Food Safety
AUTHORITY OF IRELAND

AUDIT REPORT

Audit of Irish Food Manufacturer Allergen Controls and Labelling

MAY 2012

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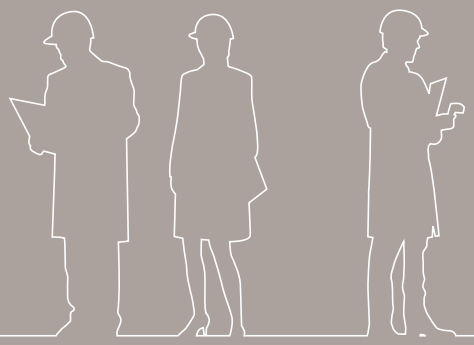

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1. GLOSSARY

EHO	Environmental Health Officer
EHS	Environmental Health Service
FSAI	Food Safety Authority of Ireland
FVO	Food and Veterinary Office
HSE	Health Service Executive
PEHO	Principal Environmental Health Officer

The information in this report relates solely to the food businesses visited as part of the audit and is not necessarily reflective of the situation in other food businesses.

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) completed a small scale audit of food manufacturing businesses in Ireland to determine the level of compliance with food allergen labelling as set out in Directive 2000/13/EC as amended (S.I. No. 483 of 2002, as amended). The audit included a site inspection of each food business in order to determine the level of control of allergenic ingredients through documented protocols and procedures. The food businesses were selected on the basis that they produced different types and quantities of food which would enable a relatively broad view of the management and control of food allergens in the food manufacturing industry.

The audit results were positive in that most establishments did consider allergen controls and had put systems in place to manage them. However, the audit revealed a diverse approach to implementing or adhering to control systems with the result that the management and control of food allergens in some establishments could be considered insufficient to protect the health of people who suffer from food allergies and intolerances. Staff training was inconsistent and not carried out at all by some food businesses. All establishments had documented protocols in place for purchasing. However, a significant number of establishments did not have adequate controls in place to manage incoming allergenic ingredients and their storage. None of the establishments operated dedicated production lines which, although gold standard in terms of risk management, is not always feasible or practical from a commercial perspective. Instead, most food businesses relied on production scheduling, equipment cleaning or, in a few cases, dedicated equipment or clothing to minimise the risk of cross-contamination. A quarter of the establishments visited were considered to have a significant risk of cross-contamination of allergens.

Food allergen labelling was applied in an inconsistent and sometimes incorrect manner by the different establishments leading to the conclusion that there is some confusion within the industry about mandatory food allergen declarations. Two thirds of the establishments audited applied allergen labelling inconsistently across products ranges. The use of voluntary precautionary labelling has been highlighted as a problem by the FSAI previously and this audit reinforced the perception that such voluntary labelling is frequently used for the wrong reasons. Ten of the twelve establishments visited applied precautionary labelling. Of particular concern was the finding that sometimes precautionary labels were applied to a food simply because the retail customer required it, even though the food posed a very low risk, if any, of containing the pertinent allergen.

3. INTRODUCTION

The FSAI is responsible for the enforcement of food law in Ireland which is achieved through service contracts with official agencies. To ensure a high level of consumer protection, the FSAI audits the work of the official agencies each year and may also carry out focused audits of food businesses.

The consumption of certain foods or food ingredients can result in responses by the human body that are termed food allergies or food intolerances depending on the type of reaction. Of the many food ingredients known to cause food allergies or intolerances, only 14 must be declared on packaging according to EU food law. However, the presence of these food allergens must be declared only when they have been used intentionally as ingredients but not when they are present as low level contaminants. In addition, certain derivatives of a number of food allergens are exempt from mandatory allergen labelling because the protein components known to elicit the allergic response have been removed during processing.

