



15 September 2006

**ISDI Q&A on
Gluten-free Foods Standard
At step 6 of the procedure**

1. Should the maximum 200 ppm for products rendered gluten-free (GF) be lowered?

To date, there has not been conclusive scientific evidence to suggest that the current proposal for a maximum gluten level, in gluten-free (GF) foods which have been rendered GF, should be lowered. Two recent studies carried out by researchers in Finland and Italy did not provide strong scientific substantiation to propose a clinically significant intake level, to require a lowering of this maximum level from 200 ppm.¹ However, as processing capabilities on supply of 'rendered' wheat starch have improved over the years, it is now possible for suppliers to provide 'rendered' gluten free wheat starch at levels below 200 ppm. The WGPAT (the Working Group on Prolamin Analysis & Toxicity), in their response to the CCNFSDU Secretariat (CX/NFSDU 06/28/5) proposes a reasonable compromise between one level at 20 ppm and one level at 200 ppm i.e. 20 ppm and a lowering of the level for rendered GF products to 100 ppm since the scientific research so far does not show that 200 ppm is unsafe.

From the outset, ISDI position² is to await recommendations from the WGPAT and would be likely to accept such a lowering, as a compromise, in the interest of making progress on this Standard. However, there is uncertainty over long term supply of GF wheat starches at low gluten levels.

2. Is there a need to differentiate in labeling between naturally GF and rendered GF products?

Currently, there is no legal labelling differentiation of products on the market whether they are 'naturally' GF or 'rendered' GF. Consumers have accommodated for this situation with help from their healthcare professional or by looking closely at labels. Any change to such a situation could lead to confusion and the need for major re-education of coeliac patients. There is an informal practice in the UK (and apparently Germany) for companies to add a further clarifying statement e.g. wheat-free, for those products which are 'naturally' GF. The UK industry believes that this system works well while there is no legal differentiation, and could be continued if two levels are finally adopted in the draft GF Standard.

However, ISDI suggested² to seek advice on labelling from the WGPAT and now welcomes the proposal made by WGPAT to CCNFSDU to have one label statement with the botanical origin of the specific cereal included in the ingredients list. ISDI is concerned with the proposal made by Peru i.e. to consider terminology such as 'low gluten' or 'reduced gluten' for products containing trace amounts of gluten e.g. those rendered gluten-free. Although this practice was adopted in Australia, such

labelling could lead to restricted choice, consumer concern and confusion which may ultimately jeopardise dietary compliance. For example, if the consumer preferred GF wheat starch-based products, and had been consuming these over a long period of time, but changed their dietary habits due to concerns with the different labelling statement while the product remained the same.

3. Can oats be considered suitable for celiac patients?

The scientific community does not have a definitive position on whether oats can be included in the diet of people with CD⁴. There is an awareness of widespread contamination of oats by other cereals which is difficult to control. Researchers from the WGPAT have discussed this situation but no position agreed. ISDI suggests that the debate needs to be fully resolved by the scientists, including gastroenterologists.

4. May the R5 ELISA method for gluten analysis be included in the standard?

In May 2006, the CCMAS finally endorsed the R5 ELISA method as a Type1 method for the determination of gluten in GF foods after the submission of scientific literature in support of the methodology.⁵ ISDI believes that this method should be accepted and named in the Standard as the approved method for the determination of gluten in GF foods as the most sensitive method available *at this moment in time*. The limitations of the method e.g. its inability to measure glutenins, are recognised by those using the method but it is proven to be significantly more accurate than methods of the past (and is already being used by many laboratories across Europe). Incorporation into the Standard does not preclude the opportunity for any further methodologies being proposed and assessed, subject to new developments and scientific progress.

ANNEX: Literature References

1.

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

**publication of work awaited*

Collin P, Thorell L, Kaukinen K, Maki M. (2004): The safe threshold for gluten contamination in gluten-free products. Can trace amounts be accepted in the treatment of coeliac disease? *Aliment Pharmacol Ther* 19:1277–1283

2. ISDI (International Special Dietary Foods Industries) comments to CNFSDU on GF Standard CX/NFSDU 06/28/5 (ISDI Ref. 06/238, 13 June 2006)

3. Position Paper prepared by R. Ward, Coeliac Society of UK, February 1999

4.

Janatuinen, E.K. *et al* (1995): A comparison of diets with and without oats in adults with coeliac disease *New Engl J Med* 333: 1033-1037

Lundin, E.K.A. *et al* (2003): Oats induced villous atrophy in coeliac disease *Gut* 52: 1649 - 1652

5.

Valdés *et al* (2003): Innovative approach to low level gluten determination in foods using a novel sandwich enzyme-linked immunosorbent assay protocol *Eur. J Gastroenterol* 15: 465-474

Garcia *et al* (2005): Development of a general procedure for complete extraction of gliadins for heat processed and unheated foods *Eur J Gastroenterol* 17: 529 – 539

Mendéz *et al* (2005): Report of a collaborative trial to investigate the performance of the R5 enzyme linked immuno assay to determine gliadin and gluten-free food *Eur J Gastroenterol* 17: 1053-1063