

# codex alimentarius commission



FOOD AND AGRICULTURE  
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**Agenda Item 4**

**CX/NFSDU 07/29/4-Add 1  
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## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

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

**29<sup>th</sup> Session**

**Bad Neuenahr-Ahrweiler, 12 - 16 November 2007**

#### **DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS**

*- Comments at Step 6 of the Procedure -*

#### **Comments from:**

**BRAZIL**

**AOECS - Association Of European Coeliac Societies**

## BRAZIL

Brazil agrees with the proposal of alteration of the title draft, considering that the application refers to the dietary needs of people intolerant to gluten and those with other diseases, besides celiac disease, as dermatitis hepetiformis, also have restriction to gluten consumption, we suggested the following title:

### **"STANDARD FOR FOODS FOR SPECIAL DIETARY USE INTENDED FOR PERSONS INTOLERANT TO GLUTEN"**

#### **4. LABELING**

In addition to the general labeling provisions contained in Standard General the for the Labeling of Prepackaged Foods (CODEX STAN 1-1985, **Rev. 1 - 1991**), and any specific labeling provisions set out in a Codex standard applying to the particular food concerned, the following provisions for the labeling of "**gluten-free foods**" shall apply:

##### **Comments:**

- a) Update the reference of the Codex "General Standard Codex for the Labeling of Prepackaged Foods."
- b) Considering the proposal of alteration of the title norm to "Standard for foods for special dietary uses intended for persons intolerant to gluten", the term "**gluten-free foods**" must be substituted for "foods for persons intolerant to gluten."

#### **4.1 The term "gluten-free" shall be printed in the immediate proximity of the name of the product.**

[Foods naturally gluten-free

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".]

[The labeling term used to describe products defined in sections 2.1 b) and 2.1.c) of the standard should be distinguishable from the labeling used to describe products defined in section 2.1 a). The product at 2.1.a) shall be labeled as naturally gluten-free or gluten-free. The labeling terms in 2.1.b) and 2.1.c) shall be determined at national level.]

##### **Comments:**

Brazil proposes to add on item 4.1 "The term "gluten-free" shall be printed in the immediate proximity of the name of the product" the expression "or in close proximity to" the name of the food in consonance with the item 4.1.2 of the "General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 1 - 1991) ".

Proposal for the composition of item 4.1: **"The term "gluten-free" shall be printed in the immediate proximity of the name of the product, or in close proximity to the name of the food."**

Brazil proposes the exclusion of the text "Foods naturally gluten-free, where food is by its nature free of gluten, the 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."

**Justification:** With the new proposal for the composition of item 4.1, the above paragraph is unnecessary.

Brazil proposes to maintain the text "The labeling term used to describe products defined in sections 2.1 b) and 2.1.c) of the standard should be distinguishable from the labeling used to describe products

defined in section 2.1 a). The product at 2.1.a) shall be labeled as naturally gluten-free or gluten-free. The labeling terms in 2.1.b) and 2.1.c) shall be determined at national level."

**Justification:** Considering the need to establish criteria for food labeling included on items 2.1.b and 2.1.c.

**Observation:**

To add the number "1" on the word "oats", regarding the baseboard note, in the whole text of the draft.

## **AOECS - Association Of European Coeliac Societies**

AOECS is an independent non-profit organisation and consists of 33 Coeliac Societies from 29 countries with approx. 270.000 members. Coeliac Societies are cooperating with medical advisors and giving any possible advice, information and assistance to the gluten intolerant population, which is suffering from coeliac disease or dermatitis herpetiformis Dühring. The prevalence of coeliac disease is estimated to be 1 % of the population world-wide (1).

We would like to comment on following subjects:

**Title:**

### **Delete the title in square brackets and keep the title as it is since 1981: Codex Standard for Gluten-free Foods**

Since over 50 years the only treatment of coeliac disease is the gluten-free diet. Additionally the claim "gluten-free" has been used in the food industry since decades. Thus we need a Codex Standard for Gluten-free Foods, therefore the title of this Standard should not be changed.

Furthermore the gluten-free diet is recommended also for some other diseases not only for individuals with coeliac disease.

### **Internal AOECS thresholds:**

Maybe it is helpful to be informed that AOECS has an internal Standard for Gluten-free Foods with following thresholds, which may not be exceeded:

- a) 20 mg/kg gluten for foods for normal consumption and drinks, which have especially been made to meet the requirements of the gluten-intolerant population e.g. soups, where wheat-flour has been replaced by potatoe-flour; or beer, where barley malt has been replaced by millet malt.
- b) 20 mg/kg gluten for dietary products gluten-free by nature.
- c) 100 mg/kg gluten for dietary products containing gluten-free wheat starch.

Food producers which comply with this AOECS Standard are permitted to use our International Gluten-Free Symbol, the Crossed Grain.

**Usually all gluten-free dietetic foods in Europe have the Crossed-Grain-Symbol on their package and all these products are already complying with the above mentioned thresholds of the AOECS Standard.**

## 2. DESCRIPTION

### 2.1 Definition

AOECS supports the Definition and the threshold as described in 2.1a). However, we suggest a modification of the footnote regarding oats (see lateron).

