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Oat Products and Blood Cholesterol Lowering

Summary of Assessment of a Health Claim about Oat Products and Blood Cholesterol Lowering

Bureau of Nutritional Sciences

Food Directorate, Health Products and Food Branch

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In January 2007, Health Canada's Food Directorate received a submission from industry requesting the approval for the use of a disease risk reduction claim on oat products. This claim would stipulate a linkage between the consumption of beta-glucan oat fibre (from eligible sources) to a reduced risk of heart disease by lowering blood cholesterol levels. The information below is a summary of the review that was conducted based on Health Canada's [*Interim Guidance Document, Preparing a Submission for Foods with Health Claims*](#) (IGD).

Health Canada has recently reconsidered the classification of food products with disease risk reduction claims or therapeutic claims in light of clarified principles for the classification of foods at the Food-Natural Health Product interface. The current position of Health Canada is that when food products are marketed for a disease risk reduction or therapeutic benefit which comes as a result of the food's normal use as part of the diet, these products may be classified and regulated as foods. In other words, the use of a disease risk reduction claim or a therapeutic claim would not be sufficient in itself to classify the product as a natural health product.

1. Eligible sources of beta-glucan oat fibre

For the purposes of this decision document, Health Canada has determined that the eligible sources of beta-glucan oat fibre are: oat bran, rolled oats (also known as oatmeal), and whole oat flour, either as food themselves (oat bran and rolled oats) or as ingredients (oat bran, rolled oats and whole oat flour) in formulated foods. The specifications for the eligible sources of oat beta-glucan are as follows:

- 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)) beta-glucan soluble fibre and at least 16 percent (dwb) total dietary fibre, and such that at least one-third of the total dietary fibre is soluble fibre.
- Rolled oats: rolled oats, also known as oatmeal, are produced from 100 percent dehulled, clean oat groats, by steaming, cutting, rolling, and flaking, and provide at least 4 percent (dwb) of beta-glucan soluble fibre, and at least 10 percent (dwb) total dietary fibre.
- 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 beta-glucan soluble fibre and at least 10 percent (dwb) total dietary fibre.

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2. Scientific evidence supporting the claim

The evidence provided by the petitioner includes the 1995 health claim petition to the US Food and Drug Administration (FDA) on oats and coronary heart disease. This claim was approved by the US FDA in its final rule in January 1997. In addition, the petitioner provided a systematic review prepared by the Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA) of the University of Toronto that spanned the literature published from 1995 to 2006. In the PFSNRA review, 36 human studies were identified which investigated oat beta-glucan fibre and its cholesterol lowering properties. As was done with other health claims approved by the US FDA under the Nutrition Labelling and Education Act, Health Canada decided to accept an update of the literature from the time of the 1997 US approval of the claim, provided that a systematic approach to reviewing the relationship was provided as part of the submission.

LDL-cholesterol and total cholesterol were the endpoints measured in the reviewed studies. These are recognized risk factors for heart disease and are considered relevant for supporting a claim concerning a reduction in the risk of heart disease.

Based on information provided in the petition to the US FDA (1995), regression analyses of a dose-response study suggested that about 3 grams of beta-glucan oat fibre would result in total and LDL-cholesterol reductions of about 5% and 8%, respectively. Overall, in the PFSNRA literature review (2006), an intake of 3 grams of beta-glucan resulted in a physiologically meaningful LDL-cholesterol reduction that was nevertheless quite variable (ranging from 0.15% to 4% LDL-cholesterol reduction on a per gram of beta-glucan basis). No dose-response was observed. Most of the studies were carried out with moderately to highly hypercholesterolemic subjects. The PFSNRA review did not provide any evidence contrary to the previous findings upon which FDA based its final health claim rule on beta-glucan oat fibre and reduced risk of coronary heart disease (by lowering blood cholesterol).

Health Canada has concluded that scientific evidence exists in support of the claim linking the consumption of beta-glucan oat fibre to a reduction of blood cholesterol. The claim is relevant and generally applicable to the Canadian population given that a high proportion of the population (44 to 69%) is hyperlipidemic and that adults with normal or mildly elevated blood cholesterol concentrations could also benefit from increased oat intake.

