

**Legislation on ‘Gluten-free’ Foods
and Avoidance of Cross-contamination
during Manufacture of ‘Gluten-free’
or ‘Very Low Gluten’ Products**

Guidance Note No. 24
Legislation on ‘Gluten-free’ Foods
and Avoidance of Cross-contamination
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or ‘Very Low Gluten’ Products

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ISBN 1-904465-71-4

CONTENTS

1	INTRODUCTION	1
2	SCOPE	2
3	STANDARDS/LEGISLATION ON ‘GLUTEN-FREE’ FOODS	2
3.1	Codex Alimentarius Standard for ‘Gluten-free’ Food	2
3.2	Commission Regulation Concerning the Composition and Labelling of Foodstuffs Suitable for People Intolerant to Gluten	3
3.3	Legal Provisions Related to the Use of Gluten-containing Ingredients in Infant Formula and Processed Cereal-based Foods and Baby Foods for Infants and Young Children	5
3.4	Packaging/Labelling	5
3.5	Notification of Foodstuffs Suitable for People Intolerant to Gluten under PARNUTS Legislation	7
4	CROSS-CONTAMINATION	9
4.1	General Obligations of Food Business Operators	9
4.2	Sources of Cross-contamination	10
4.2.1	Primary production, harvesting and storage	10
4.2.1.1	Crop production	10
4.2.1.2	Harvest	11
4.2.1.3	Storage	11
4.2.2	Other sources of contamination	11
4.3	Preventative Measures and Critical Control for ‘Gluten-free’ Products	12
4.3.1	Raw ingredients	12
4.3.2	Storing raw materials and products	13
4.3.3	Processing	13
4.3.4	Rework	14
4.3.5	Equipment	14
4.3.6	Packaging/Labelling	15
4.3.7	Sanitation	17
4.3.8	Training	18
4.3.9	Sampling and analysis	18
5	CONCLUSION	21
6	REFERENCES	23
	OTHER FOOD SAFETY GUIDANCE NOTES AVAILABLE FROM THE FOOD SAFETY AUTHORITY OF IRELAND	25

I. INTRODUCTION

Intolerance to gluten is a potentially significant cause of poor health in the Irish population, with a prevalence of 5 – 10 cases per 1,000 of the adult population. Gluten is a water-insoluble, complex mixture of cereal proteins (prolamins and glutenins) and other constituents. In wheat, barley, rye and oats, the prolamins comprise gliadins, horedins, secalins and avenins, respectively. Coeliac disease is an autoimmune disorder characterised by intolerance to gluten, which results in damage to the small intestine, characterised by symptoms including malnutrition, diarrhoea and anaemia. Adverse health effects in coeliacs can be controlled by strict adherence to a 'gluten-free' diet or one that is low in gluten due to use of cereal ingredients that have been rendered 'gluten-free'. Individual variation and clinical heterogeneity of coeliac patients makes it difficult to find an acceptable threshold value for trace amounts of gluten to be allowed in 'gluten-free' foods¹. 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 manufacture, processing, storage or transport.

In 2008, the Scientific Committee of the Food Safety Authority of Ireland (FSAI) published a report² on gluten intolerance, the coeliac condition and on 'gluten-free' or low-gluten foods. The report included recommendations for Irish standards for levels of gluten in food suitable for people who are intolerant to gluten, and also on the labelling of such foods. The report made additional recommendations on a number of related issues, including the need for surveillance of gluten in 'gluten-free' and low-gluten products and the improvement of the nutritional quality of foods suitable for consumption by coeliacs. A specific recommendation to the FSAI was that guidance should be developed on cross-contamination for industry, catering and retail establishment as applicable.

This guidance note has been developed by the FSAI in response to the above recommendation. In addition, it provides guidance on the new European legislation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

2. SCOPE

This document provides guidance on the minimum requirements for the production of foods to enable them to be described as 'gluten-free' or 'very low gluten' and is applicable to those involved in the handling, production and distribution of 'gluten-free' or 'very low gluten' products. The aim of this guidance note is to: improve food safety, quality and standards within the industry for the production of 'gluten-free' or 'very low gluten' products, and to increase the awareness of the importance of elimination of gluten from foods produced for people intolerant to gluten.

3. STANDARDS/LEGISLATION ON 'GLUTEN-FREE' FOOD

There are three basic categories of 'gluten-free' foods:

- 1) Naturally 'gluten-free' foodstuffs containing no wheat prolamins
- 2) Foodstuffs consisting of ingredients from wheat, rye, barley, oats, spelt etc. which have been either rendered 'gluten-free' (deglutenised) by alcohol extraction during processing of the grain or
- 3) Foodstuffs which have been specially processed before use to reduce the gluten to a level tolerated by most coeliacs i.e. 'very low gluten'

3.1 Codex Alimentarius Standard for 'Gluten-free' Food

Until recently, the only agreed standard for 'gluten-free' foods was the 1981 Codex Standard of 0.05g total nitrogen per 100g dry matter (Codex Standard 118-1981). However, this standard was difficult to apply as the results for total nitrogen test could not be directly compared to those obtained using the more common ELISA procedures. A revised Standard³ for foodstuffs for special dietary uses was adopted by the 31st session of the Codex Alimentarius Commission in July, 2008. The standard applies to foods for special dietary uses that have been formulated, processed or prepared to meet the special dietary needs of people intolerant to gluten.

