



Gluten-Free Foods





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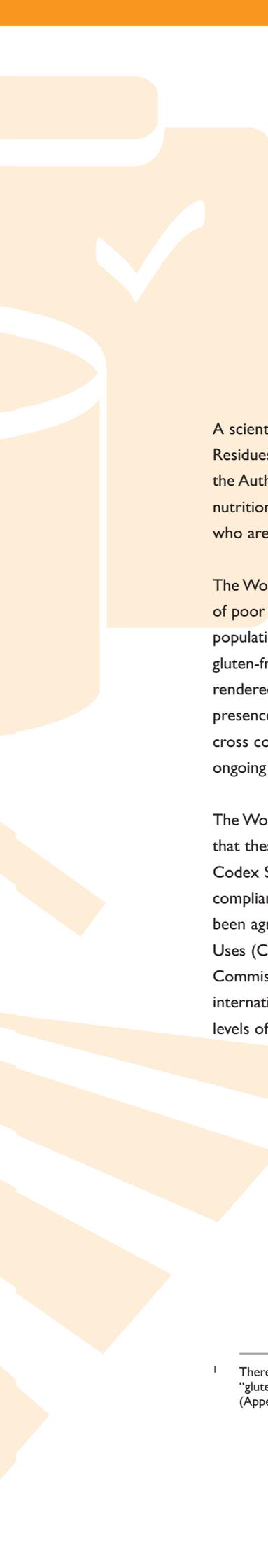


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EXECUTIVE SUMMARY

A scientific Working Group on Gluten set up under the auspices of the Additives, Contaminants and Residues Sub-committee of the Food Safety Authority of Ireland's Scientific Committee, has advised the Authority on issues of relevance to the coeliac condition, including the gluten-free diet, its nutritional quality and the need for Irish standards for levels of gluten in food suitable for people who are intolerant to gluten.

The Working Group on Gluten concluded that the coeliac condition is a potentially significant cause of poor health in the Irish population, with a prevalence of five to ten cases per 1,000 of the adult population. Adverse health effects in affected persons can be controlled by strict adherence to a gluten-free¹ diet or one that is low in gluten due to use of cereal ingredients that have been rendered gluten-free. Nonetheless, unintended exposure may occur as a consequence of the presence of gluten in foods believed by the consumer to be gluten-free or low in gluten, due to cross contamination during production or manufacture. It is therefore essential to maintain an ongoing programme of surveillance of such foods.

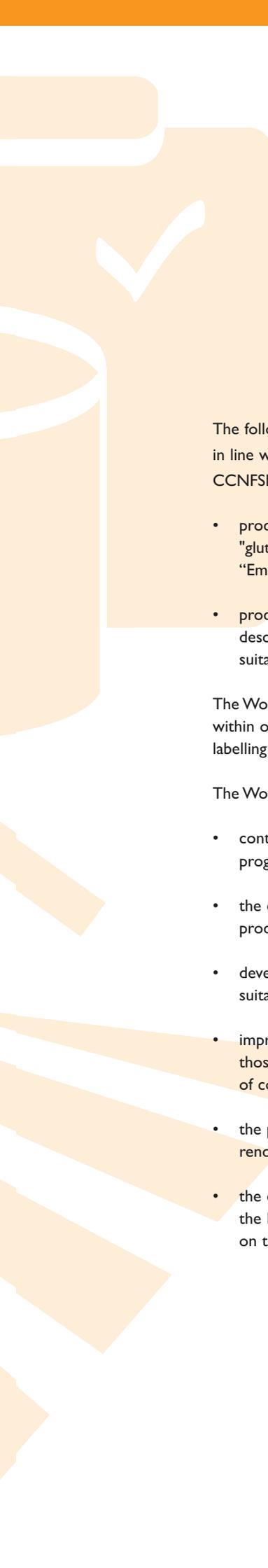
The Working Group reviewed currently available analytical techniques for gluten in food and noted that these appear to present improved alternatives to the method laid down in the out-dated 1983 Codex Standard for gluten-free food. There are limitations to the use of this standard in assessing compliance of a food product with food safety legislation, and a new Codex Standard has recently been agreed by the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), at its 2007 meeting. This will be forwarded at Step 8 to the Codex Alimentarius Commission for adoption in 2008. This Codex Standard, together with other developments at international level, has been taken into account in making recommendations for guidance values for levels of gluten in food suitable for people who are intolerant to gluten.

¹ There is considerable discussion about what constitutes a gluten-free food as outlined further in this report. The terms "gluten-free", "reduced-gluten", "rendered gluten-free" and "nominally-gluten-free" are further defined in the Glossary (Appendix II).

As an outcome of its work, the Working Group recommends, and the Scientific Committee of the FSAI endorses, the following guidance values for gluten in gluten-free and reduced-gluten foodstuffs:

1. a maximum level of 20mg/kg gluten in any food marketed for special dietary use by persons intolerant to gluten, consisting of or made only from one or more ingredients which do not contain wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer
2. a maximum level of 20mg/kg gluten in any food marketed for special dietary use by persons intolerant to gluten, consisting of one or more ingredients from wheat (i.e. all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer
3. a level in the range of 20mg/kg to a maximum of 100mg/kg gluten in any food marketed for special dietary use by persons intolerant to gluten foods, consisting of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats² or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100mg/kg in total, based on the food as sold or distributed to the consumer.

² Footnote to the 2007 Codex standard states: Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level. This footnote applies to any reference to oats in this report.



The following labelling provisions are considered appropriate for the dietary foods listed above, in line with the labelling provisions set out in the revised Codex Standard recently agreed by CCNFSDU at its 2007 meeting:

- products listed in bullet points 1 and 2 above may be labelled as “gluten-free”. The term “gluten-free” shall be printed in the immediate proximity of the name of the product, e.g. “Emer’s Rice Cakes, gluten-free”
- products in bullet point 3 above should not be labelled as “gluten-free”. An alternative description, designed not to mislead the consumer, should be used, such as “reduced-gluten, suitable for most coeliacs”.

The Working Group recommends that Irish industry should implement these labelling provisions within one year of the date of publication of this report, unless mandatory provisions for the labelling of such products are introduced within this time period.

The Working Group additionally recommends:

- continuation of the Health Service Executive/Food Safety Authority of Ireland surveillance programmes for foods suitable for consumption by coeliacs
- the drawing up of guidelines for industry for the avoidance of cross contamination in production, manufacturing, catering and retail establishments as applicable
- development of training programmes for relevant enforcement staff, those producing foods suitable for consumption by coeliacs and for the catering and restaurant trades
- improvement of the nutritional quality of foods suitable for consumption by coeliacs, especially those that are made using unenriched, refined grains or starches. Of particular note, the needs of coeliacs warrant consideration when examining folic acid fortification of flour
- the progression of standards and harmonised labelling provisions for gluten-free foods and those rendered gluten-free at EU level and at relevant Codex Alimentarius Committees
- the development of enhanced greater linkages between the Coeliac Society of Ireland, the Food Safety Authority of Ireland, *safefood*, relevant health professionals and food industries on these issues.

I. INTRODUCTION

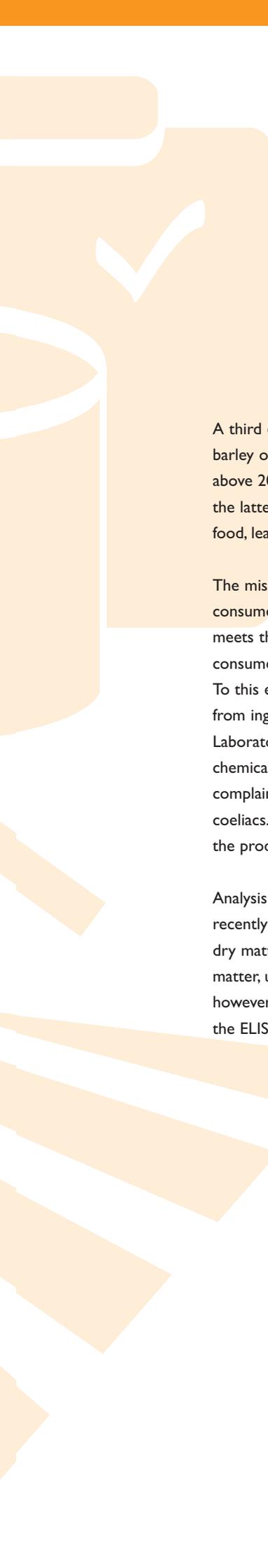
The coeliac condition (coeliac disease) is a genetically determined disorder in which affected individuals show an abnormal response (intolerance) to ingested gluten. Gluten is a water-insoluble, complex mixture of cereal proteins (prolamins and glutenins) and other constituents, the prolamins of wheat, barley, rye and oats being gliadins, hordeins, secalins and avenins, respectively.

Exposure of coeliacs to the prolamins contained in, e.g. wheat, barley and rye may result in damage to the mucosa of the small intestine, producing a variety of symptoms, typically including malnutrition, diarrhoea and anaemia. The coeliac condition has been reported to be particularly prevalent in the Irish population, with an incidence in the range of five to ten sufferers per 1,000 and also in other Caucasian populations.

Treatment of diagnosed coeliacs includes a reduced-gluten or gluten-free diet for life. In this context, the term gluten-free diet incorporates two categories of cereal-based foodstuffs:

1. those derived from cereals containing proteins that do not appear to be toxic to coeliacs, for example, corn (maize), rice millets, sorghum, teff and ragi; and
2. those consisting of ingredients (from wheat *Triticum* species), barley or rye grain which have been specially processed before use to reduce gluten to a level below 20mg/kg (rendered gluten-free).

The former are often referred to as naturally gluten-free foods. In practice, however, gluten-free foods may contain very low levels of gluten, above the limit of detection (LOD) of the analytical tests used to detect gluten (but less than 20mg/kg), due *inter alia* to minor cross contamination occurring during the primary production, harvesting and storage of grain and/or during the manufacture of gluten-free food. The presence of these very low levels of analytically-detectable gluten is the reason why it is difficult to define gluten-free food exactly, and why the proposed upper limit for gluten in gluten-free food is 20mg/kg rather than below the limit of detection.



A third category of foods (reduced-gluten) consist of ingredients (from wheat (*Triticum* species), barley or rye grain) which have been specially processed before use to reduce gluten to a level above 20mg/kg up to 100mg/kg and hence have a low level of gluten, tolerated by most coeliacs. For the latter category of reduced-gluten foods, some residual traces of gluten inevitably remain in the food, leading to the somewhat higher upper limit for gluten proposed in the draft Codex Standard.

The mission of the Food Safety Authority of Ireland (FSAI) is “to protect consumers' health and consumers' interests by ensuring that food consumed, distributed, marketed or produced in Ireland meets the highest standards of food safety and hygiene.” The FSAI aims to protect the health of all consumers, including that of coeliacs who may be at risk due to intolerance to gluten in their diet. To this end, surveillance monitoring of gluten levels in gluten-free products and those manufactured from ingredients that have been rendered gluten-free is carried out by the Public Analysts Laboratories and the enforcement officers on behalf of the FSAI, as part of the collaborative food chemical monitoring programme. Both the FSAI and the Health Service Executive (HSE) also receive complaints of adverse reactions as a result of consumption of supposedly gluten-free products by coeliacs. Such complaints have been followed up whenever possible by analysis of the gluten level in the product concerned.

Analysis of gluten in gluten-free or reduced-gluten products is complicated by the fact that until recently the only agreed standard was the 1981 Codex Standard of 0.05g total nitrogen per 100g dry matter (Codex Standard 118-1981). This corresponds to a level of 312.5mg protein/100g dry matter, using a conversion factor of 6.25 for nitrogen to protein. Much of this protein is not gluten, however, and therefore, the standard cannot be directly compared with the results obtained from the ELISA procedures now commonly used to measure gluten in food.

A new Codex Standard has recently been agreed by the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) at its 2007 meeting, and will be forwarded at Step 8 to the Codex Alimentarius Commission for adoption in 2008. The draft Standard (Codex Alimentarius, 2007) proposes that gluten-free foods are dietary foods marketed for special dietary use by persons intolerant to gluten and are:

a) *consisting of or made only from one or more ingredients which do not contain wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats³ or their crossbred varieties, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer,*

and/or are:

b) *consisting of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer.*

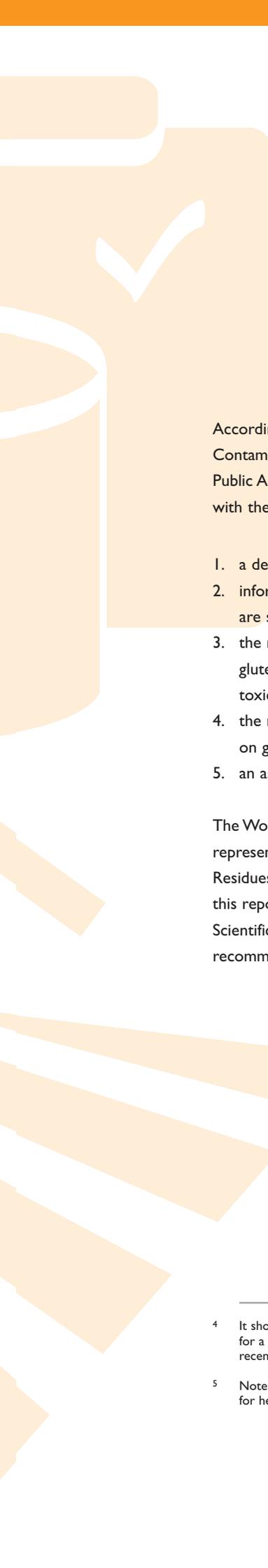
The draft standard additionally identifies the following category **“Foods specially processed to reduce gluten content to a level above 20 up to 100mg/kg”** and specifies that:

These foods consist of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100mg/kg in total, based on the food as sold or distributed to the consumer.

