

## AACC Letter to FDA

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Dr., Rm 1-23  
Rockville, MD 20857

The American Association of Cereal Chemists (AACC) submits the following comments in response to the proposed rule permitting health claims relating the consumption of certain oat products to a reduced risk of coronary heart disease (CHD) as published by the Food and Drug Administration (FDA) in the Federal Register on January 4, 1996.

AACC is an international scientific society founded in Kansas City, MO, in 1915 but headquartered since 1924 in St. Paul, MN. Since its founding it has become and remains the premier association concerning directly with the science and technology of the postharvest handling, storage, processing, analysis, and uses of the cereal grains, including the various forms in which they are consumed directly or used as ingredients in other foods. We are also concerned almost as directly with the other ingredients of cereal-based foods that influence the flavor, texture, nutrition, shelf life, and other key aspects of those foods. AACC has 19 technical committees on the analysis of cereal foods and ingredients, including, among others, committees on oat products and on dietary fiber. We publish CEREAL CHEMISTRY and CEREAL FOODS WORLD, respectively, the preeminent research and news feature journals in their field, and are also a major publisher of books dealing with cereal grain science and technology, including the only available comprehensive books on the manufacture of breakfast cereals, now in its third printing and used and referred to wherever breakfast cereals are made.

AACC numbers at this time over 4,000 individual members worldwide, three-quarters of whom are in the United States. Although American in name, AACC is the major international society for cereal science and technology, there being few comparable organizations in other countries. While some of our individual members are private consultants, most are employed in a professional, scientific, or technical managerial capacity in academia, government, or industry in some area of food science, technology, or engineering that relates to food or nutrition.

AACC is thus eminently qualified to comment on the FDA proposal in question. We endorse the concept of allowing consumer-friendly health claims on oatmeal, oat bran, and qualifying products containing them as major ingredients. We have read carefully FDA's analysis of the petition and the supporting literature and in general agree with the reasoning that led to the proposed specific addition to Section 101.28 to 21 CFR part 101, and with the particular constraints proposed to govern the language and placement of the health claims to be allowed. However, in the proposed Section 101.81, we note that oatmeal and oat bran are defined (other than by name) only by an apparent minimum content of soluble fiber as beta-glucan, used as a marker. As a result the wording of 101.81 (c)(2)(iii)(A) can be interpreted to allow a claim for products that are represented as pure oatmeal or oat bran but contain as little as 2.5% beta-glucan. This fails to adequately assure that such products would not be used as ingredients in other foods based solely on the final beta-glucan content of those foods, thus altering the health claim from one for a food (i.e., oatmeal or oat bran) to one for a nutrient (i.e., beta-glucan).

This interpretation is possible because the "reference amount customarily consumed" of both oatmeal and oat bran is clearly 40 grams, the serving size stated on the labels of these products as presently marketed. Thus the beta-glucan requirement of 1 gram would represent in both cases a content of only 2.5%, absent any other definition. This is half the typical beta-glucan content of oat bran and only one-third the typical beta-glucan content of oatmeal, thus allowing dilution with other non-beta-glucan-containing material.

Such an interpretation would be contrary to the entire thrust of the careful reasoning behind the proposed Section 101.81 (with which we agree, as already pointed out). Our concern is that what will remain to be read and used by the industry will only be Section 101.81 and not the literature analysis and reasoning that led up to it, as published in the Federal Register January 4.

The position could be taken that "oatmeal" requires no definition in view of its having been on the market for well over 100 years as a product known to be rolled from whole-grain groats (hulled oat kernels). However, the same cannot be said for oat bran, which as been

separated from whole-grain groats as a commercial product relatively recently and has not been legally defined. A clean separation from the remainder of the groat is not even possible because of the particular morphology of the oat kernel (as contrasted, for example, with that of wheat). A range of "oat brans" is thus possible from the same groats, depending on the amount and kind of extraction employed. We understand that one such product, with an extraction rate of about 40% (i.e., 40 lb of oat bran from 100 lb of groats) made by The Quaker Oats Company was the basis for the cholesterol studies that triggered the oat bran craze in the late 1980s. However, that craze also resulted in the marketing of oat brans by others that were little more than ground whole groats, or even in some suspected cases with the addition of other fiber sources such as oat hulls or other food residues.