The standard defines 'gluten-free' foods as 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^a 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^a their cross-bred 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

In addition, the Codex standard recognises another category of foodstuffs namely “Foods specially processed to reduce gluten content to a level between 20 and 100mg/kg”. This category is defined as:

- c) Foods consisting of one or more ingredients from wheat (i.e. all *Triticum* species, such as durum wheat, spelt and kamut), rye, barley, oats^a 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 foods as sold or distributed to the consumer

3.2 Commission Regulation 41/2009/EC Concerning the Composition and Labelling of Foodstuffs Suitable for People Intolerant to Gluten

Following the adoption of the new Codex Alimentarius Standard, legislation enacting the provisions of the Standard has recently been agreed at Community level. Commission Regulation 41/2009/EC concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten⁴ requires that: foodstuffs which have been specially formulated processed or prepared to meet the dietary needs of people intolerant to gluten and marketed as such should be labelled either as ‘very low gluten’ (gluten content above 20 up to 100mg/kg) or ‘gluten-free’ (gluten content not exceeding 20mg/kg). Those foodstuffs can be either foodstuffs which have been specially processed to reduce the gluten content of one or more gluten containing ingredients or alternatively they can be foodstuffs where the gluten containing ingredients have been substituted by other ingredients naturally free of gluten.

The Regulation applies to all foodstuffs other than infant formulae and follow-on formulae covered by Directive 2006/141/EC⁵ (see section 3.3). The Regulation also allows for a normal food which does not contain ingredients derived from gluten-containing grains or oats to be labelled using terms indicating the absence of gluten. However, the labelling Directive 2000/13/EC⁶ requires that such a statement does not mislead the consumer by suggesting that the food possesses special characteristics, when in fact, all similar foodstuffs possess such characteristics. The main provisions of the new Regulation are laid down in articles 3 and 4 as outlined on the following page.

^a Footnote to Codex Standard 2008: 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 national level. This footnote applies to any subsequent reference to oats in this guidance note.

Article 3: Composition and labelling of foodstuffs for people intolerant to gluten

- 1) *Foodstuffs for people intolerant to gluten, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce gluten, shall not contain a level of gluten exceeding 100mg/kg in the food as sold to the final consumer.*
- 2) *The labelling, advertising and presentation of the products referred to in paragraph 1 shall bear the term “very low gluten”. They may bear the term ‘gluten-free’ if the gluten content does not exceed 20mg/kg in the food as sold to the final consumer.*
- 3) *Oats contained in foodstuffs for people intolerant to gluten must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties, and their gluten content does not exceed 20mg/kg.*
- 4) *Foodstuffs for people intolerant to gluten, consisting of or containing one or more ingredients which substitute wheat, rye, barley, oats or their crossbred varieties shall not contain a level of gluten exceeding 20mg/kg in the food as sold to the final consumer. The labelling, presentation and advertising of those products shall bear the term ‘gluten-free’.*
- 5) *Where foodstuffs for people intolerant to gluten contain both ingredients which substitute wheat, rye, barley, oats or their crossbred varieties and ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce gluten, paragraphs 1, 2, and 3 shall apply but paragraph 4 shall not apply to such products.*
- 6) *The terms ‘very low gluten’ or ‘gluten-free’ referred to in paragraphs 2 and 4 shall appear in proximity to the name under which the food is sold.*

Article 4: Composition and labelling of other foodstuffs suitable for people intolerant to gluten

- 1) *Without prejudice to Article 2(1)(a)(iii) of Directive 2000/13/EC, the labelling, advertising and presentation of the following foodstuffs may bear the term ‘gluten-free’ provided that the gluten content does not exceed 20mg/kg in the food as sold to the final consumer:*
 - a) *Foodstuffs for normal consumption*
 - b) *Foodstuffs for particular nutritional uses which are specially formulated, processed or prepared to meet special dietary needs other than those of people intolerant to gluten but which are nevertheless suitable, by virtue of their composition to meet the special dietary needs of people intolerant to gluten.*
- 2) *The labelling, advertising and presentation of foodstuffs referred to in paragraph 1 shall not bear the term ‘very low gluten’.*

The Regulation was published in the Official Journal (OJ) of the European Union on the 20th of January 2009, and entered into force on the 10th of February, 2009. However, transitional measures will apply in order to allow food business operators to adapt their production processes to produce food meeting the new standards, and also to adapt their labelling. The Regulation does not therefore apply until 1st January, 2012. However, foodstuffs which, at the date of entry into force of the Regulation, already comply with the provisions of the Regulation may be placed on the market in the European Community as complying with the new legislation.

3.3 Legal Provisions Related to the Use of Gluten-containing Ingredients in Infant Formula and Processed Cereal-based Foods and Baby Foods for Infants and Young Children

Commission Directive 2006/141/EC on infant formulae and follow-on formulae⁵, prohibits the use of ingredients containing gluten in the manufacture of such foodstuffs. Therefore, the use of the terms 'very low gluten' or 'gluten-free' on the labelling of such products should be prohibited given that pursuant to Regulation 41/2009/EC, this labelling is used for indicating a content of gluten not exceeding 100mg/kg and 20mg/kg respectively. Furthermore, Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children⁷, requires the indication of the presence or the absence of gluten when the product is intended for infants below six months of age. The absence of gluten in such products should be indicated in accordance with the requirements laid down in Regulation 41/2009/EC.