Progress in reaching consensus on the revised Codex standard was slow for a number of years, due to problems in:

- (a) assessment of the tolerable (toxic) level of gluten and related proteins for coeliac sufferers and
- (b) the analytical methods used, which until recently showed poor cross-reactivity to hordeins, and to some heat-treated foodstuffs and acid hydrolysates.

³ Footnote to draft Codex standard: *Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level. This footnote applies to any subsequent reference to oats in this report.*



Accordingly, the Scientific Committee of the FSAI, following the recommendation of the Additives, Contaminants and Residues Sub-committee and based on a briefing paper prepared by the Galway Public Analysts' Laboratory, agreed to the establishment of a scientific Working Group on Gluten, with the objective of advising the FSAI on the following:

1. a description of the coeliac condition and an indication of its extent in Ireland
2. information on the gluten-free diet and the nutritional quality of foods on sale in Ireland that are specifically marketed as suitable for coeliacs (reduced-gluten or gluten-free)
3. the need for Irish standards⁴ for levels of gluten in gluten-free foods and those rendered gluten-free, and the consequential labelling claims, to include consideration of the issues of toxicity assessment and analytical difficulties
4. the need for provision of information to coeliacs and enforcement officers on analytical results on gluten-free and reduced-gluten available on the market
5. an assessment of the needs of coeliacs, within the confines of the FSAI remit⁵.

The Working Group included representatives of the Coeliac Society of Ireland, medical specialists, representatives from the Scientific Committee (drawn from the Additives, Contaminants and Residues Sub-committee of the FSAI) and relevant FSAI personnel, as identified in Appendix I of this report. This report of the Working Group on Gluten, operating under the auspices of the Scientific Committee, addresses the issues outlined above and provides a number of recommendations to the FSAI in relation to gluten-free foods.

⁴ It should be noted that at the time this work was initiated there had been little or progress on the draft Codex standard for a number of years, and it was agreed that there was a need to develop recommendations for national standards. The recent progress towards agreement on the Codex standard has to some extent overtaken this aspect of the work.

⁵ Note: the FSAI does not have a remit for communication with consumers or a general remit on dietary/nutritional advice for health, and these aspects were therefore excluded from this report.

2. THE COELIAC CONDITION AND ITS PREVALENCE IN THE IRISH POPULATION

2.1 Definition

The coeliac condition (coeliac disease) is a genetically determined disorder in which there is an abnormal response to ingested cereal proteins, e.g. van Heel and West, 2006. There is an over exuberant immunological reaction to prolamins from wheat, barley and rye and possibly oats resulting in a characteristic pattern of damage to the mucosa of the small intestine.

2.2 Mucosal Lesion

The surface of the normal small intestinal mucosa is covered by finger-like projections, the villi. The epithelium of the villi consists of tall, columnar cells – enterocytes, which have fine hair-like microvilli on their apices covered with the enzyme rich glycocalyx (the brush border)⁶. There are small numbers of lymphocytes between the enterocytes. At the base of the villi is the subepithelial layer consisting of the crypts of Lieberkühn (site of the division of stem cells) producing a variety of endocrine cells and enterocytes which migrate up the sides of the villi during differentiation and maturation. Surrounding the crypts is the lamina propria consisting of connective tissue and containing blood vessels, nerves and some inflammatory cells (Figure 1a).

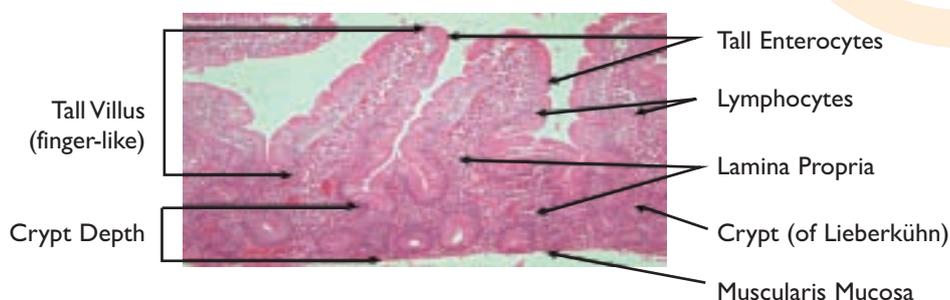


Figure 1a. Normal Small Bowel Biopsy

⁶ See Glossary (Appendix II).

In the untreated coeliac condition, the disordered immune cascade results in lack of villous formation and enterocyte maturation and is associated with crypt hypertrophy and the development of an intense infiltration of chronic inflammatory cells in the lamina propria and epithelium – producing the characteristic histological picture of total or subtotal villous atrophy which is most severe in the duodenum and proximal jejunum (Figure 1b). Removal of prolamins from the diet (the reduced-gluten diet) results in a more normal histological pattern. In children, complete restoration is achieved but in adults a mild inflammatory infiltrate persists and there is failure of the lactase activity in the glycocalyx to normalise.

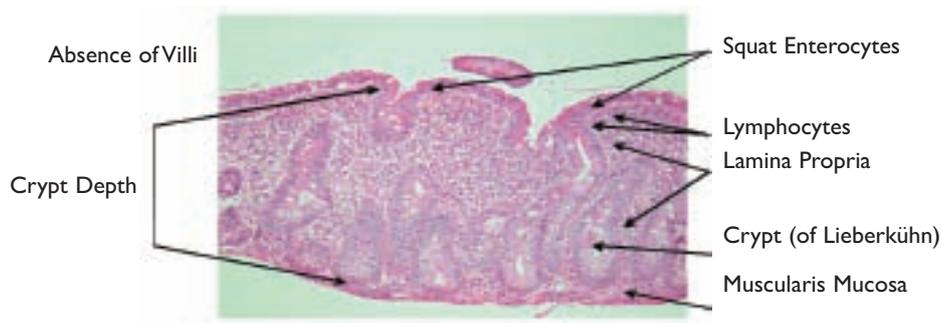


Figure 1b. Coeliac Small Bowel Biopsy

2.3 Clinical Picture

This is dependant upon the age of the coeliac, the amount of gluten being consumed and the sensitivity of the subject. The classical picture of the baby with failure to thrive is rarely seen in Ireland as all milk formulae, the only legally permitted substitute for breast milk which may be marketed as suitable for infants up to the age of four months, have strict compositional requirements which exclude gluten and all sources of gluten. The spectrum of clinical symptoms is very wide and the major ones are shown in Table 1. The majority of coeliac sufferers diagnosed nowadays have mild symptoms such as fatigue due to anaemia, flatulence and occasional diarrhoea. The availability of serology tests to screen for the coeliac condition has led to the identification of much milder symptomology than heretofore recognised.

2.4 Genetics

Thus far, only one group of genes has been identified to be linked to all populations of the coeliac condition throughout the world. These are genes coding for the HLA (human leucocyte antigens, as defined in the Glossary in Appendix II) and are located on chromosome 6. One particular gene, HLA-DQ2 is found in over 96% of coeliacs but is also found in at least 20% of the non-coeliac population in Ireland. The presence of DQ2 is associated with a variety of “auto-immune” diseases such as thyroid disease, Addison’s disease and Type 1 diabetes mellitus. These conditions are characterised by overproduction of tissue-targeted autoantibodies, and are all found more commonly in coeliacs than in the general population.

Table 1. Age of Diagnosis of the Coeliac Condition and Symptom Profile

Age Group		
Infants and young children < 2 years	Childhood 2 – 16 years	Adults
Symptoms		
Diarrhoea/steatorrhoea*	Poor growth (small for age)	Short stature
Vomiting	Delayed puberty	Anaemia (esp. in pregnancy)
Anaemia	Anaemia	Osteoporosis*
Cranky	Osteoa/rickets*	Dyspepsia*
Bloated belly	Diarrhoea/steatorrhoea	Weight loss
Wasted buttocks	Lethargy	Mouth ulcers
	Mouth ulcers	Diarrhoea/steatorrhoea
		Infertility
		Dermatitis herpetiformis*
		Tetany*

* See glossary (Appendix II) for definitions.

Table 2. Sensitivity, Specificity and Predictive Value (PV) of IgA Class Antibodies in the Untreated Coeliac Condition

Serological test	Sensitivity (%)	Specificity (%)	Positive PV (%)	Negative PV (%)
EMA	85 - 98	97 - 100	98 - 100	80 - 95
TG2	95 - 98	94 - 95	91 - 95	96 - 98
AGA	75 - 90	82 - 95	28 - 100	65 - 100

(adapted from Farrell and Kelly, 2004)

2.5 Serological tests

In the untreated coeliac condition, the B lymphocytes in the lamina propria synthesise antibodies against gluten/gliadin but they are neither specific nor sensitive enough to be used as a screening tool. However, more recently, antibodies to a fibroblast-derived enzyme, tissue transglutaminase (TG2) have been discovered with >90% sensitivity and specificity for the coeliac condition; these antibodies can be detected by TG2 ELISA or by immunofluorescence on tissue sections for endomysial antibodies (EMA). Table 2 provides a comparison of the sensitivity, specificity and predictive value of these antibodies in the diagnosis of the coeliac condition. All these antibodies, if present, are in a high titre at the time of diagnosis of the condition and once a reduced-gluten diet is commenced they fall to normal (negative) levels. Currently, TG2 antibodies are used to monitor dietary compliance in treated coeliacs and in screening for people at risk of having the coeliac condition. As these tests are frequently used as the gold standard in deciding whom to biopsy, false negative tests are underestimated in most studies.

2.6 Inheritance and Prevalence

In the early 1970s, a study of coeliacs diagnosed by biopsy and resident in Co. Galway yielded a prevalence rate of one in 550 children under the age of 12 years (one in 300 when adults with no symptoms in childhood are included) (Mylotte and Egan-Mitchell, 1973). No more recent data for the Republic of Ireland are available, however, a study from Northern Ireland using serological screening found a prevalence of one in 125 (Johnson *et al.*, 1997). Many other studies throughout Europe suggest a prevalence of the coeliac condition of five to ten per 1,000 of the Caucasian adult population (West *et al.*, 2003).

Before the days of serological screening, several family studies were performed in US, Canada and the West of Ireland in which all first-degree relatives of the sufferer (index case) were offered a small bowel biopsy. Between 5 – 15% of relatives were found to have the coeliac condition, some of these individuals had no abnormal physical signs or identifiable deficiencies. More recent studies have shown that siblings with the same HLA antigens as the sufferer have a 40% greater chance of being a coeliac. To date, not all monozygotic (identical) twins have been concordant for the condition, an 80% concordance being found; in many cases, the second twin has developed the coeliac condition many years after its sibling. Only 20% of dizygotic (non-identical) twins show concordance for the coeliac condition (Greco *et al.*, 2004).

2.7 Complications

Coeliacs who do not adhere to the reduced-gluten diet (Section 3) run the risk of continued ill health with unrelenting symptoms, as outlined in Table 2, although the amount of gluten required to produce symptoms varies considerably from individual to individual. Children who do not stick to the diet do not reach their full potential height, women may have difficulty in conceiving, have a higher rate of miscarriages and deliver babies with neural tube defects. The problems of osteoporosis occur at an earlier age and more severely than in the non-coeliac population. All these problems resolve with a strict reduced-gluten diet. The most worrisome complication is the development of malignancy, especially a lymphoma of the small bowel found only in coeliacs, the enteropathy associated T-cell lymphoma (EATL). There is evidence accruing that treatment with a strict reduced-gluten diet prevents the development of EATL.

2.8 Sensitivity of Coeliacs to Gluten in the Diet

The degree of sensitivity to gluten is exceedingly variable. This is demonstrated by the detection of asymptomatic individuals during screening programmes, consuming normal diets which included cereal-based foodstuffs containing levels of gluten greatly in excess of 100mg/kg (100ppm). Sensitive consumers may however suffer adverse reactions to products containing very low levels of gluten. In 2004, the European Food Safety Authority's Scientific Panel on Dietetic Products, Nutrition and Allergies (EFSA NDA Panel) concluded that there are insufficient data to suggest a threshold dose of gluten tolerable for all coeliac patients (EFSA, 2004). Despite this caveat, in order to attempt to establish possible safe limits for consumption of gluten by coeliacs, two types of "feeding" studies have been undertaken:

- a) acute studies – direct instillation of gluten (in the form of the prolamin gliadin) into the small intestine via an oral-duodenal tube, and
- b) chronic studies – three months daily consumption of a defined amount of gliadin added into an otherwise gluten-free diet.

