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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Docket No. 2006D-0168

Dear Food and Drug Administration,

Members of the AACC International Dietary Fiber Definition Task Force are responding to the announcement in the Federal Register, vol. 72, No. 212, Friday, November 2, 2007 regarding Food Labeling: Revision of Reference Values and Mandatory Nutrients.

The Task Force, chaired by Barry McCleary, Megazyme International Ireland, is comprised of academics, industry, and government participants seeking to arrive at the best definition with regard to dietary fiber. AACC International (formerly the American Association of Cereal Chemists) is the premier worldwide organization for advancing grain science and technology by creating, interpreting, and disseminating cereal information and providing personal and professional development opportunities for its members. Worldwide membership in AACC Intl. includes over 3500 scientists representing industry, academia, and government.

Following are our comments on the following questions:

## *II. Agency Request for Information*

### **C. Labeling of Individual Nutrients**

#### **10. Carbohydrate**

**Should the current approach for calculating grams of total carbohydrate by difference (see section I.E of this document) continue to be used? Explain why or why not. If not, what other approach or method do you recommend? If so, what should be included or excluded in the current calculation of ``total carbohydrate''?**

While CHO by difference may feel “scientifically inadequate”, it works well for determining calories in the food after accounting for moisture, ash, fat, and protein. Basically, the minor components included via the calculation (organic acids, browning products, etc after correcting for DF) probably average about 4 calories/gram and the mass always comes up to 100% for the consumer if the food

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producer chooses to label "other carbohydrates". It is likely that summing of carbohydrate fractions will result in greater variability, since carbohydrate methods other than the chromatographic assay of sugars have higher variability than moisture, ash, protein and fat, all of which have some of the lowest variability of food component analyses. The transfer from indirect to direct measurement of the carbohydrate components will involve considerable expense, both in terms of analyses necessary for labeling and the expense of building new databases, and it must first be demonstrated that this investment will yield further useful information for the consumer.

While we realize that there is a consumer demand for more information on the available/glycemic carbohydrate content of foods, there is more to be done to clearly define what should be included under the banner of glycemic e.g. should this include slowly digested starch?

**The 2005 Dietary Guidelines recommends consuming fiber-rich foods. Would the separation of dietary fiber from the "total carbohydrate" declaration in nutrition labeling affect consumer understanding of label information and its application to dietary guidelines and what would be the impact, if any, on fiber consumption? Should "sugars" continue to be included in the Nutrition Facts label?**

Dietary fiber is almost entirely carbohydrate, so it should be included in the 'total carbohydrate' value. However, when dietary fiber is directly analyzed the value should be listed separately under the general heading of 'total carbohydrate' (as is currently the practice), to assist consumers in making decisions to meet their daily needs for dietary fiber. Ideally, the Nutrition Facts Panel could include 'available carbohydrate' when methodology is agreed upon and passes required co-laboratory tests.

Sugar content on the label tends to convey some meaning to consumers. It can be useful for individuals monitoring their daily intake of available (glycemic) carbohydrates.

**Should additional types of carbohydrate (e.g. starch) be listed separately in the Nutrition Facts label? Explain why or why not.**

Only so much information can be included in a Nutrition Facts label and still be useful to a majority of consumers.

**Should carbohydrates be classified and declared in nutrition labeling based on their chemical definition or on their physiological effect? Explain why you have chosen a particular approach and why it is preferable to the other approach. If based on a physiologic effect, should the DV for carbohydrate (i.e., sugars and starch) be based on the midpoint of the AMDR (i.e., 55 percent)? Explain why or why not. Note: 55 percent of 2,000 calories/d is 1,100 calories. 1,100 calories divided by 4 calories/g would be 275 g/d.**

The report from the Joint FAO/WHO Expert Consultation, Rome, 14-18 April 1997 (FAO. 1998. Carbohydrates in human nutrition, a Joint FAO/WHO Report. FAO Food and Nutrition Paper

66, Rome) clearly recommends that: “The analysis and labeling of dietary carbohydrate, for whatever purpose, be based on the chemical divisions recommended in Figure 1 of the report. Additional groupings such as polyols, resistant starch, non-digestible oligosaccharides and dietary fiber can be used, provided the included components are clearly defined.” It is indicated that analytical methods should be clearly defined and validated. “The principal information should be total carbohydrate, measured as the sum of the individual components. Further information on carbohydrate composition, based on the classification in Figure 1, could include terms such a sugars, starch and non-starch polysaccharides.” This reasoning is still valid. Furthermore, validated analytical methods exist for virtually all the carbohydrates of interest. This is not necessarily true if a classification based on physiological function is adopted.