3.4 Packaging/Labelling

Labelling is the primary means of informing the consumer about the potential presence of gluten. The provisions of Commission Regulation 41/2009/EC concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten⁴, must be followed as outlined previously. Additionally, without prejudice to the requirements of this Regulation, in the European Union Council Directive 2000/13/EC⁶ as amended, regulates the labelling, presentation and advertising of all foods in Ireland. This Directive has been transposed into Irish legislation by S.I. No. 483 of 2002⁸ and stipulates that labelling must not mislead the purchaser as to the characteristics of the foodstuff, including its nature, identity, properties and composition. The information on the label must also be clear and unambiguous.

In order to address the issue of food allergies and intolerances, the EU Commission has also adopted Directive 2003/89/EC⁹ which amends Directive 2000/13/EC and lays down compulsory labelling of allergenic ingredients in foodstuffs. Under Directive 2003/89/EC, any ingredient listed in Annex IIIa of Directive 2000/13/EC 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 in the list of ingredients, e.g. contains wheat, rye, barley, oats, spelt or kamut as the case may be. There is no lower level under this legislation below which cereals containing gluten need not be declared (unlike some other 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. It should be noted that if it is a food product which is not required to have a list of ingredients, e.g. alcohol, then the label must either refer to the particular ingredient in the name of the product, e.g. wheat beer, or the label must state “contains wheat”.

It should also be noted however, that this labelling requirement only applies to the intentional ingredient in a food product, and does not address the issue of cross-contamination or unintentional addition of gluten to foods. Thus, when a foodstuff has become adventitiously contaminated by a gluten-containing cereal during manufacture, there is no requirement to apply the rules of Directive 2003/89/EC regarding labelling of allergens in the foodstuff.

Annex IIIa to Directive 2000/13/EC has been subsequently amended on a number of occasions and the latest amendment is Directive 2007/68/EC¹⁰. This Directive lists a number of exemptions from the labelling requirement for ingredients or substances derived from ingredients listed in Annex IIIa for which it has been scientifically established that they are not likely, under specific circumstances, to trigger adverse reactions. Commission Directive 2005/26/EC¹¹ established this list of food substances and ingredients provisionally excluded from the labelling requirements until the 25th of November, 2007. However, a number of applications for permanent exemption from these labelling requirements were subsequently submitted to the European Food Safety Authority (EFSA) for assessment. On the basis of the EFSA opinions and other available information, it was concluded that certain ingredients or substances derived from those ingredients listed in Annex IIIa to Directive 2000/13/EC are not likely, under specific circumstances, to cause adverse reactions in susceptible individuals. As a result of these conclusions, those ingredients or substances derived from those ingredients were permanently excluded from Annex IIIa to Directive 2000/13/EC. This was amended and replaced by the text in the annex to Directive 2007/68/EC and Directive 2005/26/EC was repealed. In terms of substances derived from cereals containing gluten, the following exemptions apply:

Ingredients	Products thereof excluded
I. Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof, except:	a) Wheat-based glucose syrups including dextrose ^b b) Wheat-based maltodextrins ^b c) Glucose syrups based on barley d) Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages

In relation to genetically-modified foods, exposure to gluten was considered in 2001 in the Codex General Standard for the Labelling of Pre-packaged Foods¹². With regard to the labelling of food and food ingredients obtained through genetic modification/genetic engineering, section 4.2.2. (1) of the Standard stipulates that “The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from cereals containing gluten i.e. wheat, rye, barley, [oats], spelt or their hybridized strains and products of these shall be declared”. Also, in 2001 the Codex Alimentarius Commission adopted the Codex Standard for wheat protein¹³ products including wheat gluten whereby “*wheat gluten or wheat protein products should not be used for technological reasons, e.g. coating or processing aids for foods which are ‘gluten-free’ by nature*”^c. As mentioned earlier, Directive 2003/89/EC now applies in the EU and as a result, it is now compulsory to declare all ingredients with allergenic effects on the label of a food as well as alcoholic ingredients.

3.5 Notification of Foodstuffs Suitable for People Intolerant to Gluten under PARNUTS Legislation

In accordance with article 2a of Regulation 41/2009/EC, foodstuffs suitable for people intolerant to gluten are classified as foodstuffs for particular nutritional uses (i.e. PARNUTS) and are defined as follows:

‘foodstuffs for people intolerant to gluten’ means foodstuffs for particular nutritional uses which are specially produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten;

^b And products thereof, insofar as the process that they have undergone is not likely to increase the level of allergenicity assessed by EFSA for the relevant product from which they originated. This does not preclude the use of these products as ingredients in composite pre-packaged foods provided that they are properly labelled as ingredients.

Article 11 of Directive 2009/39/EC¹⁴ on foodstuffs intended for particular nutritional uses (PARNUTS) requires notification for categories of foods **not** listed in Annex I of the Directive to the competent authority of the Member State (which in the case of Ireland, is the FSAI). ‘gluten-free’ foods are not listed in Annex I to the Directive therefore they should be notified to the FSAI. This notification procedure is included to permit the efficient official monitoring of foodstuffs intended for a particular nutritional use. The following provisions regarding the notification procedure are also contained in article 11 of 2009/39/EC.

