

## 7. Guidelines to Prevent Cross-Contamination of Gluten-free Foods.

### 7.1 Introduction

These guidelines provide guidance on the minimum requirements for the production of foods described as “naturally gluten-free” or “rendered gluten-free” and apply to all involved in the handling, production and distribution of gluten-free products.

The draft Codex Alimentarius Standard referred to in Section 5 defines gluten-free foods as:

- (a) consisting of, or made only from ingredients which do not contain any prolamins from wheat or all *Triticum* species such as spelt, kamut or durum wheat, rye, barley, oats or their cross bred varieties with a gluten level not exceeding **20ppm**;  
or
- (b) consisting of ingredients from wheat, rye, barley, oats, spelt or their crossbred varieties, which have been rendered “gluten-free”; with a gluten level not exceeding **200ppm**;  
or
- (c) any mixture of two ingredients as in (a) and (b) mentioned with a level not exceeding **200ppm**.

\*As indicated in Section 5 this is only a provisional level.

### 7.2 Cross-Contamination

In the context of coeliac disease 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. This may result in the product causing severe illness in individuals with dietary intolerance to gluten. Gluten may be unintentionally added to food as a result of practices such as improper rework addition, incorrect formulation, production sequencing, product carry-over due to use of common equipment, improper clean-up or sanitation, poor equipment design, human error or the presence of gluten products above exposed product lines.

Risks, critical control points and preventative measures need to be identified in the handling of gluten free products. Since 1998 it has been a legal requirement for all food businesses to have a food safety management system based on the principles of Hazard Analysis Critical Control Points (HACCP). The European Communities Hygiene of Foodstuffs Regulation, 2000 (S.I. No. 165 of 2000) outline what is required by a food business. 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. The gluten free quality 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 detail preventative action that can be taken to eliminate or reduce the presence of gluten in gluten-free foods.

### **7.3 Sources of Cross-Contamination**

#### **7.3.1. Primary Production, Harvesting and Storage**

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

**The following guidelines should be adhered to in primary agricultural production to ensure the purity of these raw materials.**

#### **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 high levels of impurities.
- ❖ Observe an appropriate crop rotation. Some crop seeds from previous crops remain viable in the soil, and may grow up in subsequent crops (volunteers). These plants will be an impurity in the subsequent crop.
- ❖ Clean out sowing/planting equipment, so that remaining seed from previous plantings cannot contaminate the new crop.
- ❖ Bring only one variety of seed to the field at sowing time, 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).

#### **Harvest**

- ❖ Clean out all harvest and transport equipment so that remaining material from previous harvested crops cannot contaminate the crop in question.
- ❖ In large or complex agricultural operations operate a “passport” system, 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. This helps prevent the load being deposited in an incorrect storage area.

## **Storage**

- ❖ Operate strict hygiene procedures in stores and in “tipping” and holding areas. These should be cleaned thoroughly each time they are emptied, to prevent residue 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 products.
- ❖ Inspect and ensure that all vehicles for the transport ex-store of the 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.

### **7.3.2 Other Sources of Cross-Contamination**

In the milling environment gluten-free products are also susceptible to cross-contamination by machinery and tools as well as by gluten containing flour dust in the air or being passed on through the hands and clothing of workers. If the same premises and equipment are used for the production, processing and packaging of gluten-free and gluten containing products the risk of cross-contamination is greatly increased. Workers' hygiene becomes extremely important due to the risk of passing gluten containing flour dust from hands and clothes on to gluten-free products. Also during the transport and storage of gluten-free foods the possibility of getting them mixed up with gluten containing products is still very real. As a result of the above scenarios, accurate labelling is essential in this sort of environment.

### **Critical control points and preventative measures for gluten-free products.**

Irrespective of the scale and complexity of the business, there is an absolute duty on the management and staff to ensure that they produce safe food, which is suitable in every way for its intended end use. The safety and quality of gluten-free products is ensured by the company's in house control system such as Good Manufacturing Practice's (GMP's) and HACCP. The key areas industry should focus on include raw ingredients, processing (including production scheduling and equipment design), use of rework, packaging, labelling, sanitation and training. For the system to be functioning all employees must be committed to it. The following paragraphs outline the areas where critical control points are identified and at these points the hazards maybe controlled and/or eliminated.

