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FIRST REVIEW REPORT

APPLICATION A464

DEFINITION OF ‘WHOLEGRAIN’

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EXECUTIVE SUMMARY

Food Standards Australia New Zealand (FSANZ) received an Application (A464) from BRI Australia Ltd on 6 December 2001 to amend the definition of the term ‘wholegrain’.

The current definition of wholegrain in Standard 2.1.1 – Cereals and Cereal Products of the *Australia New Zealand Food Standards Code* (the Code) is:

wholegrain means the unmilled products of a single cereal or mixture of cereals.

The revised variation to Standard 2.1.1 is:

wholegrain means the intact grain or the dehulled, ground, milled, cracked or flaked grain where the constituents – endosperm, germ and bran – are present in such proportions that represent the typical ratio of those fractions occurring in the whole cereal, and includes wholemeal.

The revised definition is consistent with the Dietary Guidelines for Australians and the Australian Guide to Healthy Eating.

This change to the definition has been requested by the cereal processing industry as the current definition is very restrictive in terms of cereal products that could qualify as wholegrain foods. The current definition of ‘wholegrain’ as intact whole grains impedes the promotion of wholegrain-based foods that is based on an encompassing term and simple concept. Very few cereal-based foods would qualify for wholegrain labelling under the current definition. For example, only limited commercial products such as brown rice and unpearled barley might qualify as unmilled cereal foods, whereas other products generally thought of as wholegrain such as wheat flakes or rolled oats would not.

The definition of ‘wholemeal’ in the cereals standard is not proposed to be changed and is not based on particle size. There will be no clear delineation between wholegrain and wholemeal foods if the proposed variation is approved. The market for wholemeal bread, muffins and other cereal-based foods is, however, well established and industry or consumer interests are not served by changing the established and familiar identity of such products from wholemeal to wholegrain.

There are many nutritional benefits of consumption of wholegrain foods over refined cereal products, and milled whole grains are nutritionally superior to intact whole grains. The positive association between the consumption of wholegrain foods and nutritional benefits and reduction of certain chronic disease risk is based upon diets containing wholegrain-based foods such as wholemeal bread, wheat flakes or rolled oats and not just intact whole grains such as brown rice. The scientific evidence strongly supports the suggestion that wholegrain-based foods, even with as little as 25% wholegrain and its milled products, protects against the development of type 2 diabetes and improves glycaemic control.

The current definition acts as a disincentive for industry to promote wholegrain-based foods because no simple, all encompassing term is permitted to describe the group of foods that confer a common range of health benefits.

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has requested a First Review of Application A464 on the grounds that the revised definition:

- does not protect public health and safety; and
- does not provide adequate information to enable informed choice.

Additional comments provided by the Ministerial Council are addressed in the table below.

FSANZ has reviewed the draft variation considering each of these comments.

In March 2005, the FSANZ Board approved the Final Assessment of Application A464, including the variation to Standard 2.1.1 and notified the Ministerial Council.

FSANZ DECISION

<p>This First Review re-affirms the FSANZ decision to approve the variation to Standard 2.1.1 of the Code as previously notified to the Ministerial Council.</p>

FSANZ has re-affirmed its decision on the basis that:

- It is appropriate that the definition of ‘wholegrain’ be amended to reflect processing techniques that retain all of the original grain components, including their milled products and allowing for dehulling.
- Inclusion of the proposed definition for ‘wholegrain’ in the Code is consistent with the growing awareness of the positive nutritional benefits that can be achieved through increased consumption of wholegrains and foods made from their milled products.
- Notwithstanding the inclusion of ‘wholemeal’ in the definition of ‘wholegrain’, the definition of ‘wholemeal’ has been retained. There is no obvious or logical delineation in processing techniques or uses in terms of particle size between the term ‘wholemeal’ and the revised definition of ‘wholegrain’. Wholegrain does not just refer to intact grain but also to the constituents of the grain.
- Consumers of wholemeal cereal products will be able to continue to choose products based on their preferences for particle size, taste and texture. There is a well established market for wholemeal products and this, together with the potential for enforcement action, acts as a disincentive to manufacturers to describe wholemeal products as wholegrain.
- The scientific evidence shows that increased consumption of wholegrain-based foods including wholemeal products confers nutritional benefits and reduces risk of several major chronic diseases.

FSANZ RESPONSES TO SPECIFIC POINTS RAISED IN MINISTERIAL COMMENTS

Ministerial Council Issue	Main Points in Lead Ministers' Comments	FSANZ Response
<p>1. Misleading consumers</p>	<p>The proposed definition of 'wholegrain' allows for ground or milled wholegrain to be called wholegrain and for wholemeal to be called wholegrain.</p> <p>A qualifying term such as 'ground wholegrain' must be used.</p>	<p>The revised definition of 'wholegrain' relates to the constituents and not to the intactness of the grain. The Code requires that the name or description of the food must be sufficient to indicate the food's true nature. This means that wholemeal should be used if more appropriate to the food.</p> <p>There is no clear delineation between milled grains and wholemeal. Wholemeal is not defined on the basis of particle size and is not restricted to wheat or bread. Prescribing terms such as 'ground wholegrain' will not provide a practical enforcement tool. Labels could use qualifying terms on a voluntary basis.</p> <p>Consumers choose wholemeal products, including bread, based upon appearance, taste and texture not just on particle size.</p>
<p>2. Public health benefits</p>	<p>Wholemeal should not be a subset of wholegrain.</p> <p>Wholegrain should only be used when the wholegrain particles are discernable/visible. Public health benefit is derived from this state.</p>	<p>Wholemeal is a subset of wholegrain since 'milled' is a process common to both definitions. There is no clear delineation between milling processes which would clearly and logically divide wholemeal from other milled grain products.</p> <p>There are significant public health benefits associated with increased consumption of wholegrain-based foods that are independent of particle size.</p> <p>Where health professionals provide advice on the inclusion or avoidance of discernable grain, the entire label (including ingredients labelling) provides sufficient information to enable appropriate choice.</p>

