

08/03
19 March 2003

INITIAL ASSESSMENT REPORT

APPLICATION A464

DEFINITION OF ‘WHOLEGRAIN’

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:

30 April 2003

(See “Invitation for Public Submissions” for details)

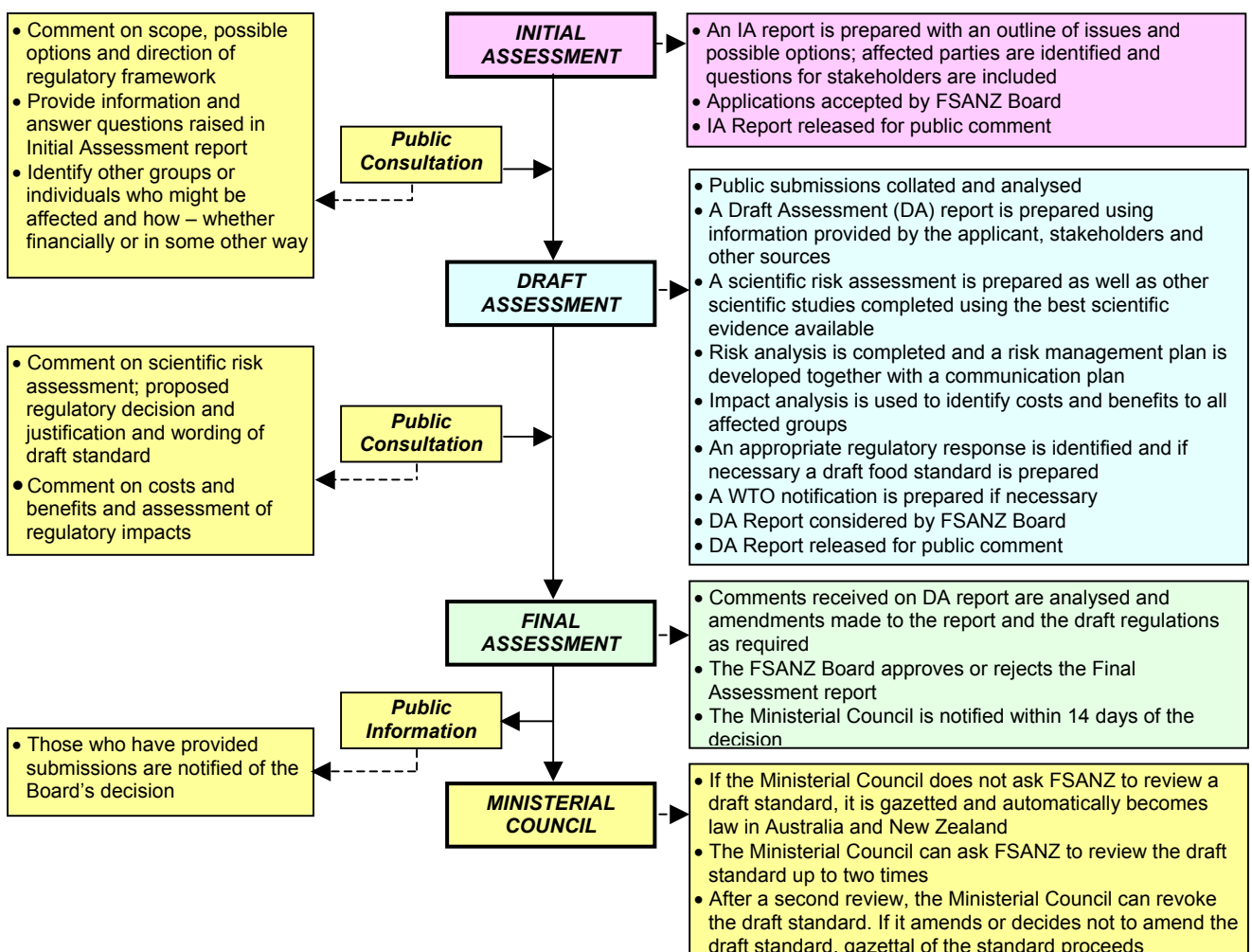
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* (the Food Standards Code) is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared an Initial Assessment Report of Application A464, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the *Food Standards Code* from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. The FSANZ Act requires the Authority to treat in confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word "Submission" and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by the Authority by: **30 April 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary

This is an initial assessment report only and based on available information provided by the applicant. Public submissions are invited on this initial assessment report and will be used as part of the draft assessment stage.