The acute studies showed that 1g of gliadin (equivalent to 25 400g loaves containing 200mg/kg gluten, in other words, a huge allergen exposure⁷) produced severe damage to the mucosa of the small intestine within four to six hours of instillation (Sturgess *et al.*, 1994).

⁷ The ratio of gliadin:gluten in wheat starch is taken as 1:2 for the purpose of this estimate.

In relation to the chronic studies, preliminary data from challenge experiments designed to determine the upper limit of gliadin which may be consumed without causing mucosal damage have shown that 50mg/day over a period of three months causes slight mucosal damage in some coeliac adults, whereas 10mg daily for the same duration appeared to be tolerated without apparent damage (Fabiani *et al.*, 2004; Catassi *et al.*, 2005). Collin and co-workers have suggested that a daily gluten intake of 30mg is safe, based on absence of histological change in mucosal biopsies (Collin *et al.*, 2004). However, challenge studies in children using 10mg of gliadin per day indicate that intestinal deterioration may be triggered in children at this level (Catassi, 2000). Vader and co-workers have also shown that there may be differences between adults and children in the range of gluten peptides able to induce the T-cell response involved in the early stages of development of the coeliac condition (Vader *et al.*, 2002).

The opinion of the EFSA NDA Panel relating to the evaluation of allergenic foods for labelling purposes (EFSA, 2004) provides the following tabular summary of results obtained from dietary survey studies and *in vivo* challenge studies with gluten or gliadin.

Table 3. Effects of Gliadin/Gluten in the Coeliac Condition: Dose-response Studies (controlled by biopsy)

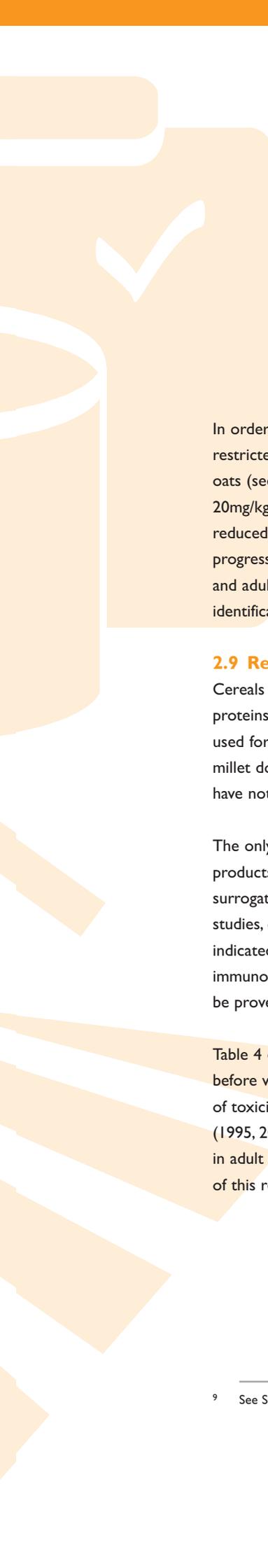
Dietary Survey Studies							
Name	Year	Children(c) Adult (a)	Number	Quantity	Gliadin/ Gluten	Time	Toxicity
Ejderhamn	1988	c	11	4-14 mg/day*	Gliadin	10 years	Non-toxic
Kaukinen	1999	a	52	34 mg/day*	Gliadin	10 years	Non-toxic
Selby	1999	a	89	Not specified	Wheat starch	8 years	Non-toxic
Peräaho	2003	a	57	Not specified	Wheat starch	1 year	Non-toxic
In Vivo Challenge Studies							
Name	Year	Children(c) Adult (a)	Number	Quantity	Gliadin/ Gluten	Time	Toxicity
Ciclitira	1984	a	7	10mg/day	Gliadin	8 hours	Non-toxic
Catassi	1993	c	20	100mg/day	Gliadin	4 weeks	Toxic
Jansson	2001	c	27	200mg/day	Gluten	4 weeks	Toxic
Jansson	2001	c	27	500mg/day	Gluten	4 weeks	Toxic
Laurin	2002	c	24	100mg/day	Gluten	13 weeks	Toxic

Table 5 of the opinion of the EFSA NDA Panel on allergenic foods (EFSA, 2004)
*calculated

It appears from these data that chronic exposure of a coeliac to gliadin in the range of 10 – 50mg/day or higher (10mg in children and 50mg in adults), equivalent to 20 and 100mg of gluten/day⁸ may trigger an adverse reaction, depending on the sensitivity of the individual. Assuming that the typical consumption of gluten-free or reduced-gluten food (cereals and cereal-derived products) is approximately 500g/day, a level of 20mg/kg gluten in such food would be equivalent to a daily intake of 10mg gluten and a level of 100mg/kg gluten would be equivalent to a daily intake of 50mg.

This suggests that, depending on the sensitivity of the individual, levels of gluten in the range of 20 – 100mg/kg in cereal-based foods will only trigger a reaction in a small minority of individuals consuming 500g of reduced-gluten or gluten-free cereals and cereal-derived products per day. However, the opinion of the EFSA NDA Panel that there are insufficient data to suggest a threshold dose of gluten tolerable for all coeliac patients, must be borne in mind. It should be noted also that the NDA Panel considered that the originally proposed Codex Alimentarius limit for gluten-free foods of 200mg gluten/kg food (200ppm) for coeliac patients required reconsideration (EFSA, 2004). In recent meetings of the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU), the proposed limit of 200mg/kg has been revised downwards to 100mg/kg, reflecting a broad consensus that the higher level could present a risk to the health of some coeliacs and that the lower level could be achieved by industry without significant economic impact.

⁸ The ratio of gliadin:gluten in wheat starch is taken as 1:2 for the purpose of this estimate.



In order to assure maximum health protection for extremely sensitive individuals who may be restricted to a reduced-gluten diet of cereals from species other than wheat, barley, rye and possibly oats (see Section 3), it would appear that the gluten content of such products should be below 20mg/kg gluten. The dietary requirements of less sensitive coeliacs may be satisfied by reduced-gluten products with a maximum level of 100mg/kg gluten. Clinical studies currently in progress will determine a possible safety threshold level for the consumption of gluten by children and adults, above which damage to the intestine is likely to occur and further inform the process of identification of a Lowest Effect Level for gluten.

2.9 Relative Toxicity of Various Prolamins

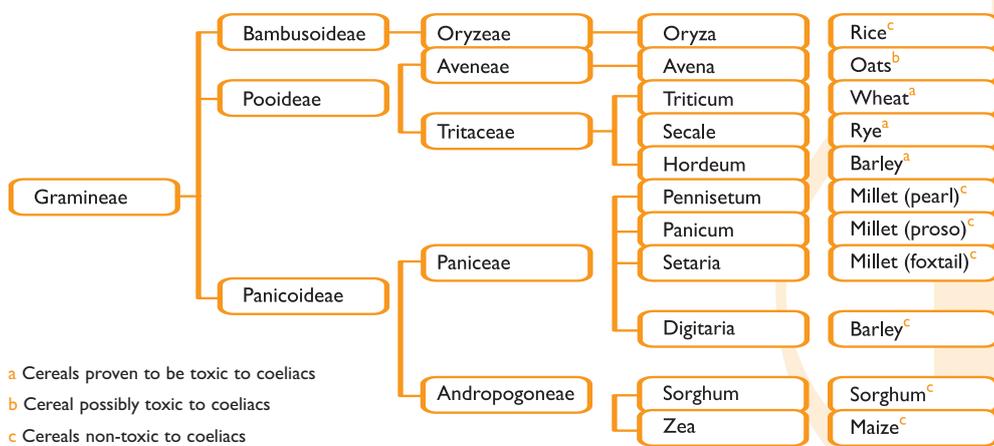
Cereals containing toxic prolamins belong to the grass family, although not all grasses contain the proteins known to be toxic to coeliacs. Table 4 shows the taxonomic relationship of various grasses used for human food. In general, it appears that the Panicoideae species such as maize, sorghum and millet do not contain these allergenic proteins, nor do Orzyeae (rice species), although many grains have not been subjected to controlled testing.

The only published studies concerning relative toxicity of prolamins from wheat and other cereal products were performed in the 1940s and 1950s in the Netherlands using stool fat content as a surrogate marker of intestinal damage, prior to the advent of intestinal biopsies (Dicke, 1950). These studies, on wheat, rye and oats, showed wheat to be more toxic, weight for weight, than rye and indicated that oats were non-toxic. Recent comparative studies on barley and rye using in vitro immunological methods have been undertaken but the clinical relevance of such studies remains to be proven. The sensitivity of coeliacs to oat gluten is not completely clear⁹.

Table 4 demonstrates that the Aveneae split from the Pooideae subfamily many thousands of years before wheat, rye and barley eventually evolved, providing a basis for the lower toxicity or absence of toxicity of oats. Although the work of Dicke and more recently that of Janatuinen *et al.*, (1995, 2000, 2002) have provided evidence of the long term safety of oats as part of a coeliac diet in adult coeliacs, other studies have yielded conflicting results, as discussed further in Section 3.3 of this report.

⁹ See Section 3 and also footnote 2.

Table 4. Taxonomic Relationship of Toxic and Non-toxic Cereal Grains



3. THE REDUCED GLUTEN OR GLUTEN-FREE DIET AND ITS NUTRITIONAL QUALITY

3.1 Introduction

As previously outlined in Section 2, coeliacs show an intolerance to gluten. The only treatment generally required is adherence to a gluten-free or reduced-gluten diet for life. Avoiding gluten in the diet is not easy since cereals are used in the preparation of many foods. However, staying on a strict gluten-free or reduced-gluten diet can dramatically improve the patient's condition. Depending on individual food choices and adherence to such a gluten diet, once the intestinal villi have regenerated, adequate amounts of most nutrients can usually be obtained from a well-balanced diet (see Section 3.5). The advice of a registered/qualified dietician may be needed in relation to nutritional quality and other aspects of the diet, since it is necessary to remain on the gluten-free or reduced-gluten diet throughout life.

3.2 Reduced-gluten and Gluten-free Foods

Adherence to the gluten-free or reduced-gluten diet means that foods such as bread, pies, cakes, biscuits, pizzas, crumpets, muffins, bagels, naan, pasta, Yorkshire pudding, semolina or couscous cannot be consumed, as they are all made of wheat. Beer is not allowed, nor is rye crisp bread, sausages or sausage rolls. No food can be eaten breaded or battered. Suitable foods for a gluten-free or reduced-gluten diet are potato, maize, rice, cornflour, tapioca, arrowroot, buckwheat, all plain meat, fish and vegetables, nuts and pulses and any of the 10,000+ commercially available reduced-gluten and gluten-free products.

The Coeliac Society of Ireland aims to “promote, safeguard and protect the interests of the members in relation to the coeliac condition”. Each member receives two newsletters per year, a list of gluten-free manufactured products and a booklet containing information about the coeliac condition. When the Coeliac Society of Ireland receives certification from the manufacturers of gluten-free foods, their products are included in the list of gluten-free or reduced-gluten manufactured products. Since the formulation of products change on a regular basis, it is necessary to obtain this booklet on an annual basis as it is continuously updated by the Coeliac Society of Ireland to accommodate such changes in the foods.

