

#### SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to beta-glucans and maintenance of normal blood cholesterol concentrations (ID 754, 755, 757, 801, 1465, 2934) and maintenance or achievement of a normal body weight (ID 820, 823) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### **SUMMARY**

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to beta-glucans and the following claimed effects: maintenance of normal blood cholesterol concentrations and maintenance or achievement of a normal body weight. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims are beta-glucans, which are soluble cereal fibres. Beta-glucans are non-starch polysaccharides composed of glucose molecules in long linear glucose polymers with mixed  $\beta$ -(1 $\rightarrow$ 4) and  $\beta$ -(1 $\rightarrow$ 3) links with an approximate distribution of 70% to 30%. This opinion applies to beta-glucans naturally present in foods and those forms added to foods. The Panel considers that beta-glucans are sufficiently characterised.

## Maintenance of normal blood cholesterol concentrations

The claimed effect is "blood lipids". In the context of the proposed wordings, the Panel notes that the claimed effect relates to the maintenance of normal blood cholesterol concentrations. The Panel considers that maintenance of normal blood cholesterol concentrations is beneficial to human health.

 $<sup>1\ \</sup> On\ request\ from\ the\ European\ Commission,\ Question\ No\ EFSA-Q-2008-1541,\ EFSA-Q-2008-1542,\ EFSA-Q-2008-1544,\ EFSA-Q-2008-1588,\ EFSA-Q-2008-1607,\ EFSA-Q-2008-1610,\ EFSA-Q-2008-2202,\ EFSA-Q-2008-3666\ adopted\ on\ 02\ July\ 2009.$ 

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In weighing the evidence, the Panel took into account that, although some human intervention studies using high doses of beta-glucans (about 10g/d) in food matrices like juices or baked products have not observed a statistically significant reduction in LDL-cholesterol, most of the randomised controlled trials investigating the effects of non-processed or minimally processed oat or barley beta-glucans at doses of at least 3g/d have shown a statistically significant decrease in LDL-cholesterol in both normocholesterolaemic and hypercholesterolaemic subjects. The Panel also considers that beta-glucans from oat bran and barley bran have similar effects on serum LDL-cholesterol.

On the basis of the data available, the Panel concludes that a cause and effect relationship has been established between the consumption of beta-glucans and the reduction of blood cholesterol concentrations. The following wording reflects the scientific evidence: "Regular consumption of beta-glucans contributes to maintenance of normal blood cholesterol concentrations". In order to bear the claim, foods should provide at least 3 g/d of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of non-processed or minimally processed beta-glucans in one or more servings. The target population is adults with normal or mildly elevated blood cholesterol concentrations.

### Maintenance or achievement of a normal body weight

The claimed effect is "weight control". The Panel considers that maintenance or achievement of a normal body weight is beneficial to human health. None of the references presented addressed the effects of beta-glucan consumption on body weight.

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of beta-glucans and the maintenance or achievement of a normal body weight.

#### **KEY WORDS**

Beta-glucans, blood cholesterol, body weight, health claims.



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#### **EFSA DISCLAIMER**

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### INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>3</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is tabulated in Appendix C.

#### ASSESSMENT

#### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims are beta-glucans, which are soluble cereal fibres. Beta-glucans are non-starch polysaccharides composed of glucose molecules in long linear glucose polymers with mixed  $\beta$ -(1 $\rightarrow$ 4) and  $\beta$ -(1 $\rightarrow$ 3) links with an approximate distribution of 70% to 30%. The molecular weight varies between 50 and 2000 kDa. Beta-glucans occur naturally in the bran of cereal grasses such as barley ( $\sim$ 7 %), oats ( $\sim$ 5 %), rye and wheat (1-2 %) and are measurable in foods by established methods. This opinion applies to beta-glucans naturally present in foods and those forms added to foods.

