

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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**Agenda Item 3**

**CX/NFSDU 01/3  
September 2001**

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

**Twenty-third Session  
Berlin, Germany, 26-30 November 2001**

**GUIDELINES FOR THE USE OF NUTRITION CLAIMS:  
DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS  
(PART B CONTAINING PROVISIONS ON DIETARY FIBRE)  
*- Comments at Step 6 of the Procedure -***

#### **Comments from:**

AUSTRALIA  
GERMANY  
MALAYSIA  
NEW ZEALAND  
SOUTH AFRICA  
SPAIN  
UNITED STATES OF AMERICA

## AUSTRALIA

### DEFINITION OF DIETARY FIBRE

#### Australia's proposed definition of dietary fibre, November 2000

Australia is currently considering a definition for dietary fibre, which is intended to be finalised by the end of 2001. The proposed definition is:

Dietary fibre is that fraction of the edible part of plants or their extracts, or analogous carbohydrates, that are resistant to digestion and absorption in the human small intestine, usually with complete or partial fermentation in the large intestine. The term includes polysaccharides, oligosaccharides (DP>2) and lignins. Dietary fibre promotes one or more of these beneficial physiological effects: laxation, reduction in blood cholesterol and/or modulation of blood glucose.

The following aspects of dietary fibre were considered in relation to the definition:

1. Relation to health — as physiological effect rather than reduction in disease risk;
2. The physiological effects must include at least one, but are not limited to, the three listed physiological effects;
3. Dietary sources — mainly from plant sources, but not excluding microbiological, fungal or animal;
4. Macro components — naturally occurring, extracts or synthetic analogues; and
5. Chemical constituents — including non-starch polysaccharides, inulin and resistant oligosaccharides, lignin plus associated plant substances; and
6. Australian food regulations currently prescribe alternate AOAC methods of analysis: 985.29 or 991.43. Fructan methods 997.08 and 999.03 are under consideration.

Australia has recently set a nutrient reference value of 30g dietary fibre for labelling purposes.

Consideration of criteria for dietary fibre claims cannot be divorced from the definition of dietary fibre. Australia notes the efforts and report of the informal Working Group, chaired by the United Kingdom, presented to the Committee's previous meeting, that it was not possible to reach consensus on definitional and analytical issues. Australia nevertheless remains hopeful that after the claims criteria are finalised, the international community will press on to complete this work by addressing issues of definition and analysis for dietary fibre.

### CONDITIONS FOR DIETARY FIBRE CLAIMS

Given that the consumption of fibre in most Western countries does not meet national recommended dietary targets, it is important that increased consumption of dietary fibre and fibre-containing foods continues to be promoted. Because the source of cereal or plant fibre may confer different effects on bowel health, cholesterol metabolism, and glucose tolerance, the appropriate classification of fibre claims should reflect those health recommendations that encourage increased or optimum fibre consumption.

Australia suggests that the current formatting is ambiguous in that no value for dietary fibre per serve is explicitly given, but is implied as the same amount as per 100 kcal. This should be made clear by either placing a comma after 100g or repeating the value allocated per 100 kcal.

Australia supports the proposed conditions for a dietary fibre 'source' claim when given as not less than 3g dietary fibre per 100g or 1.5g per serving; similarly, for a 'high dietary fibre' claim: not less than 6g per 100g or 3g per serving.

However, from detailed analysis submitted to the previous two meetings of this Committee, Australia contends that the 3 alternate criteria are not equitable; this should be the case for an international system. The proposed energy-based criteria (per 100 kcal) favour lower energy density foods such as fruit and vegetables, to the extent that some low-fibre fruits and vegetables (as low as 1g/100g) would be misclassified as high sources of fibre. However white bread, a higher energy density food would not qualify for a 'source' of dietary fibre claim even though it contains 2.7g/100g of dietary fibre. It is important that, whichever alternate condition(s) are selected by individual countries, they should deliver consistent results within and between countries. As it stands, adoption of some of the alternate criteria by different countries may not improve upon the current international situation nor contribute to facilitation of international trade.

