

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 4

CX/NFSDU 07/29/4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

29th Session

Bad Neuenahr-Ahrweiler, 12 - 16 November 2007

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS

- Comments at Step 6 of the Procedure -

Comments from:

ARGENTINA

AUSTRALIA

CANADA

COSTA RICA

GUATEMALA

MEXICO

UNITED STATES OF AMERICA

AAC - European Cereal Starch Industry Association

ISDI - International Special Dietary Foods Industries

IWGA - International Wheat Gluten Association

WGPAT - Working Group on Prolamin Analysis and Toxicity

ARGENTINA

References

Bold text: Proposal for new text from Argentina

~~Text with strike out:~~ Proposal from Argentina for text to be eliminated

Text in italics: text quoted from the original document

New title:

[STANDARD FOR FOODS FOR SPECIAL DIETARY REGIMES INTENDED FOR CELIAC PATIENTS]

Argentina agrees with the elimination of the brackets from the title as it feels that the new proposal defines more clearly foods that exhibit an untraceable level of gluten, and are therefore not gluten-free. At the same time, they suggest replacing the phrase "exento de gluten"(gluten-exempt) with "libre de gluten"(gluten-free) throughout the Spanish-language documents, which is the correct Spanish translation of the document in English.

2. DESCRIPTION

2.1 Definition

*a) products constituted of, ~~or made exclusively with,~~ ingredients which do not contain prolamins of wheat, durum wheat, rye, barley, oats¹, or any species of *Triticum*, like spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.), or hybrid varieties with a gluten content greater than 20 mg/kg measured in foods ready for consumption;*

Argentina suggests eliminating the phrase "or made only with" from paragraph a) of the Spanish version of the document since it considers this unnecessary. The resulting text would be:

a) products constituted of ingredients which do not contain prolamins of wheat, rye, barley, oats¹, or any species of *Triticum*, like spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.), or hybrid varieties with a gluten content greater than 20 mg/kg measured in foods ready for consumption:

Furthermore, Argentina feels that paragraph a) should include prolamins such as "**glutenins**" of wheat, given that both proteins are toxic for persons with coeliac disease.

(Reference bibliography: van de Wal Y, Kooy YM, van Veelen P, Vader W, August SA, Drijfhout JW, Pena SA, Koning F. Glutenin is involved in the gluten-driven mucosal T cell response. Eur J Immunol 1999; 29: 3133-3139).

*b) constituted of ingredients made from wheat, rye, barley, oats, or any species of *Triticum* like spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.) or hybrid varieties from which gluten has been removed, with a quantity of gluten no greater than [100 mg/kg] measured in foods ready for consumption;*

or

c) products constituted of a mixture of ingredients included in sections a) and b) with a quantity of gluten no greater than [100 mg/kg] measured in foods ready for consumption.

Argentina is of the opinion that in the products defined in paragraphs 2.1.b) and 2.1.c), the proposed level of 100 ppm does not sufficiently protect the more sensitive sufferers of coeliac disease.

Moreover, two different contents in "foods free of gluten" will cause consumer error. In light of this, Argentina proposes to keep a uniform content of 20 ppm. This value can also be adjusted when scientific advances in the matter justify it.

Argentina concludes that a single value should be maintained {and the minimum detectable by known analytic methods **CAN'T MAKE SENSE OF THE PART IN BRACKETS – NEED TO CHECK SOURCE TEXT**}, given that there are studies indicating that a quantity of 50 mg/day of gluten is sufficient to induce signs of change in the intestinal mucosa.

(Reference bibliography: Catassi C. et al., Am J Clin Nutr 2007)

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Gluten-free

For the purposes of this standard, "gluten-free" means a product among those defined in section 2.1 a) whose total gluten content is no greater than 20 mg/kg, or a food or ingredient among those defined in sections 2.1 b) and 2.1 c) with a total gluten content derived from wheat, rye, barley, oats, or hybrid varieties no greater than [100 mg/kg], measured in the foods ready for consumption. The content of ~~prolamin~~ in liquid food products is also expressed in mg/kg of the original product.

Argentina suggests that a change should be made in the previous paragraph, replacing the value "[100]" with the value "[20]", and replacing the term "**prolamin**" with "**gluten**" in order to be consistent with the definition at the start of the paragraph. The editing would be as follows:

"For the purposes of this standard, "gluten-free" means a product among those defined in section 2.1 a) whose total gluten content is no greater than [20] mg/kg, or a food or ingredient among those defined in sections 2.1 b) and 2 c) with a total gluten content derived from wheat, rye, barley, oats, or hybrid varieties no greater than [20] **mg/kg**, measured in the foods ready for consumption. The content of **gluten** in liquid food products is also expressed in mg/kg of the original product.*

4. LABELLING

Argentina suggests eliminating the entire section between the brackets in this section, given that regardless of the origin of the product according to point 2.1 of the document, it must be labelled as "gluten-free" in compliance with the limit of 20 ppm.

AUSTRALIA

With regard to the 'Draft Revised Standard for Gluten-Free Foods' at Step 6, Australia has no further comments at this stage. We note that a physical working group chaired by Sweden and co-chaired by Canada is to meet before the next session of CCNFSDU. Australia will await the outcomes of this working group before providing further comments.

CANADA

General comments

A strict gluten-free diet is necessary to maintain health in individuals with celiac disease or dermatitis herpetiformis. The scientific literature indicates that a strict gluten-free diet has the following positive effects: reduces the risk of lymphoma; increases bone-mineral density; and reduces antibodies associated with a variety of autoimmune diseases associated with celiac disease. Foods represented as "gluten-free" must contain the lowest level of gluten possible¹.

¹ In Canada "gluten-free" foods are foods for special dietary use (i.e. foods that have "been specially processed or formulated to meet the particular requirements of a person in whom a physical or physiological condition exists as a result of a disease, disorder or injury...") and are defined in the *Food and Drug Regulations* as follows: "No person shall label, package, sell or advertise a food in a

Canada does not support two different levels of gluten in “gluten-free” foods. Based on currently available data and analytical methodology, we would support the maximum gluten level not exceeding 20 ppm for all foods labelled “gluten-free” whether they are naturally “gluten-free” or have been rendered “gluten-free”. Maintaining the maximum at this level will protect those with celiac disease. This maximum level could be reconsidered should new data from clinical studies become available regarding the tolerance for gluten by individuals with celiac disease. Such data would need to demonstrate that those individuals with celiac disease that are perceived to be “less sensitive” to dietary gluten do not in fact suffer from mucosal damage or have an increased risk of malignancy on long term use.

