

AUDIT
REPORT

Targeted Audit of
Allergen Information
on Non-Prepacked Food

MAY 2017



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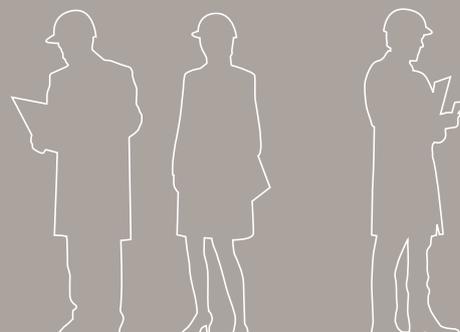


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1. GLOSSARY

FSAI	Food Safety Authority of Ireland
HSE	Health Service Executive

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

Allergic reactions to food can make people very ill and in rare situations, can be fatal. Consumers with a food allergy or intolerance rely on food businesses to provide accurate and consistent allergen information to inform their purchasing options. In December 2014, the existing requirement to declare food allergens on prepacked food was extended by the Food Information for Consumers (FIC) Regulation (EU) No 1169/2011 to include non-prepacked food (food sold loose). Food sold in loose form or packed on the premises at the request of the consumer, packed for direct sale or supply to the final consumer or mass cater, is considered non-prepacked food. In Ireland, the Health (Provision of Food Allergen Information to Consumers in respect of Non-Prepacked Food) Regulations, 2014 (S.I. No. 489 of 2014) stipulate that food allergen information for non-prepacked food must as a minimum, be provided in written format.

The Food Safety Authority of Ireland (FSAI) completed a targeted audit of food businesses to determine the level of compliance with EU and Irish legislation relating to the provision of food allergen information on non-prepacked food. Fifty food businesses were audited with respect to their allergen assessment methods and their compliance with legal requirements for the provision of written allergen information. The food businesses were selected at random in several areas across the East, West and South-East of the country.

In summary, the audit revealed that there was a low level of compliance by the food businesses selected in terms of providing proper written allergen information to consumers. A significant number of food businesses audited (32%) did not provide written allergen information. Of particular concern was the fact that in 26 of the food businesses audited, the allergen information reviewed was inaccurate or incomplete. In summary, out of the 50 food business establishments audited, 44(88%) food business establishments had findings that require corrective action and six (12%) food business establishments had no findings and were fully compliant with the allergen information requirements specified in Regulation (EU) No 1169/2011 and S.I. No. 489 of 2014.

The level of compliance identified in the 50 food businesses audited is a cause for concern. Food businesses must take their legal responsibilities seriously, particularly where the health of consumers is at stake. The FSAI and the Health Service Executive (HSE) will continue to raise awareness of food businesses regarding their legal obligation to provide written allergen labelling for consumers of loose food. However, this will be supplemented by inspections and enforcement action where it is deemed necessary in the interest of protecting consumers' health.

3. INTRODUCTION

The FSAI carries out targeted audits of food businesses each year to determine the level of compliance with current food law and the effectiveness of its enforcement.

In December 2014, the existing requirement to declare food allergens on prepacked food was extended by the Food Information for Consumers (FIC) Regulation (EU) No 1169/2011 to include non-prepacked food (food sold loose). This EU requirement is transposed to national legislation by Statutory Instrument (S.I.) No. 489 of 2014 which stipulates that food allergen information for non prepacked food must, as a minimum, be provided in written format, though it can also be provided verbally in addition to the written format.

A list of ingredients is not generally used for non-prepacked foods so the information provided to consumers must use the word 'contains' followed by the specific allergen, e.g. contains wheat, soya or egg.

Consumers may be allergic or intolerant to many different foods or food ingredients. EU food law now stipulates that 14 specific food allergens used in producing or preparing a food (including beverages) must be specifically declared. The 14 allergens include:

1. Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, except:

- (a) wheat based glucose syrups including dextrose
- (b) wheat based maltodextrins
- (c) glucose syrups based on barley
- (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin

2. Crustaceans and products thereof

3. Eggs and products thereof

4. Fish and products thereof, except:

- (a) fish gelatine used as carrier for vitamin or carotenoid preparations
- (b) fish gelatine or Isinglass used as fining agent in beer and wine