At the request of major oat millers, AACC undertook to develop a definition of oat bran that could serve as a voluntary industry standard. A series of meetings of our technical committee on oat products during 1989 culminated in a recommended definition that was adopted at our 1989 annual meeting and published in *CEREAL FOODS WORLD* 30:1033, 1989. It has stood the test of time in terms of acceptance in the food industry by major producers and users of oat bran. A recent telephone survey confirms this view. The definition was also endorsed by the American Oat Association. Among other requirements, the beta-glucan content was set at a minimum of 5.5% (dry-weight basis). However, it is important to note that the definition was intended only to distinguish oat bran from other oat products, and not to describe a typical oat bran product. Thus the 5.5% beta-glucan represented the lower boundary or minimum of the component, with typical products expected to be significantly higher. At the same time the yield of oat bran from groats in the definition was set at a minimum of 50% despite the 40% believed to be achievable. This was to represent an upper boundary, with typical products expected to be produced at lower extraction rates. At the time, some marketers were known to be using a 60% yield, with some suspected of going as high as 100% (i.e., representing ground oatmeal or oat flour as oat bran).

Also, in the definition the starting material is "clean oat groats or rolled oats," meaning oats after normal complete removal of foreign material (including broken or misshapen oats, other grains, weed seeds and nongrain material

as for traditional oat milling) and after dehulling and complete separation and removal of hulls from the remaining oat groats. The definition was and is as follows.

Oat Bran is the food which is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by sieving bolting, and/or other suitable means into fractions such that the oat bran fraction is not more than 50% of the original starting material and has a total beta-glucan content of at least 5.5% (dry-weight basis) and a total dietary fiber content of at least 16.0% (dry-weight basis), and such that at least one-third of the total dietary fiber is soluble fiber."

The absence of hulls is doubly important because there are products on the market identified as "oat fiber" that are actually made from hulls, which could be mistaken for oat bran by an unsophisticated baker or other processor and used to justify a health claim that would be misleading to consumers. Such products are high in total dietary fiber (primarily insoluble) and have useful and legitimate purposes as food ingredients, but they are not oat bran nor do they share in its metabolic properties.

To avoid health claims being made under 101.81 for oatmeal having any different composition from whole-grain groats, we recommend consideration of the following definition of oatmeal:

"Oatmeal is any cut, flaked, rolled or finely ground product having its sole starting material clean oat groats after 100% removal of the hulls that were part of the original grain, including rolled oats in any flake size or thickness, oat flour, or intermediate granular products made by dry milling of the groats such that there is no significant loss of oat bran or of beta-glucan during such cutting, flaking or other means of particle size reduction."

By this definition, oatmeal as referred to in 101.81 clearly means any granular products made only from, and having the same composition as, clean oat groats after complete removal of hulls. It does not, however, include oat flour that is produced in connection with the manufacture of oat bran. Such flour is not a whole grain product and its beta-glucan content is necessarily substantially reduced from that originally present in the groats or in rolled oats or other whole grain oat products.

Accordingly, we propose that Section 101.81(c)(2)(iii)(A) be amended by 1) inserting the AACC definition of oat bran and the above definition of oatmeal after the first sentence, 2)

the addition of a reference to AOAC method No. 991.43 for determination of total and soluble dietary fiber, 3) reference to the current (16<sup>th</sup>) edition of AOAC Methods rather than the previous (15<sup>th</sup>) edition (since AOAC method numbers are now permanent), and 4) use of the correct current name of the Association as “AOAC International.”

In addition we propose that AOAC method No. 995.16, which acquired official first action approval subsequent to receipt by FDA of the Quaker Oats petition, be considered an acceptable alternative to 922.28 for beta-glucan, and that counterpart AACC methods for beta-glucan and dietary fiber also be referenced. These methods are 32-22 and 32-23 for beta-glucan and 32-07 for total and soluble dietary fiber, as published in *Approved Methods of the American Association of Cereal Chemists*, 9<sup>th</sup> edition, 1995, available from the Association, 3340 Pilot Knob Road, St. Paul, MN 55121-2097.

Adoption of the above amendments will remove any doubt that in order to justify the health claim, all of a food labeled as oat bran must comply with the definition, as well as the 13 g of oat bran required as a minimum in a reference amount of any other product.

It will also make clear that oatmeal as referred to in 101.81 means the food product of any particle size made from clean oat groats after complete removal of hulls, and that this does not include oat flour that is produced in connection with the manufacture of oat bran. Such flour is not a whole grain product and its oat bran and beta-glucan content is necessarily substantially reduced from that originally present in the groats or in oatmeal, rolled oats, or other whole grain oat products. As a partial alternative, oat bran and oatmeal could be defined elsewhere in 21 CFR by the wording we have recommended and then referenced in (c)(2)(iii)(A) and other parts of Section 101.81 instead of being included directly therein.

In summary, AACC supports the FDA proposal to authorize health claims describing the relationship between oat product consumption and the reduction of CHD risk, while recommending its clarification by the inclusion of our established and widely accepted definition of oat bran and of the definition we have proposed of oatmeal. We encourage FDA to complete the necessary rulemaking procedures in a timely fashion so that consumers may begin to benefit from this information, and offer any

assistance or counsel of which we are capable that might expedite this.

Respectfully submitted,

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