<p>3. Consistency with any future wholegrain health claim</p>	<p>FSANZ is seeking expert reviews regarding the scientific substantiation of wholegrain and heart health.</p> <p>The definition of ‘wholegrain’ must be consistent with the criteria for any health claim. Alternatively, the proposed definition is likely not to be compatible with the requirements for a health claim for wholegrain.</p> <p>There may be criteria within the definition of ‘wholegrain’, and the amount of wholegrain required per serve/100 g.</p> <p>Wholegrain that is ground should not qualify to make a wholegrain health claim.</p>	<p>A review of the diet–disease relationship between wholegrain-based foods and cardiovascular disease is in progress. This may result in pre-approval of a high level health claim. Health claims overseas are based on the revised definition of ‘wholegrain’.</p> <p>The review of the scientific literature employs the revised definition of ‘wholegrain’, because the existing definition is not consistent with the classification of wholegrain foods in the literature. Adoption of the revised definition would simplify a potential health claim.</p> <p>Criteria that determine the valid use of a wholegrain high level health claim might refer to a proportion of wholegrain content. Adoption of the revised definition would simplify such criteria.</p> <p>The scientific evidence will determine whether ground wholegrain would qualify as a relevant food to carry a health claim. Any health claims in relation to whole grain products would need to meet the relevant nutrition and health claims standard.</p>
<p>4. The Code should be explicit</p>	<p>The Code itself should be explicit. The revised definition is open to interpretation.</p> <p>An editorial note should be included in the standard that reflects exclusion of wholemeal from wholegrain.</p>	<p>The revised definition is explicit in that it refers to intact grain as well as several acceptable processes to produce wholegrain ingredients. ‘Wholemeal’ has been explicitly included since ‘milled’ is a process common to both definitions.</p> <p>A fact sheet is being developed to explain the revised change rather than an editorial note.</p>

<p>5. Align with the work on wholegrain health claim</p>	<p>A review of the recommendation may provide for the work on the definition of ‘wholegrain’ to align with the work on the wholegrain health claim.</p>	<p>The processes have already been aligned as the revised ‘wholegrain’ definition has been employed as the basis for the review of the wholegrain heart disease relationship. Future claims could still refer to flaked or cracked if need be.</p> <p>FSANZ cannot delay its statutory decision making processes regarding the definition of ‘wholegrain’ to align with future decisions regarding the development of a possible health claim for wholegrain foods.</p>
<p>6. Cereal processing and milling terms</p>	<p>The definition of ‘wholegrain’ should not include ‘dehulled, ground, cracked or flaked grains’ and needs to be clearly differential from ‘wholemeal’.</p> <p>An alternative view: the term ‘wholegrain’ should not allow for milling and should not include wholemeal.</p>	<p>The revised definition relates to the constituents of the original grain and not to the intactness or otherwise of the processed grain. For example, only limited commercial products such as brown rice and unpearled barley might qualify as unmilled cereal foods.</p> <p>There appears to be misunderstanding about the types of ingredients produced via the processes listed in the definition; milling is a broad term that encompasses a wide range of processes including grinding.</p>
<p>7. Differentiation according to grain particle size.</p>	<p>Consumers and health professionals need to be able to differentiate between foods containing intact wholegrain and those containing milled or ground grains.</p>	<p>Additional information that specifically describes grains and their milled products (from which particle size can be inferred) will usually be given in the label ingredient lists. Percentage labelling may also be stated.</p> <p>The Code requires that the name or description of the food must be sufficient to indicate the food’s true nature. This means that wholemeal should be used if more appropriate to the food.</p> <p>Industry advises that ‘wholemeal’ will be retained for established markets to meet consumer expectation since consumers are familiar with the nature of such products and according to industry market research, wholemeal consumers prefer them to products containing ‘bits’.</p>

<p>8. Consumer information and education</p>	<p>FSANZ should consider a framework that would be introduced to enhance information and education initiatives to enable an informed choice for consumers.</p>	<p>FSANZ's role does not include general nutrition education. However, FSANZ will develop a fact sheet about the proposed change to the definition.</p> <p>Nutrition policy already accepts a broad meaning of the term 'wholegrain' as exemplified by the Australian dietary guidelines 'eat plenty of cereals (breads, rice, pasta, and noodles) preferably wholegrain'. Related education tools may already be using wholegrain as an overarching term.</p>
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1. Introduction

FSANZ received an Application on 6 December 2001 from BRI Australia Ltd to amend the definition of the term ‘wholegrain’. Application A464 –seeks to amend Standard 2.1.1 of the Code to amend the definition of the term ‘wholegrain’.

The current definition of wholegrain is:

wholegrain means the unmilled products of a single cereal or mixture of cereals.

The proposed variation to Standard 2.1.1 is:

wholegrain means the intact grain or the dehulled, ground, milled, cracked or flaked grain where the constituents – endosperm, germ and bran – are present in such proportions that represent the typical ratio of those fractions occurring in the whole cereal, and includes wholemeal.

The revised definition is consistent with public health documents such as the Dietary Guidelines for Australians and the Australian Guide to Healthy Eating.

Wholemeal is defined in Standard 2.1.1 as follows:

wholemeal means the product containing all the milled constituents of the grain in such proportion that it represents the typical ratio of those fractions occurring in the whole cereal.

In March 2005, the FSANZ Board approved the Final Assessment of Application A464, including the variation to Standard 2.1.1 and notified the Ministerial Council. The FSANZ decision was based on the conclusion below.

- It is appropriate that the definition of ‘wholegrain’ be amended to reflect processing techniques that retain all of the original grain components.
- Inclusion of the revised definition for ‘wholegrain’ in the Code is consistent with the growing awareness of the positive nutritional benefits that can be achieved through diets that contain increased amounts of wholegrain-based foods.

This First Review re-affirms the approval of the variation to Standard 2.1.1 of the Code (at **Attachment 1**) as previously notified to the Ministerial Council.

The current definition of ‘wholegrain’ relates only to intact grains and only a small number of products such as brown rice and unpearled barley could meet it. Wholegrain is a concept accepted and defined overseas as containing all the constituents of the whole grain, and this understanding is important for nutritional considerations.

