

- **A PROPOSED REVIEW of STANDARD for GLUTEN (GF) LEVELS in FOOD:**

(a) Equally, why not a similar review of the standard for wheat products generally? This is the crucial issue. Celiac disease (CD) is usually regarded as having a solely genetic basis, when in fact the rapidly rising prevalence of CD can be traced not simply to improved diagnostics, but to the changed nature of wheat. Modern wheat is markedly different to the product grown over the past 10,000 years, even over the past 5,000 years. Significant changes in wheat have occurred over the past 50 years, reflected by the four fold increase of coeliac disease (CD) over the same period, not to mention the rapid rise in gluten intolerance and various wheat allergies. Yet this modern-day product is misleadingly still called “wheat”.

CD is repeatedly showing itself in new ways besides disruption of intestinal health. The changing face of CD is believed to be due to changes in wheat itself. There have been > 25,000 different wheat cultivars in recent times. [See APPENDIX A].

'Modern commercial wheat production has been focused on delivering features such as increased yield, decreased production costs, and large scale production of a consistent commodity. All the while no questions are asked about whether these feature are compatible with human health'. This needs to be urgently addressed.

'Gluten is not the only potential cause of ill-health arising from wheat. Beyond gluten, the other 20% or so of non-gluten proteins in wheat include albumins, prolamins and globulins, each of which can also vary from strain to strain' In total there are more than a 1000 other proteins functioning in wheat.'

'Beyond coeliac disease.... there are allergic or anaphylactic (a severe reaction resulting in shock) reactions to non-gluten proteins.. Exposure in susceptible individuals triggers asthma, rashes (atopic dermatitis and urticaria) and a curious and dangerous condition called wheat-dependent exercise-induced anaphalaxis (WDEIA), in which rash, asthma or anaphylaxis are provoked during exercise.'

In addition to an apparent genetic predisposition 'various environmental factors play an important role in triggering or “unmasking” coeliac disease.' ['Food Safety, Issues in society, Ed Justin Healey, Volume 397, page 46].

[See also APPENDIX B, Bio Med Central].

(b) The wheat industry needs to take responsibility for its role in precipitating CD and related health issues.

(c) Why not similar reviews of the standard for other allergy-causing ingredients such as peanuts, nuts, fish, shellfish, eggs, milk, soy, etc? Clearly there is a special issue surrounding gluten.

The PC needs to provide the names of companies which want this lowering of the standards for gluten free products. Is it just one company or how many? Importers or Australian based companies? Why would some GF companies now want to lower their currently high standard at

the same time as they are reaping multi-billion dollar profits in a rapidly growing market? There is no shortage of money – they can afford top notch testing equipment for scientifically validating levels of gluten in their products. But under a new FDA standard for GF in USA, manufacturers would not be required to do their own testing. This raises ethical issues. ***How reliable, how safe would imported GF products be? Is the Productivity Commission suggesting Australian regulators should simply copy the unsatisfactory US FDA model? Would clients of Australian manufactured GF products be forced to accept a less safe product?***

The problem for many with coeliac disease is that gluten brings with it other health problems. Research in the field is still in its infancy. While some individuals may appear to tolerate a gluten level of as much as 20ppm in a product, many others may not. Children diagnosed with CD commonly display no symptoms. Health impacts often reveal themselves later in life. “Gluten Free” must be genuinely gluten free – no contamination.

(d) This focus on a review of gluten levels alone strongly suggests that some producers of GF foods– or some prospective producers of GF foods) – are not dedicated to the task. Or that they are not educated in food safety. Or that they are putting profits before the best interests of their clients. This is totally unacceptable. No-one should be allowed to enter into these niche markets without demonstrating to health authorities they are qualified for the task.

Regulators need to be especially active and vigilant in this area. ***It appears most people will be adversely affected by wheat at some time during their lifetimes.*** FSANZ needs to be expanded and upgraded to meet 21st century needs, with sufficient professional staff and resources to carry out their role and their duty of care. Most importantly, FSANZ must be ***genuinely*** independent, not the 'captive agency' we have at present. If Australia is to be more agile and innovative and lead in science and health, then the work of our independent medical researchers and regulators needs to be highly prioritized and resourced.

(e) THIS IS A FOOD SAFETY ISSUE.