- 1. When a product as referred to above is placed on the market for the first time, the manufacturer or, where a product is manufactured in a third State, the importer, shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for such a product.*
- 2. Where the same product is subsequently placed on the market in another Member State the manufacturer or, where appropriate, the importer shall provide the competent authority of that Member State with the same information, together with an indication of the recipient of the first notification.*
- 3. Where necessary, the competent authority shall be empowered to require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the product’s compliance with Article 1(2) and (3) together with the information provided for in point (a) of article 9 (3). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.*

As a consequence of Section 8.2 on the ‘continuation in force of certain statutory instruments’ in the European Union Act, 2009 (Number 33 of 2009)¹⁵, Directive 2009/39/EC¹⁴ is considered transposed into Irish law by European Communities (Foodstuffs for Particular Nutritional Uses) Regulations, 2006 (S.I. No. 579 of 2006)¹⁶ as amended by S.I. No. 554 of 2007¹⁷. In accordance with article 11 of Directive 2009/39/EC as outlined above, all ‘gluten-free’ and ‘very low gluten’ PARNUTS products need to be notified to the FSAI.

4. CROSS-CONTAMINATION

4.1 General Obligations of Food Business Operators

In order for products to be 'gluten-free' (or very low in gluten) when they reach the consumer, the 'gluten-free' status of the products must prevail at every link of the chain. Cross-contamination is the process by which a 'gluten-free' product loses that status because it comes into contact with something that is not 'gluten-free'.

Cross-contamination with gluten can occur at any stage during the manufacture of 'gluten-free' (or 'very low gluten') food. Gluten may be unintentionally added to food as a result of practices such as incorrect formulation, inappropriate production sequencing, poor rework, product carry-over due to use of common equipment, poor clean-up or sanitation, poor equipment design, human error or the presence of gluten products above exposed product lines (i.e. a point where one line crosses over the top of another line if the system is not enclosed)¹⁸. Potential risks, preventative measures and critical control points need to be identified in the handling of 'gluten-free' or 'very low gluten' products.

The hygiene requirements for a food business are set out in the hygiene of foodstuffs legislation. In the case of food business operations supervised by the Health Service Executive (HSE), this is the European Communities (Hygiene of Foodstuffs) Regulation, 2006 (S.I. No. 369 of 2006)¹⁹ whereas for premises supervised by the Department of Agriculture, Fisheries and Food (DAFF), the local authorities and the Sea-Fisheries Protection Authority (SFPA), the provisions in the European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009)²⁰ apply. The proprietor/manager of a food business has a legal obligation to understand what the Hygiene of Foodstuffs Regulation demands and be able to explain how it is applied in the food business. This is not only a duty of care and a due diligence requirement, but an essential means of minimising the risk of being subject to a product liability claim, and the risk of having to recall cross-contaminated products.

Under these Regulations, food business operators^c are required to develop, implement and maintain a food safety management system based on the principles of Hazard Analysis Critical Control Points (HACCP). This involves identifying the points in an operation where food hazards may occur, and identifying and implementing effective measures to control the hazards at these critical points. Incorporating HACCP into production processes removes the need to rely on end product testing alone to ensure the product meets the regulatory requirements²¹.

^c Food business operators involved in primary production are exempt from this requirement but may choose to have a food safety management plan based on the principles of HACCP or may be required to do so by their suppliers.

Safeguards should be put in place to reduce the risk of cross-contamination by all food manufacturers, retailers and caterers. The 'gluten-free' status of the product must prevail at every link of the chain for the product to truly be 'gluten-free' when it reaches the consumer. This is also the case in companies where 'gluten-free' products are manufactured or prepared randomly. The following section will outline areas where possible hazards may occur during the manufacture and handling of 'gluten-free' products and details of preventative action that can be taken to eliminate or reduce the presence of gluten in 'gluten-free' or 'very low gluten' products.

4.2 Sources of Cross-contamination

4.2.1 Primary production, harvesting and storage

At primary production level, 'gluten-free' cereals such as maize may become cross-contaminated by gluten-containing grains unless preventative measures are taken during the production, harvest, transport and storage. To minimise this risk, it is necessary for suppliers of 'gluten-free' raw materials to assemble such materials exclusively from primary producers who have appropriate control practices in place.

Adherence to the following guidance in primary agricultural production should help ensure the purity of these raw materials.

4.2.1.1 Crop production

- Plant only certified seed, which guarantees a high level of varietal and species purity, in contrast to farm saved seed, which may have varying levels of impurities.
- Observe an appropriate crop rotation. Some seeds from particular crops can remain viable in the soil, and subsequently germinate and grow in different crop plantings (volunteers). These plants will create an impurity in the second crop.
- Clean out sowing/planting equipment, so that any residual seed from previous plantings cannot contaminate the new crop.
- Bring only one variety of seed to the field at sowing time in order to avoid the risk of admixture due to the incorrect seed being put in the sower/planter.
- Where necessary, impurities may have to be removed from the crop during the growing season (rogueing).