5. Peanuts and products thereof

6. Soybeans and products thereof, except:

- (a) fully refined soybean oil and fat
- (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources
- (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources
- (d) plant stanol ester produced from vegetable oil sterols from soybean sources

7. Milk and products thereof (including lactose), except:

- (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin
- (b) lactitol

8. Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin

9. Celery and products thereof

10. Mustard and products thereof

11. Sesame seeds and products thereof

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers

13. Lupin and products thereof

14. Molluscs and products thereof

The FSAI has published two guidance documents to assist both food businesses and enforcement officers on the allergen information requirements for non-prepacked foods:

- [Guidance Note No. 28 - Food Allergen Information for Non-Prepacked Foods in Ireland](#)
- [Allergen Declarations for Non-prepacked Foods](#)

In recent years, the number of food allergen alerts has been increasing. In 2016, the FSAI, in conjunction with its official agencies, issued 28 alerts and dealt with 59 food incidents related to food allergens. The FSAI has put in place, an early warning system whereby people with a food allergy or intolerance and who are registered with the FSAI, are notified by SMS text messaging of any food incident relating to any of the 14 specified allergens.

This summary report brings together the findings from the audit of 50 food business operations from which overall conclusions can be drawn on the level of compliance with EU and Irish legislation with recommendations for improvement proposed.

3.1. Audit Objective

The objective of this audit was to assess the implementation and compliance with allergen information requirements set out in Regulation (EU) No 1169/2011 and S.I. No. 489 of 2014.

3.2. Audit Scope

The scope of the audit was the requirement for written allergen information to consumers for non-prepacked food.

3.3. Audit Criteria and Reference Documents

The principal audit criteria referred to during the audit include:

- [S.I. No. 489 of 2014](#) on the provision of food allergen information to consumers in respect of non-prepacked food
- [Regulation \(EU\) No1169/2011](#) on the provision of food information to consumers.
- [Regulation \(EC\) No178/2002](#) 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 \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [FSAI Guidance Note No.28](#) Food Allergen Information for non-prepacked foods in Ireland
- [FSAI Allergen Information](#) for non-prepacked food booklet
- Food business food safety management

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 at random and included hotels, restaurants, cafés, takeaways and public houses. The food businesses were selected in order to provide a relatively broad picture of allergen information compliance in different food business types in the geographical areas audited. All on-site audit activity took place in November, 2016. The rationale of the audit was explained to the food business operator as part of the opening meeting in each establishment. A thorough audit of the systems in place and documentation associated with allergen information was then conducted. Menu item ingredient labels were checked against the declared allergens within the information provided. All audits were unannounced to the food business operator.

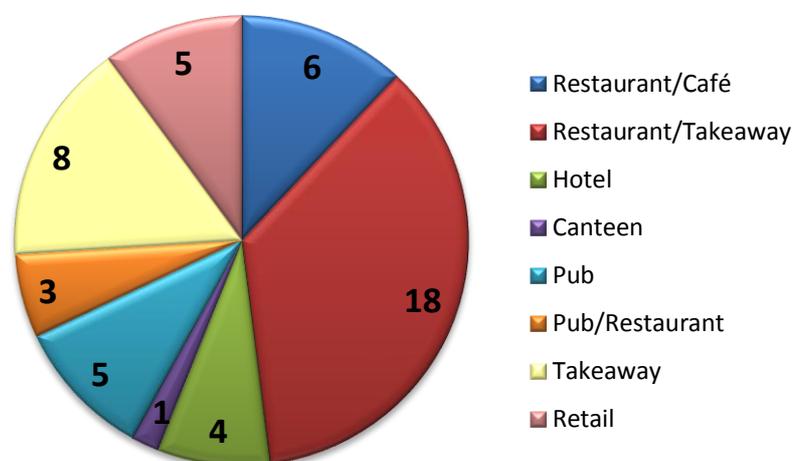
Fifty food business operations in the East, West and South East of the country were audited in total. The food businesses visited were divided into eight categories. See Table 1.

