(A) of this section.

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol;"

(3) The claim may include information from paragraphs (a) and (b) of this

section, which summarize the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and coronary heart disease and the significance of the relationship;

(4) The claim may specify the name of the eligible soluble fiber;

(5) The claim may state that a diet low in saturated fat and cholesterol that includes soluble fiber from whole oats or barley is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and reduced risk of heart disease:

(1) Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies _____ grams of the [grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] soluble fiber from [name of the soluble fiber source from paragraph (c)(2)(ii) of this section] necessary per day to have this effect.

(2) Diets low in saturated fat and cholesterol that include [_____ grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] of soluble fiber per day from [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of the food product] may reduce the risk of heart disease. One serving of [name of food] provides _____ grams of this soluble fiber.

[62 FR 3600, Jan. 23, 1997, as amended at 62 FR 15344, Mar. 31, 1997; 63 FR 8119, Feb. 18, 1998; 66 FR 66742, Dec. 27, 2001; 67 FR 61782, Oct. 2, 2002; 68 FR 15355, Mar. 31, 2003; 70 FR 40880, July 15, 2005; 70 FR 76162, Dec. 23, 2005; 73 FR 9947, Feb. 25, 2008; 73 FR 23953, May 1, 2008]

§ 101.82 Health claims: Soy protein and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soy protein and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. CHD is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing CHD. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in plant foods that contain dietary fiber and other components.

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21 C.F.R. § 101.13

(ii) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(iii) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(iv) The methodology used to collect or process data should be fully documented and should include: study design, sampling procedures, materials used (e.g., questionnaire, and interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse.

(14) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act (5 U.S.C. 561).

[58 FR 44051, Aug. 18, 1993; 58 FR 60109, Nov. 15, 1993, as amended at 59 FR 371, Jan. 4, 1994; 59 FR 24039, May 10, 1994; 62 FR 40598, July 29, 1997; 62 FR 49848, Sept. 23, 1997; 63 FR 14818, Mar. 27, 1998; 64 FR 12890, Mar. 16, 1999; 66 FR 56035, Nov. 6, 2001]

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under §101.9 or under §101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in parts 101, 105, or 107 of this chapter.

(4) Reasonable variations in the spelling of the terms defined in part 101 and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(5) For dietary supplements, claims for calories, fat, saturated fat, and cholesterol may not be made on products that meet the criteria in §101.60(b)(1) or (b)(2) for "calorie free" or "low calorie" claims, except, in the case of calorie claims, when an equivalent amount of a similar dietary supplement (e.g., another protein supplement) that the labeled food resembles and for which it substitutes, normally exceeds the definition for "low calorie" in §101.60(b)(2).

(c) Information that is required or permitted by §101.9 or §101.36, as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" food is one that may be used interchangeably with another food that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the food, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by §101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch, unless the package complies with §101.2(c)(5), in which case the disclaimer may be in type of not less than one thirty-second of an inch.

(e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food, may bear such a claim (e.g., "low sodium potato chips").

(2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium-free food").

(f) A nutrient content claim shall be in type size no larger than two times the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) [Reserved]

(h)(1) If a food, except a meal product as defined in §101.13(l), a main dish product as defined in §101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §101.9(f)(1), of all nutrients per reference amount customarily consumed, the per 50 g criterion refers to the "as prepared" form), then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: "See nutrition information for ___ content" with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., "See nutrition information for fat content."

(2) If a food is a meal product as defined in §101.13(l), and contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in §101.13(m), and contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(4)(i) The disclosure statement "See nutrition information for ___ content" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, and in a size no less than that required by §101.105(i) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclosure statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch,

unless the package complies with §101.2(c)(2), in which case the disclosure statement may be in type of not less than one thirty-second of an inch.