It should also be noted that “gluten-free” foods are consumed by many individuals in addition to those with celiac disease, including those who are allergic to wheat. A larger market for “gluten-free” foods would increase the variety and availability of such foods.

Specific Comments

Canada’s specific comments on the individual sections in the Draft Revised Standard are contained in the following table.

manner likely to create an impression that it is gluten-free unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye, or triticale or any part thereof.”

Proposal from Canada for Revised Text	Rationale
<p>Title: retain: DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS</p>	<p>Canada <u>does not</u> support the proposed new name for this standard, i.e. Standard for Foods for Special Dietary Uses Intended for People with Coeliac Disease.</p> <p>It is Canada's view that for individuals with celiac disease, the only appropriate foods for use in their diet are "gluten-free" foods which contain the lowest possible amount of gluten. The proposed new name may imply that foods other than those that are "gluten-free" are acceptable for individuals with celiac disease.</p>
<p>2. DESCRIPTION 2.1 Definition The products covered by this standard are described as follows: a) consisting of or made only from ingredients which do not contain any prolamins from wheat, durum wheat, rye, barley, oats or any <i>Triticum</i> species such as spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or their crossbred varieties with a gluten level not exceeding 20 mg/kg in total based on the foods ready for consumption as sold; or b) consisting of ingredients from wheat, rye, barley, oats or any <i>Triticum</i> species such as spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or their crossbred varieties, which have been rendered "gluten-free"; with a gluten level not exceeding 20 mg/kg [100 mg/kg] in total based on the foods ready for consumption as sold; or c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding 20 mg/kg [100 mg/kg] in total based on the foods ready for consumption as sold.</p>	<p>a) Canada supports a maximum level of gluten of 20 mg/kg or 20 ppm in the food. We suggest that the basis for the level should be the food as sold since "ready for consumption" implies the addition of ingredients by the consumer which could affect the gluten concentration in the food. It would not be possible to enforce a gluten level based on a food when ready for consumption if the food requires preparation by addition of other ingredients. We also suggest deletion of the text "prolamins from" since the foods that are the subject of this provision should not contain <u>any</u> of the listed cereals.</p> <p>b) and c) It is Canada's view that all foods labelled "gluten-free" should be subject to the same threshold level of gluten regardless of whether they are naturally gluten-free or have been rendered gluten-free. Canada would not support foods or ingredients labelled "gluten-free" that contain more than 20 ppm gluten. It is essential that foods for individuals suffering from celiac disease provide the lowest amount of gluten possible.</p> <p><i>Footnote:</i> Canada does not object to the inclusion of the proposed footnote with regard to the use of pure uncontaminated oats (<i>i.e. Oats can be tolerated by most but not all people with coeliac disease. Therefore, the use of oats not contaminated with gluten permitted in gluten-free foods for the dietary management of coeliac disease may be determined at national level.</i>)</p>

<p>3. ESSENTIAL COMPOSITION AND QUALITY FACTORS</p> <p>3.1 Gluten-free</p> <p>For the purpose of this standard "gluten-free" means that the total content of gluten in products defined in 2.1a) shall not exceed 20 mg/kg; and that the total content of gluten from wheat, rye, barley, oats or crossbred varieties of these does not exceed 20 mg/kg [100 mg/kg] in these foodstuffs products or ingredients defined in 2.1 b) and c) on the basis of the foods as sold ready for consumption. The prolamin content of liquid foods products is in the same way expressed in mg/kg of the food as sold original product.</p>	<p>As discussed above, Canada supports a maximum gluten content in "gluten-free" foods not exceeding 20 ppm and does not support 2 levels. Please see comments above with regard to the maximum threshold for gluten.</p> <p>A number of editorial comments are also proposed for clarity.</p>
<p>6. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING</p> <p>6.1 Determination of gluten</p> <p>Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method.</p> <p>6.1 6.2 Determination of gluten in foodstuffs and ingredients</p> <p>Methods used for determination should be traceable and calibrated against an internationally accepted standard, when if available. The detection limit has to be appropriate according to the state of the art and the technical standard. The quantitative determination of gluten in foodstuffs and ingredients shall be based on an immunologic method. The antibody to be used should react with the cereals that are toxic for persons sensitive to gluten and should not cross-react with the other cereals or other constituents of the foodstuffs and ingredients. The qualitative analysis as indicating presence of protein shall be based on DNA-methods or other relevant methods. The detection limit of the method should be at least 10 ppm in the product on a dry matter basis.</p> <p>6.2 Determination of gluten</p> <p>The Codex Committee on Methods and Sampling has endorsed the following Type I method for determination of gluten:</p> <p>Enzyme-Linked Immunoassay R5 Mendez (ELISA) Method.</p>	<p>Canada supports the EC proposal to switch the order of sections 6.1 and 6.2.</p> <p>6.1. (Former 6.2) It is our understanding that at the moment there is no internationally accepted standard for gluten. The 1st bullet should be changed to read "when available" rather than "if available"</p> <p>In the last bullet "The detection limit of the method should be at least 10 ppm in the product on a dry matter basis.", it is important to state what the 10 ppm refers to, i.e. gluten? and based on what reference material? As pointed out above, there is no good accepted standard reference material for gluten.</p> <p>6.2 (former 6.1) Canada notes that the ELISA method using the R5 antibody has certain limitations. The R5 antibody was designed to recognize a specific 5 peptide sequence that is found in the prolamins of wheat, rye and barley. The antibody does not recognize the high molecular weight glutenin subunits which have also been implicated as toxic for people with celiac disease. For products which contain both gliadin and glutenins the R5 test would be able to detect the presence of the gliadin. If there was a product which did not contain gliadin, but did contain the high molecular weight glutenins then the R5 test would not give a positive response. For a product like wheat starch, which can be prepared by the extensive washing of wheat flour with water, it is possible to have a product where most of the gliadin has been washed out but glutenin still remains. This would mean that the product could be more toxic than the quantitative result from the ELISA test would otherwise suggest.</p>

COSTA RICA

1. Costa Rica supports the title of the standards project proposed by Germany, given that it extends its field of application further. Furthermore, with the purpose of improving the Spanish translation, we request a correction to read: "Standard for foods for special dietary regimes intended for persons with coeliac disease".