In order to be suitable for inclusion in this gluten-free or reduced-gluten manufactured products list, products must comply with the following criteria:

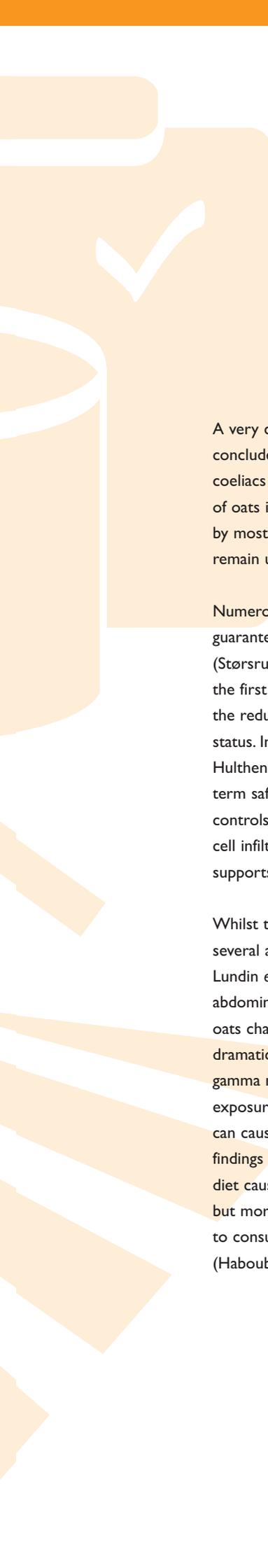
1. products must be free from the cereals wheat, rye, barley and oats. Wheat starch complying with the levels laid down for gluten in the draft Codex Alimentarius Standard of 2000 (Codex Alimentarius, 2000) is allowed, with a maximum level of 200mg/kg¹⁰ for reduced-gluten cereals and 20mg/kg for foods which do not contain any wheat, barley, rye or oats
2. starches used as carriers for spices, seasonings or flavourings, or as fillers or binders, or for dusting during the manufacturing process, must be free of wheat, rye, barley and oats. Soy sauce manufacturers are required to submit tests result to ensure that any gluten protein residue remaining in the sauce is below the draft Codex limit
3. items must not be contaminated with wheat, rye, barley and oats during production or storage
4. products must be free from malt, malt extract or natural malt flavouring. These ingredients are derived from barley which contains the prolamin hordein. The current advice of the Coeliac Society of Ireland is that it is better for sensitive coeliacs to avoid them. Synthetic malt flavourings are not harmful to coeliacs and are allowed. Malt vinegar is also allowed.

Total compliance with the gluten-free or reduced-gluten diet is necessary in order to ensure the current and future health of the coeliac patient. Appendix 3 of this report provides an overview of some diet sheets that are currently in use in Ireland by dieticians and clinical nutritionists. Coeliacs should seek advice from their dietician/clinical nutritionist with regards to these foods and the combination of such in order to have a nutritionally complete, balanced and healthy diet.

3.3 Oats and the Reduced-gluten/Gluten-free Diet

It has been known for many years that oats do not share the antigenic component (gliadin) that is present in wheat. Instead, oats contain avenin in their prolamin fraction (Kumar and Farthing, 1995). Whether or not oats should be included in a reduced-gluten diet has been debated for half a century.

¹⁰ The level of 200mg/kg has been reduced to 100mg/kg in the draft standard of 2007, and the Coeliac Society of Ireland will consider revision of their 2009 list on this basis.



A very comprehensive study on the safety of oats was published in 1995 in which the investigators concluded that moderate amounts of oats can be included in a reduced-gluten diet for most adult coeliacs without adverse effects (Janatuinen *et al.*, 1995). A recent systematic review of the inclusion of oats in the gluten-free diet for coeliacs has concluded that oats can be symptomatically tolerated by most patients with coeliac disease; however, the long-term effects of a diet containing oats remain unknown (Haboubi *et al.*, 2006).

Numerous studies have found that adult coeliacs in remission can include large amounts of guaranteed wheat-free rolled oats for an extended period of time without adverse effects (Størsrud *et al.*, 2003a). It was also found that temporary increased flatulence was experienced for the first few weeks, as well as improved bowel function with oats in the diet. The addition of oats to the reduced-gluten diet gave more variation, better taste and satiety. Oats also improved nutritional status. Including oats can help coeliacs following a strict gluten-free diet (Thompson, 2003; Størsrud, Hulthen, Lenner, 2003b). A five year study by Janatuinen *et al.*, (2002), provided evidence of the long term safety of oats as part of a coeliac diet in adult coeliacs, with no significant difference between controls and those coeliacs consuming oats with respect to duodenal villi architecture, inflammatory cell infiltration of the duodenal mucosa or antibody titre after five years of follow-up. This study supports previous findings by the research group (Janatuinen *et al.*, 2000).

Whilst the above research is encouraging with regards to the use of oats in a reduced-gluten diet, several additional studies have been published with conflicting results. In a study conducted by Lundin *et al.*, (2003), oats were well tolerated by most coeliacs but several reported initial abdominal discomfort and bloating. One patient developed villous atrophy and a rash during the first oats challenge. She improved on an oat free diet but developed subtotal villous atrophy and dramatic dermatitis during a second challenge. Five coeliacs showed positive levels of interferon gamma mRNA after challenges. More recently, in a study in nine adult coeliacs with a history of oats exposure, the same researchers showed that some coeliacs have avenin-reactive mucosal T-cells that can cause mucosal inflammation following challenge with oats (Arentz-Hansen *et al.*, 2004). These findings are supported by those of Peraaho *et al.*, (2004) who found that oats in a reduced-gluten diet caused more intestinal symptoms than the traditional diet. Mucosal integrity was not disturbed, but more inflammation was evident in the oats group. These findings indicate that coeliacs wishing to consume a diet containing oats should receive regular follow-up at a specialist clinic for life (Haboubi *et al.*, 2006).

In conclusion, oats provide an alternative in the gluten-free or reduced-gluten diet but may prove toxic to some sensitive individuals. Coeliacs should be aware of a possible increase of intestinal symptoms on a diet high in oats. A further consideration is the possibility that even if oats themselves are safe, they nevertheless may be contaminated with wheat, rye or barley (see Section 5). Unfortunately, the extent to which contamination of commercial oat products occurs is unknown. Ideally, if a coeliac appears likely to use oats, they should be advised to consume only those products tested and found to be free of contamination (Thompson, 2003).

3.4 Adherence to a Gluten-free or Reduced-gluten Diet

Adherence requires knowledgeable dietetic counselling and frequent up-dates as commercial food contents change; any product entering the digestive system must be reduced-gluten or gluten-free. Careful review of ingredient lists on food and medicine labels to determine if gluten containing ingredients are present is important. The food manufacturer can be contacted for detailed information on ingredients if an ingredient list is not available. Since many additives, stabilizers, and preservatives may contain gluten, it is best to check with each manufacturer for clarification. In addition, some medications, toothpastes and mouthwashes may contain gluten. Individuals should be advised to check with their doctor or pharmacist before taking any prescribed or over the counter medications.

Coeliacs must be alert to hidden sources of gluten such as hydrolyzed vegetable/plant protein (HVP/HPP), malt, spelt, kamut, and certain medicinal products. Particular care should be taken in the selection of soups, luncheon meats and sausages. There is a great variation in sensitivity to gluten among those with the coeliac condition, and although one may have no obvious symptoms, damage to the intestinal lining may still occur.

3.5 Nutritional Quality of the Gluten-free or Reduced-gluten Diet

As indicated above, individuals with the coeliac condition are advised to keep to a lifelong gluten free or reduced-gluten diet to remain well. Uncertainty still exists as to whether this gives a nutritionally balanced diet (Hallert *et al.*, 2002). In the Codex Alimentarius draft revised standard (Codex Alimentarius, 2007), it states that products covered by the standard that substitute important basic foods should supply approximately the same amount of vitamins and minerals as the original foods they replace.



Hallert *et al.* (2002) have found that coeliacs on a gluten-free or reduced-gluten diet for ten years showed higher total plasma homocysteine levels and signs of poor vitamin status. This may have clinical implications considering the linkage between vitamin deficiency, elevated total plasma homocysteine levels and cardiovascular disease. Bardella *et al.* (2000) examined body composition and dietary intakes. It was found that the weight, height and body mass index (BMI) of coeliac males was lower than the controls and females coeliacs had a lower weight and BMI compared to female controls. Both the fat and lean mass differed in the coeliac groups compared to controls and the bone mineral content of coeliac women diagnosed in adulthood was significantly lower than that of control women. Total energy intake was lower in patients than controls and was unbalanced with a higher percentage energy from fat than carbohydrates when compared to controls.

Reduced-gluten or gluten-free cereal products generally are not enriched/fortified and frequently are made from refined flour and/or starch. Such products have been found to have lower amounts of at least one of the following nutrients thiamine, riboflavin and niacin when compared to their gluten-containing counterpart (Thompson, 1999). These products have also been found to provide lower amounts of folate and iron than their enriched/fortified gluten-containing counterparts but contain more dietary fibre when compared to refined gluten-containing products (Thompson, 2000).

In the general population, enriched fortified cereal products contribute a large percentage to the daily intake of folate and iron. Due to the fact that the corresponding reduced-gluten or gluten-free products are generally not fortified, this major source of folic acid and iron is not available to coeliacs. As a result, a reduced-gluten diet may contain inadequate levels of these nutrients, especially if un-enriched reduced-gluten or gluten-free cereal products provide a substantial portion of total energy intake (Thompson, 2000). However, Thompson's work did not include dietary intake assessment of those consuming a reduced-gluten diet. Therefore, it cannot be concluded that adherence to a reduced-gluten diet actually results in inadequate intake of nutrients.

The issue of national folic acid food fortification was considered in order to reduce the incidence of babies born with neural tube defects (NTDs), which are a significant cause of disability in Ireland. The National Committee on Folic Acid Food Fortification considered the issue of fortification of bread or flour with folic acid and carried out a public consultation in 2005 on the options for implementing this in Ireland. Submissions were made during the consultation about the need to ensure that women of childbearing age who follow a gluten-free diet are not excluded from the benefits of folic acid fortification i.e. that reduced-gluten or gluten-free bread/flour is also included in the folic acid fortification programme. This is of particular concern given the increased risk of folate deficiency in people with the coeliac condition, which may increase the risk of having a pregnancy affected by NTDs. Presently, a group charged with implementing the recommendations, is developing the most effective means of ensuring women of childbearing age achieve adequate intake of folic acid.

The work completed to date shows that there is limited information available on the nutritional adequacy of the gluten-free or reduced-gluten diet. It has raised the question as to the nutritional quality of the reduced-gluten or gluten-free foods provided to coeliacs and the lack of nutritional awareness. Strict follow-up, review of vitamin status and dietary advice in terms of choice and composition of foods seem necessary to prevent malnutrition. Manufacturers of reduced-gluten or gluten-free foods should also be encouraged to improve the nutritional quality of their products, especially those that are made using unenriched, refined grains or starches.

3.6 Dietary Supplemental Allowances

A dietary supplemental allowance may be awarded in respect of a person or his/her adult or child dependant(s) provided he/she satisfies certain conditions. Entitlement to a dietary supplemental allowance is determined by the HSE. In determining entitlement to a dietary allowance, consideration is given to the type of diet prescribed, the household income and whether the person in respect of whom the dietary allowance is payable is an adult or a child.

Following a comprehensive report by the Irish Nutrition and Dietetic Institute, legislation was amended in 2006 (S.I. No. 146 of 2006) to reflect the report findings and recommendations. The reduced-gluten diet remains as one of the categories of medical diets for which individuals are entitled to receive a dietary supplemental allowance as determined by the HSE on a case by case basis.

4. ANALYSIS OF GLUTEN IN FOODS AND SOME RECENT RESULTS OF SURVEILLANCE

4.1 Introduction

Testing of gluten in gluten-free foods or those reduced in gluten provides a mechanism of assessing a food's safety for consumption by coeliacs. Analysis is one part of the process of ensuring the quality and safety of reduced-gluten and gluten-free foods. Used in conjunction with industry's own checks (Hazard Analysis Critical Control Points (HACCP) etc.) and with official inspection, analysis is an essential component of ensuring the safety and quality of nominally gluten-free foods.

4.2 What is Gluten?

Gluten may be described as the proteinaceous mass remaining after washing wheat dough with water to remove starch. Chemically, gluten is composed largely of a complex, water-insoluble mixture of cereal storage proteins of varying molecular mass (Weiser, 1992). The storage proteins of cereals include prolamins ('ethanol-soluble') and glutenins ('ethanol-insoluble'). Prolamins are particularly high in the amino acids proline and glutamine. The prolamins of wheat, barley, rye and oats are gliadins, hordeins, secalins and avenins respectively. Other *Triticum* species of cereal, including spelt and kamut, also contain gluten, as do their crossbred varieties. A test for "gluten" should measure quantitatively the total prolamins and glutenins of wheat, other *Triticum* species, barley and rye. In principle, gluten can be measured by:

- (a) separation and quantification of the gluten proteins (by e.g. ELISA, Mass Spectrometry, Liquid Chromatography-Mass Spectrometry (LC-MS), Western Blot (Stern *et al.*, 2001))
- (b) measuring gluten toxicity directly (bioassay)
- (c) measuring the amount of reactive/toxic fraction (epitope) present.

A general difficulty in gluten analysis has been the lack of a 'gold' standard of gliadin or gluten for calibration purposes (see also Section 4.4).

4.3 Some Earlier Methods of Estimating Gluten

4.3.1 Kjeldahl Nitrogen Method

This method, was formerly used to quantify the level of nitrogen (and thus protein) remaining in foods rendered gluten-free, e.g. wheat starch, the level of residual nitrogen/protein being inversely related to the efficacy of deglutensisation. This non-specific (to gluten) methodology pre-dated the more modern analytical techniques (including ELISA procedures); today, the method has only limited applicability, e.g. it is not applicable to gluten-free foods containing non-gluten protein or to wheat flours reduced in gluten to which any ingredient containing non-gluten protein has been added.