The FSAI operates an early warning system whereby people with a food allergy or intolerance who are registered with the FSAI are notified by SMS text messaging of any food incidents as they arise that may potentially affect their allergy. In recent years, the number of food allergen alerts has been increasing. In 2011, the FSAI in conjunction with its official agencies, issued 20 such alerts and dealt with 44 food incidents related to food allergens. The FSAI has been reviewing the whole area of food allergies and intolerances with a view to strengthening the safeguards for those people who live with these conditions. The FSAI is examining its own role and that of the official agencies in the sampling and analysis of foods and their labels. In addition, the FSAI has requested that the European Food Safety Authority (EFSA) provides information and guidance on the prevalence of food allergies in the EU as well as any scientific developments that would assist the overall work of risk assessors and risk managers. It was against this backdrop that the FSAI decided to conduct an audit to assess how a selection of Irish food businesses manage and control food allergens. The audit was part of the planned programme of targeted audits undertaken by the FSAI in 2011 and involved 12 unannounced site visits to different types of manufacturing establishments including bakeries, chocolate manufacturers, convenience foods and snack producers, as well as meat and fish establishments.

This summary report brings together the findings from the individual site inspections from which overall conclusions can be drawn and recommendations for improvement proposed.

3.1 Audit Objective

The objective of this audit was to assess the implementation of allergen controls and allergen labelling, both mandatory and voluntary in food manufacturers in Ireland. The audit focused on the businesses' food safety management system, operational controls and final product labelling.

3.2 Audit Scope

The scope of the audit was the implementation of controls for food allergen labelling by food businesses.

3.3 Audit Criteria and Reference Documents

The principal audit criteria referred to during the audit were:

- Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- Regulation 852/2004 on the hygiene of foodstuffs, as amended
- Council Directive 2000/13/EC on labelling, presentation and advertising of foodstuffs, as amended (transposed by S.I. No. 483 of 2002 as amended)
- FSAI Allergen Leaflet
- FSAI Guidance Note 24 (Legislation on 'Gluten free' Foods and Avoidance of Cross –contamination during manufacture of 'Gluten–free' or 'Very Low Gluten' Products)

3.4 Audit Methodology

This audit was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations and are in accordance with the requirements of Regulation 882/2004 (including *Article. 6.1* of Commission Decision 677/2006) and Section 48 (9) of the FSAI Act.

Food businesses were selected for site visit on the basis of the size of the business and the variety of food products manufactured. Consideration was also given to any allergen information that was provided on the packaging of select products. The rationale of the audit was explained to the food business operator as part of an opening meeting in each establishment. After a thorough audit of documentation associated with the food safety management system, allergen controls and allergen labelling, a site inspection of operational controls was conducted.

Table 1. Establishments Audited

Small	Medium	Large
Ready Meals	Bakeries x 2	Sausage Maker
Fresh Seafood Packer	Sausage Maker	Fresh Meat Packer
Bakery	Specialist Chocolate Maker x 2	Pizza Manufacturer
Bakery/Desserts		

Small =<10 tonnes per week; Medium = 10-100 tonnes per week; Large = >100 tonnes per week

3.5 Legal Requirements

Directive 2000/13/EC (as amended) on the labelling, presentation and advertising of foodstuffs stipulates that the use of certain allergenic ingredients and their derivatives (with a few exceptions) must be declared on food packaging. However, this legislation does not stipulate the position on the packaging that the information must occupy, and is silent on the use of precautionary labels such as “May contain…” or “made in a premises that uses …”. The mandatory declaration does not apply when an allergenic ingredient is present as a low level contaminant.

Food business operators are responsible for placing safe food on the market and for ensuring that consumer information is accurate and not misleading. Where labelling errors are identified by food business operators, they are required to inform the FSAI or its official agencies, including proposals to rectify the situation.

EU food law does not detail any specific controls that should be in place to control the storage, handling or use of allergenic foods in a food business. Nevertheless, Article 5 of Regulation (EC) 852/2004 on the Hygiene of Foodstuffs requires food business operators to implement and maintain a permanent procedure, or procedures based on the HACCP principles, which would include the handling or storage of ingredients containing food allergens.