Since 2005 AOECS has been suggesting the threshold of <100 mg/kg gluten for rendered gluten-free products as described in 2.1b) and 2.1c) having in mind only gluten-free wheat starch-based products.

However, because of the opinion of EFSA, the European Food Safety Association (2,3,4), the situation has changed.

We think that this item is not only important for countries belonging to the European Union but also for all governments world-wide because of the improvements to have consistency with the Codex Standard on Food Labelling regarding the first item of the list of hypersensitivities (5): There are substances, which are derived from wheat or any other gluten containing cereal, but which do not contain gluten any longer because of technological reasons. Consequently these are substances, which have been rendered “gluten-free” as described in this Draft Codex Standard for Gluten-Free Foods in 2.1b).

Therefore EFSA refers to the rendered gluten-free foods of this Draft Codex Standard in their “Opinions” (2,3,4) dated 3 May 2007 when recommending thresholds for final labelling exemption of certain ingredients and concluded that it “...is unlikely to cause an adverse reaction in individuals with coeliac disease provided that the (provisional) value of gluten considered by Codex Alimentarius for foods rendered gluten-free is not exceeded.”

The list of food ingredients and substances excluded from Annex IIIa of Directive 2000/13/EC (6) has to be finalised in November 2007 according to the EU Directive 2005/26/EC (7). The request from the industry for labelling exemptions was addressed to the European Commission for the ingredients wheat-based maltodextrins, wheat-based glucose-syrup including dextrose and distillates for spirits from cereals.

AOECS supports, that these above mentioned ingredients should not be labelled in such a way that consumers get the impression that a food with one of these ingredients contains gluten, which is not the case. It would unnecessarily restrict the diet of the gluten intolerant population too much because these substances and also their derivatives e.g. the alcohol ethanol and others are very often used for transmitting substances in aromas and flavors. It would be misleading of consumers to call foods with such ingredients a gluten containing food.

However, AOECS strongly recommends that the threshold of <20 mg/kg should be taken for the permittance of labelling exemptions and not the threshold of <100 mg/kg. According to the publications of EFSA (2,3,4) all substances requested for labelling exemptions are very far below 20 mg/kg and therefore there is no need to accept 100 mg/kg.

#### **Proposal for solution of the thresholds:**

Taking into account above mentioned fact, AOECS suggests **that all categories of gluten-free foods as described in 2.1 a) and 2.1b) should not exceed 20 mg/kg gluten with the only exception of the ingredient ‘gluten-free wheat starch’ as well as products containing the ingredient ‘gluten-free wheat starch’ should not exceed 100 mg/kg gluten.”**

**Delete 2.1c) because it is not necessary.**

AOECS understands the reservation of countries, where dietary products with the ingredient gluten-free wheat starch have never been on the market. However, we kindly ask these countries for

acceptance that such products have been available in most European countries since decades and many coeliacs do not want to miss these products.

For more than 25 years wheat starch-based products have been called “gluten-free” according to the Codex Standard 118-1981(8).

Some years ago the residual gluten content in these products was much higher than today. On the request of AOECS some wheat starch producers have taken considerably efforts with the result that the residual gluten-traces are sometimes very far below 100 mg/kg. However there can be some differences:

The main reason is the weather condition especially in the summer, which has an influence to the protein content of wheat. Therefore it can happen, that in some years the rendered gluten-free wheat starch per se is around 30 mg/kg and consequently the bread as consumed is <20 mg/kg because of the water content and other ingredients. But in other years with another weather condition during summer, wheat has a higher protein content, therefore these low figures cannot be reached and the bread or similar products as consumed will be higher than 20 mg/kg but in any case <100 mg/kg.

Because of the varying values it is not justified to call these products low gluten or reduced gluten products. It would also be misleading because it can be the case that bread or similar products as consumed with gluten-free wheat starch are <20 mg/kg gluten.

It would be very confusing for coeliacs if a gluten-free wheat starch-based product would not be allowed to be called gluten-free any longer, even though efforts have been made by some starch producers to meet the requirements of AOECS resulting that the gluten residuals in these products are much lower today compared with the past. Studies are available (9,10) which confirm that wheat starch-based products <100 mg/kg gluten are safe for coeliacs. However, the quantity of all the consumed foods has also to be considered (11) and therefore not all foodstuffs should have the threshold of <100 mg/kg.

**It should be taken into account: If all other consumed foodstuffs are <20 mg/kg and only few slices of wheat starch based bread or similar foods <100 mg/kg are consumed, coeliacs will remain far below the maximum daily intake – see the study of Catassi et al (12).**

### 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

#### 3.1 Gluten-free

We suggest to modify the following text accordingly:

For the purpose of this standard “gluten-free” means that the total content of gluten defined in 2.1a) shall not exceed 20 mg/kg, that the total content of gluten **from rendered gluten-free products as defined in 2.1b) shall also not exceed 20 mg/kg with the exception of the ingredient ‘gluten-free wheat starch’ as well as products containing this ingredient which may contain <100 mg/kg gluten because of technological reasons. All values are** on the basis of foods ready for consumption. The prolamin content of liquid food products is in the same way expressed in mg/kg of the original product.