An important point to note is that there is not any simple or defined delineation between the definitions of ‘wholegrain’ and ‘wholemeal’ based on particle size, since processing technologies for both types of products use milling. Such technologies produce a variety of particle sizes such as cracked and kibbled down to finely milled flour.

Wholemeal products do not just represent finely ground flour used to make wholemeal bread. They also include biscuits and oatmeal products.

The revised definition of 'wholegrain' is explicit in that it provides the essential characteristic of representing the typical ratio occurring in the whole cereal - as well as a finite list of the forms of processing, including no processing, that together constitute an acceptable identity for wholegrain. The inclusion of 'wholemeal' in the revision removes any ambiguity over its status, since 'milled' is a term common to both definitions of 'wholegrain' and 'wholemeal'.

'Wholemeal' is not defined as ground grain and in fact may be in coarse granule or kibbled forms. A labelling option such as 'ground wholegrain' is not a practical enforcement tool to distinguish between wholemeal and wholegrain-derived ingredients, as there is no clear delineation based on particle size.

Wholegrain and wholemeal products refer to all types of grain products, not just types of breads. The two definitions will cover many other types of cereals, such as oats, corn, rice and different products such as breakfast cereals, pasta and noodles.

2. Objective of Review

The Ministerial Council has requested a First Review of the draft variation to Standard 2.1.1 – Cereals and Cereal Products of the Code. FSANZ is required to make a decision on this Review by 19 August 2005.

Therefore, the objective of this Review is to reconsider the draft variation to Standard 2.1.1 taking into account the Ministerial Council's concerns as outlined in Section 4, below.

3. Background

The Final Assessment Report for Application A464 proposed a revision to the definition of 'wholegrain' to expand its scope, and also to refer to a variety of processes that could be applied to produce wholegrain ingredients, providing all such ingredients contained the components of the whole grain in original proportions. It also explicitly included wholemeal. The revised definition was contrasted with the Code's current definition of 'wholegrain', which was described as too narrow, severely limiting for food manufacturers, potentially misleading for consumers and inconsistent with international practice.

4. Ministerial Council Review Grounds

The Ministerial Council has requested a First Review of Application A464 on the grounds that the variation to Standard 2.1.1:

- **does not protect public health and safety; and**
- **does not provide adequate information to enable informed choice.**

Additional comments provided by the Lead Minister are at **Attachment 2** and are addressed in detail in section 6. The specific comments are generally summarised as follows:

- ‘Wholemeal’ should not be a subset of ‘wholegrain’ as this would mislead consumers.
- There is a need to distinguish between ‘wholemeal’ and ‘wholegrain’ due to nutritional differences, particularly glycaemic index.
- The definition of ‘wholegrain’ must be consistent with the text and criteria for any future wholegrain health claim.

5. Options

There are three options proposed for consideration under this review:

1. re-affirm approval of the variation to Standard 2.1.1 of the Code as notified to the Ministerial Council; or
2. re-affirm approval of the variation to Standard 2.1.1 of the Code subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the variation to Standard 2.1.1 of the Code as notified to the Ministerial Council.

6. Review on Grounds Requested by the Ministerial Council

The First Review of the variation to Standard 2.1.1 has been undertaken addressing the matters stated in the Ministerial Council’s request.

6.1 Protection of public health and safety

Milled whole grains are nutritionally superior to intact whole grains because the contents are more accessible to digestion; furthermore, their consumption as wholegrain-based foods provides many nutritional benefits over refined cereal products. There is a demonstrated association between increased consumption of wholegrain-based foods and reduced risk of certain chronic diseases such as cardiovascular disease, diabetes and some cancers. These diet-disease relationships are based upon consumption of more than intact whole grains, rather they are based on a range of wholegrain-based foods with various proportions of milled and/or intact wholegrain content.

The Public Health Impact Assessment (**Attachment 3**) concludes that increased consumption of wholegrain products relative to refined cereal products would confer significant health benefits for Australians and New Zealanders. Such benefits would be conferred irrespective of grain particle size, since the evidence relates the beneficial effect to wholegrain-based products made from grains and/or cereal flours. The evidence strongly supports the suggestion that wholegrain-based foods, even containing as little as 25% wholegrain and its milled products, protects against the development of type 2 diabetes and improves glycaemic control.

Glycaemic index increases as particle size decreases and, together with glycaemic load, is of particular importance to consumers with diabetes. Where this is an important consideration, consumers may be informed of the product’s glycaemic index (GI) by a voluntary label claim.

These consumers can usually ascertain the specific nature of the grain ingredients from the label ingredient list. There are no specific provisions in relation to the GI in the Code. However, any claims made in relation to the GI of a food must comply with the general provisions in food law and fair trading law regarding the prohibitions on misleading and deceptive conduct. Any false statements regarding the GI or GL of a food could be subject to enforcement action. GI claims will also be considered under the new health claims standard.

The importance of wholegrain and its milled products foods to health is being considered internationally, as confirmed by the letter from Professor Joanne Slavin from the University of Minnesota (**Attachment 4**). The US wholegrain health claim is based on a similar definition of wholegrain as proposed by FSANZ. The March 2004 amended definition from the American Association of Cereal Chemists is as follows:

‘Whole cereal grains and foods made from them consist of the entire grain seed usually referred to as the kernel. The kernel is made of three components – the bran, the germ and the endosperm. If the kernel has been cracked, crushed or flaked, then in order to be called whole grain, it must retain nearly the same relative proportions of bran, germ and endosperm as the original grain.

Whole grain ingredients may be used whole, cooked, milled into flour and used to make breads and other products, or extruded or flaked to make cereal products.’

6.2 Provision of adequate information to enable informed choice

This issue also relates to the potential for consumers to be misled.

The revised definition for ‘wholegrain’ would apply to grains that are:

- whole and intact, e.g. as brown rice; as an ingredient in some breads and other bakery products; or flaked in some breakfast cereals;
- coarsely milled, e.g. oatmeal or kibbled wheat found in breads such as pumpnickel; or
- finely milled, e.g. whole wheat flour used to make wholemeal bread, pasta, noodles, etc.