4. ALLERGEN CONTROLS

4.1 Allergen Controls in the Manufacturing Sites Visited

The control of food allergens in manufacturing environments should begin at raw material purchasing and follow through each stage of the manufacturing process. The potential for contamination of products with food allergens from all sources, including staff, should be considered. Allergens were identified as a hazard by the food business operator in each of the twelve establishments visited, with varying levels of controls in place to manage these hazards. Food allergen controls were assessed under the following headings (with the results summarised in Figure 1);

Purchasing
Although there was some variation in how businesses controlled incoming allergenic ingredients, all of the establishments audited documented their purchasing activity. Questionnaires were frequently used by food business operators to assess allergen controls implemented by the supplier and in a few cases, supplier audits were undertaken. The majority of food business operators held specifications on file which stipulated the allergen status of required ingredients. Following on from the information provided by suppliers, some establishments held master lists of the allergen status of all ingredients and/or end products.

In one establishment, the goods inwards area had vegetables containing sodium metabisulphite that had not been assessed, contrary to documented procedures. It became evident upon examination that these vegetables had been purchased from a new supplier without due consideration of the food allergen present.

Goods inward/Storage
Eight of the twelve establishments operated documented systems to manage goods inwards that took account of the allergen status of ingredients as they arrived on site. The types of controls that food business operators applied included:

- Identifying the allergen status of the incoming ingredients on arrival
- Segregating the storage of ingredients that contained allergens
- Labelling the allergen status of ingredients

While these eight establishments indicated that they had separate storage areas for allergenic ingredients, two food business operators were not complying with their own documented procedures in this regard.

Production scheduling
More than half (7/12) of the establishments audited considered the allergen status of ingredients when planning their production schedule. Food businesses generally scheduled the manufacture of products containing high-risk allergens such as nuts at the end of the day or before a detailed cleaning of the production line. In the remaining five establishments, other methods of allergen control, not including production scheduling, were used to control cross-contamination.

Separate equipment/Separate production lines
Only four of the establishments audited had dedicated equipment or protective clothing for the preparation of food(s) containing allergens. The procedures in these establishments detailed when particular clothing should be worn by operatives and when colour-coded equipment should be used. None of the twelve establishments audited had dedicated production lines for products containing allergens, instead relying primarily on the separation by time and cleaning of equipment to avoid cross-contamination.

Training for Staff
Some level of staff training was carried out by eight of the twelve establishments audited. Training on food allergen controls either formed part of induction training or was carried out separately through in-house or external training courses or 'on the job' training.

Rework[1]/Spillage
Documented procedures in place for dealing with rework in six of the twelve establishments took account of the allergen status of the food. In two other establishments, procedures to take account of allergens in rework were implemented but not documented. In half of the establishments, audited documented procedures were in place to deal with spillages which took account of the allergen status of the product. Typically, the procedures involved reporting the spillage to a manager and immediate clean up of the area. In some instances, there was dedicated, colour-coded equipment for cleaning up spillages of allergenic ingredients.

External sources of cross-contamination
Four of the establishments audited considered external sources such as employees, visitors and contractors as potential vectors for introducing allergens to the production site. Visitor questionnaires were used in these establishments as well as notices alerting visitors to the importance of not bringing food allergens on site.