### Modified Codex proposal

To overcome the concerns about the possible misclassification of many fruit and vegetables as high source, and to make the criteria more compatible with that of the per 100g and per serve criteria, Australia proposes that the criteria per 100 kcal be modified such that:

	CODEX
High	not less than 6g/100g <del>OR 3g/100 kcal</del> OR 3g/serve
Source	not less than 3g/100g OR <del>1.5</del> 2g/100 kcal OR 1.5g/serve

This approach provides an equitable approach to fibre claims for cereal foods and plant-based foods, which does not overemphasise the importance of one food group over another.

## GERMANY

At present, there is neither a standardised definition of dietary fibre, analytical method, nutrient reference value (NRV) nor recommendations for dietary fibre intake. Therefore, the Committee has requested the Member States to submit scientific information on the requirements for nutrition claims, recommendations for intake and analytical methods for the detection of dietary fibre, suggestions for a uniform definition of dietary fibre, analytical methods, nutrient reference value (NRV) or recommendations for the intake of dietary fibre.

The following are the comments of the Federal Republic of Germany:

### 1 Definition of Dietary Fibre

In the light of the foregoing, Germany suggests that the existing definition of dietary fibre in the Codex Guidelines on Nutrition Labelling (CAC/GL-2-1985 Rev1-1993) be revised. This suggestion should be discussed at the next session of the CCNFSDU, also soliciting the opinion of the CCFL.

**Suggestion: "Cell wall components and storage polysaccharides that occur in plants and cannot be hydrolysed by human digestive enzymes."**

These are mostly non-starchy polysaccharides and lignin. This definition includes resistant starches and fructans, provided they can be detected using gravimetric AOAC methods, or the fructan method.

The reasons for this suggestion are the following:

**Comments:** To this day, all efforts to achieve a uniform definition have failed, since the definition in place up to now has been too unspecific owing to the inclusion of "animal material".

As a consequence, non-digestible substances of animal origin and other non-digestible substances should not be included into the definition, even though they may serve as substrates for colon bacteria or have other effects in the digestive tract.

1. Such a definition would contradict what has hitherto been considered as an advantage of a high-fibre diet (a vegetable diet with plenty of whole grain, fruits and vegetables that not only supplies dietary fibre).
2. The suitability as a substrate for bacteria in the colon cannot on its own serve as a proof for any positive effect (however defined). Metabolised by the microorganisms, the substrate can end up as substances that can be insignificant for humans or even have untoward effects. If non-digestible substances of animal origin can be proven to exert a positive effect on human health, they should be reevaluated.

## **2 Analytical methods for dietary fibre**

It is necessary to agree on an analytical method that ensures the consistent labelling of foods and hence enables consumers to make informed comparisons. Meanwhile, the AOAC International procedure for the detection of dietary fibre for nutrition labelling purposes is widely used.

While identification of the individual components as suggested by the group of Englyst and Cummings is the most precise method for the determination of dietary fibre, it is also true that, if the suggested definition were to be used, several methods would be necessary to determine non-starchy polysaccharides, resistant starches, fructans and lignin. In terms of food monitoring practice, this procedure involves inputs of time and effort that make it hardly acceptable.

The gravimetric AOAC method 991.43 is acceptable for most countries (1). It can be used, with relatively easy means, as a standard method within the framework of the food control system and can be considered as a compromise. On principle, it comprises the substances that are covered by the suggested definition and that naturally occur in foods of plant origin.

It is considered as a drawback that, for instance, in addition to botanical lignin and cutin (that occurs in minute quantities) substances such as Maillard products are also covered and can feign a high contents of dietary fibre in some products. While these products may be contained in foods, some of them are also formed in the course of analysis (2). This objection is certainly legitimate, to what extent it is relevant for practice is hard to evaluate, however. While it is true that non-digestible N-containing substances contribute to the gross weight of the AOAC residue, at least part of them are adjusted by deducting the residual protein. Fructans added to foods should be declared and would then have to be determined separately (3).

