

Systematic review on tolerable levels of gluten for people with coeliac disease

Area of research interest: [Food hypersensitivity](#)

Study duration: 2006-02-01

Planned completion: 1 September 2006

Project code: T07048

Conducted by: Coeliac UK

Background

Coeliac disease is a life-long autoimmune disease caused by intolerance to gluten, a protein found predominantly in wheat, barley and rye cereals. Consumption of gluten causes damage to the gut lining, resulting in a wide range of symptoms such as bloating, diarrhoea, and nausea, as well as longer term health consequences if the disease is not managed. Management involves a strict gluten-free diet.

There has been much scientific uncertainty about what residual level of gluten in the diet is safe for those with coeliac disease, and there is currently no European or UK legislation defining 'gluten-free'. A draft Codex Standard developed in 1983, proposed a limit of 200 mg/kg of gluten in foods made from gluten-containing cereals that have been treated to reduce their gluten content and 20mg/kg for naturally gluten-free foods, and more recently there has been a proposal to reduce these thresholds to 100mg/kg for the former category and 20mg/kg for the latter. But this Standard had not been formally adopted (see below for an update on the situation with the Codex Standard) and there remains scientific uncertainty about safe thresholds of gluten for coeliacs.

This study was commissioned to evaluate published scientific articles that had investigated safe threshold amounts of gluten in foods in order to determine if it was possible to propose a clinical threshold dose of gluten or a threshold concentration of gluten in food products that would be tolerated by all people with coeliac disease.

Research Approach

The researchers carried out a systematic review of all the scientific studies published between 1966 and March 2006 that had examined the relationship between the amount of gluten ingested or the concentrations of gluten in food products, and the development of symptoms or gut mucosal abnormalities in coeliac patients. Data were identified using pre-defined literature searching databases and reference lists of retrieved articles. Data from articles was extracted and various statistical analyses applied to see if it was possible to determine a statistically robust threshold level of gluten that coeliacs can tolerate.

Results

Twelve studies met the review criteria. The amount of gluten consumed, timescales of the studies and the ways in which effects of gluten were assessed, varied greatly between studies, and this complicated their interpretation.

The evidence indicated that a daily consumption of 200 mg or more of gluten clearly induced gut mucosal abnormalities. In two studies, the ingestion of an average of 34 - 36 mg of gluten daily did not cause histological changes or clinical symptoms, but in a further study, a much smaller dose of gluten (1.5 mg daily) triggered symptoms.

The effect of the consumption of 'gluten-free' products with different degrees of gluten contamination was also inconsistent between studies. Whilst some people tolerated current Codex standard 'gluten-free' products (less than 200mg/kg gluten), others developed histological abnormalities whilst consuming the same products.

The researchers considered that it is likely that it is the total amount of gluten ingested over time rather than the concentration of gluten in the food product that is important. The researchers concluded that there was some evidence that the current Codex standard (see below for an update on the situation with the Codex Standard) of 200ppm gluten in gluten-free foods is not sufficiently protective for all people with coeliac disease and so there may be a case for lowering this. However, the researchers considered that there is insufficient evidence from this review with which to propose a clinical threshold dose of gluten or a threshold concentration of gluten in food products that would be tolerated by all people with coeliac disease.

An important and relevant study published after the review by Catassi et al., (Am J Clin Nutr. July 2007), concluded that the ingestion of gluten should be kept at lower than 50mg gluten per day in the treatment of coeliac disease, adding further weight to the case for lowering the maximum limit for gluten in gluten-free foods, below 200mg/kg.

The Agency, as the food regulatory body for the UK, has taken account of the results of this project in contributing to the Codex discussions on gluten-free thresholds that were held in November 2007 in Berlin, in recommending to Codex that the Standard is revised to lower the maximum level of gluten permitted in wheat starch based gluten-free foods, from 200 mg/kg to the proposed level of 100mg/kg, and to set the maximum limit for naturally gluten free foods at 20mg/kg. The Standard, containing these threshold levels, was agreed at that meeting and it will now be put forward for adoption by Codex during 2008.

Dissemination

For any enquiries concerning this research project, please contact the relevant Programme contact or email: cst@foodstandards.gsi.gov.uk

Published Papers

1. Akobeng, A. K. and Thomas, A. G. (2008). Systematic review: tolerable amount of gluten for people with coeliac disease. *Alimentary Pharmacology and Therapeutics*. 27: 1044-1052.

Research report

England, Northern Ireland and Wales

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