BRI Australia Ltd submitted an application on 6 December 2001 of the *Food Standards Code* to amend the definition of the term “wholegrain”. This application may require amendments to Standard 2.1.1 Cereals and Cereal Products.

The applicant considers that the definition in the Food Standards Code of “wholegrain” is too narrow, inconsistent with international practice and severely limiting for food manufacturers and potentially misleading for consumers. The applicant also claims that the current definition is inconsistent with common usage and public health documents such as the Dietary Guidelines for Australians and the Australian Guide to Health Eating.

The applicant requested that as the matter raises issues of only minor complexity that consideration be given to omitting the Inquiry Stage (now the Final Assessment stage of the process), in order to save time and resources as permitted by section 35 (1A) of the *FSANZ Act 1991*.

1. Introduction

FSANZ received an application from BRI Australia Ltd to amend if necessary Standard 2.1.1 Cereals and Cereal Products, of the *Food Standards Code* to amend the definition of the term “wholegrain”.

This application is at the initial assessment stage under section 14 of the *FSANZ Act 1991*.

2. Regulatory Problem

The applicant considers that the definition in the Food Standards Code of “wholegrain” is too narrow, inconsistent with international practice and severely limiting for food manufacturers and potentially misleading for consumers. The applicant also claims that the current definition is inconsistent with common usage and public health documents such as the Dietary Guidelines for Australians and the Australian Guide to Healthy Eating.

The applicant requests that the definition of the term “wholegrain” in Standard 2.1.1 – Cereals and Cereal Products, be amended to –

“wholegrain is the intact, dehulled, ground, cracked or flaked grains where the components of the endosperm, germ and bran are present in substantially the same proportions as they exist in the intact grain”.

The application relates to foods made from grains such as breads, breakfast cereals, pasta, biscuits, oats, rice and grain-based snack foods.

The applicant claims that most grain-based foods are nutritious and there is increasing evidence that consumption of wholegrain foods is associated with a range of health benefits not associated with consumption of refined foods. Consumers need to be provided with sufficient information to enable them to make an informed choice in line with FSANZ's objective "to provide adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception".

2.1 Current Regulations

The current definition of the term "wholegrain" in Clause 1 to Standard 2.1.1 Cereals and Cereal Products, is:

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

Clause 1 also defines the term "wholemeal" as:

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

2.2 Overseas Regulatory status

International

There is no international standard to define the term "wholegrain".

United States

The US Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) do not define wholegrain.

The FDA permits food manufacturers to make the following health claim on wholegrain food products, as possibly reducing the risk of coronary heart disease:

"Diet rich in wholegrain foods and other plant foods and low in total fat, saturated fat and cholesterol may reduce the risk of heart disease and some cancers".

For the purpose of this health claim wholegrain foods must contain 51% or more of wholegrain ingredients (bran, germ and endosperm) by weight per reference amount, with dietary fibre 2.3g per 50g or 1.7g per 35g and the food must be low in fat.

A definition is provided by The American Association of Cereal Chemists (AACC) as follows:

"Wholegrains shall consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components –the starch endosperm, germ and bran are present in substantially the same relative proportions as they exist in the intact caryopsis".

This definition does not have a regulatory status in the United States or in Australia and New Zealand.

3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the *FSANZ Act 1991*. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Historical Background

Proposal P180 (the review of Australian and New Zealand regulations to develop Standard 2.1.1 – Cereal and Cereal Products of the *Food Standards Code*) included discussions and consultations relating to definitions, including “wholegrain” and “wholemeal”. A number of submissions were received including those from the Dietitians Association of Australia and Goodman Fielder, that supported the proposed definition of “wholegrain” and was eventually gazetted as the current definition. FSANZ (formerly ANZFA) recommended the definition of “wholegrain”, noting in the Inquiry Report that manufacturers can still use the terms “kibbled”, “cracked” and “multigrain” provided that the terms are not false, misleading or deceptive. FSANZ did not define these terms in line with the general policy of minimizing unnecessary prescriptiveness.

Definitions for the terms “wholegrain” and “wholemeal” were included by FSANZ as it was considered that there was potential for misleading practices to occur if the terms were not distinguished .

4.2 Workplan Classification

This Application had been provisionally rated as complexity Category 3 and placed in Group 2 on the FSANZ standards development Workplan. This Initial Assessment confirms these ratings. Further details about the Workplan and its classification system are given in Information for Applicants at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Narrowness of current definition

The applicant claims that by retaining the current definition for “wholegrain” in Standard 2.1.1 leaves little if in any cereal or bread formulation that could be counted as “wholegrain” and means that a few breakfast cereals and crispbreads but virtually no breads, would qualify as “wholegrain foods” no matter what criteria is used.