Some jurisdictions are concerned that the expansion of the definition of ‘wholegrain’ to encompass products of several milling processes including wholemeal, no longer provides for discrete categories of ‘wholegrain’ and ‘wholemeal’ so that either term could be used to identify similar products and consumers could not make an informed choice.

‘Wholemeal’ rather than ‘wholegrain’ has been the traditional term in Australia and New Zealand. Consumers are familiar with wholemeal flour products such as bread and pasta, and manufacturers have previously identified products with discernable grains specifically through the use of the term ‘grain’ eg multi-grain. Breakfast cereal manufacturers employ ‘wholegrain’, spelled either as one word or two.

The Final Assessment Report concluded that fair trading laws apply to all food regardless of any specific labelling requirements in the Code. Although ‘wholemeal’ is proposed as a subset of ‘wholegrain’, retention of a separate definition for ‘wholemeal’ provides manufacturers with an option to select the term which best reflects the true nature of the food, which is not misleading and which meets consumer expectations.

The concern that consumers and health professionals need to be able to distinguish products on the basis of grain particle size can be addressed, in addition to the appropriately labelled identity of the product, by referral to the label ingredient list that specifies the individual ingredients and distinguishes between flours and more intact grains.

6.3 Assessment of the Specific Points Raised by the Ministerial Council

6.3.1 Misleading consumers

- That the proposed definition might allow for wholegrain ingredients that are ground or milled to a flour to be called wholegrain. This is misleading and a qualifying term such as ‘ground wholegrain’ must be used. A literal interpretation of the revised definition could be that ‘wholegrain’ can apply to wholegrain that is ground or milled.

6.3.1.1 Response

In relation to misleading consumers, the Final Assessment Report concluded that fair trading laws apply to all food regardless of any specific labelling requirements in the Code. Retaining the definition of ‘wholemeal’ in the Code provides manufacturers with an option to select the term which best reflects the true nature of the food, which is not misleading and which meets consumer expectations.

The Australian Competition and Consumer Commission (ACCC) advised that the descriptor ‘wholegrain’ has not been specifically considered in the past. Whether the revised definition of ‘wholegrain’ is considered inconsistent with fair trading provisions will ultimately depend on the circumstances of each case. Bread manufacturers have indicated that they will retain and attempt to grow the current established markets for wholemeal breads. If consumers do not get the product that they expect, the ACCC can take appropriate action.

Industry has indicated that the term ‘wholemeal’ will be retained for established and profitable markets since consumers are familiar with the nature of wholemeal products. Bread industry research indicates that bread consumers choose wholemeal products based upon their expectations of appearance, taste and texture rather than just on particle size. In particular, the research found that consumers purchase wholemeal bread for the nutritional benefits and also to intentionally avoid grain particles.

The revised definition is similar to international wholegrain definitions so assists in both promoting consistency between domestic and international food regulations and also encouraging competitiveness and efficiency in local food industries. FSANZ notes that Nestle in the United Kingdom and General Mills in the United States have independently announced in 2005 that their entire ranges of breakfast cereals will be made from wholegrain rather than refined cereals.

The US wholegrain definition is similar to FSANZ revised version. FSANZ notes that in the absence of internationally agreed terminology, nutritionists from Otago University, New Zealand, support the interim use of the definition developed by the American Association of Cereal Chemists, which is similar to the revised FSANZ definition, because ‘a lack of definition may lead to consumers in many countries being misled with the regard to potential benefits of whole grain foods’ (Venn and Mann, 2004).

6.3.2 *Public health benefits*

- Wholemeal should not be a subset of wholegrain. The term ‘wholegrain’ should only be used when the wholegrain particles are discernable/visible. It is in this state that public health benefit is derived.

6.3.2.1 Response

Wholemeal is a subset of wholegrain since ‘milled’ is a process common to both definitions. The reference to ‘wholegrain particles’ indicates that the current definition of ‘wholegrain’ as intact, unmilled grain is too limiting and if the definition were not amended as proposed, more cumbersome terms will be required by industry and educators to describe the range of particle sizes. An arbitrary definition incorporating ‘visible’ would need to be made, which would be impossible to interpret or regulate as there is not any logical processing distinction that is available to distinguish between the two terms.

The public health benefits derived from consumption of intact or processed wholegrain cereals and foods made from wholegrain ingredients are considerable. These benefits range from nutritional benefits of increased intakes of micronutrients and dietary fibre to reduction in chronic disease risk, in particular cardiovascular disease, diabetes and certain cancers. The scientific evidence shows that these benefits are derived regardless of the degree of milling and resultant particle size. Therefore, with the exception of glycaemic index under certain circumstances, it is incorrect to state that public health benefit is only derived where particles are discernable/visible. Further information is provided in Attachment 3.

Jurisdictions have noted, and FSANZ agrees, that the glycaemic index is inversely related to grain particle size such that intact whole grains have a lower glycaemic index than foods made from wholemeal flour, which is similar to refined flour. However, the evidence strongly supports the suggestion that wholegrain-based foods, even containing as little as 25% wholegrain and milled products, protects against the development of type 2 diabetes and improves glycaemic control.

Consumption of higher glycaemic loads by diabetics can limit the effectiveness of dietary control over blood glucose levels. This control is important in dietary management and retarding the progression of the disease. Health professionals already provide advice on the dietary management of diabetes, including selection of appropriate foods. Such advice is complemented by the entire label information which will provide details on the specific ingredients and possibly other information including glycaemic index. Any false claims relating to a food’s glycaemic index or load would be subject to enforcement action.

6.3.3 *Consistency with any future wholegrain health claim*

FSANZ is in the process of seeking expert reviews regarding the scientific substantiation of seven health claims, one of which is wholegrain and heart health. It is considered imperative that the definition of ‘wholegrain’ is consistent with the criteria for any wholegrain health claim. In the development of the health claim for wholegrain, there may be criteria within the definition of ‘wholegrain’, and the amount of wholegrain required per serve/100 g. For example, wholegrain that is ground to fine particles or flour should not meet the definition of ‘wholegrain’, so should not qualify to make a wholegrain health claim.