## **3 Recommendations for the intake of dietary fibre**

For several reasons, it is difficult to substantiate any desirable dietary fibre intake by scientific evidence.

**Comments:** If we look at the situation for vitamins, it is obvious that nobody would issue a recommendation such as 500 mg total vitamins/day, but the minimum requirement and the recommendation for each individual vitamin is identified according to the essential, physiological function of the individual vitamin (deficiency, disease, death) that can be scientifically proven.

Dietary fibres lack this essential character. The demonstrable physiological effects they do have, such as increasing stool weight, lowering of plasma cholesterol etc., depend on the chemical and physical properties that are specific to the structure of the components and vary as a result. They include fermentability, water-holding capacity, viscosity etc.. In addition, particle size is important. 1 g of rough bran, for example, can increase stool weight by 6 g, while 1 g of fine bran leads to a stool factor of three to four. Effects even differ between identical dietary fibre components, depending on whether they are contained in the food or have been added in an isolated form as a concentrate.

In many countries, recommendations range between 20 and 30 g/day. This range might become even narrower if uniform methods of analysis were adopted. In spite of the propagation of cereal diet, fruits and vegetables, various age groups among the population fall short of this recommended intake. Therefore, the option of enriching staple foods such as bread and bakery products with dietary fibres should not be opposed.

In an effort to use the whole spectrum of possible benefits (low energy density), dietary fibres should be both of cereal origin (ideally whole grain) and fruit and vegetables. It seems reasonable that cereal dietary fibre

make up at least half of the intake. That should be possible in our region on account of the high consumption of bread, but hardly globally owing to different dietary habits.

For these reasons it is difficult at present to identify a nutrient reference value (NRV) for dietary fibre.

#### 4 Nutrition claim of dietary fibre content of foods

If the amount of the recommended intake of a food ingredient is known, foods may be classified, in relation to this value, to groups that can be labelled as being free of, low in or rich in this substance. Foods made of whole grain, for instance, can be described as being rich in dietary fibre. In 1989, it was suggested in Germany that a content of more than 3 g dietary fibre in a defined quantity (see below) be recognised as containing dietary fibre and a content of more than 6 g in a defined quantity as being rich in dietary fibre. Using the guideline value of 30g/ day suggested at the time, this translates to more than 10% or more than 20% of the guideline level (4). The suggestion quite useful for cereal products, for instance, relating to a quantity of 100 moist weight (FS), it is less suitable for fruits and vegetables on account of the higher water contents of the products.

The defined quantity might be chosen as a function of the food group, as shown in the list:

Food	g/100 g	g/100 kcal	g/serving	serving size
Rye bread, whole meal	8.1	4.1	3.6 - 4 (slice)	45-50 g
Cabbage, white	3.0	12	6	200 g
Lettuce, head	1.4	11.7	0.7	50 g

For each group of foods (cereals, coarse vegetables, lettuces) another defined quantity would have to be chosen for the purpose of making a nutrition claim. The reference to 100 g dry substance (DS) or energy content (MJ) does not afford any improvement (CX/NFSDU 98/3-Add.2).

What has been hitherto discussed refers to nutrition claims based on the natural fibre contents of the foods which can be further increased by fortifying the latter, eg. with concentrates such as bran. Nutrition claims should also be possible for fortified products, too, to the effect that they raise inadequate fibre intakes, such as by stating: "rich in fibre, fortified with bran (figures)."

Requirements for functional or health-related nutrition claims are not covered by the terms of reference of this Committee.