## **11. Dietary Fiber**

**Should FDA continue to use the AOAC INTERNATIONAL methods to determine dietary fiber? If not, what other or additional methods should be used?**

Yes, current AOAC International Official Methods of Analysis of validated precision and accuracy through interlaboratory validation world-wide are commensurate with the dietary fiber definition of Trowell et al, the basis for dietary fiber research for over 30 years. See “Historical Perspective as a Guide for Identifying and Developing Applicable Methods for Dietary Fiber” (JAOAC International (2005), Volume 88, No 5, pp 1349-1366).

Current methodology should continue to be used for measurement of dietary fiber until a comprehensive dietary fiber method is developed and validated by interlaboratory evaluation.

**Should the IOM dietary fiber and/or functional fiber definitions replace the current FDA definition for dietary fiber? Explain why or why not.**

We recommend that FDA adopt the definition released by the 27th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)(2005), recorded in ALINORM 06/29/26:

”Dietary fibre means carbohydrate polymers with a degree of polymerization (DP) not lower than 3 which are neither digested nor absorbed in the small intestine. A degree of polymerization not lower than 3 is intended to exclude mono- and disaccharides. It is not intended to reflect the average DP of the 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 raw materials by physical, enzymatic or chemical means;
- Synthetic carbohydrate polymers.”

Current analytical methods do not permit separate analysis *and traceability* of intrinsic dietary fiber and functional fiber as defined by IOM. Some consumers may perceive functional fiber as more beneficial due to confusion with functional foods. Functional fiber as defined by IOM may lead to consumer confusion that natural or intrinsic fiber is therefore not beneficial.

**Do you recommend another name for functional fiber? If so, what do you recommend and why?**

All fiber is ‘functional.’ It is artificial and scientifically unwarranted to make this separation from ‘intrinsic’ in an effort to increase consumption of fruits, vegetables, and whole grain cereals.

A significant issue here is the lack of the ability to analytically differentiate between a compound that is an intrinsic fiber and the IOM defined “functional fiber”. An example is beta-glucan which is intrinsic to a product (such as oats) and has also been added (supplemented) with the same compound (then defined as a functional fiber). There is no analytical method to distinguish between these in a food product.

**Until FDA identifies functional fibers and analytical methods are established for distinguishing functional fiber from dietary fiber, should total fiber be used on the label to represent dietary fiber? Explain why or why not.**

There are AOAC methods for measuring all components of 'total fiber' as defined by IOM. However, it will not be possible to develop analytical methods to distinguish dietary from functional fiber.

## **12. Soluble and Insoluble Fiber**

**a) Should soluble and insoluble fiber continue to be voluntary or should they be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.**

We agree that soluble and insoluble dietary fiber should continue to be voluntary labeling categories. We disagree with the FAO recommendation to phase out these designations. From the wealth of successful scientific research that has led to health claims for soluble fiber, it seems evident that their relevance is well established.

**b) Should the terms soluble fiber and insoluble fiber be changed to viscous and nonviscous fiber, as suggested by the IOM? Explain why or why not.**

The use of the terms ‘viscous’ and ‘nonviscous’ would essentially have the same problems that many experts perceive with “soluble” and “insoluble”, with the additional refinement of having to set some limits on what is viscous versus nonviscous. Furthermore, there are, as yet, no validated methods for the measurement of viscosity in such food samples.

## **13. Sugar Alcohols**

**a) Should sugar alcohols continue to be voluntary or should they be made mandatory on the food label? Explain why you have chosen a particular approach and why it is preferable to the other approach.**

We would prefer that it remain voluntary. There is limited room on the food labels, and no compelling reason to make it mandatory. Also sugar alcohols appear in the ingredient list.

**b) How should the energy contribution of sugar alcohols be represented on the label since energy values vary (e.g., from 0.2 calories/g for erythritol to 3.0 calories/g for hydrogenated starch hydrolysates)?**

The energy contributions of sugar alcohols do not need to be highlighted on the label. In the regulations, along with the other methods for determining calories, the regulations should include a table of caloric values based on the best available science at the time the table is generated. Total calories can then be determined by applicable calculations.

**c) FDA has not defined how it would determine available energy from sugar alcohols. What analytical methods could be used to determine the energy contribution of sugar alcohols ?**

No comment.

#### **E. Process Questions**

**The following question seeks information on the process issues related to the Nutrition and Supplement Facts labels. If FDA includes functional fiber in the Nutrition Facts labels, should FDA develop criteria for identifying fibers that meet the definition of functional fiber (i.e. demonstrates a physiological benefit)? If so, what should those criteria be?**

Since dietary fiber and functional fiber are analytically and physiologically indistinguishable, functional fiber should not be part of the Nutrition Facts labels. New sources of dietary fiber should demonstrate, in human intervention trials, at least one statistically significant physiological benefit as outlined in CCFNSDU's ALINORM 06/29/26.

AACC International members on our Dietary Fiber Definition Task Force are available to meet with FDA to further discuss or clarify AACC International's position on these matters. An appointment may be set up by contacting Susan Kohn at AACC International.

Best Regards,



Bernard Bruinsma  
President, AACC International