6.3.3.1 Response

A review of the diet–disease relationship of wholegrain and cardiovascular disease is in progress as the first step towards the possible pre-approval of a high level health claim on this subject. The review employed FSANZ’s revised definition of ‘wholegrain’ in assessing the scientific literature. Although this definition gave better alignment than intact grain with the classification of wholegrain foods in the scientific literature examining the diet-disease relationship, the text of any resultant high level health claim will ultimately reflect the group of foods to which the health benefit relates rather than FSANZ’s final definition.

Adoption of FSANZ’s revised definition would simplify a potential claim, but if it were not to be adopted, a more complex claim could still be devised. However this may dissuade industry from a broad adoption of the claim and hamper promotion of wholegrain foods as a broad category of healthful products, consistent with national dietary guidelines, the Australian version of which advises ‘eat plenty of cereals (breads, rice, pasta, and noodles) preferably **wholegrain**’. Similarly, criteria that determine the valid use of such a claim might refer to a proportion of wholegrain content and, if the diet-disease relationship held in relation to a range of wholegrain-based foods, such criteria could be expressed more simply if the revised ‘wholegrain’ definition were adopted.

6.3.4 The Code should be explicit

The fact sheet to help users of the Code interpret aspects of the Code is welcomed, however, it is suggested that the Code itself should be explicit. The definition contained in the Final Assessment Report is open to interpretation and is likely not to be compatible with the requirements for a health claim for wholegrain. Another view: drafting should be amended and an editorial note included in the standard that reflects exclusion of wholemeal from wholegrain.

6.3.4.1 Response

As mentioned in Section 1, the revised definition of ‘wholegrain’ is explicit in that it provides the essential characteristic - of representing the typical ratio occurring in the whole cereal - as well as a finite list of the forms of processing, including no processing, that together constitute an acceptable identity for wholegrain. The inclusion of ‘wholemeal’ in the revision removes any ambiguity over its status, since ‘milled’ is a term common to both definitions of ‘wholegrain’ and ‘wholemeal’.

FSANZ has committed to preparing a fact sheet to explain the proposed change rather than an editorial note in the Code.

6.3.5 Align with the work on the wholegrain health claim

A review of the recommendation may provide for the work on the definition of ‘wholegrain’ to better align with the work on the wholegrain health claim.

6.3.5.1 Response

As stated above, the development of a high level health claim concerning wholegrain foods is being undertaken on the basis of the revised definition for ‘wholegrain’.

FSANZ cannot delay its decision making processes regarding the definition of ‘wholegrain’ to align with future decisions regarding the development of a possible health claim for wholegrain foods. Statutory timeframes for the processing of applications are specified in the *FSANZ Act 1991*.

6.3.6 Cereal processing and milling terms

The definition of ‘wholegrain’ should not include ‘dehulled, ground, cracked or flaked grains’ and needs to be clearly differential from ‘wholemeal’. An alternate view: the term ‘wholegrain’ should not allow for milling and should not include wholemeal.

6.3.6.1 Response

Jurisdictions made different suggestions to change the revised definition. Although all who commented desired the exclusion of wholemeal, only one sought the removal of ‘milled’.

There is clearly some misunderstanding about the many uses of different wholegrain cereals by the food industry. Whole, intact grains are rarely consumed by humans without some form of processing to make them more palatable and digestible. There are limited examples of cereal foods that correspond to unprocessed, intact whole grain (such as brown rice or unpearled barley). The general term milling includes dehulling, flaking, cracking and rolling as well as grinding. Some may contend that more specific terms do not need to be elaborated given the inclusive nature of milling. These other terms were specified however, to provide a more detailed description of acceptable forms of processing.

Most whole, intact and unmilled grains are virtually indigestible without some form of treatment or processing. Oats for example, are always dehulled in the first milling stage to provide groats, as the hull is virtually inedible. Groats are rolled or cracked and milled into oatmeal but not usually ground. Wheat is threshed and winnowed in the field to remove the straw and vestigial husk (the chaff). Wheat grains are cooked, flaked and toasted to provide breakfast cereals. Bread cannot be made from intact wheat grains as the gluten must be exposed to make a dough. If whole wheat grains are incorporated into bread doughs they must be pretreated to soften the grains or they will harden further during baking. Maize kernels can be eaten raw or boiled, but most flaked maize products such as in breakfast cereals are from cracked grains.

As discussed above, ‘wholemeal’ is not defined in terms of particle size.

6.3.7 Differentiation according to grain particle size

Consumers and health professionals need to be able to differentiate between foods containing intact wholegrain and those containing milled or ground grains i.e. wholemeal.

6.3.7.1 Response

Most consumers are likely to need to differentiate wholegrain-based cereal foods according to grain particle size because of personal preference rather than health needs. As mentioned earlier, bread industry research has indicated that a number of bread consumers do not like the grainy ‘bits’ in bread so they purchase wholemeal products with uniform texture.

Therefore there is a market for products labelled as ‘wholemeal’ and the market intends to retain these products and labels. However it is acknowledged that for some consumers, the ability to include or exclude discernable grain particles is important for health reasons. As discussed above, fair trading laws apply to all food regardless of any specific labelling requirements in the Code and on this basis, wholegrain-based products that contain grain particles will be identified differently from those made with wholemeal flour as the sole grain ingredient. The specific description of grains and/or their milled products and/or flour will be shown in the label ingredient list from which consumers can infer details about grain particle size. This information may be accompanied by percentage labelling, or a voluntary claim about the products’ glycaemic index.

6.3.8 Consumer information and education

FSANZ should consider a framework that would be introduced to enhance information and education initiatives to enable an informed choice for consumers.

6.3.8.1 Response

FSANZ’s role does not extend to general nutrition education, although information is posted on the FSANZ website about the meaning and impact of changes to regulation. FSANZ is committed to developing a fact sheet about the proposed revision of and rationale for the definition should the amendment proceed to gazettal.