4.3.2 Elisa Method

From about 1991 to 2002, the most commonly used commercially available assay for gluten in foods was based on that of Skerrit and Hill (Skerrit and Hill, 1991). Reported disadvantages with this ELISA procedure include:

- (1) poor reaction (cross-reactivity) with hordeins (barley prolamins) in particular; the antibodies are primarily reactive with gliadins (see (3) below) and also with secalins
- (2) poor sensitivity in general to heat-treated prolamins and to hydrolysates
- (3) the monoclonal antibody used in the test is directed against ω gliadin, whose content varies considerably in different gluten-containing cereals and cultivars.

4.4 'Mendez' ELISA R5 Method

A number of different methods can now be used to estimate the gluten content of foodstuffs. Although techniques such as, e.g. Western Blot, PCR (Polymerised Chain Reaction) and Mass Spectrometry (MALDI-TOF) can be used to monitor for gluten, much of the recent research has focused on a new sandwich R5 ELISA procedure developed by Mendez and co-workers (Valdes *et al.*, 2003) This method has been recently collaboratively tested and was endorsed as type I by CCMAS, the Codex Committee for Methods of Analysis and Sampling; the procedure is now available as a commercial ELISA kit from a number of companies. The R5 method has claimed equal reactivity towards the prolamins of wheat, rye and barley, with no reported interference from oats, corn (maize) etc. Using a cocktail extraction procedure improves the response to heat-treated prolamins, and it is important that both industry and the food control laboratories consistently use the most appropriate extraction procedure when testing food on or prior to release onto the market.

The new commercial ELISA procedures are generally based on calibration using the newly produced PWG (Prolamin Working Group) gliadin standard (van Eckert, 2002); this standard is now available as IRMM 480¹¹. The R5 method has good sensitivity, with stated limits of detection (LOD) of 3.0mg gluten/kg food (3ppm). The R5 ELISA method detects the potential coeliac-toxic pentapeptide QQFPF, which occurs repetitively in the toxic prolamins. Recently, Dr. Mendez's group has developed a version of the R5 ELISA method suitable for testing (partially) hydrolysed gluten in foodstuffs such as beers, for example. Analytical issues being researched and debated currently (July 2007) include: reported overestimation of barley contamination in oats and the appropriate conversion factor in going from mg/kg gliadin to mg/kg gluten.

¹¹ Available from IRMM (European Commission, Directorate-General Joint Research Centre (JRC)), Institute for Reference Materials and Measurements, Retiesweg, 2440 Geel, Belgium.

4.5 Other Analytical Considerations

4.5.1. 'Confirmatory' techniques

The current draft Codex standard for gluten-free foods (Codex Alimentarius, 2007) refers to calibration against a certified reference material, if available, following immunological (ELISA) detection of gluten. Mass Spectrometry, Western Blot and PCR techniques are examples of confirmatory methods used for confirmation of gluten detected. Most applications of these confirmatory techniques appear currently to be qualitative, rather than quantitative.

4.5.2. Quality assurance issues

Two deficiencies in current gluten testing in foods are:

- (1) the lack of established Proficiency Testing Schemes (PTS) (note: FAPAS (UK) has started a gluten-in-food scheme; to date, there have been several problems with multi-modal distributions of results)
- (2) the lack of matrix-matched, gluten-free Certified Reference Materials (CRMs), e.g. CRM breads, flours etc.

The above difficulties pose problems for laboratories aiming for accreditation of the analysis. In view of the compositional complexity of gluten, it is important that a suitably broad range of food matrices be included in PTSs and CRMs.

Laboratories analysing for gluten in food need to apply the usual quality assurance procedures. In addition to the challenges of method validation and estimation of measurement uncertainty, the laboratories will have to give due consideration to sample size and to homogenisation procedures.

4.6 Recent Results of Surveillance of Gluten-free Foods

Gluten-free products and products reduced in gluten are periodically surveyed for the presence of gluten as part of the collaborative chemical monitoring programme carried out by the Public Analysts Laboratories and the enforcement officers on behalf of the FSAI.

Using data generated by the R5 ELISA procedure, the following general comments apply to some Irish results¹² of official, programmed testing of reduced-gluten and gluten-free foods in 2002 - 2005 inclusive:

- the majority (842 out of 884, i.e. 95%) of reduced-gluten and gluten-free foods tested had gluten levels less than or equal to 100mg/kg
- 211 out of 248 (i.e. 85%) wheat-based reduced-gluten foods contained less than or equal to 50mg/kg gluten, with 231 (93%) containing less than or equal to 100mg/kg
- all infant formulae tested in 2003 had no detectable levels of gluten generally less than 20mg/kg
- a survey of corn (maize) products in 2003 indicated significant contamination in some products labelled as gluten-free and also in some others, e.g. maize meals, not labelled as gluten-free (up to 1080mg/kg); nine out of 56 samples (i.e. 16%) tested had gluten levels above 200mg/kg
- all tested cornflours labelled as gluten-free gave satisfactory (less than 20mg/kg) results.

¹² Data generated by Public Analyst's Laboratory, Health Service Executive West, Galway, Ireland, using the R5 ELISA method.

Although the results are generally satisfactory, they indicated that certain products based on corn, a naturally gluten-free grain, which coeliacs assume are safe to eat, may in fact have presented a risk to health, particularly in sensitive individuals. At present, this information is not being brought to the attention of coeliacs in a structured, coordinated way. The most likely explanation for the presence of gluten in these products is cross contamination with wheat flour (see Section 5).

In 2004, a survey of 75 locally available breakfast cereals, based mostly on corn (maize), rice, oats or mixtures thereof, were tested for gluten by the R5 ELISA method. The products tested included oatflakes, oatmeals, porridges, cornflakes, rice crispies, etc. The test results indicated that the majority (ca. 80%) of such products contain less than 200mg/kg gluten, with 70% of the total containing less than 50mg/kg.

4.7 Future Analytical Work

Although there is a pressing need to strengthen other aspects of controlling reduced-gluten and gluten-free foods through education of producers and consumers, and through HACCP and official audit/inspection, improvements in testing regimes can also be made. It is hoped that more local bakery products (sold as gluten-free) will be tested in 2008. A more diverse range of foods, particularly gluten-free foods not labelled as such, e.g. rice products, cider etc., can be tested. Testing of foodstuffs low in gluten (but not gluten-free), e.g. beers, may be beneficial in clarifying the actual gluten levels present.

To date there has been little testing of coeliac “Total-Diet” samples (i.e. composite samples of foods consumed by coeliacs over a period of time) for gluten levels.

There is also a need for nutritional testing of gluten-free foods for, e.g. vitamins and minerals.



5. CROSS CONTAMINATION OF GLUTEN-FREE AND REDUCED-GLUTEN FOODS WITH PRODUCTS CONTAINING GLUTEN

In order for products to be gluten-free or reduced in gluten when they reach the consumer, the gluten-free quality of the product must prevail at every link of the chain. Cross contamination is the process by which a reduced-gluten or gluten-free product loses that status because it comes into contact with something that is not gluten-free. Cross contamination may happen during primary production, harvesting and storage of grain and/or during the manufacture of gluten-free food or food reduced in gluten, when contamination may occur as a result of practices such as poor rework, incorrect formulation, product carry-over due to use of common equipment, clean-up or sanitation, poor equipment design, etc. (Deibel *et al.*, (1997)).

This may be a particular problem in companies where gluten-free or reduced-gluten products are manufactured or prepared on an intermittent basis. Since 1998, it has been a legal requirement in Ireland for all food businesses to have a food safety management system based on the principles of HACCP. In relation to reduced-gluten or gluten-free products, whether the final product destined for the consumer or the raw materials, critical control points and preventative measures need to be identified. The Working Group identified a need for guidance for industry and enforcement authorities on appropriate controls to avoid cross contamination during the production of reduced-gluten or gluten-free foods marketed in Ireland.

6. AVAILABILITY OF INFORMATION TO COELIACS

Coeliacs need information on the reduced-gluten diet, its nutritional status and which foods to avoid in order to maintain a healthy diet. As mentioned in Section 3.2 of this report, the Coeliac Society of Ireland provides valuable information on the coeliac condition and on the availability of gluten-free foods and reduced-gluten foods in Ireland via its website (www.coeliac.ie/) and via publications such as its newsletters and its list of reduced-gluten and gluten-free manufactured products. In 2007, the Society produced a catering list, tailored for the hospitality industry which will ensure that chefs planning to provide gluten-free meals have access to accurate information on the gluten-free status of catering sized products and general foods suitable for the gluten-free diet. The website also provides links to other relevant websites and a message board where topics of interest can be discussed.

The Working Group identified the need for agencies such as *safefood* and the FSAI to work closely with the Coeliac Society of Ireland and with relevant health professionals and food industries in areas within their respective remits. In the case of *safefood*, this could involve enhancement of the provision of advice and information to consumers, including nutritional advice and advice on reduced-gluten and gluten-free manufactured products, and involvement in the integrated educational programme identified by the Society in its Health Strategy for Persons with Coeliac Disease (Coeliac Society, 2001). In addition, given its role in promotion of research on issues related to food safety, *safefood* could play a role in progressing research to further understanding and treatment of the coeliac condition including a national needs-based study of Irish coeliacs, as also identified in the 2001 Health Strategy.

7. CURRENT LEGISLATION AND STANDARDS APPLIED TO THE CONTROL OF GLUTEN-FREE FOODS IN IRELAND

7.1 Categories of Reduced-gluten and Gluten-free Food

As already discussed in the introduction to this report, the term gluten-free incorporates two categories of cereal-based foodstuffs:

- those derived from cereals containing proteins that do not appear to be toxic to coeliacs, for example corn (maize), rice millets, sorghum, teff and ragi; and
- those consisting of ingredients (from wheat (*Triticum* species), barley or rye grain) which have been specially processed before use to reduce gluten to a level below 20mg/kg (rendered gluten-free).

The former are often referred to as naturally gluten-free foods. In practice, however, gluten-free foods may contain very low levels of gluten, above the limit of detection (LOD) of the analytical tests used to detect gluten (but less than 20mg/kg), due *inter alia* to minor cross contamination occurring during the primary production, harvesting and storage of grain and/or during the manufacture of gluten-free food. The presence of these very low levels of analytically-detectable gluten is the reason why it is difficult to define gluten-free food exactly, and why the proposed upper limit for gluten in gluten-free food is 20mg/kg rather than below the limit of detection.

A third category of foods (reduced-gluten) consist of ingredients (from wheat (*Triticum* species), barley or rye grain) which have been specially processed before use to reduce gluten to a level above 20mg/kg up to 100mg/kg and hence have a low level of gluten, tolerated by most coeliacs. For the latter category of reduced-gluten foods, some residual traces of gluten inevitably remain in the food, leading to the somewhat higher upper limit for gluten proposed in the draft Codex Standard.

Gluten-free foods and those rendered gluten-free by processing can be considered in several ways from a regulatory perspective. Compositionally different requirements can be applied to gluten-free foodstuffs such as corn and rice-based products and foodstuffs consisting of ingredients which have been reduced in gluten (deglutenised) during processing of the grain.

Labelling is the other major aspect to consider. Reduced-gluten or gluten-free foods can be subdivided into those which are labelled as such and those which are not. Claims and descriptions such as “naturally gluten-free”, “gluten-free” and “suitable for coeliacs” are regulated under labelling controls and may or may not be permitted depending on the food and the usage of the terms. More recently, new legislative provisions on allergens include specific requirements on declaration of any ingredient containing gluten.

Foods for infants and young children must also be considered separately as there are specific regulatory provisions on composition and declaration of any ingredient containing gluten for some products.

7.2 General Provisions

All foodstuffs marketed in Ireland must:

- (a) be of “the Nature, Substance and Quality demanded” (Sale of Food and Drugs Act, 1875), and
- (b) not be “unsafe food” (Article 14, Regulation (EC) 178 of 2002¹³).

These requirements apply to gluten-free foods or those reduced in gluten, subsequently found to contain gluten and which hence may present a risk to the health of coeliacs, in the same way as they apply to any foodstuff presenting a risk to the health of consumers. Foods will normally be assessed against these criteria, following testing as a result of consumer complaints, targeted surveys or general food sampling and surveillance programmes.

In assessing whether in general a food product fulfils the conditions set out in (a) or (b) above, accepted standards may sometimes be applied to support the determination, in the absence of specific national legal provisions. This has been the case in recent years in relation to products containing gluten, with the Public Analysts’ Laboratories applying the draft Codex standard of 2000 (Codex Alimentarius, 2000) (see Section 7.3). In considering the two categories of (i) rendered gluten-free products and (ii) products “consisting of or made only from ingredients which do not contain any prolamins from wheat, durum wheat, rye, barley, oats or any *Triticum* species”, the draft Codex proposal of 2000 set out a more stringent requirement for the latter (20mg/kg) compared to the requirement for products using reduced-gluten ingredients (200mg/kg).