Table 1. Types of Food Business Establishments Audited

Type of food business establishments	Explanation
Restaurant/Café	Food business that offers breakfast, lunch, dinner and/or snack menus
Restaurant/Take-away	Food business that is a restaurant as described above but also provides a take-away service
Hotel	Food business that offers accommodation and has a restaurant
Canteen	Food business that provides a staff catering services
Pub	Food business that has a full drinks menu but no food menu
Pub/Restaurant	Food business that has a full drinks menu and a food menu
Takeaway	Food business with no dine-in facilities
Retail	Food business with delis and loose foods

The number of food business establishments audited per category is represented in Figure 1.

Figure 1. Number and Type of Food Business Establishments Audited



3.5. Legal Requirements

Under the Food Information to Consumers (FIC) Regulation (EU) No 1169/2011, allergen information must be provided for non-prepacked foods. This requires all food businesses, e.g. restaurants, delis, canteens, public houses, takeaways, retail outlets etc. providing non-prepacked foods, e.g. unwrapped foods, meals etc., to indicate to consumers, the use of any of the listed allergenic ingredients in the production or preparation of food.

The FIC Regulation permits each EU Member State to determine how allergen information for non-prepacked food is provided within their jurisdiction. In Ireland, food allergen information for non-prepacked food must, as a minimum, be provided in written format, but can also be provided verbally at any time. S.I. No. 489 of 2014 on the provision of food allergen information to consumers in respect of non-prepacked food has applied since the 13th of December, 2014. It requires that:

The food business operator must indicate the allergens in writing at the point of:

- a) Presentation, or
- b) Sale, or
- c) Supply

The written information must be:

- 1) Freely and easily accessible before the sale or supply of the food
- 2) At least in the English or in the Irish language and in the English language
- 3) In a conspicuous place, such that it is easily visible and available to the final consumer or mass caterer
- 4) In clear legible script, and
- 5) Presented in a manner such that there is no possibility of confusion as to which food the information relates

Food business operators are responsible for placing safe food on the market and for ensuring that information provided to consumers is accurate and not misleading.

4. AUDIT FINDINGS

4.1. Allergen Awareness by Food Businesses

Regulation (EU) No1169/2011 on the provision of food information to consumers, states

'Article 44(1) - National measures for non-prepacked food - where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale the provision of the particulars specified in point (c) of Article 9(1) is mandatory.

Point (c) of Article 9(1) - any ingredient or processing aid listed under the specific 14 food allergens or derived from a substance or product listed under the specific 14 food allergens causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form.'

As part of the audit, food business operators were assessed as to whether they were able to provide allergen information to the auditors for the food prepared and sold in their establishments. A total of 34 food business operators (68%) had allergen information in some form for the food prepared and sold in their establishments.

Sixteen food business operators (32%) were not able to provide any allergen information for the food prepared and sold in their establishments and so were not compliant with this requirement of Regulation (EU) No 1169/2011 and S.I. No. 489 of 2014.

Figure 2. Awareness of Allergen Information provided to the Auditors

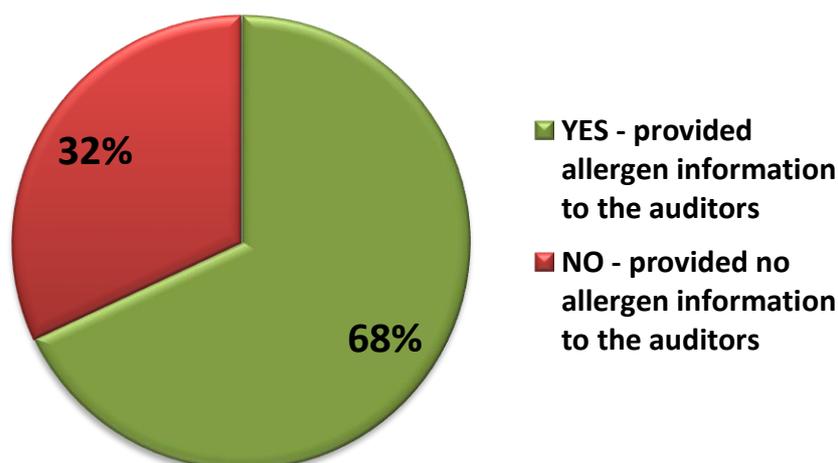


Figure 2: Out of the 50 food businesses audited, this pie chart shows the results of those that provided allergen information (34 - 68%) and those that did not provide allergen information (16 - 32%).