#### References:

1. Official Methods of Analysis. 16<sup>th</sup> Ed. 1996. AOAC INTERNATIONAL; Gaithersburg, Maryland US
2. Englyst, H.N.; G.J. Hudson: The classification and measurement of dietary carbohydrates, *Food Chemistry* 57: 15-21 (1996)
3. Official Methods of Analysis, 17<sup>th</sup> Ed. 2000, Chapter 45, p 74-78. Fructans in food products ion exchange chromatographic method. Publ. AOAC INTERNATIONAL, Gaithersburg, Maryland US (ISBN 0935594676)
4. Comments of the Sub-group "Ballaststoffe" of the Working Group on "*Fragen der Ernährung*" der Fachgruppe "*Lebensmittelchemie und gerichtliche Chemie*" in the GDCh. *Lebensmittelchem. Gerichtl. Chem.* 43: 113-117 (1989)

## MALAYSIA

Malaysia supports the AOAC Method to be used for determination of fibre in view that it is the official method in Codex which has been fully validated and endorsed by CCMAS.

## NEW ZEALAND

New Zealand supports the need for a single definition for dietary fibre and for a single recognised method of analysis such as AOAC or equivalent method. New Zealand favours the use of a single serving size for the expression of fibre claims.

## SOUTH AFRICA

TABLE B: CONDITIONS FOR NUTRIENT CONTENTS

COMPONENT	CLAIM	CONDITIONS
NOT LESS THAN		
Fibre	Source	2,5 g per 100 g and 1,5 g per 418 kJ
	High	5 g per 100 g and 3 g per 418 kJ

## SPAIN

In the Spanish version we propose replacing the term ‘fibra dietética’ by ‘fibra alimentaria’. The word ‘dietética’ refers to foods for special dietary uses and could cause confusion. We suggest using ‘fibra alimentaria’ in order to emphasize that fibre is a general component of foodstuffs.

Moreover, we believe a clear and concrete definition of ‘fibre’ needs to be worked out, and that agreement needs to be reached on an analysis technique to be used for measuring fibre.

## UNITED STATES OF AMERICA

Below are our comments on two aspects of the draft table of conditions for dietary fiber claims at Step 6. These comments mainly address the definition of dietary fiber, and the importance of retaining the serving size option as a basis for expressing dietary fiber and other nutrient content claims.

### **Definition of Dietary Fiber**

Nutrition Labeling and Nutrient Content Claims. For purposes of declaring a food’s dietary fiber content for nutrition labeling and for nutrient content claims (e.g., “good source” of dietary fiber), the U.S. Food and Drug Administration (FDA) uses an analytical definition for dietary fiber based on appropriate dietary fiber methods listed in the Official Methods of Analysis of the AOAC International (21 Code of Federal Regulations (CFR) § 101.9(g)(2)).

Disease Risk Reduction Claims. For purposes of making certain claims about reduction of disease risk, the FDA has used requirements that pertain to specific types of dietary fiber with documented functional effects.

For example, an authorized claim relating soluble dietary fiber from certain foods and reduced risk of coronary heart disease (21 CFR § 101.81) specifies as eligible fibers (1) beta-glucan soluble fiber from whole oats and (2) psyllium husk soluble fiber as follows:

21 CFR § 101.8(c)(2)(ii) Nature of the substance. Eligible sources of soluble fiber.

(A) Beta ( $\beta$ ) glucan soluble fiber from the whole oat sources listed below.  $\beta$ -glucan soluble fiber will be determined by method No. 992.28 from the "Official Methods of Analysis of the Association of Official Analytical Chemists International," 16th ed. (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW, Suite 700, Washington, DC.

(A)(1) Oat bran. Oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry weight basis (dwb))  $\beta$ -glucan soluble fiber and a total dietary fiber content of 16 percent (dwb), and such that at least one-third of the total dietary fiber is soluble fiber.

(A)(2) Rolled oats. Rolled oats, also known as oatmeal, produced from 100 percent dehulled, clean oat groats by steaming, cutting, rolling, and flaking, and provides at least 4 percent (dwb) of  $\beta$ -glucan soluble fiber and a total dietary fiber content of at least 10 percent.

(A)(3) Whole oat flour. Whole oat flour is produced from 100 percent dehulled, clean oat groats by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of  $\beta$ -glucan soluble fiber and a total dietary fiber content of at least 10 percent (dwb).