2. In section 2.1 in points b) and c), we request a substitution of "100 mg/kg" with "20 mg/kg". And in point 3.1 in the reference to sections 2.1 b) and 2.1 c), a substitution of "100" mg/kg" with "20 mg/kg".

Justification: Since this is a standard for foods intended for persons with coeliac disease and given the significant differences between individuals in terms of responses to different concentrations of gluten, we consider that these should be kept to a minimum in foods that are commercially sold for such purposes.

Persons with coeliac disease need to be clearly informed of the quality of the foods offered on the market and if a product is marketed as "gluten-free", they expect it not to contain gluten. Foods intended for coeliacs could be introduced into the diet of such persons, but for this they must contain the minimum possible quantities of gluten.

Earlier it was reported on the confidence which coeliacs have in the industries that have undertaken to develop foods intended to be used in their diets, given the consequences they would suffer after ingesting gluten even in small quantities.

Establishing two values for the concentration of gluten in different types of foods and designating both of them as "gluten-free" is considered inexact and confusing, especially since, strictly speaking, the descriptions in sections 2.1 b) and c) contain small quantities of gluten (i.e. they are not free of gluten) while those in 2.1 a) could contain gluten only by contamination by other foods they contain.

3. Also, for section 2.1 we would like to incorporate a sentence at the bottom of the page indicating that the definitions will evolve according to improvements in gluten identification methods. The following edit is proposed:

“² The values established will be revised periodically according to improvements in the accepted method for the determination of gluten so that they can be reduced as far as possible.”

4. With respect to the footnote, given that 5% of coeliac patients do not tolerate oats, it would seem more practical that their introduction into the diet be determined individually by the handling physician instead of establishing at national level whether their use is permitted and in what quantity. The following edit is proposed:

“¹ Oats are tolerated by the majority of coeliacs, but not by all. As a consequence, the use of oats not contaminated with gluten as part of the dietary regime of persons with coeliac disease should be determined according to medical criteria, individually and subject to the consent of the patient.”

5. Furthermore, we would like to modify section 3.1 so that it indicates in a general manner that the composition of foods covered by the standard is the same as for the products defined in section 2.1 a), b), and c), since the labelling issues are handled in point 4 of the standard. The following edit is proposed:

"Foods for special dietary regimes intended for coeliacs are those adapted to the definitions established in 2.1a), b), and c)."

6. In section 4, we would like to replace the term "gluten-free" with "covered by this standard". In addition, we would like to eliminate the first sentence of point 4.1, which also only refers to the term "gluten-free". Instead we are in favour of eliminating the brackets from this section around the sentences that refer to the designations for foods naturally free of gluten and those indicated in points 2.1 b) and c).

7. The text in point 5 does not match the new focus of the standard and should be eliminated. In sections 3.1 and 4, the reference to the designations for products covered by the standard was already made clear. In this section we would have to reference the directives on declarations of properties, but this would not be strictly necessary.

8. Finally, we would like to reiterate that in section 6.2, it is recommended that we clarify that the value of 10 ppm corresponds to the content of gliadins according to the Report of the 26th meeting of CCNFSDU of 2004 (Alinorm 05/28/26) for the sentence referring to the limit of detection of the R5 Mendez method.. Also, in concordance with the use of the metric system in other Codex standards, we suggest replacing ppm in this point with mg/kg.

GUATEMALA

Comments from Guatemala			Justification
Page	Original text	Modifications	
76	PROJECT FOR THE REVISED STANDARD FOR GLUTEN-FREE FOODS (CODEX STAN 118-1981, AMENDED IN 1983) or [STANDARD FOR FOODS FOR SPECIAL DIETARY REGIMES INTENDED FOR COELIAC PATIENTS]	We are not in favour of changing the name of the document, and suggest instead: PROJECT FOR THE REVISED STANDARD FOR GLUTEN-FREE FOODS (CODEX STAN 118-1981, AMENDED IN 1983)	There are population groups not diagnosed as coeliacs who may be susceptible to minimum quantities of gluten, which could predispose them to associated allergic reactions.
76 2.1	Definition: b) constituted of ingredients made from wheat, rye, barley, oats, or any species of Triticum like spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or hybrid varieties, from which gluten has been removed, with a quantity of gluten no greater than [100 mg/kg] measured in foods ready for consumption;	We suggest adding the word "products" Definition: b) products constituted of ingredients made from wheat, rye, barley, oats, or any species of Triticum like spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or hybrid varieties, from which gluten has been removed, with a quantity of gluten no greater than [100 mg/kg] measured in foods ready for consumption;	For the purposes of better understanding and editing.
77 3.1	Gluten free For the purposes of this standard, "gluten-free" means a product among those defined in section 2.1 a) whose total content of gluten is no greater than 20 mg/kg, or a food or ingredient	Eliminate the brackets and approve the 100 mg/kg.	We agree with the values of 100 mg/kg in accordance with scientific documentation available to date.

	among those defined in sections 2.1 b) and 2.1 c) with a total gluten content derived from wheat, rye, barley, oats, or hybrid varieties no greater than [100 mg/kg], measured in foods ready for consumption. The content of prolamins in liquid food products is also expressed in mg/kg of the original product.		
77 3.3	The product must be prepared with special care in compliance with best manufacturing practices (BMP) in order to avoid contamination with prolamins.	We suggest: The product must be manufactured subject to good manufacturing practices and with special care to avoid contamination with prolamins.	For a more concrete translation of the English version, and better understanding.
77 4.1	Labelling: The term "gluten-free" must appear on the label very close to the name of the product. [Foods naturally free of gluten: When a food is gluten-free by nature, as indicated in paragraph 2.1 a), the descriptive term for the quantity of gluten may not precede the name of the food, but rather must appear in the following form: "(name of food), gluten-free food".] [The term used on the label to describe the products defined in sections 2.1 b) and 2.1 c) of the standard must be distinguished from the labelling used to describe products defined in section 2.1 a). The latter are described on the label as products naturally free of gluten or gluten-free. The terms used on the label of products indicated in sections 2.1 b) and 2.1 c) will be determined at national level.]	Eliminate the brackets and approve what is between them.	We agree with the declaration on the label in accordance with the terms established in points 2.1 a, b, and c.