The general food law provision which applies to most food business operations is the European Communities (Hygiene of Foodstuffs) Regulations, 2006, S.I. No. 369 of 2006. Under these Regulations there is a general obligation on food business operators to carry out their activities in accordance with HACCP principles. These include identifying the points in those operations where food hazards may occur, and identifying and implementing effective measures to control the hazards at these critical points. It would be expected that for businesses manufacturing gluten-free products, the presence of gluten would be considered a hazard. Measures would need to be taken to control cross contamination with gluten and gluten ingredients¹⁴.

¹³ Data generated by Public Analyst’s Laboratory, Health Service Executive West, Galway, Ireland, using the R5 ELISA method.

¹⁴ A lower level of 100mg/kg has now been agreed (Codex Alimentarius, 2007).

7.3 Codex Alimentarius Standard for Gluten-Free Foods

The 1983 Codex Standard established a limit of 0.05g total nitrogen per 100g dry matter as an indicator of total protein and hence the gluten content, meaning that the total nitrogen content of any gluten-containing cereal grains used in the product should not exceed 0.05g per 100g of such grains, on a dry matter basis. It is applicable to “processed foods which have been specially prepared to meet the dietary needs of persons intolerant to gluten”, and does not apply to foods which, in their normal form, do not contain gluten.

This standard is now outdated and in practice is difficult to apply (see also Section 4, Analysis of Gluten in Foods), since the results for total nitrogen cannot be directly compared with the results obtained from the ELISA procedures most commonly used to measure gluten at the present time. Also, non-gluten protein may be incorporated into reduced-gluten or gluten-free foods, resulting in a false positive result for the presence of gluten. A new Codex Standard has therefore recently been agreed by the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) at its 2007 meeting, and will be forwarded at Step 8 to the Codex Alimentarius Commission for adoption in 2008. The draft Standard (Codex Alimentarius, 2007) proposes that gluten-free foods are dietary foods:

a) *consisting of or made only from one or more ingredients which do not contain wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer,*

and/or

b) *consisting of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer.*

The draft standard additionally identifies the following category “Foods specially processed to reduce gluten content to a level above 20 up to 100mg/kg” and specifies that:

These foods consist of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100mg/kg in total, based on the food as sold or distributed to the consumer.

7.4 Labelling Provisions

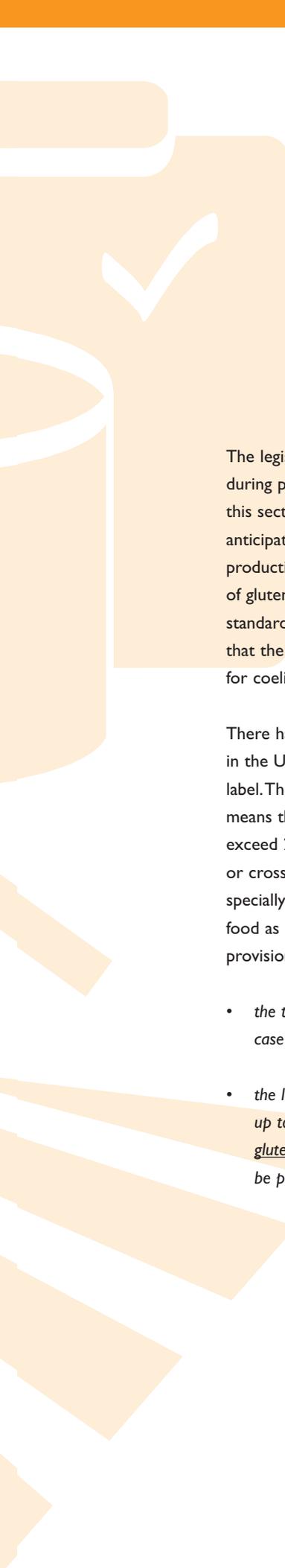
There are several important labelling regulations which apply to foods generally and also more specifically to gluten-free foods or those reduced in gluten. For coeliacs, labelling of products can be of more significance than for other consumers. The use of the terms ‘gluten-free’ and ‘suitable for coeliacs’ can also be considered under labelling controls.

The European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2002 (S.I. No. 483 of 2002), as amended, implementing Council Directive 2000/13/EC as amended, regulates the labelling, presentation and advertising of all food in Ireland. Under this legislation the labelling must not mislead the purchaser as to the characteristics of the foodstuff including its nature, identity, properties and composition (article 2). The information on the label must also be clear and unambiguous (article 13 (2)).

Products containing gluten must be labelled in accordance with Directive 2000/13/EC as amended and outlined in Section 7.4.1. Gluten-free products can be considered under the following headings from a labelling point of view.

7.4.1 Food labelled as “Gluten-Free”

Under Directive 2003/89/EC, amending Directive 2000/13/EC, any ingredient listed in Annex IIIa of the Directive must be declared on the label of a product. These ingredients include “Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof”, and the label should therefore provide the information “Contains wheat” (or rye, barley, oats, spelt, kamut as the case may be). There is no lower level under this legislation below which gluten need not be declared (unlike some allergenic ingredients such as sulphur dioxide). Thus, if gluten is known to be present, the source of the gluten, e.g. wheat, must be declared.



The legislation does not however apply to unintentional cross contamination of foods with allergens during primary production, harvesting and storage and manufacture. As indicated at the beginning of this section, this can result in low levels of analytically-detectable gluten in a food that was anticipated to be gluten-free. Given the potential for cross contamination to occur in the production of gluten-free foods, it is likely that a number of such foods may contain residual traces of gluten, while still being labelled as gluten-free. This is acceptable under current legislation and standards and means that a “zero tolerance” approach cannot be applied. However, it is emphasised that the limits (for gluten in gluten-free foods) being set by Codex will set a high level of protection for coeliacs.

There has been considerable debate at European and international level (in Codex Alimentarius and in the US) as to the standard applicable to products which make a claim to be gluten-free on the label. The draft Codex Standard (Codex Alimentarius, 2007) states that the term “gluten-free” means that the total content of gluten in products defined in (a) and (b) (in Section 7.3) shall not exceed 20mg/kg. It additionally states that the total content of gluten from wheat, rye, barley, oats or crossbred varieties of these should not exceed 100mg/kg in those foodstuffs or ingredients specially processed to reduce gluten content to a level above 20 up to 100mg/kg, on the basis of the food as sold or distributed to the consumer. The draft Standard indicates that the following provisions for the labelling of “gluten-free foods” shall apply:

- *the term "gluten-free" shall be printed in the immediate proximity of the name of the product in the case of products described in section (a) and (b) (in Section 7.3)*
- *the labelling of foodstuffs or ingredients specially processed to reduce gluten content to a level above 20 up to 100mg/kg should be determined at the national level. However, these products must not be called gluten-free. The labelling terms for such products should indicate the true nature of the food, and shall be printed in the immediate proximity of the name of the product.*

7.4.2 Food labelled as “Suitable for Coeliacs”

Declaring a product “suitable for coeliacs” is an indication that the product would not pose a risk to coeliacs and the expectation would be that such a food product would either not contain gluten or that gluten would be present at such low levels as not to pose a risk, i.e. within agreed predefined limits.

A food label claiming such suitability and not containing gluten must adhere to the provisions of Directive 2000/13/EC insofar the claim must be true and the manufacturers must be able to substantiate the claim. The current proposal for a Regulation on Nutrition and Health Claims may apply, although this is not clear as yet, in which case, the claim would have to be approved by the European Food Safety Authority (EFSA).

A food claiming “suitable for coeliacs” but containing gluten within agreed limits where the product would not pose a risk to coeliacs is not necessarily considered as misleading under the labelling legislation. A clarifying statement declaring the gluten level is within levels considered to pose no risk to coeliacs may assist in preventing misunderstanding in the mind of all consumers.

A food claiming “suitable for coeliacs” but containing gluten above any agreed limits would be considered misleading to the consumer and would not be permitted.

7.4.3 Other foods suitable as part of a gluten-free diet

There are many foods, e.g. meat, fish and vegetables, nuts and pulses, see Section 3 of this report, that are anticipated to be completely gluten-free. Section 4 of the draft Codex Standard indicates that such foods should not be designated “special dietary”, “special dietetic” or any other equivalent term, but indicates that such a food can bear a statement on the label that “this food is by its nature gluten-free” provided that it complies with the essential composition provisions for gluten-free as set out in the Standard and provided that such a statement does not mislead the consumer.

7.4.4 Cross contamination issues

It would be expected that in the manufacture of such food products, precautions are also taken to eliminate the possibility of cross contamination in the production of the food (see Section 5). The scope of the Directive 2003/89/EC regarding allergenic ingredients applies only to ingredients voluntarily used for manufacturing food and not to involuntary contamination. The presence of cross contamination would still need to be addressed, but gluten resulting from such would not be declared in the ingredients. There is a general responsibility on food business operators to minimise the occurrence of cross contamination.

7.5 Infant Formulae and Baby Foods

Foods for infants and young children are covered by specific provisions in Regulations. Under the current framework¹⁵, the only legally permitted substitute for breast milk which may be marketed as suitable for infants up to the age of four months is infant formulae, which has strict compositional requirements. These exclude gluten and all sources of gluten. Compositional testing of infant formulae should be done to assess compliance with the schedules outlined in the Regulations. Any test for gluten should yield a result below the limit of quantification.

Processed cereal based foods and baby foods are subject to further Regulations¹⁶, and any marketed as suitable for infants between four to six months must declare the presence or absence of gluten on the label. Any of these products where a statement is made indicating the absence of gluten, should give results below the limit of quantification when tested.

¹⁵ EC (Infant Formulae and Follow On Formulae) Regulations, 2004 (S.I. No. 242 of 2004) and EC (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2007 (S.I. No. 242 of 2007)

¹⁶ EC (Processed Cereal Based Foods and Baby Foods for Infants and Young Children) Regulations, 2007, (S.I. No. 776 of 2007).

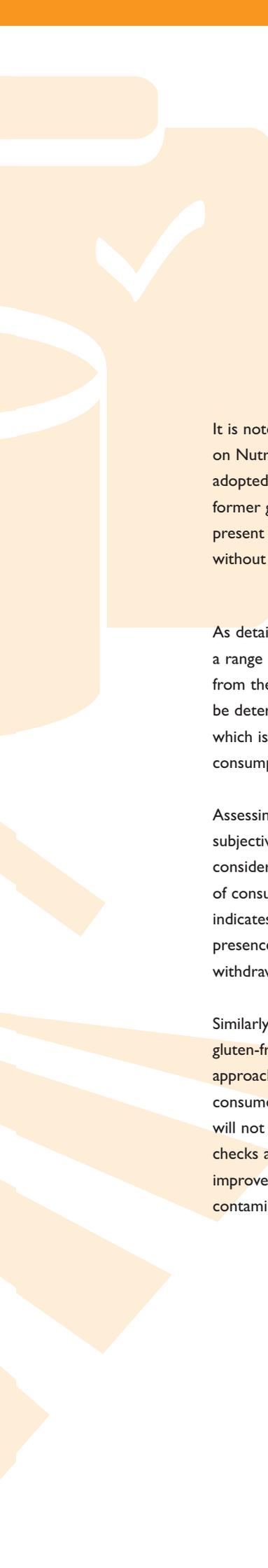
7.6 Enforcement

Enforcement of the legislative provisions relies on a clear indication that a food product does not comply with one or more aspects of food safety legislation and presents a risk to public health. Environmental health officers and the FSAI are able to initiate a variety of actions on food failing to comply with such food safety requirements. This includes requiring remedial action by food business operators, withdrawing food from the market, recalling food from consumers and initiating prosecution. The action taken would be determined by circumstances, contraventions and the degree of risk to consumer health.

When a Public Analysts' Laboratory examines food in relation to gluten content, the samples are reported as either satisfactory or unsatisfactory within the food law framework. An environmental health officer should then be able to initiate appropriate action. As there is no specific accepted Irish standard on levels of gluten for gluten-free foods or foods reduced in gluten, the general provisions of Irish food law as cited in Section 7.2 apply, namely that foodstuffs marketed in Ireland must:

- (a) be of "the Nature, Substance and Quality demanded" (Sale of Food and Drugs Act, 1875),
- (b) not be "unsafe food" (–Article 14, Reg. (EC) 178 of 2002), and
- (c) comply with the general labelling requirements of the European Communities (Labelling, Presentation and Advertising of Foodstuffs) Regulations, 2002 (S.I. No. 483 of 2002).

In deciding whether a gluten-free food is satisfactory or unsatisfactory, the Public Analysts' Laboratories currently apply the proposed maximum levels in the 2000 Codex Alimentarius Standard for Gluten-Free Foods (Codex Committee on Nutrition and Foods for Special Dietary Uses, 2000). Up to the date of this report, these were 200mg/kg for foodstuffs specially processed to render them low in gluten and 20mg/kg for foods containing gluten-free ingredients.