(f) The simple answer for those manufacturers wanting to allow traces of gluten into their products, is that potential clients requiring genuinely Gluten Free will not buy that product. Grains are not necessary in the diet. Wheat is not necessary in the diet. Those companies not dedicated to providing a truly GF product for their clients will need to move to a different business avenue. Dedication is a highly valued ingredient.

As with traces of nuts, peanuts, shellfish etc, 'cutting red tape' by allowing traces of gluten is not an option. ***All foods are assimilated at a molecular level.*** Zero gluten content in a food product is necessary for those with coeliac disease and possibly also for those with other related gluten issues.

(g) The argument that Australia should copy regulators in other countries, like USA, is deeply flawed as we discovered after contacting US FDA last week.

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362880.htm>

- **All those with coeliac or gluten issues should take special note that US FDA appears to be misleadingly perpetuating the notion that celiac disease is solely due to inheritance. The role of modern wheat is ignored.**
- **US FDA also appears to be ensuring that the interests of American Gluten Free manufacturers are put before the interests and welfare of their clients. “GLUTEN FREE” is no longer ensured in their products so labelled.**
- **Also that the current Australian government, to its disgrace, appears to be following like sheep by proposing a lowering of our Australian standards for the convenience of gluten free manufacturers with sloppy standards, to arrive at “a level playing field”. (See “Who does the rule benefit?” below).**
- **The resulting “level playing field” would be a 20ppm contaminated one.**

On its above website, US FDA, has this to say:

“Who does the rule benefit?”

These actions benefit people with celiac disease, an inherited chronic inflammatory auto-immune disorder that is estimated to affect up to 3 million Americans. For people who have celiac disease, consumption of gluten results in the destruction of the lining of the small intestine and the risk of other serious health conditions. The definition also benefits the food industry by establishing a level playing field among manufacturers of products labeled “gluten-free.”

➔ *This strongly suggests the multi-billion dollar GF manufacturing industry wants to benefit by lowering the standard for gluten free to save themselves the time and expense of producing a quality, genuinely gluten free product for their clients, and FDA is bowing down to their pressure. What kind of standard would that “level playing field” end up having?*

“Gluten Levels

1. Why didn’t FDA adopt zero ppm gluten rather than less than 20 ppm gluten as one of the criteria for a food labeled gluten-free?

FDA used an analytical methods-based approach to define the term gluten-free and adopted < 20 ppm gluten as one of the criteria for a food labeled gluten-free because the agency relies upon scientifically validated methods for enforcing its regulations. Analytical methods that are scientifically validated to reliably detect gluten at a level lower than 20 ppm are not currently available. In addition, some celiac disease researchers and some epidemiological evidence suggest that most individuals with celiac disease can tolerate variable trace amounts and concentrations of gluten in foods (including levels that are less than 20 ppm gluten) without causing adverse health effects”.

When we wrote to FDA with these queries below, they would not answer and could only suggest we join a petition.

➔ *What was the analytical methods-based approach used to define the term gluten free,*

causing them to adopt < 20 ppm gluten as one of the criteria for a food labeled gluten-free?

➔ *What are the scientifically validated methods FDA relies on for enforcing its regulations?*

➔ *FDA would not disclose how many “some” are in relation to celiac disease researchers, nor would FDA disclose what the “some epidemiological evidence” was. “Some” is imprecise and unprofessional. FDA did not disclose the views of other celiac researchers or discuss other epidemiological evidence that apparently disagreed with the conclusions on which FDA based its decision about gluten levels. This is biased, unscientific and unacceptable.*

➔ *FDA incorrectly states under “Gluten levels”: “Analytical methods that are scientifically validated to reliably detect gluten at a level lower than 20 ppm are not currently available”. This is blatantly untrue. It is at odds with America's claims to be world leader in science. This is also invalidated by their following statement under “Gluten levels” which discusses the availability of detected levels of 5 or 10ppm gluten: (See below).*

2. “A manufacturer’s foods labeled gluten-free are certified by a third-party organization to contain either less than 5 or 10 ppm gluten, which is lower than the final rule’s criterion of less than 20 ppm for a food labeled gluten-free. May manufacturers state on the label that their foods contain less than 5 or 10 ppm gluten?”