MEXICO

We propose modifying the title of the standard as follows: **"STANDARD FOR FOODS INTENDED FOR GLUTEN-INTOLERANT PEOPLE"**

If we consider the differences among people who cannot consume gluten, there are different levels:

Given these differences, both the current title PROJECT FOR REVISED STANDARD FOR GLUTEN-FREE FOODS and the proposed title STANDARD FOR FOODS FOR SPECIAL DIETARY REGIMES INTENDED FOR SUFFERERS OF COELIAC DISEASE do not consider those intolerant to gluten in its various levels.

Mexico considers that having two maximum values to define "gluten-free" could confuse the consumer, and consequently we propose that the limit be a maximum of 20 mg/kg.

We also suggest that the products be labelled to differentiate between those which comply with the limit by nature, describing them in the label as *naturally gluten-free products* and those which have been treated to that end, which would be described on the label as *gluten-free*.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

The United States supports work to revise the Standard for Gluten-Free Foods to provide for truthful and non-misleading labeling in the selection of "gluten-free" products by people with celiac disease. The United States notes the importance of this work for the protection of consumers' health, and further notes that the U.S. Food and Drug Administration recently issued a proposed regulation on the Gluten-Free Labeling of Foods: <http://www.cfsan.fda.gov/~lrd/fr070123.html>.

Below are a few general comments, followed by a table identifying more specifically our proposed revisions to the draft standard for the Committee's consideration.

Title of Standard and Scope (Section 1)

The United States anticipates the Committee will further discuss the title and scope of this standard at the next session. We recognize that when the standard was first developed, it was called a Codex Standard for "Gluten-Free Foods" but applied only to "those processed foods which have been specially prepared to meet the needs of persons intolerant to gluten" and did not apply to foods "which in their normal form do not contain gluten" (CODEX STAN 118-1981, amended 1983).

In revising this standard, we support a broad scope to provide for truthful and non-misleading "gluten-free" labeling on all types of foods that meet the specified criteria. We believe a broad scope will be most responsive to the needs of people with celiac disease. This recognizes that many food products have multiple ingredients, and some consumers may not be able to readily identify which contain only ingredients naturally free of gluten without the provision of "gluten-free" labeling. It would also provide for "gluten-free" labeling on foods in which ingredient(s) naturally free of gluten have been substituted for gluten-containing ingredient(s). Accordingly, we propose to retain the title, "Draft Revised Standard for Gluten-Free Foods."

Definition of "Gluten-Free" (Sections 2 and 3)

The United States supports a definition of "gluten-free" that is truthful and non-misleading, facilitates the goal of protecting consumers' health, and considers the sensitivity of the analytical method that would be used to verify compliance. Based on consideration of these factors, in January 2007, the U.S. Food and Drug Administration (FDA) proposed a single maximum gluten level of less than 20 ppm as part of conditions for a "gluten-free" claim. The U.S. FDA awaits additional information from a safety assessment and public comment before finalizing this regulation.

We agree with the delegations at the last Committee meeting who indicated that setting two maximum levels for "gluten-free" might be misleading (ALINORM 07/30/26, para 102). Specifically, we support further consideration of a single maximum level of 20 mg/kg for all types of products as proposed by the delegation of Canada.

In the attached comments, we propose that the Committee consider expressing the maximum gluten level for a “gluten-free” claim on the basis of “food as sold” or “food as packaged” in lieu of “food ready for consumption.” This is because gluten levels based on “food ready for consumption” could be interpreted to mean gluten levels after a consumer adds ingredients to the purchased food product (e.g., adding liquid to prepare a dry cereal grain product), which would affect its gluten concentration. We believe the Committee’s intent is for this standard to address gluten levels in food products “as sold.”

In addition, the United States notes that the Type I method for gluten determination (i.e., Enzyme-Linked (ELISA) R5 Mendez method) endorsed by the Codex Committee on Methods, Analysis and Sampling (CCMAS) does not detect the gluten proteins (e.g., avenin) naturally found in oats. Gluten detected in oats by this method is based on contamination by other gluten proteins naturally found in wheat, rye, barley or their crossbred varieties.

Labeling (Section 4)

We support additional clarifying language in the labeling provisions of this standard to address truthful and non-misleading language for “gluten-free” claims for both: 1) foods naturally free of gluten and 2) foods rendered free of gluten. Separate labeling provisions for foods naturally free of gluten are based on the general principle in Sec. 5.1(v) of the Codex General Guidelines on Claims, and a related provision in Sec. 5.2 of the Codex Guidelines for Use of Nutrition and Health Claims.

Methods (Section 6)

We agree with comments from other delegations that suggested that the Committee considering clarifying and reorganizing certain text in this section. For example, the Committee may wish to consider reversing the order of Sec. 6.1 and 6.2 and revising these section headings to distinguish between them.

With regard to the identification of the ELISA R5 Mendez method for the determination of gluten, we propose adding an introductory sentence to clarify that it was endorsed by CCMAS as a Type I method. This Committee may continue to consider, however, whether there are equivalent or better methods, which if endorsed by CCMAS, would assumedly prompt a revision of this section.

Terminology

The Committee may wish to first decide on appropriate terminology for all other sections of this standard before considering the need to retain and/or revise the definitions of “gluten” and “prolamins” or to add new definitions.

II. SPECIFIC COMMENTS

Please refer to the attached table for proposed revisions to the latest draft standard.