### 4. LABELLING

Any ingredient has to be labelled on the food product, therefore products with the ingredient ‘gluten-free wheat starch’ can easily be identified. If somebody does not wish to consume products with the ingredient gluten-free wheat starch she/he has a free choice.

We support to keep the text as it is in 4.1 "The term "gluten-free" shall be printed in the immediate proximity of the name of the product."

**Delete the other sentences in square brackets.**

## **6. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING**

We suggest following additions to 6.1, that the whole chapter should be read:

### **6.1 Determination of gluten in foodstuffs and ingredients**

**Enzyme-Linked Immunoassay Sorbent R5 Mendez (ELISA) method. This method was endorsed as a Type 1 method by CCMAS in May 2006.**

**The R5 ELISA is a method based on a monoclonal antibody raised against secalin, the rye prolamins and is able for detection of gluten in natural and heat-processed samples (sandwich ELISA). The antibody reacts with the pentapeptide QQPFP, which is presented in all gliadins, secalins and hordeins; QQPFP is also present in coeliac-active epitopes. For the detection of hydrolyzed gluten a modification of the R5 assay (competitive ELISA) has to be applied.**

**Delete 6.2**

We know from studies (13) and various practical experiences that analytical results vary considerably when the same food is analysed with different methods. It will be a disaster if different methods will be allowed and the same product is below the Codex-threshold in one country and higher than the Codex-threshold in the neighbour country.

AOECS is of the opinion that only the best analytical method, which has been successfully ringtested, is commercially available and approved by CCMAS as a Type 1 method, has to be used.

If a better method that fulfills the above mentioned criteria shall be available in the future the method should be replaced. However, reviewing all current studies, it is not envisaged that a better method that fulfils all necessary criteria shall be available in the next few years.

### **Footnote regarding oats:**

We suggest a modification of the wording:

Instead of ....."*therefore the use of oats not contaminated with gluten*"... we suggest .."***not contaminated with wheat, rye and barley permitted for the dietary management of coeliac disease may be determined on an individual basis***".

The footnote includes already that oats can be tolerated by most but not all coeliacs. Based on this fact it cannot be a decision on a national level. The tolerance or otherwise to oats can only be determined individually.

When it is up to national level, these coeliacs who do not tolerate oats, are not protected if a national authority permits oats in their dietary management. On the other hand, if a national authority does not permit oats, the coeliacs who can tolerate oats, will not have the chance to get uncontaminated oats products. Furtheron it is confusing for coeliacs, if oats is allowed in few countries and not in others.

**References:**

- (1) Detection of Celiac Disease in Primary Care: A Multicenter Case-Finding Study in North America – What is Current Knowledge; Carlo Catassi et al, American Journal of Gastroenterology, 2007, ISSN 0002-9270
- (2) Detection of Celiac Disease in Primary Care: A Multicenter Case-Finding Study in North America – What is Current Knowledge; Carlo Catassi et al, American Journal of Gastroenterology, 2007, ISSN 0002-9270
- (3) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a notification from AAC on wheat-based glucose syrups including dextrose pursuant to Article 6, paragraph 11 of Directive 2000/13/EC, adopted on 3 May 2007
- (4) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a notification from AAC on wheat-based maltodextrins pursuant to Article 6, paragraph 11 of Directive 2000/13/EC, adopted on 3 May 2007
- (5) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a notification from CEPS on cereals used in distillates for spirits pursuant to Article 6, paragraph 11 of Directive 2000/13/EC, adopted on 3 May 2007
- (6) Joint FAO/WHO Food Standards Programme, Codex Alimentarius, Food Labelling, Complete Texts, Fourth Edition, General Standard for the Labelling of Prepackaged Foods: para 4.2.1.3, 4.2.1.4, 4.2.3.1. and 4.2.4.2
- (7) Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
- (8) Commission Directive 2005/26/EC of 21 March 2005 establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council
- (9) Codex Standard for “Gluten-free Foods” (World-wide Standard) CODEX STAN 118-1981
- (10) The safe threshold for gluten contamination in gluten-free products. Can trace amounts be accepted in the treatment of coeliac disease; Collin P. et al, Aliment Pharmacol Ther 2004; 19:1277-1283
- (11) Review article: safe amounts of gluten for patients with wheat allergy or coeliac disease; C. Hischenhuber et al; Aliment Pharmacol Ther 2005; 23: 559-575
- (12) Consumption of gluten-free products: should the threshold value for trace amounts of gluten be 20, 100 or 200 p.p.m.? Anna Gibert, Montserrat Espadler et al, European Journal of Gastroenterology & Hepatology 2006, Vol 18 No 11, 1187-1195
- (13) A prospective, double-blind, placebo-controlled trial to establish a safe gluten threshold for patients with celiac disease; Carlo Catassi et al, Am J Clin Nutr 2007; 85:160-6
- (14) Contribution to Quality Assessment during Production of Gluten-free Food; Van Eckert R. et al, Ernährung/Nutrition 1992; 16:511-512