The final rule does not prohibit manufacturers from stating any truthful and non-misleading information on their food labels, including declaring the maximum amount of gluten the food may contain. However, doing so would mean that each food bearing the label statement does not contain gluten at a level that exceeds the amount declared”

➔ *Having made available a gluten safety assessment for gluten exposure for people with celiac disease in 2011, FDA announced only a “tentative conclusion to follow the approach in the proposed rule”. Medically speaking, “tentative” is not good enough.*

➔ *As a result of this unsatisfactory encounter with FDA we wrote to the Productivity Commission asking that these observations be included in our submission, asking that unacceptable deficiencies, discrepancies / errors in the FDA website be noted. It confirms the lack of trust and confidence in the US FDA felt by so many of us here in Australia, and shared by millions of Americans. That lack of trust spills over to our Australian regulators, who appear to rely heavily on the US FDA .*

The US response to coeliac diseases is far behind countries like Italy, because there is no screening of children, so no one really knows the true rate of incidence in US. What screening for CD in children is done in Australia? What is done for children at all? What would the outlook be for children, were this proposed eroding / corrupting of essential regulatory standards to be vetoed?

(h)Possibilities are open for Australian companies to provide a competitive organic GF product. If some international companies are no longer willing - or competent enough - to supply a top quality GF product, let Australia become the champion GF producer and exporter. Australia has the brains and grains. Ca 3 million Americans are diagnosed with CD ; many more are believed to be, as yet, undiagnosed.

(i)Western Australia (like Australia) wants to build its tourism industry but it lacks the Gluten-Free Friendly credentials. Asking for this review sends a negative message about Australia, it gives a poor image, it conveys a lack of know-how, innovation and care. It lacks the cultural advancement, dedication and commitment of Italy.

“...the country didn’t just know about celiac disease, they accepted it. They embraced that this was an issue and moved around it to accommodate their meals, and did so with gusto. I asked Letizia and she gave a thoughtful response: that Italians are very conscious of the connection between health and food”. (Tourist family in Italy). <http://www.legalnomads.com/gluten-free/italy>

“The exposure goes much deeper than that. Children are routinely screened for celiac disease in Italy, and celiacs receive a state subsidy to compensate them for the higher cost of gluten-free foods. Furthermore, Maria Ann Roglier, the author of [The Gluten-Free Guide to Italy](#), notes that Italian law requires that gluten-free food be available in schools, hospitals, and public places. And that you can study for a masters in celiac disease, from diagnosis to management thereof.”

Children with coeliac disease receive a €140 monthly stipend to cover the additional cost of food, as well as extra holiday time. In addition, there is the fact that food is central to Italian life and community.

Associazione Italiana Celiachia publishes a restaurant guide and provides annual reports for the Italian Parliament.

Italy also provides a travel card for tourists. The **English** version: I have celiac disease, and I cannot eat gluten, which is found in wheat, barley, rye, orzo, farro, and often in oats. I will become very ill if I eat food, marinades, soup or sauces containing wheat, barley, rye, semolina, or oats. This disease affects me if I eat these ingredients, but also if the food is fried in the same oil used to fry unsafe foods. In those cases, the cross-contamination will also make me sick. Even a sprinkle of flour on the grill pan, or in the sauce or soup will make me ill. I cannot eat soup that has bread blended into it, or meat/sausages with bread as an ingredient (such as meatballs or some sausages). Can you please help me choose something that does not include any wheat, rye, barley, oats, bread or pasta? I can eat food containing rice, chickpeas, tapioca, cassava, potatoes, corn, beans, lentils, vegetables, cheese, fruit, eggs, meat, chicken, or fish – as long as they are not cooked with wheat flour or breadcrumbs. This means I also cannot eat battered or breaded dishes, unless they are breaded in only rice flour, corn flour, chickpea flour or tapioca flour, and fried in separate uncontaminated oil. Thank you for your help. I am sorry for any inconvenience this may cause you,

but I have to be very careful when I eat. **Read on.....**



Sono celiaco/a, non posso mangiare glutine. Frumento, orzo, kamut, farro, segale e spesso l'avena contengono glutine.

Mangiare pietanze, cibi marinati, zuppe o salse che contengono frumento, orzo, segale, farro, kamut causa gravi sintomi di intossicazione. I sintomi si manifestano anche nel caso in cui il cibo sia fritto in olio utilizzato per friggere pietanze contenenti glutine. La contaminazione incrociata dovuta per esempio anche ad un pizzico di farina sulla piastra, o nella salsa o nella zuppa anche porta a gravi sintomi di intossicazione. Non posso mangiare zuppe che contengono pane, o carne o salsicce che contengono pane (come le polpette o alcuni insaccati e o le cotolette).