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p><i>Note: Bolded text identifies proposed text to be added, with the exception of headings in which shaded text identifies proposed text to be added. Proposed deletions are identified with strikeouts.</i></p>	
<p>DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS (CODEX STAN 118-1981, AMENDED 1983)</p> <p>or</p> <p>[STANDARD FOR FOODS FOR SPECIAL DIETARY USES INTENDED FOR PEOPLE WITH COELIAC DISEASE]</p>	<ul style="list-style-type: none"> Propose retain this title to provide for “gluten-free” labeling on the broadest range of food products that may be useful in the dietary management of celiac disease.
<p>1. SCOPE</p> <p>1.1 This standard applies to those foodstuffs and ingredients that are naturally free of gluten and those that which have been specially processed or prepared to meet the dietary needs of persons intolerant to gluten.</p> <p>1.2 The standard refers only to the specific provisions related to the special dietary purpose for which these foodstuffs and ingredients are intended.</p>	<ul style="list-style-type: none"> Editorial comments for consideration. Committee may wish to consider if the proposed new text (from 1981 standard) provides clarification.
<p>2. DESCRIPTION</p> <p>2.1 Definition</p> <p>The products covered by this standard may be characterized by “gluten-free” and are described as follows:</p> <p>a) consisting of or made only from one or more ingredients which do not contain any prolamins from wheat (i.e., all <i>Triticum</i> species, such as durum wheat, spelt, and kamut), rye, barley, oats¹ or any <i>Triticum</i> species such as spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or their crossbred varieties, and the with a gluten level does not exceeding 20 mg/kg in total, based on the foods as sold; ready for consumption.</p>	<ul style="list-style-type: none"> Suggest add bolded text to make some reference to “gluten-free” in this Definition section. Propose only 1 level to define “gluten free” for products in 2.1 a-c below, but to retain differentiation of products in a-c to refer to in the labeling provisions. Propose add “one or more” to provide for “gluten-free” claims on products with only one ingredient. Propose delete “any prolamins.” It appears confusing and

¹ Oats can be tolerated by most but not all people with coeliac disease. Therefore, the use of oats not contaminated with gluten permitted in gluten-free foods for the dietary management of coeliac disease may be determined at national level.

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p>or</p> <p>b) consisting of one or more ingredients from wheat (i.e., all <i>Triticum</i> species, such as durum wheat, spelt, and kamut), rye, barley, oats or any <i>Triticum</i> species such as spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or their crossbred varieties, which have been specially processed to remove gluten, rendered "gluten-free"; and the with a gluten level does not exceeding [20 mg/kg] in total, based on the foods as sold ready for consumption.; or</p> <p>c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding [20 mg/kg] in total, based on the foods as sold. ready for consumption.</p>	<p>unnecessary with subsequent references to gluten levels.</p> <ul style="list-style-type: none"> • Propose list wheat species together. • Propose slight edits to clarify that the 20 mg/kg refers to the final gluten level in the food/product rather than in any single ingredient used to make the food. • Propose replace “ready for consumption” with “as sold” or “as packaged,” because the former can imply a gluten level after ingredients are added to a purchased product. • Propose add “one or more” to provide for “gluten-free” claims on products with only one ingredient. • Propose replace “rendered gluten-free” with “specially processed to remove gluten” to allow use of a specially processed ingredient that does not meet the level for “gluten free”, but for which the final product will meet this level. • Propose that the Committee consider alternative level of 20 mg/kg for 2.1 b) and 2.1 c).
<p>2.2 Subsidiary Definitions</p> <p>2.2.1 Gluten</p> <p>For the purpose of this standard, "gluten" is defined as a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and that is insoluble in water and 0.5M NaCl.</p> <p>2.2.2 Prolamins</p> <p>Prolamins are defined as the fraction from gluten that can be extracted</p>	<ul style="list-style-type: none"> • The Committee may wish to first decide on appropriate terminology for all other sections of this standard before considering the need to retain and/or revise the definitions of “gluten” and “prolamins” or to add new definitions.

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p>by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin.</p> <p>It is however an established custom to speak of gluten sensitivity. The prolamin content of gluten is generally taken as 50%.</p>	
<p>3. ESSENTIAL COMPOSITION AND QUALITY FACTORS</p> <p>3.1 Gluten-free</p> <p>For the purpose of this standard, "gluten-free" means that the total content of gluten in the products defined in 2.1a), b), or c) shall not exceed [20 mg/kg] , that the total content of gluten from wheat, rye, barley, oats or crossbred varieties of these does not exceed [100 mg/kg] in these foodstuffs or ingredients defined in 2.1 b) and c)- on the basis of the foods as sold ready for consumption. The gluten prolamin content of liquid food products is in the same way expressed in mg/kg of the original product as sold.</p> <p>3.2 Products covered by this standard, when substituting for important basic foodstuffs, should supply approximately the same amount of vitamins and minerals as the original foodstuffs they replace.</p> <p>3.3 The product shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with gluten. prolamins.</p>	<ul style="list-style-type: none"> • Propose one level to define "gluten free" for products in 2.1 a-c, and propose place 20 mg/kg in brackets for the Committee's further consideration. • Suggest other edits to simplify and clarify text. • Edits suggested for clarification, because not all products covered by this standard will substitute for important basic foods. • Suggest replace "prolamins" with "gluten" for consistency.
<p>4. LABELLING</p> <p>In addition to the general labelling provisions contained in the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), and any specific labelling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labelling of "gluten-free foods" shall apply:</p> <p>4.1 Placement of "Gluten-Free" Claims</p> <p>4.1 The term All "gluten-free" claims should shall be printed in the immediate proximity of the name of the product.</p> <p>[4. 2 Claims for Foods Naturally Gluten-Free</p>	<ul style="list-style-type: none"> • Propose refer to "gluten-free," or alternatively, to remove "gluten-free food" from quotes. • Propose new 4.1 sub-heading to address placement of all gluten-free claims. • Propose replace "shall" with "should" and other edits for clarification. • Propose separate labeling provisions (and