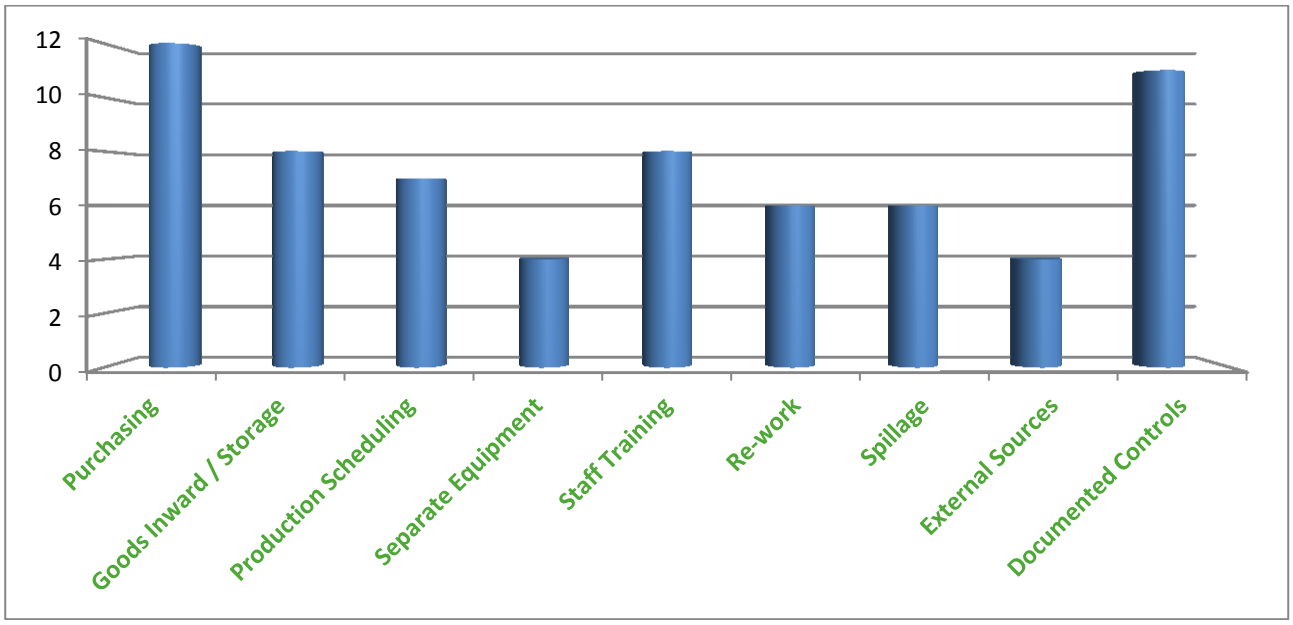
Allergen controls for the research and development of new products were in place in a limited number of businesses audited. In the remaining establishments, the potential risk posed by the introduction of food allergens through product development had not been considered.

[1] Rework is food that comes off the processing line and is reprocessed to meet a product specification for re use

4.2 Documented Controls for Allergens

Documented procedures for some or all of the controls listed in 4.1 were available in eleven of the twelve establishments. Inconsistencies in documented procedures were noted at two of the establishments audited. In one case, food allergens were controlled on site but were not included in the food safety management system. In a second establishment, only one allergenic ingredient was identified in the food safety management system despite a number of ingredients containing different food allergens being used on site.

Figure 1. The number of sites controlling allergen risks at different processing steps