Mi può consigliare delle pietanze che non contengano frumento, segale, orzo, avena, farro, kamut, pane o pasta?

Posso mangiare riso, ceci, tapioca, manioca, patate, mais, fagioli, lenticchie, vegetali, formaggio, uova, pollame e pesce - l'importante è che non siano cotti con farina di frumento o semola o pangrattato. Non posso mangiare cibi in pastelle o impanati, a meno che non contengano esclusivamente farine di riso, ceci o tapioca, e fritti in olio non contaminato dal glutine.

Grazie per il suo aiuto. Mi scuso per le mie richieste speciali, ma devo essere estremamente attento/a a ciò che mangio.

www.legalnomads.com

Click on this card to save to your computer or phone.

A big thanks to Alanna Tyler and Letizia Mattiacci for their help in translating this card.

Australia has a lot of catching up to do. Children in Australia are not likely to be diagnosed

until age eight or much older, if they are lucky. What is Australia doing for its children? In Alberta Canada (Stollery Childrens Hospital) the number of children diagnosed with CD increased 11 fold from 1998 to 2007. 53% displayed no symptoms, but reported feeling better with gluten diminished. There seems to be a fundamental change in the disease – suggesting that something in wheat itself indeed changed sometime over the past 50 years.

See also:

INDEPENDENT UK <http://www.independent.co.uk/life-style/food-and-drink/features/gluten-free-food-in-italy-the-land-of-pizza-and-pasta-is-remarkably-clued-up-about-catering-for-9670164.html>

Italians are understandably in the lead in dealing with the issue, but the rest of Europe isn't far behind. The Swedish government sends gluten-free staples to families of coeliac children for a subsidised €12 a month until they are 18.

We were advised at the PC hearing that traditional pasta has gluten added to give it elasticity when shaped and cooked. Like many we are fans of Italian cooking. To the credit and ingenuity of some Italian companies, a variety of delicious GF pasta is now available, with vegetables added to improve nutritional value and fibre. Also to the credit of Italian farmers, they are producing einkorn wheat, the original ancient form. What are Australian farmers doing? And what are Australian regulators doing to assist them? Helpful strong regulation is needed.

(j) Full Gluten Free labelling is essential. The “Gluten Free” label should only apply to genuinely Gluten Free products. An indication of zero gluten is the key selling point. The standard for GF labelling needs to be raised in Australia. If a product is found to have a gluten content above zero but is labelled “Gluten Free”, this is an error in labelling and should be dealt with accordingly.

Looking on supermarket shelves lately, we observe most processed GF food products are imported, selling at considerably higher prices than non-GF foods. Labeling gives no indication of the standard used by the countries of origin, so it is not possible to know gluten content. We saw only one GF product that is (US) Certified Organic. At times it was difficult to find the GF label. Obviously products with easy-to-find labels gain more custom and respect.

(k) Electron microscopy / SEM techniques provides the best tool for necessary detection of gluten at a molecular level. Could this be a multi-use tool, not only for maintaining zero gluten levels in foods, but also used to advance Australia's medical research into wheat-related health issues? CD is the prototype for wheat intolerance, a standard against which we compare all other forms of wheat intolerance. In turn could knowledge gathered assist in finding grains that are naturally safe and compatible for 21st century citizens?

Italian Enzo du Fabrizio at the Italian Institute of Technology in Genoa, became a world leader in 2012, being the first to use electron microscopy to detect the structure of DNA. It was anticipated the technique would let researchers see how proteins, RNA and other biomolecules interact with

DNA. I don't know what advances have been made since then, but for a country like Australia that also needs to advance its science capabilities; greater understanding of the history of gluten in wheat would be an excellent start.

NEGLIGENCE?

It seems unwise indeed for Australia to bow down under questionable pressure to introduce GM wheat. *Already the serious health issues associated with existing non-GM modern wheat strains are not being addressed, they have not been resolved.* This negligence is raising mounting concerns on many fronts and “crunch-time” is imminent. A crash in our export markets in this one area could be disastrous. Being led down the GM Wheat path it already seems to be embarking on, would drag Australia in a one-way direction – there is no recalling once it is released into the environment. Australia would remain tied to subsidizing overseas Biotech corporations indefinitely, supposing a market for USA GM wheat is being contemplated.