The mixed linkages are important for the physical properties, such as solubility and viscosity. The viscosity is a function of the concentration of dissolved beta-glucans and of its molecular weight (Wood et al, 2000) and further depends on differences in raw materials, processing and methods of determination.

The Panel considers that the food constituent, beta-glucans, that is the subject of the health claim is sufficiently characterised.

#### 2. Relevance of the claimed effect to human health

# 2.1. Maintenance of normal blood cholesterol concentrations (ID 754, 755, 757, 801, 1465, 2934)

The claimed effect is "blood lipids". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the maintenance of normal blood cholesterol concentrations.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160mg/dL, may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood cholesterol concentrations is beneficial to human health.

<sup>&</sup>lt;sup>3</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.



## 2.2. Maintenance or achievement of a normal body weight (ID 820, 823)

The claimed effect is "weight control". The Panel assumes that the target population is the general population.

Weight control can be interpreted as the contribution to the maintenance and/or achievement of a normal body weight. In this context even a moderate weight loss in overweight subjects without achieving a normal body weight is considered beneficial to health.

The Panel considers that maintenance or achievement of a normal body weight is beneficial to human health.

## 3. Scientific substantiation of the claimed effect

## 3.1. Maintenance of normal blood cholesterol concentrations (ID 754, 755, 757, 801, 1465, 2934)

The effects of oat products on serum lipids have been studied in numerous independent clinical trials in normal or mildly hypercholesterolaemic adults. Two meta-analyses of randomised controlled clinical trials (Ripsin et al., 1992; Brown et al., 1999) included 20 and 25 studies, respectively. They concluded that consumption of oat products reduced serum LDL-cholesterol concentrations, but the effect was relatively small and variable within the range of realistic intakes. The analyses suggested a dose-dependent effect on LDL-cholesterol lowering. Ripsin et al. (1992) demonstrated a reduction of 0.13 to 0.16 mmol/L after intake of, on average, 3.2 g/d oat soluble fibre, which is considered by the Panel to be mainly beta-glucans. Brown et al. (1999) found a statistically significant reduction of serum LDL-cholesterol in 16 out of the 25 studies considered and estimated a change in serum total and LDL cholesterol of -0.037 mmol/L and -0.032 mmol/L per g of soluble fibre, respectively. More recent studies have shown similar statistically significant effects with oat beta-glucan at doses of 3-6 g/d (Karmally et al., 2005; Queenan et al., 2007). No effects on HDL cholesterol have been observed.

Studies on barley beta-glucan at doses 3-12 g/d have also shown significant lowering of serum LDL-cholesterol concentrations (Newman et al., 1989; McIntosh et al., 1991; Behall et al., 2004a and 2004b; Keenan et al., 2007; Shimizu et al., 2008).

In some studies, even relatively high doses (10 g/d) of beta-glucan from oats (Törrönen et al., 1992) or barley (Keogh et al., 2003) have failed to show significant effects on serum LDL-cholesterol. Kerckhoffs et al. (2003) found that oat beta-glucan at 5 g/d reduced serum LDL-cholesterol concentrations when mixed into juice but the effect was weaker and statistically non-significant when the same amount of fibre was baked into bread. Biörklund et al. (2005) found no difference between the effects of beta-glucan from oats and from barley (10 g/d mixed into juice) on serum LDL-cholesterol concentrations, which were small and statistically non-significant.

The cholesterol-lowering effect of beta-glucan depends on the increased viscosity that reduces the reabsorption of bile acids, increases the synthesis of bile acids from cholesterol, and reduces circulating (LDL) cholesterol concentrations. Viscosity in the small intestine is determined by the concentration, molecular weight and solubility of beta-glucan. Beta-glucan may be degraded during purification and manufacturing of foods by factors such as shear, heat and the action of enzymes, and its cholesterol-lowering effect may be weakened or even disappear. Differences in viscosity are thought to explain, at least in part, the large variation between the LDL-cholesterol lowering effects found in individual studies.