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p>Where a food is by its nature free of gluten, as described in paragraph 2.1 a), the term describing the level of gluten should not precede the name of the food, but gluten-free claim should be in the form “(the name of the food), a gluten-free food”.</p> <p>[The labelling term used to describe products defined in sections 2.1 b) and 2.1.c) of the standard should be distinguishable from the labelling used to describe products defined in section 2.1 a). The product at 2.1.a) shall be labelled as naturally gluten free or gluten free. The labelling terms in 2.1.b) and 2.1.c) shall be determined at national level.]</p> <p>5. CLAIMS</p> <p>4.3 Claims for Foods Rendered Gluten-Free</p> <p>5.1 Where a food has been rendered free of gluten, as described in paragraph 2.1 b) and c), A the foodstuff or ingredient that meets the requirement set out in Section 3.1 may be labelled "gluten-free".</p>	<p>corresponding 4.2 subheading) for foods naturally free of gluten based on the general principle in Sec. 5.1(v) of the Codex General Guidelines on Claims, and a related provision in Sec. 5.2 of the Codex Guidelines for Use of Nutrition and Health Claims.</p> <ul style="list-style-type: none"> • We support the proposed language in new 4.2 and 4.3 in lieu of this bracketed text. • We believe claim provisions are most appropriately placed under the major heading of “Labelling” rather than as a separate major heading for “Claims.” • Suggest add 4.3 subheading. • Suggest edits for clarification.
<p>6. 5. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING</p> <p>6.1 Determination of gluten</p> <p>Enzyme Linked Immunoassay R5 Mendez (ELISA) Method.</p> <p>6.2 5.1 Considerations in the determination of gluten in foodstuffs and consisting of one or more ingredients</p> <p>Methods used for determination should be traceable and calibrated against an internationally accepted standard, if available.</p>	<ul style="list-style-type: none"> • Change Sec. “6” to “5”. • We support the EC proposal in CX/NFSDU 06/28/5 (August 2006) to switch the order of 6.1 and 6.2. • We also propose slightly revising the headings to distinguish between these sections. <p>-Change “6.2.” to “5.1”</p> <ul style="list-style-type: none"> • Propose add shaded text for clarification.

U.S. Specific Comments: Proposal for Revised Text	Nature of Proposed Revision and Rationale
<p>The detection limit has to be appropriate according to the state of the art and the technical standard.</p> <p>The quantitative determination of gluten in foodstuffs and ingredients shall be based on an immunologic method.</p> <p>The antibody to be used should react with the cereals that are toxic for persons sensitive to gluten and should not cross-react with the other cereals or other constituents of the foodstuffs and ingredients.</p> <p>The qualitative analysis as that indicates the presence of gluten protein shall be based on DNA methods or other relevant methods (e.g., ELISA-based methods, DNA methods).</p> <p>The detection limit of the method should be at least 10 mg/kg ppm [gluten] in the product on a dry matter basis.</p>	<ul style="list-style-type: none"> • With clarification in the above revised title that a food/product can be a single ingredient (e.g., flour), “ingredients” need not be repeated here. • Propose edits for clarification and to add ELISA-based methods as an example. • We believe the detection limit refers to gluten based on para 7 in ALINORM 05/28/26, but the Committee may wish to confirm this.
<p>6.42 Method for Determination of gluten</p> <p>The Codex Committee on Methods and Sampling has endorsed the following Type I method for determination of gluten:</p> <p>Enzyme-Linked Immunoassay (ELISA) R5 Mendez (ELISA) Method.</p>	<ul style="list-style-type: none"> • Propose add “Method for ...” to the heading, and the following introductory sentence in bolded text. • Minor edit for consideration.

AAC - European Cereal Starch Industry Association

The revision of the Codex Standard for Gluten-Free Foods started in 1992 but was put on hold in 2001 due amongst other things to a lack of science based data on the safe exposure to gluten of coeliac people. Based on new data from the Finnish dietary survey study and the Italian microchallenge study, the discussion was resumed at the 2006 CCNFSDU meeting. The proposed levels of maximum 20 and 200 ppm gluten respectively for naturally gluten-free foods and for foods rendered gluten-free were amended to respectively 20 and 100 ppm². We regret however that the scientific data were not taken into account in setting that level of 100 ppm gluten in foods rendered gluten-free for direct human consumption.

In the Italian microchallenge study, exposure to 10 and 50 mg gluten didn’t show a significant change in the clinical situation and in serological testing, while a slightly lower average value for the ratio villous height on crypt depth (vh/cd) and a slightly higher average value for the intraepithelial lymphocytes (IELs) count was found for the 50 mg group. Due also to the low number of participants per group, the statistical significance of these values however is not clear, and the low average vh/cd value at the start of the challenge test raises questions about the initial condition of the participants. At the XIIth International Symposium on Coeliac Disease (New York, November 2006) A. Fasano, co-author of the study, concluded that a challenge study with a larger sample of people and quantitative data on dietary exposure to gluten were necessary.

² ppm means “parts per million” and 1 ppm is equal to 1 milligram per kilogram

In a market context where 200 ppm is currently used as the limit level of gluten for wheat-starch based gluten-free food and for wheat starch used in gluten-free foods, the Finnish dietary survey showed that more than 90 % of the wheat starch-based gluten-free flours contained 100 ppm gluten or less, the remainder being between 100 and 200 ppm. The daily use of gluten-free flours ranged from 10 to 300 grams, with more than 90 % consuming 150 grams per day or less. For a very large majority of coeliac people using wheat-starch based gluten-free flours, the daily exposure to gluten is thus 15 milligrams or below. No correlation was found between the level of consumption of gluten-free products and the mucosal morphology and antiendomysial antibodies of the coeliac patients. It is recognized however that some individuals may be extremely sensitive to trace amounts of gluten.

Since two categories of gluten-free foods will be available on the market, coeliac people will have a choice depending on their sensitivity to gluten.

The AAC therefore believes that - based on the available data - the maximum level of gluten for rendered gluten-free foods can be safely set at 200 ppm.

The availability of naturally gluten-free foods with a maximum content of 20 ppm gluten will fulfil the needs of the most sensitive coeliac people and this will be reflected through appropriate labelling rules.

The AAC is of the view that any further reduction of the maximum gluten content for foods rendered gluten-free would limit the use of wheat starch and unnecessarily reduce the availability of wheat-starch based gluten-free foods that can be safely used by a majority of coeliac people, and decrease their quality of life.

