

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

CX/NFSDU 03/4-Add. 1
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-fifth Session
Bonn, Germany, 3-7 November 2003

PROPOSED DRAFT REVISED STANDARD FOR GLUTEN-FREE FOOD *AT STEP 7*

Comments from:

SWEDEN
FINLAND

AOECS – ASSOCIATION OF EUROPEAN COELIAC SOCIETIES
IWGA – INTERNATIONAL WHEAT GLUTEN ASSOCIATION

SWEDEN

Proposals

1. **CCNFSDU at its 25th session in November this year suggests to forward the following two methods to CCMAS for approval:**

AOAC Official Methods of Analysis; Supplement March 1995; Chapter 32:13.32.1.24. AOAC Official Method 991.19 Gliadin as a measure of gluten in foods. Colorimetric monoclonal antibody enzyme immunoassay method

R 5 ELISA method. See CX/NFSDU 03/4

Rationale: Without any evaluated appropriate methods it is impossible to protect consumer against fraud and present reliable and credible research data on tolerance. Forwarding methods to CCMAS for approval would be an appropriate step forward. Not forwarding any methods to the responsible Codex body CCMAS would be against progress and would not facilitate research on tolerance data.

- 1) **Modifications of document CX/NFSDU 00/4, see below and separate document "DRAFT REVISED STANDARD WITH THE PROPOSED AMENDMENTS 14 Oct"**

Due to recent progress we see a need to improve the draft regulatory text.

Five square brackets have to do with the levels. Concerning the figures it might be more appropriate to use "mg/kg" instead of "ppm".

Ex: A gluten level not exceeding [20 mg/kg]

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS 3.1 GLUTEN-FREE

According to ALINORM 97/26 PARA 36 where the meeting expressed the view that the levels shall refer to products as ready-for-consumption, rewrite to read as follows:

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 ppm], that the total content of gluten from wheat, rye, barley, [oats] or crossbred varieties of these does not exceed [200 ppm] in these foodstuffs or ingredients defined in 2.1 b) and c) **as ready for consumption.**

The last sentence referring to liquid food products is thus suggested to be deleted.

6. GENERAL OUTLINE OF THE METHOD OF ANALYSIS AND SAMPLING

Rewrite the title to read as:

METHODS OF ANALYSIS AND SAMPLING

6.1 INTRODUCTION

Delete the whole text under this title as the text refers to general conditions regarding analysis and anyhow is not complete. For instance accuracy is mentioned, but not reproducibility and

repeatability which will apply for all methods. If this text on introduction is needed at all, it should be rewritten to include

DETERMINATION OF GLUTEN IN FOODSTUFFS AND INGREDIENTS

Methods used for determination should be traceable and calibrated against an internationally accepted standard, 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.

7. REMARKS

Most of the text should be deleted as it refers to an old method and is thus irrelevant.

The figure 10 mg prolamin per day in 7.1 has been put into question. If 7.1 should remain in the proposed draft it might be more appropriate to put it in quality factors.

DISCUSSION

Two levels a way to come forward

In the CCNFSDU discussions when two levels were introduced it was also suggested to call the 200 ppm level “low-gluten” and the 20 ppm level “gluten free”. This is not reflected in the last version of the standard, and we believe it would be useful to reintroduce the wording “naturally free of gluten” (which is mentioned in the present standard CODEX STAN 118-1981) for the 20 ppm-level. Thus

| | |
|--------------|--------------------------|
| 20 ppm level | naturally free of gluten |
| 200 ppm | gluten free |

The Codex Alimentarius Commission expressed in June 1997 that the level of gluten of 200 ppm proposed for some types of glutenfree foods did not adequately protect sensitive consumers and that the value of 20 ppm should be generally applied to all such foods.

An overall limit of 20 ppm for all gluten free products would rule out the wheat starch products which have been consumed by many celiacs for decades and very appreciated due to the baking properties.

We therefor believe that these two levels is a good compromise.