(ii) The disclosure statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the disclosure statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

(iii) If a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single disclosure statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(i) Except as provided in §101.9 or §101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is consistent with a definition for a claim, as provided in subpart D of this part, for the nutrient that the label addresses. Such a claim might be, "less than 3 g of fat per serving;"

(2) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not "low" in or a "good source" of the nutrient, such as "only 200 mg sodium per serving, not a low sodium food." The disclaimer must be in easily legible print or type and in a size no less than that required by §101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch unless the package complies with §101.2(c)(5), in which case the disclaimer may be in type of not less less than one thirty-second of an inch, or

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with §101.62(b)(6).

(j) A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food. These statements shall be known as "relative claims" and include "light," "reduced," "less" (or "fewer"), and "more" claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared to an amount of nutrient in an appropriate reference food as specified below.

(i)(A) For "less" (or "fewer") and "more" claims, the reference food may be a dissimilar food within a product category that can generally be substituted for one another in the diet (e.g., potato chips as reference for pretzels, orange juice as a reference for vitamin C tablets) or a similar food (e.g., potato chips as reference for potato chips, one brand of multivitamin as reference for another brand of multivitamin).

(B) For "light," "reduced," "added," "extra," "plus," "fortified," and "enriched" claims, the reference food shall be a similar food (e.g., potato chips as a reference for potato chips, one brand of multivitamin for another brand of multivitamin), and

(ii)(A) For "light" claims, the reference food shall be representative of the type of food that includes the product that bears the claim. The nutrient value for the reference food shall be representative of a broad base of foods of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient

value is representative of the food type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than "light," including "less" and "more" claims, the reference food may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section, or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting label is internally consistent to (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information and the declaration of the percentage of nutrient by which the food has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For foods bearing relative claims:

(i) The label or labeling must state the identity of the reference food and the percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient in the labeled food differs (e.g., "50 percent less fat than (reference food)" or "1/3 fewer calories than (reference food)"),

(ii) This information shall be immediately adjacent to the most prominent claim. The type size shall be in accordance with paragraph (h)(4)(i) of this section.

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that in the reference food; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition label, except that if the nutrition label is on the information panel, the quantitative information may be located elsewhere on the information panel in accordance with § 101.2.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the requirement for a "low" claim for that nutrient (e.g., 3 g fat or less).

(k) The term "modified" may be used in the statement of identity of a food that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "Modified fat cheesecake"). This statement of identity must be immediately followed by the comparative statement such as "Contains 35 percent less fat than _____." The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a "meal product shall be defined as a food that:

(1) Makes a major contribution to the total diet by:

(i) Weighing at least 10 ounces (oz) per labeled serving; and

(ii) Containing not less than three 40-g portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts group; except that;

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, or meal. Such representations may be made either by statements, photographs, or vignettes.

(m) For purposes of making a claim, a "main dish product" shall be defined as a food that:

(1) Makes a major contribution to a meal by

(i) Weighing at least 6 oz per labeled serving; and

(ii) Containing not less than 40 g of food, or combinations of foods, from each of at least two of the following four food groups, except as noted in paragraph (m)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts groups; except that:

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces) gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a main dish (e.g, not a beverage or a dessert). Such representations may be made either by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with §101.9, §101.10, or §101.36, as applicable, shall be provided for any food for which a nutrient content claim is made.

(o) Except as provided in §101.10, compliance with requirements for nutrient content claims in this section and in the regulations in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in §101.9.

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in §101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by §101.12(g) (e.g., "very low sodium, 35 mg or less per 240 milliliters (8 fl oz.)").

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size in accordance with paragraph (h)(4)(i) of this section.

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989, may continue to be used as part of that brand name for such product, provided that they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act). However, foods bearing such claims must comply with section 403(f), (g), and (h) of the act;

(2) A soft drink that used the term *diet* as part of its brand name before October 25, 1989, and whose use of that term was in compliance with §105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act. Such claims are exempt from the requirements of section 403(r)(2) of the act (e.g., the disclosure statement also required by §101.13(h)). Soft drinks marketed after October 25, 1989, may use the term "diet" provided they are in compliance with the current §105.66 of this chapter and the requirements of §101.13.