4.1.1 Reasons provided by the food business operators for non-compliance

Of the 16 (32%) food business operators that did not provide allergen information for the food prepared and sold in their establishments, the following reasons were provided:

- The food business operator did not have time to conduct an allergen assessment
- The food business operator was unaware of the requirements to provide this information
- The food business operator was unsure how to review its foods for allergen content

- There was an over-reliance on the head chef completing an allergen assessment and no other staff member was able to provide allergen information at the time of the audit
- The food business operator did not consider drinks as a food and therefore, did not include them in the allergen assessment and information process
- The food business operator was of the opinion that the legislation was not currently in force
- The food business operator considered the listing of the 14 allergens on a poster or on the menu to comply with allergen information requirements
- The food business operator did not understand what an allergen was

4.1.2 Accuracy of the allergen information

Of the 34 (68%) food business operators that had provided allergen information, the audit team then assessed it for accuracy based on the documentation available for the ingredients. Based on the information provided, eight food business operators (24%) were deemed to be providing accurate and correct allergen information. Twenty six food business operators (76%) had inaccurate allergen information where the food business operator had either excluded a food or incorrectly recorded the allergen content of food in the allergen information.

Figure 3. Accuracy of Allergen Information

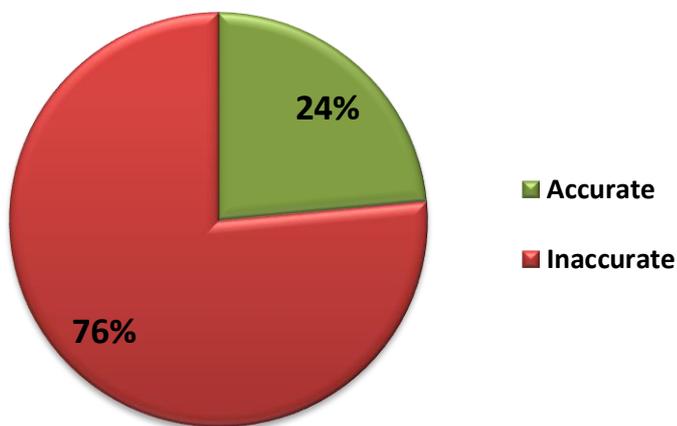


Figure 3: Out of the 34 food businesses audited that had allergen information, this pie chart shows the results of the accuracy of that information when compared to ingredient labels. Eight (24%) had accurate allergen information and 26 (76%) had inaccurate allergen information.

The inaccuracies noted in the allergen information provided to consumers by 26(76%) food business operators are set out in Table 2 following.

Table 2. Inaccuracies in Allergen Information

Inaccuracies	Legal requirement	Out of the 26 food business establishments, the issue was found in
Allergen content incorrect and/or menu items missing from the information	It is mandatory to provide allergen information on all foods sold.	24 (92%)
The allergen 'sulphites' was missing from the information – most commonly seen for sausages and vinaigrettes	The allergen 'sulphur dioxide and sulphites' must be within the allergen information if present.	11 (42%)
Cereals containing gluten were specified as 'gluten' within the information	The cereal itself is considered the allergen, e.g. wheat, oats, rye etc. Gluten may be placed in brackets after the name of the cereal.	10 (39%)
Nuts not specified	The specific nut needs to be within the allergen information. These include; almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia (Queensland) nuts.	10 (39%)
Drinks not included in the allergen information	All food containing allergens must be within the information provided and this includes drinks.	8 (31%)
Milk incorrectly specified as 'lactose' or 'dairy'	Milk is the correct allergen to specify within the information.	4 (15%)
Pine nuts listed in information as a nut	Pine nuts are not considered part of the category 'nuts and products thereof' and do not have to be listed within the information.	3 (12%)
Cereal containing gluten were not specified	Cereals containing gluten must be specified, namely – wheat, rye, oats and barley.	3 (12%)
Crustaceans incorrectly specified as 'fish' or 'shellfish'	Crustacean is the allergen to specify within the information. These include; prawns, crabs, lobster, crayfish etc.	2 (8%)
Lupin within the information but not present – confusion over what lupin was	Only allergens that are present need to be in the information.	2 (8%)
Fish incorrectly specified as 'molluscs' or 'crustacean'	Fish is the correct allergen to specify in the information. Molluscs include clams, mussels, whelks, oysters, snails and squid.	2 (8%)