ISDI - International Special Dietary Foods Industries

ISDI PROPOSAL	JUSTIFICATION
TITLE	
DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS (CODEX STAN 118-1981, AMENDED 1983) ∅ {STANDARD FOR FOODS FOR SPECIAL DIETARY USES INTENDED FOR PEOPLE WITH COELIAC DISEASE}	<u>Delete</u> the first proposal and keep the second one <u>Rationale:</u> The second proposal better defines the fact that those foods are not normal foods but foods especially formulated to meet the needs of coeliac people.
1. SCOPE 1.3 This standard does not apply to foods for general consumption which do not contain gluten. 1.4 This standard applies only to foods for special dietary uses intended for people with coeliac disease.	<u>Add</u> the sentences in bold <u>Rationale:</u> These additions clarify the scope of the document and the fact that normal foods do not fall under this standard and therefore cannot use the term “gluten-free” on their labelling.
2. DESCRIPTION 2.1 Definition	<u>Keep</u> the footnote ¹ <u>Rationale:</u> Since the comments made by the WGPAT, as reproduced in CX/NFSDU 06/28/5,

<p>a) consisting of or made only from ingredients which do not contain any prolamins from wheat, durum wheat, rye, barley, oats¹ or any <i>Triticum</i> species such as spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or their crossbred varieties with a gluten level not exceeding 20 mg/kg in total based on the foods ready for consumption.;</p> <p>¹ Oats can be tolerated by most but not all people with coeliac disease. Therefore, the use of oats not contaminated with gluten permitted in gluten-free foods for the dietary management of coeliac disease may be determined at national level.</p>	<p>provided no advice on the consumption of oats, ISDI can support the sentence to allow the acceptance of oats on a national level.</p>
<p>or</p> <p>b) consisting of ingredients from wheat, rye, barley, oats or any <i>Triticum</i> species such as spelt (<i>Triticum spelta</i> L.), kamut (<i>Triticum polonicum</i> L.) or their crossbred varieties, which have been rendered "gluten-free"; with a gluten level not exceeding {100 mg/kg} in total based on the foods ready for consumption.;</p>	<p><u>Keep</u> the footnote ¹</p> <p><u>Rationale:</u> Since the comments made by the WGPAT, as reproduced in CX/NFSDU 06/28/5, provided no advice on the consumption of oats, ISDI can support the sentence to allow the acceptance of oats on a national level.</p> <p><u>Delete</u> the square brackets</p> <p><u>Rationale:</u> ISDI supports the advice from the WGPAT.</p>
<p>or</p> <p>c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding {100 mg/kg} in total based on the foods ready for consumption.</p>	<p><u>Delete</u> the square brackets</p> <p><u>Rational:</u> ISDI has always maintained it would support the recommendations of the WGPAT and thus supports the advice from the WGPAT.</p>
<p>3. ESSENTIAL COMPOSITION AND QUALITY FACTORS</p> <p>3.1 Gluten-free</p> <p>For the purpose of this standard "gluten-free" means that the total content of gluten in products defined in 2.1a) shall not exceed 20 mg/kg, that the total content of gluten from wheat, rye, barley, oats or crossbred varieties of these does not exceed {100 mg/kg} in these foodstuffs or ingredients defined in 2.1 b) and c) on the basis of foods ready for consumption. The prolamins content of liquid food products is in the same way expressed in mg/kg of the original product.</p>	<p><u>Delete</u> the square brackets</p> <p><u>Rational:</u> ISDI has always maintained it would support the recommendations of the WGPAT and thus supports the advice from the WGPAT.</p>
<p>4. LABELLING</p> <p>4.1 The term "gluten-free" shall be printed in the immediate proximity of the name of the product. If ingredients (starches) derived from gluten-containing cereals are present (rendered gluten-free), the botanical origin of the cereal from which the starch originates shall be stated in the ingredients list."</p>	<p><u>Add</u> the sentence in bold as proposed by WGPAT in its comments made in 2006</p> <p><u>Rationale:</u> ISDI supports such a paragraph as a mean of adding clarification in product labelling, as this is in line with the provision in the Codex Standard for the labeling of prepackaged foods (CODEX STAN 1-1985 (Rev. 1-1991) - Section 4.2.1.4) recently amended to require declaration</p>

<p>{Foods naturally gluten-free</p> <p>Where food is by its nature free of gluten, as described in paragraph 2.1 a), the term describing the level of gluten should not precede the name of the food, but should be in the form “(the name of the food), gluten-free food”.</p> <p>{The labelling term used to describe products defined in sections 2.1 b) and 2.1.c) of the standard should be distinguishable from the labelling used to describe products defined in section 2.1 a). The product at 2.1.a) shall be labelled as naturally gluten-free or gluten-free. The labelling terms in 2.1.b) and 2.1.c) shall be “rendered low gluten products” or “very low gluten products”-determined at national level..</p> <p>These labelling wordings shall be reserved to product category defined in section 1.</p>	<p>of the cereal source of any gluten-containing starch used in the ingredients list.</p> <p><u>Delete</u> “food” and the square brackets.</p> <p><u>Reserve</u> the term “gluten-free” to products from category 2.1.a) and do not let any labelling provision to national advice.</p> <p><u>Rationale:</u> The labelling of those products should be consistent across the world in order to make celiac clearly and simply distinguish the products on the shelves on the basis of the final different content of gluten as suggested by the WGPAT.</p> <p>Therefore the labelling should be:</p> <ul style="list-style-type: none"> - “gluten-free” in case of naturally gluten-free products (below 20 ppm), and - “rendered low gluten products” or “very low gluten products” for rendered gluten-free products (below 100 ppm).
<p>5. CLAIMS</p> <p>5.1 A foodstuff or ingredient that meets the requirement set out in Section 3.1 2.1.a) may be labelled “gluten-free”.</p> <p>A foodstuff or ingredient that meets the requirement set out in Section 2.1.b) or 2.1.c) may be labelled “rendered low gluten products” or “very low gluten products”</p>	<p><u>Replace</u> the reference to section “3.1” by a reference to section 2.1.a).</p> <p><u>Add</u> the sentence in bold.</p> <p><u>Rationale:</u> It is consistent with the section 4 on labelling rules.</p>
<p>6. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING</p> <p>6.2 [...]</p> <p>The detection limit of the method should be at least 10 ppm in the product on a dry matter basis ready for consumption.</p>	<p><u>Replace</u> “on a dry matter basis” by “ready for consumption”.</p> <p><u>Rationale:</u> It is consistent with the rest of the standard.</p>

IWGA - International Wheat Gluten Association

The revision of the Codex Standard for Gluten-Free Foods started in 1992 but was put on hold in 2001 due amongst other to a lack of science based data on the safe exposure of coeliac people to gluten. Based on new data from the Finnish dietary survey study and the Italian microchallenge study the discussion was resumed at the 2006 CCNFSDU meeting. The proposed levels of maximum 20 and 200 ppm gluten for naturally gluten-free foods and for foods rendered gluten-free were amended to respectively 20 and 100 ppm. We regret however that the available scientific data were not rightly considered in lowering the limit level for gluten for foods rendered gluten-free to 100 ppm.