4.2.1.2. Harvest

- Clean out all harvest and transport equipment so that any remaining material from previous harvested crops cannot contaminate the crop in question.
- In large or complex agricultural operations, a “passport” system should be operated, whereby drivers are given a paper passport or document for the load of the produce being transported from the field. This passport is given to the operative in charge of stores when the load is being delivered and helps prevent the load being deposited in an incorrect storage area.

4.2.1.3. Storage

- Operate strict hygiene procedures in stores and in “tipping” and holding areas. These should be cleaned thoroughly each time they are emptied, in order to prevent any residues from contaminating the next batch. The operation of in-store handling equipment should be in such a way as to prevent the possibility of cross-contamination.
- Make sure all temporary holding areas and stores are clearly identifiable.
- Operate a passport system for produce entering the store (as above).
- Either in conjunction with the supplier/assembler of ‘gluten-free’ raw materials or on his/her own initiative, the primary producer should take representative samples of the raw materials in store for analysis in a laboratory accredited for the purpose, to determine their status in meeting the criteria set for their suitability for use in ‘gluten-free’ or ‘very low gluten’ products.
- Inspect and ensure that all vehicles used in the transport of ‘gluten-free’ raw materials are clean and free of contaminants.

Records should be maintained on all steps taken to minimise the possibility of cross-contamination.

4.2.2 Other sources of cross-contamination

In the milling environment, ‘gluten-free’ products are also susceptible to cross-contamination by machinery and tools, airborne gluten-containing flour dust or contaminated hands and clothing of workers. The risk of cross-contamination is greatly increased when the same premises and equipment are used for the production, processing and packaging of gluten-containing products together with products which are ‘gluten-free’ and/or very low in gluten. Workers’ hygiene becomes extremely important due to the risk of passing gluten-containing flour dust from hands and clothes on to ‘gluten-free’ products; therefore it is imperative that all staff, including maintenance workers and engineers, are trained in the prevention of cross-contamination. Accurate labelling is essential to reduce the risk of mixing up ‘gluten-free’ foods with gluten containing products during the transport and storage of ‘gluten-free’ foods.

4.3 Preventative Measures and Critical Control Points for ‘Gluten-free’ Products

Irrespective of the scale and complexity of the business, there is an absolute duty of care on the management and staff to ensure that they produce safe food, which is suitable in every way for its intended end use and that food safety legislation is complied with in their establishments^d. The safety and quality of ‘gluten-free’ products is ensured by the company’s in-house control system which should include Good Manufacturing Practices (GMPs)/Good Hygiene Practices (GHPs) and HACCP. The key areas for industry, retailers and caterers to focus on include raw ingredients, processing (including production scheduling and equipment design), and use of rework, packaging, labelling, sanitation and training. For the system to function effectively, all employees must be committed to it. The following paragraphs outline where hazards may most appropriately be controlled and/or eliminated.

4.3.1 Raw ingredients

Both raw ingredient suppliers and manufacturing firms using these ingredients should employ the best gluten control practices including routine surveillance of their products for the presence of gluten. Manufacturing firms using ‘gluten-free’ or ‘very low gluten’ ingredients should:

- Obtain a certificate of analysis or guarantee that the raw materials meet the criteria set for their use in ‘gluten-free’ or ‘very low gluten’ products
- Ensure the purity of the product in relation to gluten through laboratory analyses
- Determine whether suppliers have gluten control plans
- Determine whether suppliers clearly label any gluten-containing ingredients
- Request prior notification of any change in suppliers’ product formulations
- Ensure that transport vehicles and associated materials are free of gluten residues from previous shipments
- Confirm that unlabelled gluten is not in formulated, multi-component ingredients
- Have a method to identify and trace product distribution

^d Regulation (EC) No 178/2002 laying down the general principals and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

4.3.2 Storing raw materials and products

- Use dedicated storage areas for 'gluten-free' raw materials and products or place them in a clearly marked area in order to prevent cross-contamination with gluten containing material.
- Use clearly marked storage containers.
- Reserve containers for 'gluten-free' ingredient use only.
- The 'gluten-free' raw materials should be stored in their original packages or in covered containers where labels have been placed in order to prevent mixing with other raw materials.

4.3.3 Processing

Good manufacturing practice (GMP) should be employed. System design should minimise the amount of equipment exposed to gluten.

- Designate and label equipment (scoops, pails, totes, bins and hoppers) for use with specific products.
- If gluten-containing products are also manufactured on the same premises, the ingredients used in their manufacture should be uniquely identified by using colour coding such as coloured stickers or containers.
- 'Gluten-free' products should be stored in a separate or an isolated area if possible, away from gluten-containing products.
- Enclose the system or avoid line crossovers.
- Design the product flow such that gluten containing ingredients are added at the end.
- Scheduling can minimise potential gluten cross-contamination. Make 'gluten-free' products first or at the start of the production day when contamination from dust is at a minimum and all equipment and clothing are thoroughly clean.
- Follow 'gluten-free'/'very low gluten' products with gluten-containing products before cleaning for changeover. Alternatively, gluten-containing products may be produced on separate days than 'gluten-free'/'very low gluten' products.
- Schedule longer run times that minimise changing from one product to another.
- Protect work-in-process from contamination by other product on adjacent conveyors, etc.
- Do not use gluten-containing materials as processing aids, e.g. do not use flour to prevent sticking of confectionery products.