4.1.4 Possible reasons for inaccuracies in the allergen information

Where inaccurate allergen information was identified during the audits, the audit team endeavoured to determine the possible reasons for this:

- Incorrect assessment methods. In several food businesses, the assessment was based on the food

business operator's knowledge of the foods and guessing the allergens present rather than checking the labels or supplier information

- Misunderstanding the type of allergens, e.g. food business operators were unsure as to the difference between fish, mollusc and crustacean
- The exclusion of drinks. Several food business operators audited did not consider drinks as a food and therefore, did not include them in their allergen information
- Some food business operators were unaware of the requirement that cereals containing gluten must be specified. The cereal itself is considered the allergen and so must be written, e.g. wheat, oats, rye etc. Gluten may be placed in brackets after the name of the cereal
- Unaware of the requirement that the particular nut species must be specified. The actual nut is considered the allergen so this should be written and not just the word 'nut', e.g. hazelnut, almond etc.
- An allergen assessment was completed as a one-off exercise. In various food business operations, the audit team found that an allergen assessment had been completed once. There was no regular review and or update, new menu items were not assessed and the allergen information available to consumers was not being amended as necessary.
- Food business operators are unsure how to conduct allergen assessments correctly.

4.2. Allergen Information

4.2.1 Format of written allergen information

The audit assessed compliance with requirements for the provision of written allergen information for consumers in accordance with S.I. No. 489 of 2014;

Regulation 4 - A food business operator shall not present or make available food for sale or supply, or sell or supply food, unless written particulars of any allergen in the food are indicated at the point of:

(a) Presentation

(b) Sale, or

(c) Supply

in accordance with the applicable requirements of this part

Regulation 5(1) - Manner in which allergen information is to be provided

(1) A food business operator shall provide written particulars of any allergen in food presented or made available for sale or supply such that the information is—

(a) Freely and easily accessible before the sale or supply of the food,

(b) At least in the English or in the Irish language and in the English language,

(c) In a conspicuous place, such that it is easily visible and available to the final consumer or mass caterer,

(d) In clear legible script, and

(e) Presented in a manner such that there is no possibility of confusion as to which food the information relates

Of the 34 food business operators that provided allergen information, 21 (62%) had written allergen information available for consumers at the point-of-sale or the point-of-supply (see Figure 5).

Figure 4. Format of Written Allergen Information

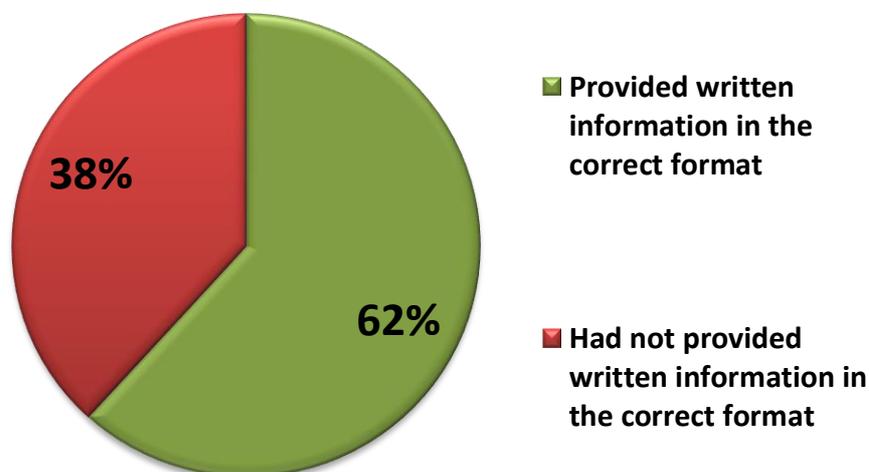


Figure 4: Out of the 34 food businesses audited that provided allergen information, this pie chart shows the results of those that had the allergen information available in writing for consumers to review. Twenty-one (62%) had provided written allergen information in the correct format and 13 (38%) had not provided their allergen information in the correct format.

4.2.1.1 Reasons provided by the food business operators for non-compliance

Many of those food business establishments that had not provided written allergen information to consumers did not realise that the information must be made available without a consumer having to ask for it. Folders of allergen information created by the food business operator were kept behind the sales counter or in staff only areas for reference purposes should a staff member get an allergen query from a consumer. In several food businesses, allergen information was on the main dinner menu but not on the children's menus, early bird menus etc. One food business was awaiting the next print of its menu before adding the allergen information.