It is noted, however, that the draft Standard recently agreed by the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) which it is anticipated will be adopted by the Codex Alimentarius Commission in 2008 specifies a level of 100mg/kg for the former group (Codex Alimentarius, 2007), reflecting a broad consensus that the higher level could present a risk to the health of some coeliacs and that the lower level could be achieved by industry without significant economic impact.

As detailed above, in the case of a food being designated as unsatisfactory enforcement can include a range of options including requiring remedial action by food business operators, withdrawing food from the market, recalling food from consumers and initiating prosecution. The action taken would be determined by assessing the degree of risk to consumer health. A product labelled gluten-free which is a source of gluten at a level above 20mg/kg, on the basis of the product ready for consumption, will clearly not comply with labelling requirements.

Assessing a product as 'unsafe' or 'not of the nature, substance and quality demanded' is more subjective and the risk to health and appropriate application of standards would be taken into consideration in making such a determination. Coeliacs would be considered as a specific category of consumers with particular health sensitivities. Labelling a product as 'gluten free' specifically indicates that the product should be suitable for those consumers. In order to manage the risk, the presence of gluten at levels above 20mg/kg in products labelled as 'gluten free' is likely to lead to withdrawal of products from the market and recall of products from consumers.

Similarly, where gluten is detected in foodstuffs expected to be consumed by coeliacs as part of a gluten-free diet but not specifically labelled as such, it may be necessary to adopt a cautious approach to managing the risk. It would be expected that these types of foods would be eaten by all consumers, not only coeliacs. Even when gluten levels are higher than 100mg/kg, as most consumers will not be put at risk, the appropriate enforcement action is likely to involve the carrying out of checks at the point of production and supply to try and identify the source of contamination and to improve the food safety management systems in handling establishments to prevent future cross contamination, but not to withdraw or recall product.

8. CONCLUSIONS/RECOMMENDATIONS

The Working Group on Gluten has considered:

- the prevalence of the coeliac condition (coeliac disease) in Ireland;
- the potential exposure of Irish coeliacs to gluten in their diet;
- the likelihood of adverse health effects as a consequence of exposure;
- the importance of the gluten-free or reduced-gluten diet in maintaining good health;
- the availability of information to coeliacs on (1) reduced-gluten and gluten-free foods, (2) the nutritional status of such foods, and (3) results of analyses carried out on reduced-gluten or gluten-free products
- the current gluten limits/standards applicable to food control
- the need for regulation and control, including guidance material, because of possible contamination of reduced-gluten or gluten-free foods with gluten, and hence possible adverse effects on the health of individuals sensitive to gluten.

The data detailed in this report suggest a prevalence of the coeliac condition of five to ten cases per 1,000 of the adult European population overall, with the incidence in Ireland, Italy and Scandinavia lying at the upper end of this range. The coeliac condition can therefore be considered as a potentially significant health issue in the Irish population. This can be controlled by minimising exposure to gluten by strict adherence to a gluten-free or reduced-gluten diet. It is recognised, however, that coeliacs may still be exposed to gluten for a number of reasons; these include non-adherence to a reduced-gluten diet or inadvertent exposure to gluten.



Non-adherence to a gluten-free or reduced-gluten diet may be related to lack of availability of varied and attractive gluten-free foods and/or to the cost of such foods, while inadvertent exposure may occur as a consequence of the presence of gluten in foods believed by the consumer to be low in gluten or gluten-free. The Working Group has identified that cross contamination of gluten-free products or products manufactured with ingredients that have been rendered gluten-free by products that are not gluten-free, notably wheat flour, may be a significant cause of inadvertent exposure to gluten. Cross contamination may happen during primary production, harvesting and storage of grain and/or during the manufacture or preparation of reduced-gluten or gluten-free food.

In assessing the risk to coeliacs, due to exposure to gluten in their diet, the Working Group has considered the intake of gluten likely to trigger adverse health effects. The Working Group noted that there exists considerable inter-individual variation in susceptibility to gluten, making it difficult to identify a single level that may be considered to present a significant risk of triggering adverse health effects in the majority of coeliacs. It also noted the opinion of the EFSA NDA Panel, that there are insufficient data to suggest a threshold dose of gluten tolerable for all coeliac patients and that, in general, a system of risk evaluation based on the assessment of no observed adverse effect levels (NOAEL) does not apply currently to allergens such as gluten.

However, available data suggest that exposure of a coeliac to gluten in the range of 20 – 100mg/day or higher is only likely to trigger an adverse reaction in very sensitive individuals. The particular sensitivity of some individuals, including young children, who may react to levels of gliadin as low as 10mg/day would argue for the need for a low limit of 20mg/kg for gluten in food which coeliacs see as gluten-free such as corn-based products and rice cakes, and which is labelled as gluten-free while less sensitive individuals may be adequately protected by levels of 100mg/kg.

The Working Group has also considered currently available analytical techniques for gluten in food and noted that recent research has focused on the new sandwich R5 ELISA procedure which has been recently collaboratively tested and temporarily endorsed in 2004 by CCMAS, the Codex Committee for Methods of Analysis and Sampling. The R5 method has good sensitivity, with stated limits of detection (LOD) of 3.0mg gluten/kg food (3mg/kg) and appears to present, together with other methodologies, a suitable alternative to the method laid down in the 1983 Codex Standard which is based on measurement of total nitrogen.

The Working Group notes that there are limitations to the use of the latter standard in assessing compliance of a food product with food safety legislation. The Public Analysts' Laboratories are currently applying the proposed levels in the 2000 draft Codex Standard of 20mg/kg for foods consisting of or made only from ingredients which do not contain any prolamins from *Triticum* species such as bread wheat/durum wheat, spelt, kamut, rye, barley, [oats] or their crossbred varieties ("naturally gluten-free") and 200mg/kg for reduced-gluten foodstuffs. The Working Group notes, however, that in the draft revised Codex Standard recently agreed by the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses at its 2007 meeting, which will be forwarded at Step 8 to the Codex Alimentarius Commission for adoption in 2008, the 2000 proposed limit of 200mg/kg has been revised downwards to 100mg/kg, reflecting a broad consensus that the higher level could present a risk to the health of some coeliacs and that the lower level could be achieved by industry without significant economic impact.

As a standard for gluten-free foods has to date not been finally agreed, either at Codex level or at European level, enforcement officers may face challenges when carrying out enforcement activities initiated on use of the draft Standard. The Working Group notes the dilemma that this presents in relation to assessment of the safety of gluten-free food for coeliacs and food that has been rendered gluten-free, and stresses the need for nationally-endorsed guidance values for gluten in reduced-gluten and gluten-free foods.

The Working Group has also considered the availability of information to coeliacs on reduced-gluten and gluten-free foods, the levels of gluten contained therein and their nutritional status. It noted that the availability of analytical results from the surveillance programme carried out by the HSE/FSAI would help coeliacs to make informed choices regarding their diet, in addition to the excellent information made available by the Coeliac Society of Ireland. It also noted that there is limited information available on the nutritional quality of the reduced-gluten and gluten-free foods available to coeliacs.

As a consequence of these considerations and conclusions, the FSAI Working Group on Gluten recommends, and the Scientific Committee of the FSAI endorses, the guidance values laid out in Table 5 for gluten in gluten-free foods and foods manufactured from ingredients that have been reduced in gluten, based on the proposed (2007) Codex recommended levels.

Table 5. Gluten-free and Reduced-gluten Food Categories and Guidance Values for Gluten Content

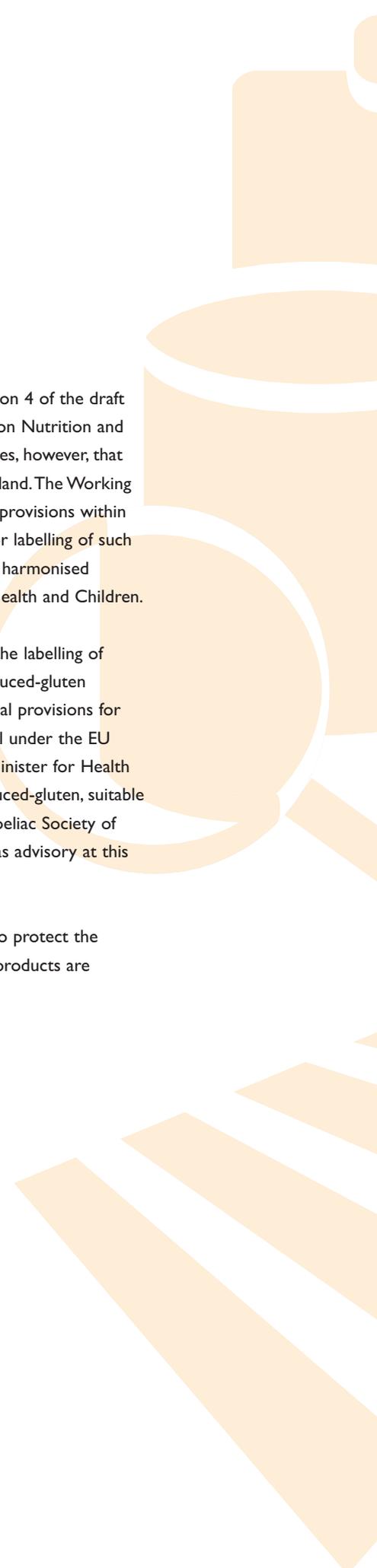
Food Category	Recommended Maximum Limit for Gluten (see Note 1)
<i>Dietary foods consisting of or made only from one or more ingredients which do not contain wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer.</i>	20mg/kg ¹⁷
<i>Dietary foods consisting of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to remove gluten, and the gluten level does not exceed 20mg/kg in total, based on the food as sold or distributed to the consumer.</i>	20mg/kg ¹⁷
<i>Dietary foods consisting of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100mg/kg in total, based on the food as sold or distributed to the consumer.</i>	100mg/kg ¹⁷

Note 1: Based on results obtained using the R5 ELISA method. These limits are provisional, pending the final establishment of standards at EU and/or Codex level.

The Working Group on Gluten recommends that Irish Industry should implement the following labelling provisions for the dietary foods listed in Table 5.

- Products in categories 1 and 2 of Table 5 may be labelled as “gluten-free”. The term “gluten-free” shall be printed in the immediate proximity of the name of the product, e.g. “Emer’s Rice Cakes, gluten-free”.
- Products in Category 3 of Table 5 should not be labelled as “gluten-free”. An alternative description, designed not to mislead the consumer, should be used, such as “reduced-gluten, suitable for most coeliacs”.

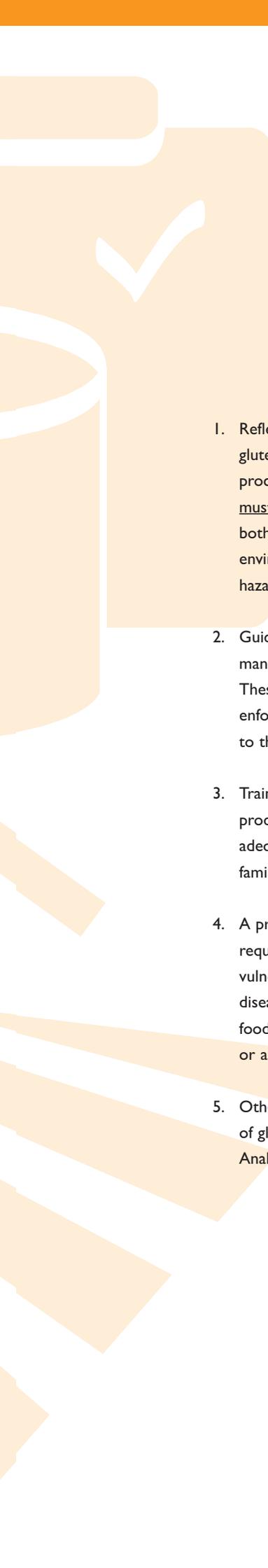
¹⁷ The maximum levels of gluten as set out in Table 5 apply to the foodstuffs as marketed. By way of derogation from this principle, for dried and/or concentrated foods which need to be reconstituted the maximum levels apply to the food as reconstituted according to the instructions on the label taking into account the minimum dilution factor. The limits apply directly to ingredients such as gluten-free flour, wheat starch and similar ingredients as marketed.



The recommended labelling is in line with the labelling provisions set out in Section 4 of the draft revised Codex Standard recently agreed by the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses at its 2007 meeting. The Working Group recognises, however, that this labelling may be at variance with the current labelling of such products in Ireland. The Working Group recommends therefore that Irish industry implements the above labelling provisions within one year of the date of publication of this report, unless mandatory provisions for labelling of such products are introduced within this time period, either at EU level under the EU harmonised legislation on labelling, or via national legislation introduced by the Minister for Health and Children.