4.3 Risk of Cross-contamination

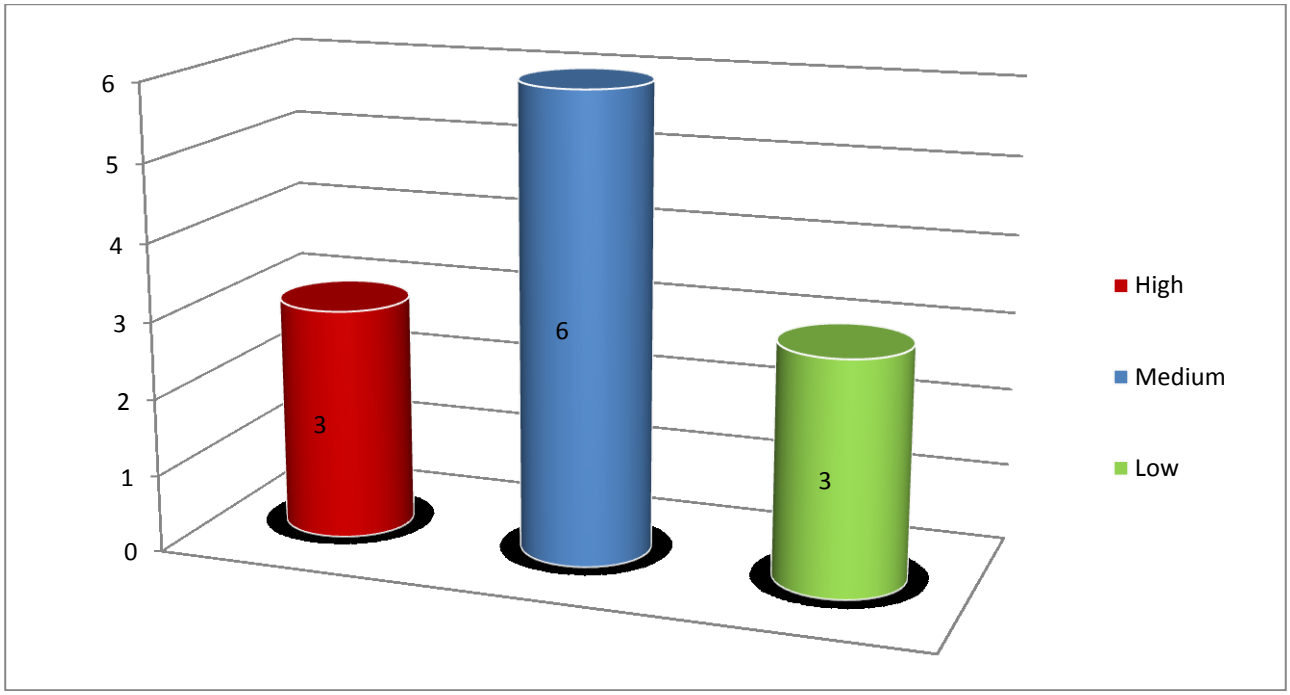
The risk of cross-contamination in manufacturing environments where products of different allergen status are being produced should be assessed. Cross-contamination can occur due to incorrect production sequencing, inadequate cleaning, recipe errors, transfer of allergens by staff, etc. Taking into account the documented procedures in place and their implementation as observed on the days of the site visits, the risk of cross-contamination with allergenic ingredients in each establishment was ranked into 3 categories (Figure 2):

- Low risk – Adequate controls
- Medium risk – Controls require some improvement
- High risk – Inadequate controls

The risk of cross-contamination was considered low in three establishments, and medium in six others. In these establishments, opportunities for improvement in the documented and/or operational controls for allergenic ingredients were identified. There was a high risk of cross-contamination by food allergens identified in three establishments which included a sausage production facility and two bakeries. The food allergen controls in place in these establishments were inadequate and the relevant food business operators were asked to undertake a significant review of their food safety management system as well as relevant controls within their establishments.

All of the establishments audited relied heavily on cleaning as a control measure as they did not have separate production lines for products with different allergen status.

Figure 2. Risk of Cross-contamination



High – Inadequate controls; Medium – Some improvement in controls required; Low – Adequate controls

4.4 Allergen Testing

The analysis of final products for the presence of allergenic ingredients is not a legal requirement, but is used by some food businesses to verify the functioning of their HACCP system in respect to the risk of food allergens. Some businesses also test for the food allergen residues on production equipment to check the efficacy of cleaning procedures.

Of the twelve establishments audited:

- Four establishments did not carry out any allergen testing
- Four establishments tested equipment for allergen residues following cleaning
- Five establishments sampled end products for allergen contamination or to verify the level of allergens in the products
- One establishment tested both equipment and end products

The analytical results examined were found to be satisfactory.

4.5 Allergen Labelling

EU legislation stipulates that 14 food allergens must be declared on pre-packaged foodstuffs [2] when used as ingredients in the production of those foods. An examination of 240 packaging samples from the 12 establishments visited found that food allergens were indicated on the packaging from all establishments.