In any case what we have now , with the present standard (CODEX STAN 118-1981) is two levels. We allow certain amount of gluten in wheat starch products, and the claim for “naturally free of gluten” applies for products that has no gluten.

DRAFT REVISED STANDARD WITH THE PROPOSED AMENDMENTS 14 Oct

Agenda Item 4 CX/NFSDU 00/4

**Amendments suggested 2003 JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-second Session
Berlin, Germany, 19-23 June 2000**

DRAFT REVISED STANDARD FOR GLUTEN-FREE FOODS**(step 7)1****1. SCOPE**

1.1 This standard applies to those foodstuffs and ingredients which have been especially processed or prepared to meet the dietary needs of persons intolerant to gluten.

1.2 The standard refers only to the special dietary purpose for which these foodstuffs and ingredients are intended.

2. DESCRIPTION**2.1 DEFINITION**

"Gluten-free" foods are foodstuffs so described:

a) consisting of or made only from ingredients which do not contain any prolamins from wheat or all *Triticum* species such as spelt (*Triticum spelta* L.), kamut (*Triticum polonicum* L.) or durum wheat, rye, barley, [oats] or their crossbred varieties with a gluten level not exceeding [20 mg/kg]; or

b) consisting of ingredients from wheat, rye, barley, oats, spelt or their crossbred varieties, which have been rendered "gluten-free"; with a gluten level not exceeding [200 mg/kg];

or

c) any mixture of the two ingredients as in a) and b) with a gluten level not exceeding [200 mg/kg]

2.2 SUBSIDIARY DEFINITIONS**2.2.1 Gluten**

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.

1 This text was previously published as CX/NFSDU 98/4.

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2.2.2 Prolamins

Prolamins are defined as the fraction from gluten that can be extracted by 40 - 70% of ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin.

It is however an established custom to speak of glutensensitivity. The prolamin content of gluten is generally taken as 50%.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS**3.1 GLUTEN-FREE**

For the purpose of this standard "gluten-free" means that the total content of gluten in products defined in 2.1 a) 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 [200 mg/kg] in these foodstuffs or ingredients defined in 2.1 b) and c) as ready for consumption..

3.2 "Gluten-free" foodstuffs, substituting important basic foodstuffs should supply approximately the same amount of vitamins and minerals as the original foodstuffs they replace.

3.3 The product shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with prolamins.

4. LABELLING

The term "gluten-free" shall be given in the immediate proximity of the name of the product.

5. CLAIMS

5.1 A foodstuff or ingredient that meets the requirement set out in Section 3.1 may be labelled "gluten-free".

6. METHOD OF ANALYSIS**6.1 INTRODUCTION****6.2 DETERMINATION OF GLUTEN IN FOODSTUFFS AND INGREDIENTS**

Methods used for determination should be traceable and calibrated against an internationally accepted standard, 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.

See Codex Alimentarius Volume 13

the total daily intake of prolamin for coeliac patients should not exceed 10 mg per day.

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FINLAND

In 1998, Finland submitted to the CC/NFSDU comments provided by the Finnish Coeliac Society on the safe use of oats in the diet of celiacs. Since then new data has appeared. This data is annexed to this paper (“Oats, wheat starch and trace amounts of gluten in the treatment of coeliac disease”). The new data, like also the previous one, confirms that the use of oats is safe even if it recognizes studies where patients, on oat based gluten free diets, have reacted to gluten. A major problem with oats is the possible contamination by gluten containing cereals. This could happen during the manufacturing processes, but there is also evidence of contamination in the agricultural production of oats. We therefore want to stress the importance of HACCP in all production stages of gluten free products and products naturally free from gluten.

The Finnish Coeliac Society reported this year that 70% of the coeliac patients successfully use oats as a part of their diet. Oats diversify the diet and increase the intake of fibres by over 20 %. Oats are easily available and compared to many other gluten free foods, cheap to buy. Oats are palatable and are normally used by the whole family, as breakfast cereals or as an ingredient of other foodstuffs. Oats markedly improve the baking properties of bakery products.