Nutrition policy already accepts a broad meaning of the term wholegrain as exemplified by the Australian dietary guidelines advice to ‘eat plenty of cereals (breads, rice, pasta, and noodles) preferably wholegrain’. Education tools developed from this policy may refer to wholegrain as the overarching term and not distinguish wholegrain and wholemeal as currently required by the food regulations.

The current definition acts as a disincentive for manufacturers to promote wholegrain-based foods because no simple term is permitted in food regulations to describe the group of foods that confer a common range of health benefits. An expanded scope of wholegrain as defined in regulation will facilitate industry’s interest in promoting a class of foods based on a single concept that will complement nutrition education efforts. Being able to draw on ‘wholegrain’ as the encompassing term will simplify the message to consumers about the health benefits of wholegrain and encourage manufacture of a diverse range of acceptable products containing wholegrain ingredients.

7. Impact Analysis

This First Review has not identified issues that are likely to change the impact analysis as presented at Final Assessment. Specific considerations in reaching this conclusion are:

- the current definition of ‘wholegrain’ in the Code is narrow, inconsistent with international use and potentially misleading to customers;
- there are net benefits to consumers and industry if diets can be improved to include more wholegrain foods; and

- retaining the definition of ‘wholemeal’ in the Code provides manufacturers with an option to select the term which best reflects the true nature of the food, which is not misleading and which meets consumer expectations.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*.
2. Additional Comments Provided by Lead Minister.
3. Public Health Impact from Wholegrain Consumption.
4. Letter from Professor Joanne Slavin.

ATTACHMENT 1

DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: On gazettal

[1] *Standard 2.1.1 of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from clause 1 the definition of wholegrain, substituting –*

wholegrain means the intact grain or the dehulled, ground, milled, cracked or flaked grain where the constituents – endosperm, germ and bran – are present in such proportions that represent the typical ratio of those fractions occurring in the whole cereal, and includes wholemeal.

ATTACHMENT 2

ADDITIONAL COMMENTS PROVIDED BY LEAD MINISTER

The Ministerial Council has requested a First Review of Application A464 on the grounds that the draft Standard:

- does not protect public health and safety; and
- does not provide adequate information to enable informed choice.

Additional comments provided by the Lead Minister - specifically:

- That the proposed definition might allow for wholegrain ingredients that are ground or milled to a flour be called wholegrain. This is misleading and a qualifying term such as 'ground wholegrain' must be used. A literal interpretation of the draft standard could be that wholegrain can apply to wholegrain that is ground or milled.
- Wholemeal should not be a subset of wholegrain. The term 'wholegrain' should not allow for milling, and should not include wholemeal. The term wholegrain should only be used when the wholegrain particles are discernable/visible. It is in this state that public health benefit is derived (see next point). Drafting should be amended and an editorial note included in the standard that reflects the above.
- FSANZ is in the process of seeking expert reviews regarding the scientific substantiation of seven health claims, one of which is wholegrain and heart health. It is considered imperative that the definition of wholegrain is consistent with the criteria for any wholegrain health claim. In the development of the health claim for wholegrain, there may be criteria within the definition of wholegrain, and the amount of wholegrain required per serve/100 g. For example, wholegrain that is ground to fine particles or flour should not meet the definition of wholegrain, so should not qualify to make a wholegrain health claim. - The fact sheet to help users of the Code interpret aspects of the code is welcomed, however, it is suggested that the Code itself should be explicit. The draft definition contained in the Final Assessment Report is open to interpretation and is likely not to be compatible with the requirements for a health claim for wholegrain.
- A review of the recommendation may provide for the work on the definition of 'wholegrain' to better align with the work on the wholegrain health claim.
- The definition of wholegrain should not include 'dehulled, ground, cracked or flaked grains' and needs to be clearly differential from wholemeal.
- Consumers and health professionals need to be able to differentiate between foods containing intact wholegrain and those containing milled or ground grains i.e. wholemeal.
- FSANZ should consider a framework that would be introduced to enhance information and education initiatives to enable an informed choice for consumers.

PUBLIC HEALTH IMPACT OF WHOLEGRAIN CONSUMPTION

The discussion of wholegrain and wholemeal raises the issue of health benefits associated with the entire wholegrain category compared with those that vary according to particle size. Wholegrain foods are associated with several considerable benefits irrespective of particle size although one health effect is related to particle size. These issues have been addressed individually in the following sections.

1 Health Benefits of Consuming Wholegrain Foods

Wholegrain foods have been promoted over their refined counterparts by dietary guidelines and other authoritative advice for many years because of the increased nutrient content of wholegrain foods particularly for dietary fibre, vitamins and minerals. Over the last ten years, a growing body of evidence has supported a link between intake of wholegrain foods and a reduction in the risk of developing certain chronic illnesses. This risk reduction has been observed with the consumption of products that have as little as 25% wholegrain content by weight.

The greatest volume of research in this area relates to the impact of wholegrain consumption on cardiovascular disease (CHD). A key review on this subject was undertaken by Truswell (2002), which involved literature published up to 1999. The studies in this review, most of which were of a prospective ecological design (Rimm *et al.*, 1996; Pietinen *et al.*, 1996; Jacobs *et al.*, 1998b; Jacobs *et al.*, 1999; Wolk *et al.*, 1999; Liu *et al.*, 1999; Jacobs *et al.*, 2001), although one randomised trial was included (Burr *et al.*, 1989), show that the evidence base for the relationship of wholegrain intake with CHD is very robust. The reviewed studies showed that wholegrain consumption provided a consistent and protective effect on CHD risk. Anderson *et al.* (2000) also conducted a meta-analysis of three studies from Truswell's review (Jacobs *et al.*, 1998b; Jacobs *et al.*, 1999; Liu *et al.*, 1999) and two additional studies (Fraser *et al.*, 1992; Liu *et al.*, 2000), and showed CHD risk was reduced by 28% when the highest to lowest wholegrain percentiles of intakes were compared.