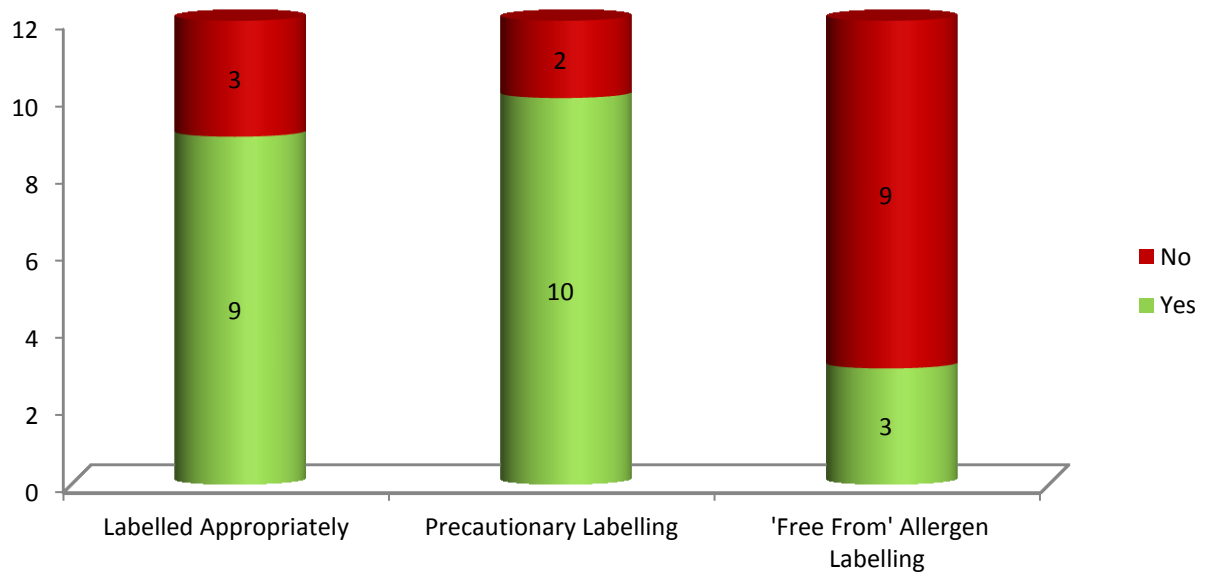
4.5.1 Presentation of allergen information

Any clear declaration on a package indicating the presence of a specified food allergen can be considered as fulfilling the food allergen labelling requirements.

The majority of packaging samples inspected listed the food allergens in separate allergen boxes in addition to the list of ingredients. The format of food allergen declarations varied between the 12 establishments visited. Four businesses were consistent in their approach to allergen labelling in that they used the same allergen labelling format for all their products, while the remaining 8 used different allergen labelling formats depending on the product. Figure 3 summarises some of the main findings regarding allergen information; 10 of the 12 businesses applied precautionary allergen labelling, 3 businesses applied 'free from' declarations and in 9 of the 12 establishments allergen labelling was considered appropriate.

[2] 'Pre-packaged foodstuff' shall mean any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging

Figure 3. Product labelling



A number of general issues were identified relating to food allergen declarations:

- Allergenic ingredients present in the final product were not declared in three establishments. The food business operators agreed to correct these labels immediately
- Products from four establishments declared some allergens in food allergen panels and the remainder in the list of ingredients. This can be misleading to consumers who may only read the information in specific food allergen panels
- In a number of cases, the presence of an allergen was not clearly indicated on the packaging, e.g. consumers may not be aware that an ingredient such as whey is derived from milk. Where pre-packaged food is for supply only to mass caterers, the food business operator has the option to include the labelling information required under Directive 2000/13/EC (including allergen information)[3] on the commercial documents which can either accompany the food to which they refer or be sent before the delivery of the food. In two establishments, food allergen information was not being supplied to catering customers
- Sulphur dioxide (SO_2) and sulphites at concentrations of more than 10mg/kg or 10mg/litre expressed as SO_2 must be indicated on the packaging. Three of the seven establishments that purchased ingredients containing sulphites had not considered sulphite labelling for their finished products

[3] The following information must also appear on the external packaging of the foodstuff - the name of the food, date of minimum durability and the name and address of the manufacturer or packager, or seller in the EU. If the food is a beverage with greater than 1.2% by volume of alcohol, the actual alcoholic strength by volume must also appear on the external packaging.