(3)(i) A statement that describes the percentage of a vitamin or mineral in

the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in §101.9 may be made on the label or in labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral unless such claim is expressly prohibited by regulation under section 403(r)(2)(A)(vi) of the act.

(ii) Percentage claims for dietary supplements. Under section 403(r)(2)(F) of the act, a statement that characterizes the percentage level of a dietary ingredient for which a reference daily intake (RDI) or daily reference value (DRV) has not been established may be made on the label or in labeling of dietary supplements without a regulation that specifically defines such a statement. All such claims shall be accompanied by any disclosure statement required under paragraph (h) of this section.

(A) *Simple percentage claims.* Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV, the statement of the actual amount of the dietary ingredient per serving shall be declared next to the percentage statement (e.g., "40 percent omega-3 fatty acids, 10 mg per capsule").

(B) *Comparative percentage claims.* Whenever a statement is made that characterizes the percentage level of a dietary ingredient for which there is no RDI or DRV and the statement draws a comparison to the amount of the dietary ingredient in a reference food, the reference food shall be clearly identified, the amount of that food shall be identified, and the information on the actual amount of the dietary ingredient in both foods shall be declared in accordance with paragraph (j)(2)(iv) of this section (e.g., "twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)").

(4) The requirements of this section do not apply to:

(i) Infant formulas subject to section 412(h) of the act; and

(ii) Medical foods defined by section 5(b) of the Orphan Drug Act.

(5) A nutrient content claim used on food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

(i) Such claim is exempt from the requirements for disclosure statements in paragraph (h) of this section and §§101.54(d), 101.62(c), (d)(1)(ii)(D), (d)(2)(iii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C); and

(ii) In lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. This reasonable basis may derive from recognized data bases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (e.g., types and amounts of ingredients, cooking temperatures, etc.). Firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim; and

(iii) A term or symbol that may in some contexts constitute a claim under this section may be used, provided that the use of the term or symbol does not characterize the level of a nutrient, and a statement that clearly explains the basis for the use of the term or symbol is prominently displayed and does not characterize the level of a nutrient. For example, a term such as "lite fare" followed by an asterisk referring to a note that makes clear that in this restaurant "lite fare" means smaller portion sizes than normal; or an item bearing a symbol referring to a note that makes clear that this item meets the criteria for the dietary guidance established by a recognized dietary authority would not be considered a nutrient content claim under §101.13.

(6) Nutrient content claims that were part of the common or usual names of

foods that were subject to a standard of identity on November 8, 1990, are not subject to the requirements of paragraphs (b) and (h) of this section or to definitions in subpart D of this part.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the Food and Drug Administration. Petitions requesting approval of such a claim may be submitted under § 101.69(o).

(8) The term *fluoridated, fluoride added* or *with added fluoride* may be used on the label or in labeling of bottled water that contains added fluoride.

[58 FR 2410, Jan. 6, 1993; 58 FR 17341, 17342, Apr. 2, 1993, as amended at 58 FR 44030, Aug. 18, 1993; 59 FR 393, Jan. 4, 1994; 59 FR 15051, Mar. 31, 1994; 60 FR 17205, Apr. 5, 1995; 61 FR 11731, Mar. 22, 1996; 61 FR 40332, Aug. 2, 1996; 61 FR 67452, Dec. 23, 1996; 62 FR 31339, June 9, 1997; 62 FR 49867, Sept. 23, 1997; 63 FR 14818, Mar. 27, 1998; 63 FR 26980, May 15, 1998]

§ 101.14 Health claims: general requirements.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

(2) *Substance* means a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement that includes vitamins, minerals, herbs, or other similar nutritional substances.

(3) *Nutritive value* means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(i) The levels for a meal product as defined in § 101.13(l) are 26.0 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per label serving size, and

(ii) The levels for a main dish product as defined in § 101.13(m) are 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per label serving size.

(5) *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to § 101.14 or § 101.70).

(b) *Eligibility.* For a substance to be eligible for a health claim:

(1) The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health-related condition