4.2.2 The provision of written allergen information for distance selling

Written food allergen information must be provided by food businesses engaged in 'distance selling'. These include food businesses that receive food orders by phone or electronically and deliver those foods to the final consumer.

S.I. No. 489 of 2014 - Regulation 5(2) - in the case of food presented or made available for sale or supply by means of distance selling, the food business operator shall provide particulars of any allergen in such food

(a) Before the purchase is concluded, on the material supporting the distance selling or through other appropriate means clearly identified by the food business operator which do not involve charging consumers supplementary costs, and

(b) At the moment of delivery, and such particulars shall be provided in writing at least one of the stages referred to in subparagraphs (a) and (b).

Written allergen information can be provided before the food is ordered, e.g. supporting material such as leaflets/catalogues or online information used to order the food. Alternatively or in addition, it can be provided at the moment of delivery of the food product, e.g. leaflets/catalogues or other printed material. Written food allergen information provided at the point-of-delivery could be specific to the purchased product or it could be general supporting material.

Many of the food business establishments visited provided an online food ordering and delivery service. Out of the 50 food businesses audited, 13 (26%) provided this service (distance selling) but only one (8%) of these was compliant with the requirements of S.I. No.489 of 2014. Seven food businesses with distance selling services (54%) had no allergen information for the food prepared and sold in their establishments. The remaining five food businesses (38%) had allergen information but did not include written allergen information on their online menu or within leaflets distributed for consumers to review prior to placing an order.

Figure 5. Written Allergen Information for Distance Selling

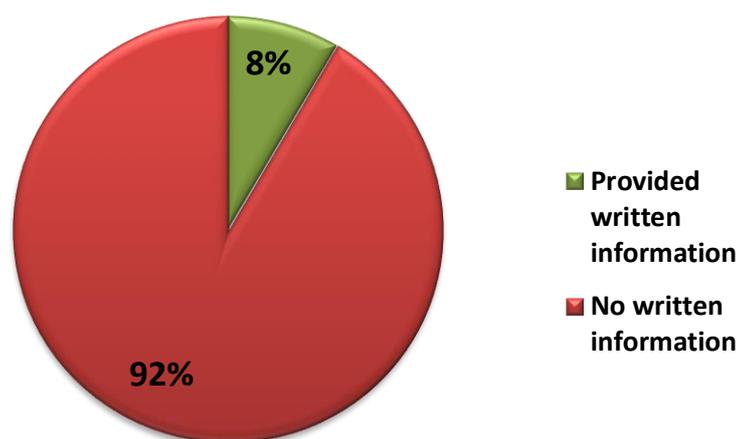


Figure 5: Out of the 13 food businesses audited that provided distance selling services, this pie chart shows the results of those that had allergen information available in writing, for consumers to review. One (8%) had written allergen information available and 12 (92%) had not made their allergen information available to review by consumers.

4.3. Overall Compliance with Allergen Information

The objective of this audit was to assess the implementation and compliance with allergen information requirements as set out in Regulation (EU) No 1169/2011 and S.I. No. 489 of 2014 in food businesses supplying non-prepacked food. After each audit, the food business operator received a report which outlined all findings. It is the responsibility of the food business operator to close out all audit findings. Corrective actions should be developed by the food business operator in liaison with the environmental health service in order to address and close out all audit findings.

In summary, out of the 50 food business establishments audited, 44(88%) food business establishments had findings that require corrective action and six (12%) food business establishments had no findings and were fully compliant with the allergen information requirements specified in Regulation (EU) No 1169/2011 and S.I. No. 489 of 2014.