In weighing the evidence, the Panel took into account that, although some human intervention studies using high doses of beta-glucans (about 10g/d) in food matrices like juices or baked products



have not observed a statistically significant reduction in LDL-cholesterol concentrations, most of the randomised controlled trials investigating the effects of non-processed or minimally processed oat or barley beta-glucans at doses of at least 3g/d have shown a statistically significant decrease in LDL-cholesterol in both normocholesterolaemic and hypercholesterolaemic subjects. The Panel also considers that beta-glucans from oat bran and barley bran have similar effects on serum LDL-cholesterol.

The Panel concludes that a cause and effect relationship has been established between the consumption of beta-glucans and the reduction of blood cholesterol concentrations.

## 3.2. Maintenance or achievement of a normal body weight (ID 820, 823)

A total of 77 references were cited for the substantiation of the claimed effect. Most references related to the association between the consumption of dietary fibre (either general or specific types of fibres other than beta-glucan) and different measures of satiety. Only a few studies on the consumption of oat or barley products and subsequent measures of satiety were presented (Berti et al, 2005; Granfeldt et al, 1994; Holt et al, 1995; Lilleberg et al, 1999). None of the references presented addressed the effects of beta-glucan consumption on body weight.

The Panels concludes that a cause and effect relationship has not been established between the consumption of beta-glucans and the maintenance or achievement of a normal body weight.

## 4. Panel's comments to the proposed wordings

# 4.1. Maintenance of normal blood cholesterol concentrations (ID 754, 755, 757, 801, 1465, 2934)

The Panel considers that the following wording reflects the scientific evidence: "Regular consumption of beta-glucans contributes to maintenance of normal blood cholesterol concentrations"

### 5. Conditions and possible restrictions of use

# 5.1. Maintenance of normal blood cholesterol concentrations (ID 754, 755, 757, 801, 1465, 2934)

In order to bear the claim, foods should provide at least 3 g/d of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of non-processed or minimally processed beta-glucans in one or more servings. The target population is adults with normal or mildly elevated blood cholesterol concentrations.

## **CONCLUSIONS**

On the basis of the data presented, the Panel concludes that:

• The food constituent, beta-glucans, which is the subject of the health claims is sufficiently characterised.



## Maintenance of normal blood cholesterol concentrations (ID 754, 755, 757, 801, 1465, 2934)

- The claimed effect is "blood lipids". The target population is assumed to be the general population. Maintenance of normal blood cholesterol concentrations is beneficial to human health.
- A cause and effect relationship has been established between the consumption of beta-glucans and the reduction of blood cholesterol concentrations.
- The following wording reflects the scientific evidence: "Regular consumption of beta-glucans contributes to maintenance of normal blood cholesterol concentrations".
- In order to bear the claim, foods should provide at least 3 g/d of beta-glucans from oats, oat bran, barley, barley bran, or from mixtures of non-processed or minimally processed beta-glucans in one or more servings. The target population is adults with normal or midly elevated blood cholesterol concentrations.

## Maintenance or achievement of a normal body weight (ID 820, 823)

- The claimed effect is "weight control". The target population is assumed to be the general population. Maintenance or achievement of a normal body weight is beneficial to human health.
- A cause and effect relationship has not been established between the consumption of beta-glucans and the maintenance or achievement of a normal body weight.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: No EFSA-Q-2008-1541, EFSA-Q-2008-1542, EFSA-Q-2008-1544, EFSA-Q-2008-1588, EFSA-Q-2008-1607, EFSA-Q-2008-1610, EFSA-Q-2008-2202, EFSA-Q-2008-3666). The scientific substantiation is based on the information provided by the Members States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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#### **APPENDICES**

#### APPENDIX A

### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>4</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

## ISSUES THAT NEED TO BE CONSIDERED

## IMPORTANCE AND PERTINENCE OF THE FOOD<sup>5</sup>

Foods are commonly involved in many different functions<sup>6</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

<sup>&</sup>lt;sup>4</sup> OJ L12, 18/01/2007

<sup>&</sup>lt;sup>5</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>&</sup>lt;sup>6</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).



#### SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, doseresponse, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

#### WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps



maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## TERMS OF REFERENCE

# HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- ➤ Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- > the claimed effect of the food in the identified function is beneficial.
- ➤ a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.



- ➤ where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- ➤ the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

> on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.



### APPENDIX B

#### **EFSA DISCAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.



#### APPENDIX C

Table 1. Main entry health claims related to beta-glucans, including conditions of use from similar claims, as proposed in the Consolidated List.

| ID  | Food or Food component | Health Relationship | Proposed wording  |
|-----|------------------------|---------------------|---|
| 754 | Oats/ Oat beta-glucan  | blood lipids        | oats contribute to healthy cholesterol level              |
|     |                        |                     | Oat beta-glucan contributes to healthy cholesterol levels |

### Conditions of use

- Minimum 3 g oat beta-glucan in the daily portion of the product.
- Oat cereal with 3g/100g of beta-glucan, 1.5g/serving (=50g) Very strong heat treatments may influence the physiological state of beta-glucan.
- Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated Whole oats,/rolled oats/whole oat flour (min 4% beta-glucan), oat bran (min 5.5% beta glucan) 3g beta glucan/day a portion or in an amount that is customarily consumed in a day should contain at least 0,75g of beta-glucan. The claim should be set in the context of a diet that is low saturated fat and a healthy lifestyle The claim relates to whole oats, oat bran, rolled oats and whole oat flour as long as oat bran provides at least 5.5%, rolled oats and whole oats flour at least 4% beta-glucan soluble fibre Products carrying the claim should contain at least 0.75 g oat beta-glucan soluble fibre per serving, or in an amount that is customarily consumed in a day that makes a reasonable contribution to a healthy diet. Products carrying the claim should state what constitutes a serving; the amount of oat beta-glucan soluble fibre provided in each serving, expressed as grams; and the proportion it contributes to a 3 gram suggested daily intake.
- Wholemeal oat flour with 4.5g/100g, of beta-glucan, 2g/dl (=45g) Baking process and freezing may weaken the physiological activity of beta-glucan.
- Tootja poolt esitatud andmete põhjal on beeta-glükaani päevane soovitatav kogus 3 g, märgistuselt peaks ilmnema, kui suure koguse sellest toode annab.

|     | Food or Food component     | Health Relationship | Proposed wording                                 |
|-----|----------------------------|---------------------|--|
| 755 | Barley/ barley beta-glucan | blood lipids        | barley contributes to healthy cholesterol level. |

#### Conditions of use

- Tootja poolt esitatud andmete põhjal on beeta-glükaani päevane soovitatav kogus 3 g, märgistuselt peaks ilmnema, kui suure koguse sellest toode annab.
- Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated 3g/day