- Lecithin was used as an ingredient in a number of products and two of the businesses were unsure whether the source of the lecithin meant that food allergen labelling was required
- Three establishments applied precautionary allergen declarations to their products without an assessment of the risk of cross-contamination with those food allergens
- Four businesses included precautionary declarations for seeds/seed oil in their allergen information sections on the packaging even though the ingredients (seeds) used are not included in the 14 food allergens that require specific labelling. The food business operators advised that some of these statements were included at the request of customers.
- Two businesses declared the presence of a food allergen which was not used in the production of the product. The food business operators agreed to amend these declarations
- Gelatine was included in the allergen information of one product even though it does not require food allergen labelling under EU law

4.5.2 Precautionary labelling

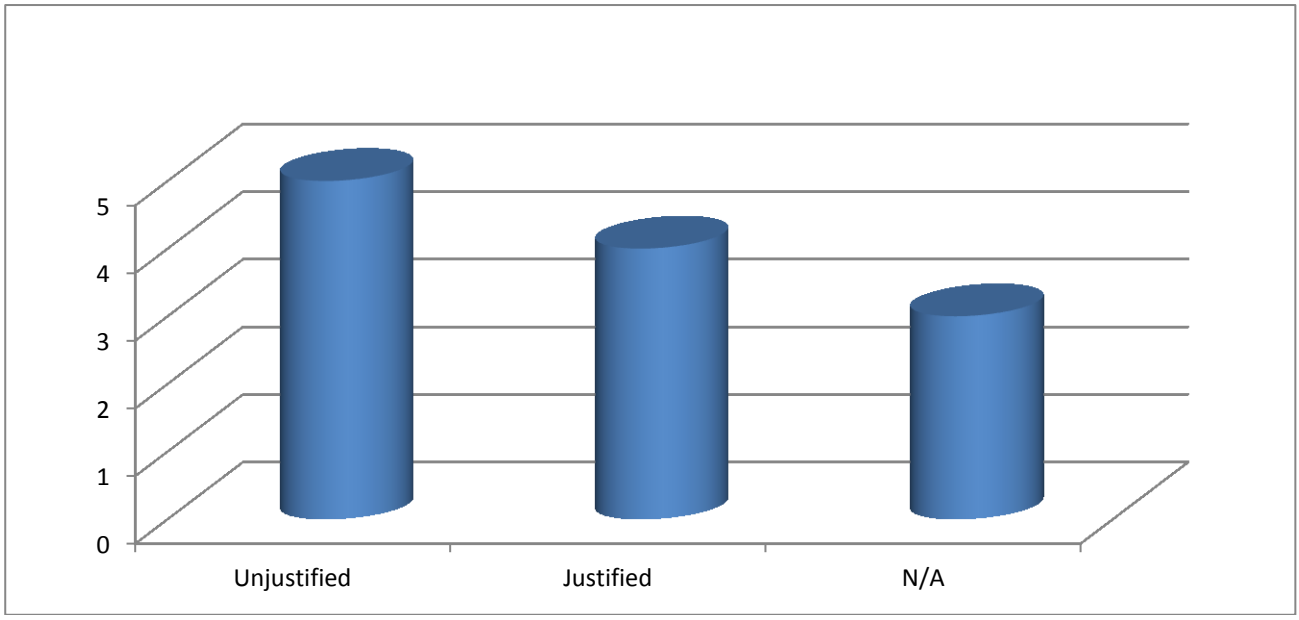
Food businesses sometimes use precautionary allergen labels such as 'may contain…' or 'produced in a factory that uses…' to alert vulnerable consumers that their product may inadvertently contain low levels of certain allergens. While such labelling can provide a valuable warning to consumers when prudently applied, it should not be used by food businesses as a substitute for adequate controls. In general, precautionary labelling was used for nuts and sesame seeds, and to a lesser extent, for other allergens. For the purpose of this report, precautionary labelling is considered a statement or advice on food packaging alerting the consumer to the possibility of a food allergen being present even though it was not used as an ingredient. Two types of precautionary labelling were identified:

- Type A refers to an allergen that was not used in the product but was included in other products manufactured on the premises
- Type B refers to an allergen that was not used in any products manufactured on the premises

Ten of the 12 businesses applied type A precautionary allergen labelling regarding nuts and some included statements regarding other allergens also, e.g. may include nuts and sesame seeds.