- In the case of 'gluten-free' bakery products, after baking they must be cooled in a separate area, where no handling of gluten-containing products takes place. If this cannot be arranged, 'gluten-free' products must be covered, labelled and clearly separated from other products to avoid cross contamination and mixing of products.
- Ensure maintenance tools and staff do not act as sources of gluten contamination.
- Colour code tools for specific areas (gluten vs. 'gluten-free').
- Specify pre-operational cleaning procedures.

4.3.4 Rework

Rework that contains gluten ingredients should only be reincorporated into the same product. Adequate control on rework is necessary to verify that cross-contamination does not occur.

- Document procedures and train employees.
- Clearly identify and label rework.
- Clearly identify rework area, equipment, containers etc.
- Identify gluten-containing products when reworked.
- Track the use of rework for like-into-like only.
- Try to use rework within the same run.

4.3.5 Equipment

The chances of contamination can be greatly minimised by dedicating production facilities to the production of 'gluten-free' foods¹⁸. If this is the case, producers, suppliers and manufacturers can be more confident of the gluten status of their products.

Where possible, the industry should use dedicated plant/room/systems for the preparation of 'gluten-free' foods in order to prevent cross-contamination. This may be possible for some large scale manufacturers or large volume products where continual production on the same or multiple lines is needed to meet demand. It is not always feasible, however, to have a dedicated system for each product that is manufactured by a company.

When a dedicated plant/room or system is not an option for a manufacturer, they will then need to use “separation” as a means to minimise inadvertent contact. This can be accomplished by physical barriers such as the use of dedicated containers for raw materials that contain gluten as already mentioned. These principles also apply to caterers and butchers where the main problem is cross-contamination by equipment such as ladles, fryers, chopping boards etc., which is likely to happen in busy kitchens and establishments.

- Separate premises should be arranged for preparing ‘gluten-free’ products if possible.
- The use of separate equipment, dishes, baking forms, deep fryers, cutting boards, working surfaces (in direct contact) in preparing, baking and packing ‘gluten-free’ products should also be employed. If this is not possible, equipment, dishes and working surfaces must be carefully cleaned before preparing ‘gluten-free’ products, and it should be checked that there is no gluten-containing products manufactured first in the morning for instance.
- Colour code areas, equipment, containers and/or utensils for ‘gluten-free’ use.
- Be aware of how equipment design affects potential cross-contamination.
- Be vigilant in maintenance of equipment, especially ventilation and dust control equipment, in order to prevent air-borne contamination.
- Include any utensils and equipment tools in allergen planning.
- Encourage workers’ involvement by asking them to suggest any improvements that could be made.

4.3.6 Packaging/Labelling

When developing a HACCP based system for the manufacture of ‘gluten-free’ food, it should be noted that (a) packaging equipment has the potential to cross-contaminate ‘gluten-free’ products; and (b) incorrect labelling may have serious consequences for people with gluten intolerance.

- Ingredient labels must accurately reflect the actual ingredients used (carton or package labels match the formulation).
- Ensure that the correct labels are used on the product.
- Where the ingredient ‘starch’ (or modified starch) originates from a source that contains gluten, such as starch from wheat, oats^a, barley or rye, the source of its cereal origin must always be given in the list of ingredients, e.g. wheat starch.

- Ensure the allergen labelling requirements⁹ are followed to highlight the fact that the food may contain gluten. Such information does not only apply to products packed for retail sale but also to products bulk packed for use in catering operations. In relation to catering operations, similar information should be given adjacent to appropriate items on menus or self-service display notices.
- Use commonly understood terms for gluten warnings and locate them close to the ingredient declaration in order to provide clear communication with coeliacs.
- Supplemental allergen statements are designed to alert coeliacs that the product in question may have gluten. It is recognised that a certain percentage of a given product bearing the supplemental gluten statement may be free of gluten and safe for consumption by coeliac consumers. However, the fact that gluten may be present in some of the foods manufactured on that line necessitates the use of the supplemental statement.
- Precautionary labelling (“may contain”) should not be used in lieu of GMP.
- Each roll, sheet or package of labels should be dedicated solely to one product.
- Conduct label audits and confirm that labels match the finished product.
- Verify label accuracy when ingredients or formulations change.
- Discard old labels or packaging materials.
- Processing aids that contain allergens must appear on the finished product label.
- According to Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (PARNUTS), ‘gluten-free’ products such as bread and confectionery products must always be pre-packed and labelled when sold in shops. Packing and labelling ensures that ordinary and ‘gluten-free’ products cannot be mixed.
- The packaging material in direct contact with the food should be checked to make sure that it does not contain any allergens, e.g. foil coated with wheat ingredients as a releasing agent.
- If a part of the manufacturing or packing process is done by a subcontractor, the manufacturer or packer must assess the ability of the subcontractors’ HACCP based system for ensuring the safety of ‘gluten-free’ products’.

