

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

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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

- Comments at Step 6 of the Procedure -

Comments from:

AAC - ASSOCIATION OF EUROPEAN CEREAL STARCH INDUSTRY ASSOCIATIONS

AOECS - ASSOCIATION OF EUROPEAN COELIAC SOCIETIES

AAC (ASSOCIATION OF EUROPEAN CEREAL STARCH INDUSTRY ASSOCIATIONS)

We would first like to recall that the AAC supports the ISDI (International Special Dietary Food Industries) position paper on CX/NFSDU 00/4 that was already sent to Codex on 28 March 2000 (see list of supporters of the ISDI position paper in which the AAC is included).

Further to this ISDI position paper, the AAC would like to point out the following elements:

1. Method of analysis

During its 21st session in September 1998, the CCNFSDU correctly noted that "without an appropriate method of analysis it was not scientifically justified to advance the draft further". The AAC would like to confirm that unfortunately there is still today no reliable and accurate method of analysis available for the determination of gluten in foodstuffs and ingredients. Taking into account the absence of such a method, the AAC believes that:

- The gluten-free level should be maintained at 200 ppm for all foods.
- The development of a reliable method of analysis for gluten should be encouraged by all means.

2. Maximum gluten level

The definition of gluten-free foods presently proposed in CX/NFSDU 00/4 makes a distinction between two maximum gluten levels in gluten-free foods (20 ppm and 200 ppm).

The AAC would like to stress that:

- There is no scientific ground for a maximum gluten level lower than 200 ppm
(there is no clinical evidence suggesting that a maximum gluten level of 200 ppm would lead to adverse effects for coeliac patients).
- There is no scientific ground for a distinction between two types of gluten-free foods (with maximum gluten levels at 20 ppm and 200 ppm).

In addition the setting of two different maximum gluten levels for the same type of product (i.e. gluten-free foods) would be confusing for the consumer. Any artificial differentiation (e.g. through different labelling statements) between products 'naturally gluten-free' and products 'rendered gluten-free' would create a misleading and unjustified discrimination between products which are in any case gluten-free and harmless to coeliac patients.

Taking into account the elements mentioned above, **the AAC therefore supports a single maximum level of 200 ppm to define a single category of "gluten-free" foods.**

Paragraphs 2.1 (definition) and 3.1 (gluten-free) of Codex document CX/NFSDU 00/4 should therefore be amended as follows:

- 2.1 Definition: "Gluten-free" foods are foodstuffs consisting of ingredients with a gluten level not exceeding 200 ppm.

- 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 shall not exceed 200 ppm on a dry matter basis. The prolamin content of liquid food products is in the same way expressed in ppm of the original product.

AOECS (ASSOCIATION OF EUROPEAN COELIAC SOCIETIES) comments to the ISDI paper published in CX/NFSDU 00/4-Add.1

Additional to our comments sent to Codex in January 2000 and in order to avoid severe misunderstandings, AOECS would like to clarify that:

* AOECS do not support the ISDI paper.

* AOECS is very surprised that the ISDI paper „should be read in conjunction with the separate paper submitted to CCNFSDU presenting results of a recent discussion between representatives of ISDI, AOECS and the scientific expert group on Prolamin Analysis and Toxicity“: AOECS informed ISDI several days before mailing their paper to Codex that we do not agree to the draft of a „separate paper“.

Regarding to the ISDI comment we think it is very important to clarify:

„Background“:

The draft Codex Standard for gluten-free foods defines three groups according to their gluten content in dry matter basis and not in the endproduct! The difference between dry matter basis and the endproduct may vary considerably up to 100 % or even more, e.g. bread consists of around 50 – 60 % flour, the rest is water, fat and further ingredients. A gluten-free cake contains sometimes only 10 % flour and 90 % other ingredients! To take the value of 200 ppm gluten in dry matter basis (according to the Draft Codex Standard for Gluten-free Foods) and transfer it to the endproduct means a considerable increase of gluten in „gluten-free“ products.

„Analytical methodology“

It is not correct that no analytical method is available. It is well known that a lot of laboratories are using the method adopted by AOAC and some laboratories are using other methods. But of course any improvement/harmonisation of the methodology/reference-standard/antibodies is welcomed for the future.

„Limit of determination“

We agree that more work about the clinical tolerance of gluten-traces should be done, but we think this issue is so difficult that it could not be solved in the near future.

„Naturally gluten-free (20 ppm)“

The paper contains „to control such a low level of 20 ppm is currently virtually impossible“. This is not correct.

Since years there are gluten-free products on the market below this level. It is misleading to give the impression that such foods are not available. According to a study from the National Food Administration in Sweden 105 gluten-free products were analysed, 48 products gluten-free by nature and 9 products rendered gluten-free were below the limit of detection of 20 ppm, that is 54 % of all analysed products. (1)

Dr. Mendez from Spain published in the report of the Working Group on Prolamin Analysis and Toxicity from November 1999 analysis of 1097 food samples: 232 products were below 1,5 ppm gluten, 281 products were between 1,5 and 20 ppm gluten, that means 47 % of the analysed products! (2) In summary: two experienced laboratories achieved nearly the same result with different analytical methods: half of all tested gluten-free products are below 20 ppm gluten.

„Rendered gluten-free (200 ppm)“

It is misleading to calculate a daily intake of 34 mg gluten according to the study of Finland. The real gluten-content of the products is not reported in this study.

According to the above mentioned study of Sweden, from 37 „rendered gluten-free products“ (30 based on wheat starch, 5 on barley starch and 2 on wheat fibre)

9 were below 20 ppm gluten (2 mg/100 g)	24 %
3 between 20–39 ppm gluten (2-4 mg/100 g)	8 %
17 between 40-99 ppm gluten (4-10 mg/100 g)	<u>46 %</u>
summary: 29 products were below 10 mg/100g	78 %
3 between 100-199 ppm gluten (10-20 mg/100 g)	8 %
5 higher than 200 ppm gluten	14 %

„Conclusion“

AOECS do not agree to „a limit of 200 ppm for all foods presented for coeliacs.“

From 105 products of the above mentioned Swedish study 90 products (gluten-free by nature and rendered gluten-free) were below 100 ppm gluten, which are 86 %. The analysis from Spain presents also nearly the same result: from 1097 products 877 were below 100 ppm gluten, which are 80 %.

The Swedish study informed that only 10 products were between 100 and 200 ppm gluten, which are 10 %. The study from Spain also informed that 108 products were between 100 and 200 ppm gluten, that are also 10 % from all analysed products.

Based on the practical situation what we have, it is not necessary to accept 200 ppm gluten in all kinds of gluten-free foods. Coeliac Societies from 17 member countries support this position, one country, United Kingdom, does not agree.

References:

(1)) Malmheden-Yman I., Everitt G. „Gluten in gluten-free products“, National Food Administration, Uppsala, Sweden, published at the poster exhibition at the Seventh International Symposium on Coeliac Disease in September 1996 in Tampere, Finland

(2) Mendez et all „Massive analysis of food samples by a sandwich ELISA based on a unique monoclonal antibody“ Proceedings of the 14th Meeting of the Working Group on Prolamin Analysis and Toxicity in November 1999, page 53 – 61.