## **Raw Ingredients**

A product may become contaminated through raw ingredients. A close working relationship and communication with ingredient suppliers is important. Suppliers of raw materials should be required to identify and control gluten. Raw ingredient suppliers and manufacturing firms should address the same gluten control practices.

- ❖ Obtain a certificate of analysis or guarantee that the raw materials meet the criteria set for their suitability for use in gluten-free products.
- ❖ If gluten is removed from gluten containing cereals, manufacturers must ensure the product is sufficiently pure 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 vehicles, tanker or pallets 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.

## **Storing Raw materials**

- ❖ Keep gluten containing raw materials stored separately and prevent cross-contamination.
- ❖ Use clearly marked storage containers.
- ❖ Reserve containers for gluten use only.
- ❖ Use dedicated storage areas for gluten products.
- ❖ Gluten-free raw materials must be stored in a separate storeroom or in a clearly marked area.
- ❖ The gluten-free raw materials should be stored in their original packages or in covered containers where original labels have been added in order to prevent mixing with other raw materials.

## **Processing**

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 from gluten-containing products.
- ❖ Enclose the system or avoid line crossovers.
- ❖ Design the product flow such that gluten 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 products with gluten containing products before cleaning for changeover or gluten containing products may be produced on separate days than gluten-free products.
- ❖ Schedule longer run times that minimise changing from one product to another.
- ❖ Protect work-in-process from contamination from 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.
- ❖ Maintenance tools are potential sources of allergen contamination.
- ❖ Colour code tools for specific areas (gluten vs. gluten-free).
- ❖ Specify pre-operational cleaning procedures.

## **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.

## **Equipment**

Ideally the chances of contamination can be greatly minimised by dedicating production facilities to the production of gluten-free foods. Producers, suppliers and manufacturers can therefore be more confident of the gluten content of their products. So 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 scale volume products where continual production on the same or multiple lines is needed to meet consumer demand. It is not financially possible, however, to have a dedicated system for each product that is manufactured by a company. When the issue of a dedicated plant/room or system is not an option for the 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 and other means to prevent the inadvertent contact of gluten with gluten-free ingredients and products.

- ❖ Separate premises should be arranged for preparing gluten-free products if possible.
- ❖ The use of separate equipment, dishes, baking forms, cutting boards, working surfaces (in direct contact) in preparing, baking and packing gluten-free products should also be employed. If this is impossible, 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, ventilation and dust control equipment.
- ❖ Include any utensils and equipment tools in allergen planning.
- ❖ Encourage workers to speak up if they see need for changes or improvements.

### **Packaging/Labelling**

Packaging equipment has the potential to cross-contaminate gluten-free products. Labelling is the primary means to inform the consumer about the potential presence of gluten. Gluten containing cereals and their products must always be declared on the label of pre-packaged foodstuffs according to the Codex-Labelling Standard. The trade around the globe must follow these improvements because of the adoption of the Codex Standards by the World Trade Organisation. In the European Union an amendment to council Directive 2000/13/EC on labelling of foodstuffs will be published by the end of 2003 which will make it mandatory to list all potentially allergenic sub-ingredients of compound ingredients, which will mean allergens will no longer be hidden. The directive will be transposed into national legislation in 2004 after which member states will have a transitional period of a year to bring in the legislation so consumers can expect to see allergen labelling on their foodstuffs in 2005. The new legislation will deal with a wide range of food allergens among others cereals containing gluten and products thereof.

- ❖ Ingredient labels must agree with actual ingredients used (carton or package labels match the formulation).

