

Modifying the gluten-free threshold for foods: first do no harm

TO THE EDITOR: The gluten-free (GF) diet for people with coeliac disease (CD) is complex, costly, and compliance with the diet is variable. Coeliac Australia, with the Australian Food and Grocery Council, are lobbying to increase the mandated gluten threshold for GF foods.¹ The situation in Australia since 1995 has been that there must be “no detectable gluten” in foods labelled “gluten free”. The proposed new standard is “< 20 parts per million (ppm)”. This has been proposed because food testing has become increasingly sensitive over the years, resulting in fewer foods being considered gluten free. The current detection level of food testing is about 3 ppm. Unfortunately, the proposed new GF standard may not be safe for patients with CD.

There are few high-quality studies determining a safe gluten intake for patients with CD, although it is known that tolerable amounts vary between patients.² In one study, 42 patients with CD who were eating a GF diet received 0, 10 or 50 mg of gluten daily for 3 months (10 mg in 500 g of food represents 20 ppm; 10 mg gluten is ingested in 1/250th of a slice of bread containing 2.5 g gluten). Patients’ duodenal mucosa were examined histologically before and after the gluten challenge. The study concluded that, for patients with CD, the daily dietary intake of gluten should be < 50 mg.³ This study has been interpreted as suggesting that 10 mg of gluten daily is safe.¹ Regrettably, the patients in the study were a selective group, possibly less sensitive to gluten and, of those receiving 10 mg of gluten daily, one had symptomatic relapse and several showed worsening CD on histological examination.³ It is therefore surprising this study has been particularly influential in recommending a GF standard of < 20 ppm.¹

In 2011, a comprehensive United States Food and Drug Administration (FDA) safety report concluded that gluten levels in food of < 1 ppm are required to protect the greatest number of patients with CD.⁴ Despite

this, a long-awaited FDA ruling, released on 2 August 2013, sets the GF standard at < 20 ppm.⁵ This formalises tighter standards than previously existed in the US. Establishing a standard is complex, requiring consideration of issues such as industry and consumer concerns, industry regulation, economics, international precedent and safety.

The concept of doing no harm in health care is paramount. In Australia, where concerns about the availability of GF foods have been raised,¹ it may be prudent to allow GF foods an increase in “measurable” gluten (eg, from undetectable to < 1–3 ppm). By contrast, increasing the “permissible” level of gluten (from undetectable to < 20 ppm) will increase overall gluten ingestion in a GF diet. For an undetermined proportion of patients with CD, this will lead to adverse health outcomes and generate additional health care costs.

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- 1 Coeliac Society of Australia. Submission dated 25 July 2008. Melbourne: Australian Government Productivity Commission. 2008. http://www.pc.gov.au/_data/assets/pdf_file/0008/82286/sub046.pdf (accessed Aug 2013).
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- 5 United States Food and Drug Administration. FDA defines “gluten free” for food labelling [media release]. 2 Aug 2013. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm363474.htm> (accessed Aug 2013). □