Five businesses applied type B as well as type A precautionary advice. Type B advice was generally used in relation to nuts and or seeds/sesame seeds, except in one case where it included a warning about soya. Some food businesses indicated that type B precautionary labelling was applied in response to requests from customers and sometimes despite being in conflict with the results of the food business operator's own risk assessment. Only two of the 12 food businesses audited did not use any precautionary food allergen advice on their packaging.

Figure 4. Justification of precautionary labels



The use of precautionary labelling by five of the establishments was considered unjustified and therefore inappropriate but was considered to be justified when used by four other food businesses. Due to the poor operation controls in one establishment, the use of precautionary labelling required strengthening.

5. CONCLUSIONS

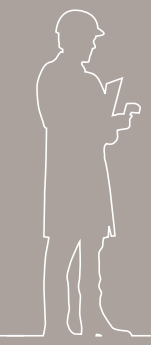
All food businesses audited had considered allergens to some extent as part of their food safety management systems and had implemented varying levels of controls. Purchasing was identified by all businesses as being central to the control of food allergens and seven considered the risk of contamination by allergens when planning their production schedule. In general, food businesses relied on cleaning procedures and production scheduling rather than dedicated equipment, production lines or areas to prevent or minimise cross contamination. Two thirds of the food businesses provided some form of food allergen training to staff while half had controls in place to manage allergen spillages and rework. Only four of the businesses considered the risk of allergen contamination from external sources such as visitors, contractors etc. It was apparent that businesses supplying large retailers, particularly retailers with own brand products had more advanced systems of controls in place. Eight of the twelve businesses carried out their own allergen tests on final products or equipment.

A certain amount of allergen information was provided on all packaging examined. However, the format and extent of food allergen declaration was found to be inconsistent and in some instances could be confusing if not misleading to consumers. The use of precautionary labelling can have detrimental effects on food allergy sufferers when not applied prudently. Most of the food businesses utilised some form of precautionary labelling, primarily for nuts, but the level of justification in many cases was limited. In some cases, food business operators revealed that such labels were used solely because the customer requested them and in the knowledge that there was little or no risk of that food allergen being present. Such unjustifiable use of precautionary labelling could be considered misleading to consumers and thereby in breach of general food labelling law.
This audit has been beneficial in determining the level of compliance by food businesses with EU food allergen labelling requirements and while there are positive aspects to the results, areas with room for improvement were also highlighted.

6. RECOMMENDATIONS

To assist the food manufacturing industry to fully meet its obligations in regard to food allergens, the FSAI along with pertinent stakeholders will develop guidance on best practice for the management and control of food allergens in the food manufacturing environment. In addition, food businesses should strengthen their own food allergen controls and in particular, they should:

- Review food allergen controls to ensure that all risks of contamination with food allergens have been considered
- Review the purchasing system to ensure that food allergens are adequately controlled, in particular with respect to new or alternative suppliers/ingredients
- Review the goods inwards function to ensure that all products entering a manufacturing site are adequately controlled
- Review the ingredients storage area to ensure the segregation and identification of allergenic ingredients
- Review production scheduling to minimise the potential for cross-contamination
- Review staff training to ensure they are aware of procedures for the handling and storage of food allergens
- Review labelling strategies to ensure that legal requirements are met and that precautionary labels are applied on a risk basis
- Review the system for approving new or revised labels to ensure that legal requirements are met
- Carry out risk assessments where ‘free from’ allergen declarations are used



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