Australia urgently needs to evaluate the health status of the present wheat cultivars it currently produces and use its own powers of innovation to come up with a safe, superior alternative. I can think of a number of ways that can possibly be explored and can't understand why our conventional plant breeders have not.

APPENDIX A :

'Modern wheat is not the same grain our predecessors used over tens of thousands of years – Einkorn. Einkorn is not unhealthy and many hundreds of generations of people were well adapted to it. Modern wheat has a markedly different genetic make-up, it has many more chromosomes. It has undergone countless new formations since our grandparent's day, and has been changed significantly in the past 50 years by scientists. It has been hybridised, cross-bred and introgressed to produce a plant resistant to environmental conditions, e.g. to drought or pathogens such as fungi'.

'Deliberate changes to the genetic structure are mostly focused on increasing yield per acre. Today the average yield has increased as much as tenfold since a century ago. Such enormous yields have required drastic changes to the genetic code. Scarcely resembling einkorn at all, it is now the stiffly upright, 45 cm tall, high production 'dwarf' wheat of today. Such fundamental changes have come at a price to human health'.

'The science of genetics has progressed over the past 50 years permitting human intervention at a much more rapid rate than nature's slow, year by year breeding influence. The pace of change has increased exponentially. It is a process of evolutionary acceleration. From original strains of wild grass harvested by humans, has exploded to more than 25,000 varieties, virtually all the result of human intervention'. Dr William Davis (cardiologist)

https://en.wikipedia.org/wiki/William_Davis_

<http://www.wheatbellyblog.com/>

'Elsheva Rogosa, founder of the Heritage Wheat Conservancy ([ww.growseed.org](http://www.growseed.org)) is devoted to preserving ancient food crops and cultivating them using organic principles. Traditional eikorn bread has a rich, subtle and complex flavour, unlike modern wheat which tastes like cardboard.

Original wheat is not unhealthy. Instead yield-increasing, profit expanding and practices of past few decades are a source of adverse health effects of wheat. Einkorn and Emmer are seen as a solution restoring original grasses, grown under organic conditions to replace modern industrial wheat'.

APPENDIX B

<https://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-10-13>

Spectrum of gluten-related disorders: consensus on new nomenclature and classification

BIOMED CENTRAL Anna Sapone et al, 2012

'CD is one of the most common disorders in countries predominantly populated by people of European origin (for example, Europe, North and South America and Australia) affecting approximately 1% of the general population. Interestingly, recent studies indicate a trend toward a rising prevalence of CD during the last several decades for reasons that are currently unclear [15, 16].'

'Conclusions

It is now becoming apparent that reactions to gluten are not limited to CD, rather we now appreciate the existence of a spectrum of gluten-related disorders. The high frequency and wide range of adverse reactions to gluten raise the question as to why this dietary protein is toxic for so many individuals in the world. **One possible explanation is that the selection of wheat varieties with higher gluten content has been a continuous process during the last 10,000 years, with changes dictated more by technological rather than nutritional reasons. Wheat varieties grown for thousands of years and mostly used for human nutrition up to the Middle Ages, such as *Triticum monococcum* and *T. dicoccum*, contain less quantities of the highly toxic 33-mer gluten peptide [65]. Apparently the human organism is still largely vulnerable to the toxic effects of this protein complex, particularly due to a lack of adequate adaptation of the gastrointestinal and immunological responses.**

Additionally, gluten is one of the most abundant and diffusely spread dietary components for most populations, particularly those of European origin. In Europe, the mean consumption of gluten is 10 g to 20 g per day, with segments of the general population consuming as much as 50 g of daily gluten or more [66, 67] **All individuals, even those with a low degree of risk, are therefore susceptible to some form of gluten reaction during their life span. Therefore, it is not surprising that during the past 50 years we have witnessed an 'epidemic' of CD [68, 69] and the surging of new gluten-related disorders, including the most recently described GS [44, 62]. This review provides some rationale to explain these epidemiological phenomena and expands our current knowledge to gain more insights into gluten-related disorders.'**

(GS = Gluten sensitivity).