From the consumer point of view, a larger acceptance of oats in the treatment of celiacs would benefit patients world wide. In the revised draft standard for gluten free foods, oats appear in square brackets as a cereal not suitable for coeliac patients. If and when the gluten free standard will be a subject to review in Codex, *we ask the Committee to consider deleting oats as a cereal not suitable for celiac patients.*

The two-level approach and the labelling of foods “naturally free from gluten”

Finland supports the two-level approach for maximum amounts of gluten in foods that are naturally free from gluten (<20 ppm) and foods that are rendered gluten free (<200 ppm). We feel that it is important to include a zero-level, close to the detection limit of the chosen analysis method. This will help to control the possible contamination of foodstuffs that are naturally free of gluten. The choice of products for the consumer would also be much easier if the products were labelled as suitable for

celiacs. *Therefore, we would like to propose that these products be labelled “naturally free from gluten”.*

When using the proposed maximum level (200 ppm) of gluten, it is important to stress that it applies to the ready-to-eat product. A flour mix for example may contain more gluten (> 200 ppm) than the bread it will be used for. Today the derivation of the gluten content from the nitrogen content per cereal dry matter is a method that is burdensome for the laboratories and out-of-date. However, from the patients' point of view, the advantage of this approach is recognized, because the gluten content is indicated in proportion to the amount of the cereal in the product. Therefore, when analysing gluten in ready-to-eat products, some kind of conversion factors for flour mixes to bread may be possible to develop in the food control.

Methods of analysis

Finland considers that the general outline of the methods of analysis should reflect the fact that suitable methods for analysing gluten content in foodstuffs may change from time to time. Therefore, it is not necessary to describe any specific method in the draft standard. However, we think it is quite clear that the methods of today are immunological and that their detection limit is at least 10 ppm (on a dry matter basis) as described in the draft standard. If some of the recently proposed methods could be forwarded to CC/MAS for approval, we believe that it would be a step forward for the gluten free standard.

Oats in the treatment of coeliac disease

Wheat, rye and barley prolamins should be withdrawn from the coeliac diet, but the issue whether oats can be safely consumed by coeliac patients has been debated since the gluten-free diet was advocated over 40 years ago. Oats clearly would diversify the gluten-free diet, and would also increase its fibre content, which otherwise remains often rather low. The amino acid sequence of oat prolamins differs from that of wheat prolamins, and avenin is considered to have less, if any harm, for coeliac disease patients (1). The avenins contain significantly lower percentages of proline residues than harmful cereals, which might explain the lack of toxicity of oats (2).

In earlier studies the effect of oats was assessed for only short periods in a small number of patients, and the results were contradictory. The conclusion of oat toxicity was based on observation of symptoms or fat malabsorption without small bowel biopsies (3, 4). The first large controlled study appeared in 1995 (5): both patients with treated and newly-detected coeliac disease tolerated well oats. Oats did neither have any untoward effect on mucosal integrity.

As seen in Table 1, these findings have later been confirmed in several studies (Table 1), both in coeliac disease and dermatitis herpetiformis. Similarly, children seem to tolerate oats as well as adults. The long-term safety of oats has been verified in follow-up studies, at most for five years (6). Our clinical experience also supports that even the long-term use of oats is mostly well tolerated. The safe limit of daily oats seems to be more than most patients are willing to take, in a Swedish study daily oats of 93 grams in average was well tolerated (7)

Recent in vitro studies have indicated that oat prolamins does not stimulate endomysial antibody (8) or inflammatory cytokine production (9) in cultured coeliac disease intestinal mucosa.