- ❖ Ensure that the labels are used on the correct product.
- ❖ Where the ingredient ‘starch’ (or modified starch) originates from a source that contains gluten, such as starch from wheat, oats, barley or rye, the source of its cereal origin must always be given in the list of ingredients *e.g.* wheat starch.
- ❖ Advocate the use of terms commonly understood by consumers for gluten within, or in the immediate proximity to, the ingredient declaration, to provide clear communication with coeliacs.
- ❖ Use warning statements to highlight the fact that the food may contain gluten. These warning labels do not only apply to products packed for retail sale but also to products bulk packed for use in catering operations.
- ❖ Supplemental allergen statements are designed to alert coeliac consumers that the product in question may have gluten that they need to avoid. 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 gluten may be present in some of the foods manufactured on that line, thus, necessitating the use of a supplemental statement that alerts coeliacs to the possible presence of gluten.
- ❖ Precautionary labelling ("may contain") should not be used in lieu of GMP.
- ❖ Each roll, sheet or package of labels should be dedicated to only 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 allergen ingredients must be on the finished product label.
- ❖ Gluten-free food products must always be pre-packed and labelled according to the regulations when sold in shops. This applies to bread and confectionery products. 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 manufacturing or packing is done by subcontractor, manufacturer or packer must know the subcontractors’ critical control point system plan for ensuring gluten-free products’ safety.

Genetically-modified foods present severe risks for coeliacs if their components are not known. The health of coeliacs was considered in 2001 in the Codex General Standard for the Labelling of Pre-packaged Foods. With regard to the labelling of food and food ingredients obtained through genetic modification/genetic engineering, section 4.2.2. (1) 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 protein 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*” (\*). “*Cautionary statements for gluten intolerant*

*persons shall be on the label as required by national legislation.” At the moment there is no obligation under Irish legislation to include cautionary statements on products and it is up to the discretion of the manufacturers themselves to do so. However, this situation will change with the introduction of the allergen labelling legislation which will be in place by 2005.*

*\* This does not preclude the use of these products as ingredients in composite pre-packaged foods provided that they are properly labelled as ingredients.*

## **Sanitation**

Ensuring good hygiene is even more important in the making of gluten-free products than ordinary products. Companies must have a cleaning plan and a person in charge of its implementation. Temporary members of the workforce must also be guided in preventing gluten contamination by hygiene and working methods. If separate premises cannot be arranged the sufficiency of cleaning between different stages of work must be ensured. Cleanup following the processing of a gluten-containing product is essential. Equipment may need to be disassembled and manually cleaned to ensure hard-to-clean areas are free of gluten residue. All surfaces that come in contact with gluten-free products must be carefully cleaned before preparing gluten-free products and it must be checked that there is no gluten containing dust in the air, on the surfaces, on working clothes or on hands.

- ❖ Document cleaning instructions (SSOP).
- ❖ 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 requiring cleaning after gluten containing product runs.
- ❖ Include splash zones, indirect product contact surfaces and utensils on the cleaning program.
- ❖ Allow adequate time for cleaning.
- ❖ Use correct 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 cleaning gluten areas with blown air. This offers the potential to spread gluten to other areas.
- ❖ Areas around or above the production system should be free of visible gluten containing product or dust that may possibly fall into or come in contact with a product.
- ❖ Verify sanitation of equipment (sampling or testing for allergen residues).
- ❖ Ensure proper storage of clean items.
- ❖ Allow for appropriate time between changeovers.



- ❖ Review cleaning documentation and inspect equipment prior to the start up of non-allergen products.
- ❖ Once appropriate procedures for cleaning are established, a checklist may be utilized to verify systems are clean and inspected.
- ❖ Use of immunoassays may detect gluten proteins; swabbing equipment may pinpoint the source.

## **Training**

Employee awareness and training are the best defences against the cross-contamination of gluten-free products. Persons handling gluten-free products must understand that gluten-free products may become contaminated through hands, clothes, air and working surfaces containing flour dust. Flour dust is carried around in hands and clothes. It is essential that all employees believe 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. Employee training should be ongoing and include:

- ❖ A clear definition of an allergen and the consequences for allergic individuals *i.e.* gluten and 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 recognize and report potential cross-contamination with allergens.
- ❖ Training should be provided as part of employee orientation. Temporary or part-time employees should also be trained.
- ❖ Verification of training should be documented for each employee.
- ❖ Annual refresher training is expected.
- ❖ Training material should be reviewed annually to incorporate new information or changes in strategies.

## **Sampling and Analysis**

Manufacturers of gluten-free products will need to perform analysis and spot checks on their products when certain issues arise such as a consumer complaint, an ingredient or process has changed 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 also be required on a regular basis in order to check the integrity of the product in relation to its gluten-free status.