In the Italian microchallenge study, exposure to 10 and 50 mg gluten didn’t show a significant change in the clinical situation and in serological testing, while a slightly lower average value for the ratio villous height on crypt depth (vh/cd) and a slightly higher average value for the intraepithelial lymphocytes (IELs) count was found for the 50 mg group. Due also to the low number of participants per group, the statistical significance of these values however is not clear, and the low average vh/cd

value at the start of the challenge test raises questions about the initial condition of the participants. At the XIIth International Symposium on Coeliac Disease (New York, November 2006) A. Fasano, co-author of the study, concluded that a challenge study with a larger sample of people and quantitative data on dietary exposure to gluten were necessary.

In a market context where 200 ppm is currently used as the limit level of gluten for wheat-starch based gluten-free food and for wheat starch used in gluten-free foods, the Finnish dietary survey showed that more than 90 % of the wheat starch-based gluten-free flours contained 100 ppm gluten or less, the remainder being between 100 and 200 ppm. The daily use of gluten-free flours ranged from 10-300 g, with more than 90 % consuming 150 g/day or less. For a very large majority of coeliac people, the daily exposure to gluten through the use of wheat-starch based gluten-free flours is thus 15 mg or below. No correlation was found between the level of consumption of gluten-free foods and the mucosal morphology and antiendomysial antibodies of the coeliac patients. It is recognized however that some individuals may be extremely sensitive to trace amounts of gluten.

Since two categories of gluten-free foods are and will continue to be available on the market, coeliac people will have a choice depending on their sensitivity to gluten.

The IWGA therefore believes that -based on the available data- the maximum level of gluten for foods rendered gluten-free can be safely set at 200 ppm.

The availability of naturally gluten-free foods with a maximum content of 20 ppm gluten will fulfil the needs of the most sensitive coeliac people.

A further reduction of the maximum gluten content for foods rendered gluten-free, would limit the use of wheat starch and unnecessarily reduce the availability of wheat-starch based gluten-free foods that can be safely used by a majority of coeliac people, and decrease their quality of life.

WGPAT - Working Group on Prolamin Analysis and Toxicity

WGPAT welcomes the formation of a physical Ad hoc working group chaired by Sweden and co-chaired by Canada and offers its full cooperation.

This group comment addresses the current draft revised standard for gluten-free foods (ALINORM 07/30/26, pages 72-74, at step 6 of the procedure).

Concerning terminology, WGPAT agrees to the position given by the US Food and Drug Administration (Federal Register volume 72 number 14, January 23, 2007, page 7297), "In discussions of coeliac disease in the medical literature the term 'gluten' is used to refer to either gluten in wheat or, collectively, to the proteins (e.g., prolamins and glutelins) in just those grains that have been demonstrated to cause harmful health effects in individuals who have coeliac disease." Wheat, rye, barley are certainly "prohibited grains" in patients with coeliac disease. Conflicting data have been reported on oats (Janatuinen EK *et al.*, A comparison of diets with and without oats in adults with coeliac disease, *N Engl J Med* 1995; 333: 1033-1037; Lundin KE *et al.* Oats induced villous atrophy in coeliac disease. *Gut* 2003; 52: 1649-1652). WGPAT considers that scientific evidence is not sufficient to exclude oats from the list of prohibited grains in coeliac disease at present.

WGPAT underlines its report to CCNFSDU given in August 2006 (CX/NFSDU 06/28/5, page 21-23). Based on the gliadin reference material introduced by WGPAT (van Eckert *et al.* Towards a new gliadin reference material - isolation and characterization. *J Cer Sci* 2006; 43: 331-341), the R5 ELISA method for gluten determination in food has been evaluated (Méndez E *et al.*, Report of a collaborative trial to investigate the performance of the R5 enzyme-linked immuno assay to determine gliadin in gluten-free food, *Eur J Gastroenterol Hepatol* 2005; 17: 1053-1063). This method has been endorsed as a type 1 method by the Codex Committee on Methods of Analysis and Sampling (CCMAS) in 2006.

New information is available from recent clinical studies on the question of how much gluten might be tolerable in the gluten-free diet for coeliac patients (Collin P *et al.* The safe threshold for gluten contamination in gluten-free products. Can trace amounts be accepted in the treatment of coeliac disease? *Aliment Pharmacol Ther* 2004; 19: 1277-1283; Catassi C *et al.* A prospective double-blind

placebo-controlled trial to establish a safe gluten threshold for patients with celiac disease. *Am J Clin Nutr* 2007; 85: 160-166). Taking all available data into account, WGPAT proposes with a majority of 9 out of 12 votes the two-step approach:

- Naturally gluten-free foods do not contain any prolamins from wheat, rye, barley, oats or their cross-bred varieties with a gluten level not exceeding 20 mg per kg on a dry matter basis.
- Gluten-free foods rendered gluten-free consist of ingredients from wheat, rye, barley, oats or their cross-bred varieties with a gluten level not exceeding 100 mg per kg on a dry matter basis.

The reason for the two-step approach is that foods based on wheat starch rendered gluten-free have been shown to be safe in patients with coeliac disease (Collin P *et al.*, see above) and should not be excluded from dietary treatment by regulatory solutions. Patients with coeliac disease should be enabled to take an informed choice about which products are naturally gluten-free and which are rendered gluten-free by appropriate labeling.

Questions remain open on the clinical long-term data of gluten toxicity, on the integration of consumption data in different regions of the world into regulations, and on the inclusion of glutenins into analytical standardization and toxicity testing. Gluten analysis and the investigation of clinical effects of gluten still remain open to further new development and scientific progress.