A body of evidence thus shows that oat prolamins are not toxic for coeliac disease patients. It is still not excluded that some coeliac patients develop symptoms after taking oats. In these cases oats should be avoided, even though to our experience, the symptoms do not correlate with mucosal inflammation or coeliac antibodies (7, 10). On the other hand, the safety of oats has recently been questioned. Lundin et al. (11) observed that coeliac patients might develop symptoms and even intestinal mucosal deterioration after taking oats. Of note, this uncontrolled case report included only two patients.

As stated earlier, patients with dermatitis herpetiformis usually tolerate oats. In accordance with the findings of Lundin et al, some patients with dermatitis herpetiformis may develop rash after starting to take oats. However, in a controlled study, the rash did not recur more often by oats containing than by conventional strict gluten-free diet (12).

To summarize, most coeliac disease patients tolerate well oats. It must be recognized, however, that some patients may develop symptoms, which is not likely to be due to avenin toxicity. Nevertheless, in such occasional cases using of oats should be avoided. Another issue is of course that oats may be contaminated with other gluten containing cereals. The same problem is evident in other food products, even in naturally gluten-free ones. The problem can be solved by separating the production of oats totally from other cereals.

Wheat starch-based gluten-free products

Wheat starch-based gluten-free products, meeting today's Codex Alimentarius standard, may contain residual gluten (13). Theoretically these trace amounts of gluten can be harmful, but in recent studies wheat starch-based gluten-free products have been tolerated well, and they have had no effect to clinical outcome or to the recovery of small-bowel mucosa in coeliac disease (Table 2). In our controlled, randomized one-year follow-up study, naturally gluten-free diet was not superior to wheat starch-based diet in newly-detected coeliac disease; the mucosal recovery and quality of life were similar in both groups(14).

Epidemiological studies suggest that the treatment with wheat starch-based gluten-free products has not resulted in excess morbidity or mortality in coeliac disease patients (15). It is still evident that some patients with coeliac disease or dermatitis herpetiformis are very sensitive to even trace amounts of gluten, and in such cases naturally-gluten-free diet is the treatment of choice. Wheat contamination of gluten-free products may be one reason for poor clinical or histological recovery, both in wheat starch-based and in naturally gluten-free products.

How much gluten is allowed?

The question of the safety of wheat starch based gluten free diet should be extended to a more relevant point: what is the safe limit of gliadin contamination in the daily gluten-free diet? Catassi et al (16) showed that 100 mg of daily gliadin may cause inflammation in the intestinal mucosa of coeliac children, and 500 mg some morphological changes. However, here we will face many problems. As to the tolerance to trace amounts of gliadin, individual differences may be outstanding. We have learned for instance from gluten challenge studies (17) that in some individuals, the mucosal deterioration starts immediately when the patient is placed on gluten-containing diet, whereas in others the development of villous atrophy or appearance of antibodies make take 10 years or even longer (18). Clearly, the safe limit should be set on a sincere level. At the moment, we recommend that the safety of the diet could be

evaluated individually. When the mucosal recovery is evident after one year on apparently gluten-free diet, or when the rash is controlled by diet alone, the diet of the respective patient is strict enough.

The safe limit can be in the future assessed roughly by measuring the gliadin content of such products, wheat starch based or naturally gluten-free ones, by which the mucosal recovery has been shown to be evident. Nevertheless, as to the treatment of coeliac disease, a poor dietary compliance seems to be much more deleterious and common than the untoward effects of trace amounts of gluten in otherwise gluten-free products.

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AOECS – ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

Analytical issue:

We appreciate very much all the efforts which were taken by the members of the Working Group on Prolamin Analysis and Toxicity (WGPAT) and other scientists to improve the analysis to detect gluten in foodstuffs. Important progresses were made with the development of the European Gliadin Reference-Standard, the development of the R5 Sandwich ELISA for gliadin/gluten determination and the result of the international collaborative trial, which was carried out by WGPAT (details are described in CX/NFSDU 03/4).

However, we have concern about the fact that the “proprietary” aspects of this method could have a negative effect on research aiming to developing alternative methods. A research project is already funded by the European Commission with the aim to define the molecular basis for coeliac disease and to apply this knowledge to develop a new and novel assay to detect toxic gluten peptides in food-products, which could give new perspectives for the future.

