



17 November 2005

### **ISDI Position Paper**

#### **Draft Revised Codex Standard for Gluten-Free Foods intended to Gluten Tolerance**

*(Intended for individuals with gluten intolerance)*

**(Alinorm 04/27/26, Appendix III)**

1. The 27<sup>th</sup> Session of the Codex Committee on Nutrition for Special Dietary Uses (CCNFSDU) will take place in Bonn in November 2005.
2. The draft revised Standard for Gluten-free foods has been under debate since September 1992. In September 2001, the Codex Alimentarius Commission recommended that the Standard should not be progressed until there was a scientific basis to support discussions on a method of determination and on clinical levels.
3. Progress has been made on the analytical methodology, which was given temporary Type 1 endorsement by CCMAS in April 2005, awaiting publication of the supporting documentation and the outcome of any CCNFSDU discussions.
4. New clinical research in this field has suggested different tolerable levels of gluten in patients with Coeliac Disease, based on consumption of gluten-free foods, with associated recommendations for residual levels in gluten-free foods<sup>1,2</sup>.

<sup>1</sup> Collin P, Thorell L, Kaukinen K, Maki M. 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.

<sup>2</sup> Catassi C, Fabiani E, Mandolesi A, Bearzi I, Iacono G, D'Agate C, et al. The Italian study on gluten microchallenge: preliminary results. In: Stern M (editor): Proceedings of the 19th Meeting of the Working Group on Prolamin Analysis and Toxicity, 30 September–3 October 2004, Prague, Czech Republic. Zwickau: Verlag Wissenschaftliche Scripten; 2005

5. The federation of the International Special Dietary Foods Industries (ISDI) submitted a detailed position to CCNFSDU (ref. No. 99/435) in March 2002 but has always been prepared to reconsider its position in the light of any new clinical evidence. ISDI now presents its position, on the basis of progress made to date. At this time, ISDI:
- Supports the expert work of the Working Group on Prolamin Analysis and Toxicity (WGPAT) in their efforts to determine a suitable test method and in their work to determine the level of gluten of clinical significance to most coeliac consumers;
  - Believes that a single limit for the maximum permitted gluten content should be adopted for all foods presented for coeliacs;
  - Welcomes the new scientific work completed in an attempt to bring clarity to the issue of tolerable levels of gluten in patients with coeliac disease following a gluten-free diet, however notes that there are serious limitations with these studies (Annex 1) to draw any final conclusions.
  - Considers that current scientific data still justifies a limit of 200ppm gluten for all foods presented for coeliac consumers.<sup>3</sup>
6. ISDI kindly requests that CCNFSDU, at this stage, does not try yet to resolve the debate on clinical levels, or set a safe maximum level of consumption significantly below 200ppm, since
- i. The new clinical studies do not support such a position,
  - ii. The gluten-free wheat starch suppliers cannot give any guarantees that gluten levels significantly below 200ppm will be achievable, year on year, especially in times of poor harvest, and
  - iii. The earlier CCNFSDU discussions on limits to be on an '*as consumed*' basis need to be re-considered within this Standard.

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<sup>3</sup> Kaukinen, K. *et al* (1999) *Scand J. Gastroenterol.* 34: 163-9; Selby, W.A. *et al* (1999) *Scand J. Gastroenterol.* 9:909-914

## ANNEX I

Recent clinical studies on the tolerable daily gluten intake in patients with coeliac disease:

Study	Main Findings	Study Conclusions	Observations/Limitations
<b>Collin <i>et al</i><sup>1</sup></b>	<ul style="list-style-type: none"> <li>• Median daily use of flours in adults was 80g (range 10-300g).</li> <li>• The daily amount of flour intake was mostly &lt;100g.</li> <li>• Specially manufactured gluten free foods contain 50-100ppm gluten or more, all contain &lt;200ppm gluten.</li> <li>• Clinical practice and previous studies have shown that a daily gluten intake of 30mg is safe.</li> </ul>	<ul style="list-style-type: none"> <li>• On the basis that a daily intake of 30mg gluten is safe and that daily consumption of gluten-free foods is not above 300g of flour, an acceptable threshold for gluten in gluten-free products can, from the clinical point of view, be set at 100ppm.</li> <li>• This level can be achieved by industry.</li> </ul>	<ul style="list-style-type: none"> <li>• Daily gluten-free flour intake was estimated, rather than analysed, from 4 day food records.</li> <li>• There is inconsistent use of the terms 'flour' and 'product' leading to confusion.</li> <li>• 300g of gluten-free flour equates to &gt;600g of gluten free product e.g. bread. This is far in excess of normal intake of cereal-based foods.</li> <li>• Not all gluten-free products contain &lt;100ppm gluten, inc. naturally gluten-free foods.</li> <li>• Currently suppliers cannot guarantee supply of gluten-free wheat starch at levels significantly below 200ppm on an ongoing basis.</li> </ul>
<b>Catassi <i>et al</i><sup>2,4</sup></b>	<ul style="list-style-type: none"> <li>• Daily ingestion of a capsule containing 50mg of gluten does not lead to clinical or serological changes.</li> <li>• However, a trend towards minimal histological changes on intestinal biopsy was seen.</li> <li>• Patients challenged with 10mg gluten daily did not show changes in clinical, serological or histological markers.</li> <li>• Mean gluten free flour intake was 150g (range 50-300g)<sup>3</sup>.</li> </ul>	<ul style="list-style-type: none"> <li>• 10mg of gluten should be considered the maximum tolerable daily intake of gluten in treated coeliac patients.</li> <li>• Based on a daily intake of 300g of gluten-free flour, the maximum level of gluten in gluten free foods should be no more than 20ppm<sup>3</sup>.</li> </ul>	<ul style="list-style-type: none"> <li>• No adverse effect was seen with a daily gluten intake of 10mg and minimal changes on 50mg, therefore the acceptable maximum level of gluten is most probably between 10mg and 50mg per day.</li> <li>• Dietary intake data was collected only from an interview with a dietician.</li> <li>• 300g of gluten-free flour equates to &gt;600g of gluten-free product e.g. bread. This is far in excess of normal intake of cereal based foods.</li> </ul>

<sup>4</sup> Catassi C. (2005) Oral Presentation. Round Table discussion 'Is there a safe threshold for gluten contamination?' Associazione Italiana Celiachia (AIC) Meeting" Coeliac Disease from basic research to therapeutic perspectives". 15 -17 April, 2005 Florence