(B)(1) Psyllium husk from the dried seed coat (epidermis) of the seed of *Plantago* (*P.*) *ovata*, known as blond or Indian psyllium, *P. Indica*, or *P. Psyllium*. To qualify for this claim, psyllium seed husk, also known as psyllium husk, shall have a purity of no less than 95 percent, such that it contains 3 percent or less protein, 4.5 percent or less of light extraneous matter, and 0.5 percent or less of heavy extraneous matter, but in no case may the combined extraneous matter exceed 4.9 percent, as determined by U.S. Pharmacopeia (USP) methods described in USP's "The National Formulary," USP 23, NF 18., p.1341, (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St., NW, Suite 700, Washington, DC.

(B)(2) FDA will determine the amount of soluble fiber that is provided by psyllium husk by using a modification of the Association of Official Analytical Chemists' (AOAC's) method for soluble dietary fiber (991.43) described by Lee et al., "Determination of Soluble and Insoluble Dietary Fiber in Psyllium-containing Cereal Products," *Journal of the AOAC International*, 78 (No. 3):724-729, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St., NW, Suite 700, Washington, DC.

For two other authorized claims relating dietary fiber-containing fruits, vegetables and grains to reduced risk of cancer and coronary heart disease (21 CFR § 101.76 and

§ 101.77), FDA regulations require that to be eligible for these claims, a specified amount of dietary fiber must be present without fortification.

#### Review of Dietary Fiber Definitions

A panel established by the Institute of Medicine of the National Academy of Sciences has undertaken a review of dietary fiber definitions. In April of 2001, the panel released a document for comment with a proposed definition. As of July 2001, a PDF file of the document containing the proposed definition and the rationale used in deriving it was available at the following web site:

<http://www4.nationalacademies.org/IOM/IOMHome.nsf/Pages/ongoing+studies#FNB>

Based on the comments received, the proposed definition will be revised and included in an Institute of Medicine Report on Dietary Reference Intakes for Macronutrients. The final report is anticipated to be released in early 2002.

#### Justification for Expressing Dietary Fiber Claims on a Per Serving Basis

We emphasize the importance of retaining the option to express dietary fiber claims (as well as other nutrient content claims) on a per serving basis. For example:

- It is recognized as a valid option in other Codex Guidelines;
  - i.e., as a basis for declaring a food's nutrient content for nutrition labeling (in the Codex Guidelines on Nutrition Labelling), and as a basis for nutrient content claims (in the recently adopted table on conditions for protein, vitamin and mineral claims in the Codex Guidelines for Use of Nutrition Claims).
- It has been found to be the best option to help U.S. consumers construct healthful diets; and
- It is preferred and understood by U.S. consumers.

In the U.S., serving size is the main basis for declaring a food's nutrient content for both claims and nutrition labeling because it reflects amounts that consumers commonly consume. In contrast, the declaration of nutrient content based on a single standard weight such as 100 grams (or volume such as 100 ml) will often not reflect the nutrient levels in amounts commonly consumed. For example, for many ready-to-eat cereals and snack products such as crackers, cookies, and chips, 100 grams is about three times the average amount eaten by consumers in the United States. Further, for certain other food products such as butter, cream, and condiments, 100 g (or 100 ml) is six or more times the amount commonly consumed on one occasion. Many of these products would contain at least 15% of the Recommended Daily Intake (RDI) for certain nutrients per 100 g or per 100 ml.

However, when commonly consumed in gram amounts of 30, 15, or less, these foods would only provide 5%, 2% or less of the RDI, respectively, and thus would not contain sufficient amounts to justify a nutrient content claim.

In addition, U.S. consumers most often make comparisons within a food category when purchasing products—which is aided by the use of standardized serving sizes. We further note that the weight of products can vary considerably within certain food categories. For example, a cup of some ready-to-eat cereals weigh less than 20 grams while others weigh more than twice that amount.

#### Other Comments

We suggest that the table be revised to clarify the levels on a per serving basis. The current table specifies levels in conjunction with per 100 g and per 100 kcal but not with per serving. For example, the table identifies conditions for a "source" claim as "3 g per 100 g or 1.5 g per 100 kcal or per serving".