|                   | Food or Food component  | Health Relationship | Proposed wording  |
|-------------------|---|---------------------|---|
| 757               | BarleyTrim™ Barley Bran   | blood lipids        | Barley beta glucan soluble fiber from BarleyTrim <sup>TM</sup> Barley Bran, as part of a diet low in saturated fat and a healthy lifestyle, can help maintain healthy blood cholesterol levels.   |
|                   |   |                     | BarleyTrim <sup>™</sup> Barley Bran helps maintain healthy blood cholesterol levels.  |
|                   | Conditions of use   |                     |   |
|                   | - 5 grams of BarleyTrim® Barley Bran per serving provides 0.75 grams of beta-glucan barl soluble fiber 20 grams of BarleyTrim™ Barley Bran per day provides 3 grams beta-gluca barly soluble fiber Barley Soluble Fiber = 15% Insoluble Dietary Fiber = 5% Total Dietar Fiber = 20%           |                     |   |
|                   | Food or Food component  | Health Relationship | Proposed wording  |
| 801               | Nutrim® Oat Bran  | blood lipids        | The inclusion of 3 grams oat beta glucan soluble fiber per day from Nutrim® Oat Bran, as part of a diet low in saturated fat and a healthy lifestyle, can help maintain healthy blood cholesterol levels.  Oat beta glucan soluble fiber from Nutrim® Oat Bran, as part of a diet low in saturated fat and a healthy lifestyle, can help maintain |
|                   |   |                     | healthy blood cholesterol levels.   |
| Conditions of use |   | 10 (010)            |   |
|                   | <ul> <li>7.5 grams of Nutrim® Oat Bran per serving provides 0.75 grams of beta-glucan oat soluble fiber 30 grams of Nutrim® Oat Bran per day provides 3 grams of beta-glucan oat soluble fiber Oat Beta Glucan Soluble Fiber = 10% Insoluble Fiber = 16% Total Dietary Fiber = 26%</li> </ul> |                     |   |
|                   | Food or Food component  | Health Relationship | Proposed wording  |
| 820               | Barley grain fibre  | Weight control      | Helps with weight control.  |
|                   |   |                     | For long-lasting sense of satiety.  |
|                   |   |                     | Frees energy slowly.  |
|                   | Conditions of use   |                     |   |
|                   | - Bakery products which contain beta-glucan of barley grain fibre ≥3g/daily serving.  Processing of the product does not influence presenting health claims concerning weight control, only the amount of beta-glucan is significant.   |                     |   |



|     | Food or Food component | Health Relationship | Proposed wording                   |
|-----|------------------------|---------------------|------------------------------------|
| 823 | Oat grain fibre        | Weight control      | Helps with weight control.         |
|     |                        |                     | For long-lasting sense of satiety. |
|     |                        |                     | Frees energy slowly.               |

#### Conditions of use

- Bakery products with ≥3g/100g of beta-glucan of oat grain fibre Processing of the product does not influence presenting health claims relating to weight control, only the amount of beta-glucan fibre is significant.

|   |      | Food or Food component | Health Relationship | Proposed wording   |
|---|------|------------------------|---------------------|--|
| 1 | 1465 | Beta-glucans           | blood lipids        | Beta-glucans help to<br>maintain healthy blood lipid<br>levels |

### Conditions of use

- Oral dosing of between 3 and 16 g have been studied. Beta-glucans normally derived from yeast, fungus or cereals (e.g. oats, barley).
- Minimum 3 g oat beta-glucan in the daily portion of the product.

|      | Food or Food component               | Health Relationship | Proposed wording   |
|------|--------------------------------------|---------------------|--|
| 2934 | CalorieControl Trim® Oat<br>Bran 20% | blood lipids        | The inclusion of 3 grams oat beta glucan soluble fiber per day from Calorie ControlTrim® Oat Bran, as part of a diet low in saturated fat and a healthy lifestyle, can help maintain healthy blood cholesterol levels. |
|      |                                      |                     | Oat beta glucan soluble fiber from Calorie ControlTrim® Oat Bran, as part of a diet low in saturated fat and a healthy lifestyle, can help maintain healthy blood cholesterol levels.                                  |
|      |                                      |                     | Calorie ControlTrim® Oat<br>Bran helps maintain healthy<br>blood cholesterol levels.   |

## **Conditions of use**

- 3.25 grams of Calorie ControlTrim® Oat Bran per serving provides 0.75 grams of beta-glucan oat soluble fiber. 15 grams of Calorie ControlTrim® per day provides 3 grams beta-glucan oat soluble fiber Oat Beta Glucan Soluble Fiber = 20% Insoluble Fiber = 6% Total Dietary Fiber = 26%.



## GLOSSARY AND ABBREVIATIONS

LDL Low density lipoprotein

HDL High density lipoprotein