Therefore we would like to suggest that any new method, which might be available in the future, should also have the chance to be accepted by CCNFSDU and CCMAS.

Gluten-traces in Gluten-Free Foods:

Gluten analysis in products, which are gluten-free by nature, show in some cases a higher gluten content compared with wheat starch based products. A safe threshold for gluten detection in commercial available test-kits is mandatory for the food industry to detect and avoid contamination in the raw material and also during production procedure e.g. in bakeries.

Recent studies confirm, that the gluten content in wheat starch products is very considerable lower than the proposed threshold of 200 ppm gluten. Although the protein content in wheat starch depends on the harvest and can vary from one year to another, since years some wheat starch products especially made for the gluten-free diet are available with a much lower protein level than 0,3 %, which is the reason for having products on the market with such a considerable reduction of the gluten residue. AOECs appreciates very much the efforts of some wheat starch producers to meet the request of coeliacs as already wrote in the AOECs comment to CCNFSDU five years ago “AOECs asks the manufacturers to continue to work to produce wheat starch at the safest possible level.”

An in vivo challenge study (Catassi et al., 1993) reports about a “toxic” effect caused by a daily intake of 100 mg gliadin. A further unpublished study came to the same result. To calculate a factor of 10 for considering a safe level seems to make sense. Around ten years this is already included in the Draft Revised Codex Standard for Gluten-Free Foods in 7.1. *“It is however important to stress that the total daily intake of prolamins for coeliac patients should not exceed 10 mg per day”*.

Therefore the maximum daily intake of 10 mg prolamins (= 20 mg gluten according to 2.2.2) could be considered as a safe level for most coeliacs, however, not for all: the preliminary result of a study gave indication, that around 10 % seems not to tolerate even gluten traces of 10 mg gluten, whereas 90 % seems to have no problem with such few traces. Of course preliminary results should be taken very carefully, however, coeliac societies know from their work with members that very sensitive coeliacs do exist.

Although it would be very helpful to have only one threshold of “gluten-free” in products, in practise it will be very difficult to come to such an agreement: The large majority of products gluten-free by nature are manufactured without contamination and this quality should remain, but on the other hand the term “gluten-free” for wheat starch based products, which are specially made for coeliacs, is used more than 30 years and coeliacs will not understand, why such products should not be called “gluten-free” any longer, even if the threshold cannot be guaranteed to be as low as in products gluten-free by nature. Coeliacs can easily see on the label of the product, whether it contains “gluten-free wheat starch” to make their own choice whether or not to consume such products.

Oats:

An investigation of all 20 member countries of AOECs shows, that today in 15 countries oats is not allowed in the gluten-free diet. In the rest of 5 countries either coeliacs got individual advice from their doctors, or oats is only permitted for adults or oats is already permitted for adults and it is expected to be extended also for children in the near future. Today only in one country (Finland) oats is already permitted for children and adults. The medical advisory-boards of the national coeliac societies are re-evaluating the research on the toxicity of oats based on the latest reported data. We suggest to postpone any decision regarding oats to the near future.

IWGA – INTERNATIONAL WHEAT GLUTEN ASSOCIATION

The International Wheat Gluten Association’s position is:

- § No new data has become available since then on the tolerable daily intake of gluten by people affected by Coeliac Disease.
- § In order to define the maximum level of gluten in gluten-free foods, food consumption data also needs to be considered, that allows for estimation of the exposure of people to gluten through the coeliac diet, including also the use of wheat starch-based, gluten-free foods.
- § Based on current scientific literature, IWGA considers that a single level for the maximum gluten content of gluten-free foods at 200 ppm, is justified. However, prior to any final decision on the maximum gluten content of gluten-free foods, a validated methodology should be established, that allows for reliable measurement of the gluten content in processed foods, so as to be assured that decisions are based on reliable data.