The Working Group notes that under the draft revised Codex Standard (2007), the labelling of products in Category 3 should be determined at national level. In the case of reduced-gluten products placed on the market in Ireland, there is currently no mandatory national provisions for labelling of such products. Such may be developed in the future, either at EU level under the EU harmonised legislation on labelling, or via national legislation introduced by the Minister for Health and Children. While the Working Group recommends a description such as “reduced-gluten, suitable for most coeliacs” for these products, and a recent survey of members of the Coeliac Society of Ireland showed reasonable support for such a phrase, this can only be regarded as advisory at this point in time.

Finally, the Working Group suggests the following additional measures, designed to protect the health of coeliacs in Ireland and consumers in countries to whom relevant food products are exported, who may be at risk due to intolerance to gluten in their diet.

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1. Reflecting the fact that gluten-free foods or foods manufactured from ingredients rendered gluten-free can be potentially cross contaminated with gluten at various stages of production, processing and distribution before such food reaches the ultimate consumer, such contamination must be regarded as a hazard under obligatory HACCP food safety management systems where both reduced-gluten and gluten-free and products containing gluten are dealt with in the same environment. It is a legal obligation for all food business operators to adequately control the hazards associated with their activities.
 2. Guidelines should be drawn up for industry for the avoidance of cross contamination in manufacturing premises, and also in catering and retail establishments as applicable. These guidelines should be brought to the attention of all appropriate food businesses, and enforcement organisations. Each individual premises should be assessed for adherence to the proposed guidelines on a risk analysis basis.
 3. Training programmes should be developed for enforcement officers, staff working in the production of reduced-gluten and gluten-free foods and food services staff to ensure they are adequately aware of the hazards that gluten presents to certain consumers and that they are familiar with appropriate control requirements.
 4. A programme of surveillance of compliance of foods for infants and young children with the requirements of the relevant Regulations should continue, in order to protect the health of this vulnerable subpopulation, particularly those who may have a genetic predisposition to coeliac disease. This surveillance should include, in particular, processed cereal-based foods and baby foods marketed as suitable for infants from four to six months which must declare the presence or absence of gluten on the label.
 5. Other reduced-gluten and gluten-free products should be periodically surveyed for the presence of gluten as part of the collaborative chemical monitoring programme carried out by the Public Analysts' Laboratories and the enforcement officers on behalf of the FSAI.

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6. Recognising the excellent work carried out by the Coeliac Society of Ireland and its branches in providing information to coeliacs, the FSAI and organisations under service contract to them should continue to build greater linkages between the Society, researchers involved in the study of the coeliac condition and with relevant food services industries to explore ways by which they can cooperate with each other to provide continual improvement in the protection of persons with the coeliac condition.
 7. The work done to date has raised the question as to the nutritional quality of the reduced-gluten and gluten-free diet and the lack of awareness among coeliacs of this possibility. More work should be done to investigate this. Manufacturers of reduced-gluten and gluten-free foods should also be encouraged to improve the nutritional quality of their products, especially those that are made using unenriched, refined grains or starches. Of particular note, the needs of coeliacs warrant consideration when examining folic acid fortification of bread or flour.
 8. Discussions should be initiated with *safe*food to identify possible interest in progressing recommendations laid out in this report, relevant to their role in promoting food safety in Ireland, in particular, provision of advice to consumers, including nutritional advice, and the building of linkages with the Coeliac Society of Ireland, its branches, and researchers involved in the study of the coeliac condition.
 9. In view of the complexities of gluten testing and the deficiencies of both Certified Reference Materials (CRMs) and Proficiency Testing Schemes (PTSs), the FSAI should request the EU Commission to facilitate:
 - (a) the IRMM (EC Institute of Reference Materials and Measurements) and other agencies, where appropriate, to provide a broad range of suitable gluten-free CRMs, e.g. gluten-free flours, starches, for validation use by testing laboratories, and
 - (b) the IRMM and other appropriate organisations, e.g. CSL (FAPAS UK) and other PTS providers, to develop a suitable range of Proficiency Testing Schemes for laboratories.

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APPENDIX II: GLOSSARY

Brush border

The apical surface of the columnar epithelial cells covering the luminal surface (sides and apices) of the villi or the flat surface mucosa of the untreated coeliac condition. The brush border consists of microvilli and a covering layer of mucus rich in digestive enzymes and secretory immunoglobulins.

Dermatitis herpetiformis

An extremely itchy skin rash which is characterised by small vesicles (shingles-like blisters + herpetiformis), especially on elbows, knees, shoulders and buttocks. It is associated with the coeliac condition and responds to a gluten-free diet and/or dapsone therapy.

Dyspepsia

A non-specific upper abdominal discomfort also known as indigestion. Symptoms such as bloating, burning and rumbling vary from individual to individual.

Gluten-free

A description of some foods, by way of labelling, advertising or presentation indicating that they are essentially free of gluten. Levels of gluten in such foods must be below 20mg/kg. Gluten-free foods can be either specially processed to reduce gluten levels below 20 mg/kg or “naturally gluten-free”.

HLA antigens

Genes on the short arm of chromosome 6 which encode proteins on the surfaces of nucleated cells which are implicated in the handling and presentation of antigenic proteins. HLA DQ2 is associated with increased frequency of a variety of “auto-immune” diseases.

Hypoproteinaemia

A decrease in the concentration of protein in the blood. In the coeliac condition this is mainly secondary to impaired absorption of dietary protein.

Naturally gluten-free

A description of some gluten-free foods indicating by way of labelling, advertising or presentation that they are essentially free of gluten, and consist of or are made only from ingredients which do not contain any prolamins from Triticum species such as bread wheat/durum wheat, spelt, kamut, rye, barley, (oats), or their crossbred varieties. Levels of gluten in such foods must be below 20mg/kg.

Nominally gluten-free

A description of a food that consists of one or more ingredients from wheat (i.e., all Triticum species, such as durum wheat, spelt, and kamut), rye, barley, oats⁵ or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100mg/kg in total, based on the food as sold or distributed to the consumer. See also “Reduced-gluten” and “Rendered gluten-free”.

Osteopenia

A non-specific generalised or regional decrease in bone density, although lower than normal for sex and age the density is not sufficiently severe to be classified as osteoporosis.

Osteomalacia/Rickets

A condition of bone in which during development there is inadequate mineralisation of osteoid, the bone matrix.

Osteoporosis

Osteoporosis and osteopenia are conditions of bone, in which the trabecular structure (internal scaffolding) is thinner than normal rendering the bone more brittle and likely to fracture. DEXA scan are currently widely used to assess bone density. Osteoporosis is defined as a bone density of >2.5 SD below the average for healthy bones and osteopenia bone density of 1 - 2.5 SD below average healthy bones. The reference population is healthy 25 year old males and females.



Reduced-gluten

A description of a food that consists of one or more ingredients from wheat (i.e., all *Triticum* species, such as durum wheat, spelt, and kamut), rye, barley, oats⁵ or their crossbred varieties, which have been specially processed to reduce the gluten content to a level above 20 up to 100mg/kg in total, based on the food as sold or distributed to the consumer. See also “Rendered gluten-free” and “Nominally gluten-free”.

Rendered gluten-free

Refers to foods originating from wheat (or rye or barley etc) which have undergone some technological process to remove gluten, e.g. the production of wheat starch from wheat flour. This special processing must reduce the gluten content to a level above 20 up to 100mg/kg in total, based on the food as sold or distributed to the consumer. See also “Reduced-gluten” and “Nominally gluten-free”.

“Suitable for coeliacs”

A description of a food or drink indicating that normal consumption of such a food product would not pose a risk to coeliacs (see Section 7.4 of this report).

Steatorrhoea

The passage of faeces containing abnormally high levels of fat. The faeces are greasy, pale, malodorous and difficult to flush away.

Tetany

Involuntary spasm of muscle (cramp). It is associated with a reduction in the level of ionized calcium in the blood.

APPENDIX III: A TYPICAL REDUCED-GLUTEN DIET

Food Type	Dietary Indications ¹⁸	Dietary Contra-indications
Bread	Gluten-free bread	Ordinary bread (including naan, ciabatta and chapatti), breadcrumbs
Flour	Gluten-free flour, gluten-free bread mix, gluten-free baking powder, potato/sago/soya/corn/rice/chickpea/maize/bean/split pea flours, sorghum	Wheat/ordinary flour, ordinary bread mix, ordinary baking powder, wheat germ, bulgar, wheat, spelt, triticale.
Biscuits/Cake	Gluten-free biscuits/crackers/cakes, meringues, pies made with gluten-free flour, rice cakes, crispbreads, *poppadoms	Ordinary biscuits/crackers, ordinary cakes, ice-cream wafers and cones
Cereals	Buckwheat, sago, tapioca, millet, corn or maize, rice, potato starch, arrow root, birds custard powder	Barley, wheat, rye, oats , semolina, farina, custard powder*, modified starch*, couscous
Breakfast Cereals	Puffed rice, gluten-free muesli, gluten-free cereals	Based cereals, wheat based cereals, oat ¹⁹ based cereals muesli, *all other cereals
Bran	Soya bran, corn bran, maize bran, rice bran	Oat bran, wheat bran
Pasta	Gluten-free pasta, rice or corn pasta	Ordinary pasta including spaghetti, noodles, macaroni, lasagne
Rice	White rice, wholegrain rice, rice noodles	
Eggs	Cooked as desired without flour or breadcrumbs	Scotch eggs
Baby Foods ²⁰	*Check label	
Pizza	Gluten-free pizza base topped with gluten-free ingredients	Ordinary pizza
Fruit	Fresh, stewed, tinned or dried	Fruit tart/pie, *pie fillings, all fruit in breadcrumbs, sauce/batter

¹⁸ It is advisable to check the gluten-free manufactured product list published by the Coeliac Society of Ireland when considering the suitability of processed foods not specifically labelled as "gluten-free".

¹⁹ Some studies have provided evidence of the long term safety of oats as part of a coeliac diet in adult patients; other studies have yielded conflicting results. Usage should be based on individual dietetic advice.

²⁰ Please see Section 7.5 Infant Formulae and Baby Foods.

Food Type	Allowed	Not Allowed
Alcohol	Gin, vodka, rum, wine, champagne, sherry, port, Ritz, Perry, cider, *liqueurs, whiskey and alcoholic lemonades	All types of beer including home made, stout and lager.
Milk and milk products	Fresh, tinned, condensed, UHT, evaporated or powdered milk, low fat/skimmed milk, butter milk, coffee creamers, fresh and soured cream, yoghurt (plain and fruit), crème fraîche, most hard cheeses including cheddar, cottage cheese or curd	Synthetic and artificial cream, *milk shakes, muesli yoghurt, *diet yoghurt, cream cheese, *cheese spread, *processed cheese, *ice-cream, *dessert mixes
Meat, poultry and fish	Fresh and frozen meat, poultry and fish, prepared without breadcrumbs/batter/sauces, fish tinned in oil/brine, gluten-free sausages	Meat, poultry and fish in breadcrumbs or batter, *processed/tinned meats, *ordinary sausages, black and white pudding, meatloaf, Cornish pasties, *pate, *casseroles, *beef burgers, *kebabs, *fish fingers, *fish in batter or crumbs, *fish cakes, meat and fish spreads, chicken in breadcrumbs or batter
Vegetables	Fresh, frozen or dried vegetables, potatoes including home made chips, *most tinned vegetables, pickled vegetables, peas, beans lentils, chickpeas, soya beans, tomato puree	Vegetables in pastry, breadcrumbs, batter/sauces, tinned vegetables in a sauce thickened with flour, batter/breadcrumbs, e.g. onion rings, *baked beans, vegetable burgers, *coleslaw, *baked beans, *potato, waffles/croquettes, *potato cakes/salad, *instant potato, *crisps, *take away chips, frozen chips
Soups and sauces	Homemade soups and sauces made from and thickened with gluten-free ingredients, Bovril, Marmite, gravy made without Bisto or ordinary flour, oil and vinegar based salad dressing	*Tinned/packet soups, *bottled/packet sauces, *stock cubes, *gravy thickener, *salad cream and dressings, *mayonnaise, *curry powder, custard powder, soya sauce, Worcester sauce
Miscellaneous	Sugar, jam, marmalade, honey, jellies, jelly, boiled sweets, popcorn, nuts, herbs, pure spices and certain brands of ready mixed spices, seasonings and curry powder, nuts, seeds, tofu, butter, margarine, oils, fresh suet, lard, French dressing, salt, pepper, treacle, monosodium glutamate, certain brands of baking powder, fresh and dried yeast, colours, essences and *gelatine, bicarbonate of soda, cream of tartar, tartaric acid	*Plain and milk chocolate, *chocolate or sweets with a biscuits or cream filling, *mincemeat, salad dressings thickened with flour, packaged suet, *liquorice, nougat, *caramels, *toffee, *crisps, *lemon curd, *medications, dessert mixes tarts, pies, *communion hosts, peanut butter, dry roasted peanuts, shredded suet, white pepper

*Check the gluten-free manufactured product list published by the Coeliac Society of Ireland on an annual basis.

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Health Service Executive West, Sligo General Hospital, Sligo

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Navan, Co. Meath

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