Figure 6. Findings Requiring Corrective Action

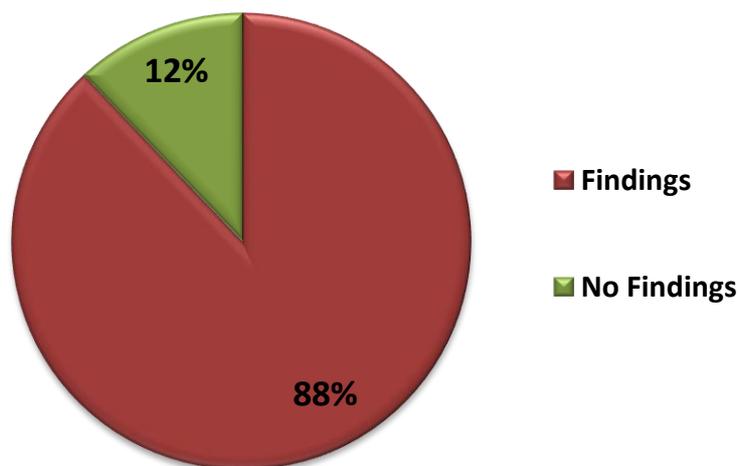


Figure 6: Out of the 50 food businesses audited, this pie chart shows the results of those that had audit findings requiring corrective action. Forty-four (88%) had audit findings and six (12%) had no audit findings.

5. POSITIVE PRACTICES OBSERVED DURING THE AUDIT

In one area audited, the local environmental health officer provided a generic allergen template for use by relevant food business operations under its supervision. The template on completion was then placed in a folder and was in a format easy to read and review by consumers.

In one food business establishment, the audit team observed a self-designed electronic allergen management tool. This tool allowed the food business operator to enter ingredients, create menus and the allergen information was generated automatically. This electronic tool allowed the menu for each menu service to be made available on line for review by its customers who also had the ability to tailor the menu according to their allergen requirements, e.g. if the allergen 'wheat' was ticked, the menu would only list items that did not contain wheat.

The Vintners Federation of Ireland, the trade association for licensed establishments, has assisted its members by the development of allergen information posters. These posters list the general list of alcoholic drinks available in public houses and have the allergen information next to each drink. These posters have been sent to its members and the audit team saw them in three out of the five public houses audited.

6. CONCLUSIONS

The food business operator is legally responsible for providing accurate allergen information to those who consume food produced in their establishment. Failure to comply with this legal requirement can have serious health consequences for a significant minority of the Irish population. The findings of this audit indicate that the majority of food businesses audited are not fully complying with their legal obligations and may therefore, be putting vulnerable consumers at risk.

Overall compliance with the requirements for the provision of allergen information in Regulation (EU) No 1169/2011 and S.I. No. 489 of 2014 was low.

- Thirty-two percent of the food businesses audited did not provide any written allergen information on the food prepared and sold in their establishment on the day of audit.
- Sixty-two percent of food businesses that provided written allergen information had made it available for review by the consumer. However, 76% of these food businesses had incorrectly identified allergens and so the information consumers was reviewing was inaccurate.
- The majority of the food business establishments engaging in distance selling (88%) were not compliant with the requirements to provide written allergen information.
- The majority of the food business establishments audited (88%) had findings that required corrective action.

The reasons provided to the audit team by food business operators for the high level of non-compliance include confusion and lack of awareness about food allergens in general and the precise nature of the 14 food allergens that must be provided in the information for non-prepacked food. Some of the food businesses audited had hired consultants to help put their allergen information in place but did not fully understand the risks to health posed by food allergens and that it was a process rather than a one-off project.

None of the food businesses audited were aware of MENUICAL, a free FSAI online application (www.menucal.ie) designed to help food business operators meet their statutory responsibilities regarding the management of allergens.

7. RECOMMENDATIONS

Seven recommendations are made as part of this report:

1. Food business operators marketing non-prepacked food must put in place, systems to ensure they fully comply with the legal requirements which apply in relation to allergen information for their business type
2. Food businesses marketing non-prepacked food should make food allergen training a central component of staff training programmes
3. Food businesses marketing non-prepacked food must fully inform themselves about food allergens and ensure they provide accurate allergen information to consumers of their products
4. Food business establishments engaging in distance selling must provide written allergen information on their online menu or within leaflets distributed for consumers to review prior to placing an order
5. MENCAL is a free allergen management tool available on the FSAI website and should be considered by food businesses to help them comply with the requirement to provide written allergen information to consumers
6. The FSAI and the HSE should continue to assist and engage with industry groups to improve compliance rates
7. Where food businesses fail to comply with legislative requirements, enforcement action should be considered to ensure vulnerable consumers are fully protected in accordance with the law



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