4.3.7 Sanitation

Ensuring good hygiene is even more important in the making of 'gluten-free' or 'very low gluten' products. Companies must have a cleaning plan and a person in charge of its implementation and ensure that staff are trained and supervised (see section 4.3.8). This is particularly important for temporary staff. If separate premises cannot be arranged, the efficiency of cleaning between different stages of work is critical and must be ensured. Clean-up following the processing of a gluten-containing product is essential and may require disassembly of equipment for manual cleaning. All surfaces that may come in contact with 'gluten-free' products must be pre-cleaned and checks also carried out to ensure that there is no gluten dust in the air, on the surfaces, on clothing or on hands.

- Document cleaning instructions as part of Standard Operating Procedures (SOP).
- Ensure that the design and installation of the equipment allows easy, adequate cleaning, with dead spots, rough surfaces, void areas etc. minimised.
- Identify all equipment, conveyors and food contact surfaces that require cleaning following gluten-containing product runs.
- Include splash zones, indirect product contact surfaces and utensils on the cleaning schedule.
- Allow adequate time for cleaning.
- Use appropriate chemicals, strengths and methods for cleaning (i.e. dry or wet cleaning).
- Thoroughly clean all equipment especially between formulation changes and visually inspect it after cleaning.
- Focus on hard to clean areas and look for hidden residues.
- Minimise or avoid the use of blown air, e.g. hand driers, as it may spread gluten to other areas.
- Areas around or above the production system should be free of visible product or dust that could contain gluten which may fall into or come in contact with a product.
- Verify sanitation of equipment (sampling or testing for allergen residues).
- Ensure storage of clean items will not lead to recontamination.
- Allow for appropriate time between production changeovers.
- Review cleaning documentation and inspect equipment prior to initiating 'gluten-free' production.
- Once appropriate procedures for cleaning are established, a checklist may be utilised to verify systems are clean and inspected.
- Immunoassays of equipment swabs may be used to detect a source of gluten proteins (see section 4.3.9).

4.3.8 Training

It is essential that all employees understand that the prevention of cross-contamination of 'gluten-free' foods is a necessary part of the manufacturing operation and will result in the delivery of safe products to the consumer. In addition, maintenance workers, casual staff and engineers who may be employed from time to time should be instructed on the importance of preventing cross-contamination. Employee training should be ongoing and include:

- A clear definition of the consequences of cross-contamination for coeliac patients
- Procedures on the control and prevention of gluten contamination (employee practices, hand contact/washing, clothing)
- Proper documentation of production line cleaning
- Control of rework and waste
- How to recognise and report potential cross-contamination with gluten
- Training should be provided as part of employee orientation. Temporary or part-time employees should also be trained
- It is important that chefs are given training in identification of gluten-containing and 'gluten-free' products, the principles of minimising risk in respect of the allergen and the need to notify any use of gluten in meals prepared
- Verification of training should be documented for each employee
- Supervision of staff should identify when refresher training is needed
- Training material should be reviewed annually to incorporate new information or changes in strategies

To ensure that training is implemented, staff should be supervised.

4.3.9 Sampling and analysis

Manufacturers of 'gluten-free' products will need to perform periodic analysis and spot checks on their products, and in some cases, their equipment, particularly when certain issues arise such as a consumer complaint, an ingredient or process change in the formulation of a product or a new product is being manufactured. If the company manufactures large quantities of 'gluten-free' products, sampling and analysis of the product will be required on a regular basis in order to check the integrity of the product in relation to its 'gluten-free' status and also to verify any of the claims made on the label. Testing of gluten in 'gluten-free' and 'very low gluten' foods provides a mechanism of assessing the safety of the product for consumption by coeliacs and should be used to verify the correct function of the HACCP based system. Analysis is one part of the process of ensuring the quality and safety of 'gluten-free' and 'very low gluten' foods and when

used in conjunction with industry's own checks (HACCP) and with official inspection, analysis is an essential component of ensuring the safety and quality of such foodstuffs. A balance must be achieved between any risk of cross-contamination involved and the frequency of testing required. It is imperative that any testing carried out on behalf of the food business operator is done by a competent laboratory which is accredited to carry out gluten analysis.

Early enzyme-linked immunosorbent assay (ELISA) methods based on antibodies to ω -gliadin, detected wheat gliadins and rye secalins. However, the antibodies have limited reactivity to barley horedins. The detection of gluten in malt and foods containing malt using this methodology is unreliable as barley horedins are not well detected. If required, there are other methods, e.g. high performance liquid chromatography (HPLC), to detect the presence of oat avenins, however, these methods may not be as readily accessible for food manufacturers as an ELISA test²².

It should be noted that acid hydrolysis may destroy those properties of gluten which are responsible for the elicitation of coeliac disease, however, partial hydrolysis, enzymatic degradation and heat treatment during food processing do not destroy coeliac-triggering peptide units. All food technology processes, however, affect extractability and detectability of gluten which are important in any attempts to quantitatively measure gluten in food²³.