Since the articles by Anderson *et al.* and Truswell, several other key prospective studies have been published that reinforce the relationship between wholegrain consumption and CHD (Liu *et al.*, 2003; Bazzano *et al.*, 2003; Steffen *et al.*, 2003; Mozaffarian *et al.*, 2003).

Significant findings have also been identified with the intake of wholegrain foods and the risk of developing cancer. Positive benefits have been predominantly observed with the risk of developing colorectal cancer, although limited evidence suggests that the risk of developing prostate and breast cancer may be reduced through increased wholegrain intake (Jacobs *et al.*, 1995; Livesey *et al.*, 1995; Jacobs *et al.*, 1998a; McIntosh, 2001).

The above findings on the health benefits associated with wholegrain consumption were reported at the Draft and Final Assessments for Application A464, where it was concluded that there is a significant positive influence on health from consuming foods containing all of the components found within cereal grains.

2 *Types of Grain Products Associated with Health Benefits*

A central argument given in jurisdictional comments is that it is the *discernable/visible* state of cereal grains that confers the health benefits identified for wholegrains. However, this argument is not borne out in the scientific literature.

Often the term wholegrain is applied as broadly as possible in both the scientific literature, in the *Australian Dietary Guidelines for Australian Adults*, and in the *New Zealand Food and Nutrition Guidelines*. In scientific papers, wholegrain breads/breakfast cereals may not necessarily refer to products containing a majority of wholegrain ingredients by weight, and products that have a grain particle size consistent with wholemeal are routinely classified as wholegrain. As an example, several of the largest studies on CHD classified either ‘dark bread’ and/or breakfast cereals with a wholegrain/bran content $\geq 25\%$ by weight as wholegrain (Jacobs *et al.*, 1998b; Liu *et al.*, 1999; Steffen *et al.*, 2003).

As the current evidence base has not separately assessed wholemeal products from other cereal products containing the entire grain, it is not possible to conclude that any identified health benefits are solely the result of discernable/visible grain consumption patterns.

3 *Glycaemic Index, and risk of diabetes*

The Nutrition Assessment in the A464 Final Assessment Report indicated that, as the size of the cereal grain particle decreases, the glycaemic index (GI) value of foods containing those particles increases. In particular, the processing of wholegrains to a particle size consistent with wholemeal flour significantly increases a product’s GI value in comparison with the intact grain (Venn and Mann, 2004), and is similar to the GI for a refined/white flour.

However, as summarised by Venn and Mann, 2004, ‘the evidence from epidemiological studies as well as dietary intervention and metabolic studies strongly supports the suggestion that whole grain¹ foods protect against the development of type 2 diabetes and improve diabetic glycaemic control. The risk reduction is evident even when foods containing as little as 25% whole grain are consumed. Large prospective studies have consistently found that people consuming about three servings per day of whole grain foods are less likely to develop type 2 diabetes than people consuming less than 3 servings per week with a risk reduction in the order of 20-30%. The association is robust after controlling for other risk factors such as age, body mass index, physical activity, total energy intake with a dose response across quintiles of whole grain food intake. Randomised controlled trials using lifestyle interventions that have included the use of whole grain foods have shown the potential to delay progression of impaired glucose tolerance to diabetes and to reduce insulin resistance.’

Higher-GI foods pose a potential health risk for diabetic consumers, as consumption of higher-GI foods instead of lower-GI foods can limit the effectiveness of dietary control over their blood glucose levels (Buyken *et al.*, 2001; Brand-Miller *et al.*, 2003) although it is the overall glycaemic load is of direct relevance to glycaemic control. Such control is important in dietary management and retarding the progression of the disease course.

Two information sources that assist diabetics to pursue consumption of lower GI foods are:

¹ In this quotation, ‘whole grain’ means the same as the revised FSANZ definition

- the entire food label indicating the true nature of the food, possible information about glycaemic index, and the specific details of ingredients so that consumers can choose products compatible with their health needs;
- health professional advice on appropriate food selection for dietary management of diabetes.

Conclusion

It is concluded that an increase in consumption of wholegrain products relative to refined cereal products would produce significant health benefits including reduction in risk of burdensome chronic disease including cardiovascular disease, diabetes and possibly some cancers for Australians and New Zealanders. These benefits would be derived irrespective of grain particle size, as demonstrated from epidemiological and intervention studies that to date have routinely defined wholegrain products as made entirely or partially from grains and /or flours.

It is acknowledged that wholemeal products have GI values similar to comparable refined products, and that these values are higher than products containing larger grain particles; also that the related impact of glycaemic load on blood glucose control is important for dietary management of diabetes. Knowledge of appropriate food choice and dietary management and use of the entire label information enables diabetics to manage their diets appropriately.

References

- Anderson, J.W., Hanna, T.J., Peng, X. and Kryscio, R.J. (2000) Whole grain foods and heart disease risk. *J Am Coll.Nutr* 19(3 Suppl):291S-299S.
- Bazzano, L.A., He, J., Ogden, L.G., Loria, C.M. and Whelton, P.K. (2003) Dietary fiber intake and reduced risk of cardiovascular disease in US men and women: the National Health and Nutrition Examination Survey I Epidemiologic Follow-up Study. *Arch.Intern.Med* 163(16):1897-1904.
- Brand-Miller, J., Hayne, S., Petocz, P. and Colagiuri, S. (2003) Low-glycemic index diets in the management of diabetes: a meta-analysis of randomized controlled trials. *Diabetes Care* 26(8):2261-2267.
- Burr, M.L., Fehily, A.M., Gilbert, J.F., Rogers, S., Holliday, R.M., Sweetnam, P.M., Elwood, P.C. and Deadman, N.M. (1989) Effects of changes in fat, fish, and fibre intakes on death and myocardial reinfarction: diet and reinfarction trial (DART). *Lancet* 2(8666):757-761.
- Buyken, A.E., Toeller, M., Heitkamp, G., Karamanos, B., Rottiers, R., Muggeo, M. and Fuller, J.H. (2001) Glycemic index in the diet of European outpatients with type 1 diabetes: relations to glycated hemoglobin and serum lipids. *Am J Clin Nutr* 73(3):574-581.
- Fraser, G.E., Sabate, J., Beeson, W.L. and Strahan, T.M. (1992) A possible protective effect of nut consumption on risk of cardiovascular disease. The Adventist Health Study. *Arch.Intern.Med* 152(7):1416-1424.
- Jacobs, D.R., Marquart, L., Slavin, J. and Kushi, L.H. (1998a) Whole-grain intake and cancer: an expanded review and meta-analysis. *Nutr Cancer* 30(2):85-96.
- Jacobs, D.R., Meyer, H.E. and Solvoll, K. (2001) Reduced mortality among whole grain bread eaters in men and women in the Norwegian County Study. *Eur J Clin Nutr* 55(2):137-143.