5.2 Other usage of the term “wholegrain”

The applicant states that the common usage of the term “wholegrain” refers to grain-based foods that contain all the components of the grain (bran, germ, and endosperm). This interpretation is reflected in The Dietary Guidelines for Australians which encourage consumers to -

“Eat plenty of breads and cereals (preferably wholegrain), vegetables (including legumes) and fruits”.

and the Australian Guide to Healthy Eating recommends -

“Wholegrain breads, breakfast cereals, brown rice and wholemeal pasta more often than white or refined varieties”.

The applicant claims that the intent of these documents is not to direct consumers only to foods made from intact grains but to encourage consumption of foods that contain all the components of the grain.

6. Regulatory Options

Options available are:

- Option 1. Reject the application pursuant to section 15A(1)(b) of the *Food Standards Australia New Zealand Act 1991*;
- Option 2. Accept the application and prepare a draft assessment report to consider amending Standard 2.1.1 Cereal and Cereal Products by providing a different definition for “wholegrain”.
- Option 3. Accept the application and prepare a draft assessment report to consider amending Standard 2.1.1 Cereal and Cereal Products by removing the definition for “wholegrain”.

7. Impact Analysis

Parties affected by the options outlined above include:

- 1. Those sectors of the food industry manufacturing and selling foods made from grains such as breads, breakfast cereals, pasta, biscuits, oats, rice and grain-based snack

foods. Changes to the definition of “wholegrain” may result in labelling changes to grain based foods offered for sale to consumers.

2. Consumers of foods containing wholegrain ingredients.
3. Government agencies enforcing the food regulations.

8. Consultation

8.1 Public consultation

This Initial Assessment Report will be made available for public submissions. This allows interested parties (food industry groups, food companies, consumers and consumer groups and government agencies) to make submissions including any technical matters that may be relevant.

Areas that FSANZ is seeking public comment on in order to assess this application include:

- The need for a definition of the term “wholegrain” in Standard 2.1.1 Cereal and Cereal Products;
- The appropriateness and level of public understanding of the term “wholegrain”;
- Any public health implications arising from amendment of the definition; and
- Cost implications of changes to labelling of grain based food products if the definition of the term “wholegrain” is amended or removed.

8.2 World Trade Organization (WTO) Notification

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

Amending the Code to change or remove the definition for “wholegrain” is unlikely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment (formerly Full Assessment) and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

9. Conclusion and Recommendation

Section 13 of the *FSANZ Act 1991* prescribes those matters that must be taken into account by FSANZ in making an Initial Assessment. FSANZ has taken those matters into account, and accepts the application.

In making an initial assessment of the application, the Authority must have regard to the following matters:

- (a) whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure, as the case requires;
- (b) whether the application is so similar to a previous application for the development or variation of a food regulatory measure that it ought not to be accepted;
- (c) whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the measure or variation;
- (d) whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application;
- (e) any other relevant matters.

The Application relates to a matter that may warrant a variation of a food regulatory measure.

Accordingly the Authority has decided to accept the application and will now proceed to the Draft Assessment Report - section 15.

If subsequently agreed by the Authority and supported by the Australia and New Zealand Food Regulation Ministerial Council, an amendment to the *Food Standards Code*, as suggested by the applicant, would provide a different definition of the term “wholegrain” in Standards 2.1.1 - Cereal and Cereal Products.

The applicant has requested that as the matter raises issues of only minor complexity that consideration be given to omitting one round of public submissions, in order to save time and resources as permitted by Section 36 (1A) of the FSANZ Act 1991. The applicant made that request pursuant to the provisions of the *ANZFA Act 1991*. Under section 36 (1A) of the *FSANZ Act 1991* which provides:

The Authority may decide not to do something that the Authority is required to do under this Part (except sections 13, 13A, 16, 17, 17AA and 19) in relation to the application or the proposal if the Authority is satisfied that:

- (a) omitting to do the thing will not have a significant adverse effect on the interests of anyone; or
- (b) the application or proposal raises issues of minor significance or complexity only.

FSANZ is permitted to combine the Initial Assessment and the Draft Assessment stages and remove one round of public consultation. However it is considered that this matter is not of minor significance. It is not recommended that Section 36 (1A) be applied to simplify this application.