3. Health Canada's Conclusions

Based on the evidence available, as well as consumer research, preliminary feedback from industry, and consideration of decisions made in other jurisdictions, it is Health Canada's opinion that the health claim statements set out below are substantiated in relation to oat products as food themselves and as ingredients in formulated foods when specific conditions for the food carrying the claim are met.

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Health claim

The following statements may be made in the labelling and advertising¹ of food products that meet the qualifying criteria. These statements are intended for the general population who want to maintain or lower their blood cholesterol.

Primary statement:

“[serving size from Nutrition Facts table in metric and common household measures]² of (Brand name) [name of food] [with name of eligible fibre source]* supplies/provides [X % of the daily amount] of the fibres shown to help reduce/lower cholesterol.”

If the oat fibre source is specified in the brand name (e.g. Quaker Oatmeal), it does not need to be repeated subsequently in the claim. Names of eligible sources of oat fibre are oat bran, rolled oats/oatmeal, and whole oat flour. The term “oats” may also be used as a synonym or generic name for these sources.

For example:

If the eligible fibre source is a food itself: **“1 cup (X g) of Quaker Oatmeal supplies X % of the daily amount of the fibres shown to help reduce cholesterol”**

If the eligible fibre source is an ingredient: **“1 muffin (X g) with oat bran provides X % of the daily amount of the fibres shown to help lower cholesterol”**

The following additional statements, which can be placed, adjacent to the primary statement, in letters up to twice the size and prominence as those of the primary statement:

- 1) Oat fibre helps reduce/lower cholesterol**
- 2) High cholesterol is a risk factor for heart disease**
- 3) Oat fibre helps reduce/lower cholesterol, (which is) a risk factor for heart disease.**

¹ The information in this document complements the guidance on using health claims on food labels and in advertising in the *Guide to Food Labelling and Advertising* available on the Canadian Food Inspection website (<http://www.inspection.gc.ca/english/fssa/labeti/guide/tab8e.shtml>). It is the responsibility of all manufacturers and importers to ensure that their products comply with all relevant Canadian legislation.

² [] = mandatory; () = optional; []* = mandatory when the eligible source of oat fibre is an ingredient; / = or

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The “**daily amount**” referred to in the primary statement is 3 grams beta-glucan oat fibre. This amount is based on the evidence available concerning the lowest observed efficacious daily dose for lowering cholesterol. In this statement, the percentage of the daily amount of beta-glucan oat fibre provided in one serving should be expressed to the nearest multiple of 5%.

Conditions for foods to carry the claim

Oat products, whether consumed as food or as ingredients, must meet the specifications for eligible sources of oat beta-glucan described in section 1 of this document. Where the food carrying the claim is a formulated food to which oat products are added as ingredients, the formulated food must not be subject to non-typical or novel treatments. Formulated food products containing the eligible oat products, but processed by non-typical or novel treatments, may require individual authorization in order to carry the claim.

In addition, the food must meet the following qualifying criteria:

1. Contain at least 0.75 g beta-glucan oat fibre³ per reference amount and per serving of stated size from the eligible sources;
2. Contain at least 10% of the weighted recommended nutrient intake of a vitamin or a mineral nutrient per reference amount and per serving of stated size;
3. Contain 100 mg or less of cholesterol per 100 g of food;
4. Contain 0.5% or less of alcohol;
5. Contain 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference is 30 g or less; and
6. Meet the definition of “free of saturated fatty acids” or “low in saturated fatty acids”.

In previous consultation with stakeholders, there was strong support from all sectors that foods carrying a health claim should meet certain nutritional criteria. For example, in the case of health claims about blood cholesterol lowering, it is expected that limits are set on those nutrients associated with risks of high blood cholesterol and heart disease. Conditions 2 to 6 above have already been outlined in section B.01.603 of the *Food and Drug Regulations* for foods carrying a heart disease risk reduction claim.

Health Canada will propose regulatory amendments to confirm that foods with the above stated health claims are not governed by the provisions of the *Food and Drugs Act* with respect to drugs; nor do they contravene subsections 3(1) and (2) of the Act.

³ Acceptable methods for measuring beta-glucan oat fibre are methods 992.28 and 995.16 of the Official Methods of Analysis of the Association of Official Analytical Chemists International.