Jacobs, D.R., Meyer, K.A., Kushi, L.H. and Folsom, A.R. (1998b) Whole-grain intake may reduce the risk of ischemic heart disease death in postmenopausal women: the Iowa Women's Health Study. *Am J Clin Nutr* 68(2):248-257.

Jacobs, D.R., Meyer, K.A., Kushi, L.H. and Folsom, A.R. (1999) Is whole grain intake associated with reduced total and cause-specific death rates in older women? The Iowa Women's Health Study. *Am J Public Health* 89(3):322-329.

Jacobs, D.R., Slavin, J. and Marquart, L. (1995) Whole grain intake and cancer: a review of the literature. *Nutr Cancer* 24(3):221-229.

Liu, S., Manson, J.E., Stampfer, M.J., Rexrode, K.M., Hu, F.B., Rimm, E.B. and Willett, W.C. (2000) Whole grain consumption and risk of ischemic stroke in women: A prospective study. *JAMA* 284(12):1534-1540.

Liu, S., Sesso, H.D., Manson, J.E., Willett, W.C. and Buring, J.E. (2003) Is intake of breakfast cereals related to total and cause-specific mortality in men? *Am J Clin Nutr* 77(3):594-599.

Liu, S., Stampfer, M.J., Hu, F.B., Giovannucci, E., Rimm, E., Manson, J.E., Hennekens, C.H. and Willett, W.C. (1999) Whole-grain consumption and risk of cardiovascular disease: results from the Nurses' Health Study. *Am J Clin Nutr* 70(3):412-419.

Livesey, G., Wilkinson, J.A., Roe, M., Faulks, R., Clark, S., Brown, J.C., Kennedy, H. and Elia, M. (1995) Influence of the physical form of barley grain on the digestion of its starch in the human small intestine and implications for health. *Am J Clin Nutr* 61(1):75-81.

McIntosh, G.H. (2001) Cereal foods, fibres and the prevention of cancer. *Australian J Nutrition and Dietetics* 58(Suppl 2):S37-S42.

Mozaffarian, D., Kumanyika, S.K., Lemaitre, R.N., Olson, J.L., Burke, G.L. and Siscovick, D.S. (2003) Cereal, fruit, and vegetable fiber intake and the risk of cardiovascular disease in elderly individuals. *JAMA* 289(13):1659-1666.

Pietinen, P., Rimm, E.B., Korhonen, P., Hartman, A.M., Willett, W.C., Albanes, D. and Virtamo, J. (1996) Intake of dietary fiber and risk of cardiovascular disease in a cohort of Finnish men. The Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study. *Circulation* 94(11):2720-2727.

Rimm, E.B., Ascherio, A., Giovannucci, E., Spiegelman, D., Stampfer, M.J. and Willett, W.C. (1996) Vegetable, fruit, and cereal fiber intake and risk of cardiovascular disease among men. *JAMA* 275(6):447-451.

Steffen, L.M., Jacobs, D.R., Jr., Stevens, J., Shahar, E., Carithers, T. and Folsom, A.R. (2003) Associations of whole-grain, refined-grain, and fruit and vegetable consumption with risks of all-cause mortality and incident coronary artery disease and ischemic stroke: the Atherosclerosis Risk in Communities (ARIC) Study. *Am J Clin Nutr* 78(3):383-390.

Truswell, A.S. (2002) Cereal grains and cardiovascular disease. *Eur J Clin Nutr* 56(1):1-14.

Venn, B.J. and Mann, J.I. (2004) Cereal grains, legumes and diabetes. *Eur J Clin Nutr* 58(11):1443-1461.

Wolk, A., Manson, J.E., Stampfer, M.J., Colditz, G.A., Hu, F.B., Speizer, F.E., Hennekens, C.H. and Willett, W.C. (1999) Long-term intake of dietary fiber and decreased risk of cardiovascular disease among women. *JAMA* 281(21):1998-2004.

LETTER FROM PROFESSOR JOANNE SLAVIN

June 15, 2005

Melanie Fisher
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AUSTRALIA

Dear Dr. Fisher:

Scientific support for the health benefits of whole grains is strong. In epidemiological studies whole grains as typically consumed protect against cardiovascular disease, diabetes, cancer, and help prevent weight gain. The food frequency instruments used in these studies identify whole grains as whole grain breads, brown rice, popcorn, whole grain crackers and other whole grain food products. The American Association of Cereal Chemists has proposed definitions for whole grains and these definitions have been debated in the scientific community.

The following definition supports the need for whole grain to contain all parts of the grain, but also allows for reconstituting of the whole grain into food products acceptable to consumers:

‘Wholegrain is intact, dehulled, ground, cracked or flaked grains where the components - endosperm, germ and bran are present in substantially the same proportions as they exist in the intact grain’.

I support this definition since it acknowledges that different grains require different processing steps in food production. But it requires that all parts of the grain be retained.

I have recently spoken about whole grains and health in both Canada and the United Kingdom so I appreciate that different countries have different standards for whole grains. It is difficult for food companies to manufacturer whole grain foods when there are inconsistencies in the definitions for whole grains.

My goal is to encourage consumption of more whole grains and I hope that definitions for whole grain products in all countries support that goal.

Sincerely,

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