

Reference #5

**Memorandum**

Date: July 1, 2002

From: Office of Nutrition Products, Labeling, and Dietary Supplements
Division of Nutrition Science and Policy, HFS-830

Subject: Memorandum to the Record Concerning Oatrim Beta-Glucan Health Claim
Petition

To: Administrative Record for Quaker-Rhodia Petition (Docket No. 01Q-0313)

Via: Office of Food Additive Safety, HFS-200 *George J. Paul, July 3, 2002*

Background

The Agency has received a petition from the Quaker Oats Company and Rhodia Inc. to amend 21 CFR 101.81 (Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD)) authorizing a health claim for the relationship between consumption of beta-glucan soluble fiber from whole oat sources and a reduced risk of coronary heart disease (CHD) by adding, as an additional eligible source of whole oat beta-glucan soluble fiber, the soluble fraction of hydrolyzed oat bran or whole oat flour. We concluded previously that there was significant scientific agreement for the relationship between the consumption of beta-glucan soluble fiber from certain whole oat sources and the risk of CHD by lowering blood cholesterol levels. We have now concluded, based on the totality of the publicly available scientific evidence that, in addition to rolled oats, oat bran and whole oat flour, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan content up to 10 percent (oatrim) is an appropriate source of beta-glucan soluble fiber for the health claim.

GRAS Self-Determination for Oatrim

The petitioners assert that the basis for safe and lawful use of oatrim in food as a food ingredient, at levels necessary to justify the health claim is that such food use of oatrim is GRAS (generally recognized as safe) by GRAS self-determination. In addition, the petitioners have declared that oatrim derived from either oat bran or whole oat flour, and subjected to hydrolysis by treatment with safe and suitable food grade enzymes and/or GRAS listed food grade acids or bases, is GRAS through scientific procedures for use as a fat substitute in a variety of foods.

The petitioners also declared that over the last several years, Quaker Oats and Rhodia have sold oatrim with a concentration of 4-6 percent beta-glucan soluble fiber, which has been incorporated by food manufacturers into a number of foods, including low-fat pancakes, muffins, biscuits, a low-fat, high-fiber nutrition bar, and fat-free frankfurters. The petitioners submitted documentation of a 1992 GRAS self-determination for oatrim by The Quaker Oat Company, a 1991 GRAS self-determination for oatrim by ConAgra as well as an individual

opinion regarding the GRAS status of purified forms of beta-glucan soluble fiber from oats as evidence that oatrim meets the safe and lawful requirement.

The 1992 Quaker Oats Company documentation of GRAS self-determination characterized oatrim as the water soluble, partially enzymatically hydrolyzed starch fraction of whole oat flour. Oatrim was described as representing about 60 percent of the whole oat flour starting material, and containing 4-6 percent beta-glucan soluble fiber and 6.9 percent total dietary fiber.

The Quaker Oats Company gave examples of how they would use oatrim. The examples cited were the use of oatrim as a fat replacer in fresh ground and processed meats and poultry products, salad dressings, baked goods, baking mixes, processed cheese, yogurt, ice cream and frozen desserts, snack foods, vegetable oil spreads, icings and frostings, frozen entrees, and confections.

The 1991 ConAgra Specialty Grain Products Company documentation of GRAS self-determination characterized the processing of oatrim as “oat flour or oat bran [that] is pre-gelatinized and enzyme thinned, by alpha-amylase, to facilitate separation and recovery of the soluble fraction,” and noted that oatrim functions as a humectant and texture modifier in a wide variety of foods.

The petitioners’ basis for the ingredient being safe and lawful was the similarity of oatrim to oat starch and maltodextrin, two substances that are generally recognized as safe for food use.

Based on the information submitted in the petition, we have no questions at this time regarding the petitioners’ conclusion that oatrim is GRAS for use in food.

Matrix Effects

We have considered the effects of the food matrix on the delivery of beta-glucan and find no reason to expect that the food matrix will have an appreciable effect on oatrim functional utility or on beta-glucan availability. In the scientific studies on the effects of beta-glucan/soluble fiber on blood lipids, oat fiber extracts were added to the diet in many foods, including fruit juice, applesauce, muffins, cookies, cake, brownies, waffles, gelatin, yogurt, spaghetti sauce, and meat loaf. These foods cover a wide range of viscosities, densities, and textures, and appeared to adequately deliver soluble fiber to the gut. The foods containing the added fiber were functional, and neither the petitioners nor the authors of the scientific studies noted any matrix effects on beta-glucan availability. Therefore, it is our opinion that there are no significant food matrix effects that would warrant restricting the health claim for oatrim to any particular food category or type.



Michael A. Adams, Ph.D.

HFS-800 (r/f); HFS-830; HFS-006 (Yetley); HFS-200 (Tarantino, Pauli); HFS-024 (Dimasin); GCF-1 (Overholser, Tave)

HFS-830:MAAdams:301-436-1450;oatrim.doc:6-27-02