Considerable progress has been made in gluten analysis of food. For this purpose, immunochemical assays and non-immune methods have been introduced^{24,25,26,27}. Sensitivity, specificity and reproducibility of earlier methods for gluten analysis have been unsatisfactory²³. A European gliadin reference is now available and certified by the EC Institute for Reference Materials and Measurements. This material serves as a reference for the detection of gliadin/gluten in food samples. A large collaborative study²⁸ of a new R5 ELISA assay accompanied by non-immunological cross-testing has been finished recently. The R5 ELISA method was developed specifically to address the two main deficiencies in earlier ELISA tests, namely the poor response to barley and to heat-treated gluten. The method does not respond to oat avenins. The R5 method was endorsed as type I^e by CCMAS (the Codex Committee for Methods of Analysis and Sampling). The current Codex Standard³ for 'gluten-free' foods (Codex Standard 118-1979-revised in 2008) requires the quantitative determination of gluten to be based on an immunologic, e.g. ELISA, method or other method providing at least equal sensitivity and specificity. The Standard specifically lists one test, the R5 ELISA method developed by Méndez as the method for determining gluten. The R5 ELISA method is now available as a commercial sandwich ELISA kit from a number of companies. The R5 method has general applicability but is not suitable for hydrolysed gluten. A competitive ELISA

^e Codex Type I methods are defined as methods which determine a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured, Examples include Howard Mould Count, loss on drying, salt in brine density. Codex methods of analysis are primarily intended as international methods for the verification of provisions in Codex standards. They should be used for reference, in calibration of methods in use or introduced for routine examination and control purposes.

method has been developed for 'gluten-free' foods containing hydrolysed gluten, e.g. beers etc, and is now commercially available. Regulation 41/2009/EC, which sets limits for 'gluten-free' and 'very low gluten' products in the European Community, does not specify an analytical method but does state that the Codex Standard³ (118-1979, revised in 2008) should be taken into consideration for the purposes of the Regulation.

Gluten analysis is important in the control of gluten free products but food business operators should be aware that some analytical problems remain outstanding²³.

As a guide for manufacturers of 'gluten-free' foods and other businesses as appropriate, the following combinations indicate the 'gluten-free' food type and the analytical tests to be used:

- (1) **General 'gluten-free' foods:** the quantitative R5 (sandwich ELISA) method, when there is no hydrolysed gluten present (or no evidence/suspicion of the presence of hydrolysed gluten). By default, the procedure should incorporate the use of the cocktail extractant, unless it is known that there will be no reduced response due to heat-treated gluten

Alternatively, another quantitative immunologic method or other procedure can be used, provided that it meets all of the criteria set out in the Codex Standard³ (118/1979, revised 2008)

- (2) **'Gluten-free' foods where hydrolysed gluten may be present:** the competitive R5 ELISA method

Alternatively, another quantitative immunologic method, or other method meeting all of the criteria set out in the Codex Standard³ (118/1979, revised 2008) can be used.

5. CONCLUSION

In 2009, the European Commission published new food labelling and compositional rules aimed at helping people who are intolerant to gluten. Under this new legislation, i.e. Regulation 41/2009/EC, only foodstuffs that contain less than 20mg/kg of gluten will be permitted to use the term 'gluten-free' on their packaging. This low level offers a high level of consumer protection for those coeliacs extremely sensitive to gluten. Previously, a food labelled 'gluten-free' could have contained up to ten times more gluten than this. Foodstuffs which consist of or contain one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce gluten, shall not contain a level of gluten exceeding 100mg/kg and shall bear the term 'very low gluten'. The Regulation also allows for a normal food which does not contain ingredients derived from gluten-containing grains or oats to be labelled using terms indicating the absence of gluten as long as such a statement does not mislead the consumer.

The introduction of this new labelling regime will allow people with coeliac disease to make safe and informed choices about the types of food they eat. Food business operators can use the new labelling system immediately if they are in a position to do so but for those that need to adapt their production processes in order to meet the new compositional and labelling requirements, transitional measures will apply until the 1st January, 2012 at which time all products must comply with the Regulation.

The 'gluten-free' status of food must prevail at every link of the chain for the product to truly be 'gluten-free' when it reaches the consumer. Dealing with gluten is an essential part of GMP. Therefore, safeguard measures need to be put in place to reduce the risk of cross-contamination during the production process by all food manufacturers, retailers and caterers. Food business operators have a responsibility to minimise the risks of gluten contamination for coeliac consumers of their products. The safety and quality of 'gluten-free' products is ensured by the company's in-house control system including GMP/GHP and HACCP.

The chances of contamination can be greatly minimised by dedicating production facilities to the production of 'gluten-free' foods only. Food business operators should use dedicated plant/room/systems where possible for the preparation of 'gluten-free' foods in order to prevent cross-contamination. In the cases where it is not always feasible to have a dedicated plant/room or system for each product that is manufactured by a company, "separation" will be needed in order to minimise inadvertent contact. This can be accomplished by physical barriers such as the use of dedicated equipment and utensils and separate containers for raw ingredients used in the production of 'gluten-free' or 'very low gluten' products. The key areas for manufacturers, retailers and caterers to focus on include raw ingredients, processing (including production scheduling and equipment design), use of rework, packaging, labelling, sanitation and training. The use of precautionary labelling, i.e. "may contain" for possible gluten cross-contamination should not be used as a substitute for GMP and should be justified on the basis of a risk assessment applied to a reasonably managed operation. The growing use of precautionary labelling goes against the interest of consumer protection and further reduces the choices available for coeliacs. In any event, it is recommended that food business operators quantitatively assess the risks of contamination and take all the appropriate and necessary steps to prevent it.

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ISBN 1-904465-71-4