

TiFSiP

The Institute of Food Safety
Integrity & Protection

Chartered
Institute of
Environmental
Health



CIEH/TiFSiP white paper: Improving the use of ‘**may contain**’ allergen statements

> Advice > Guidance > Good Practice

May
contain...



Contents

Introduction	3
The context	4
What is 'may contain' labelling?	6
Providing allergen information	7
Managing allergen cross-contamination	8
Legal liability and the provision of precautionary 'may contain' allergen information	9
What next?	10
Additional resources	12
About TiFSiP	14
About CIEH	15



Introduction

When most people buy a pre-packed sandwich from a supermarket, or a freshly made salad from a café, they do not think much about its safety. It is taken for granted that there will not be any problems. But for consumers with food allergies the situation is very different. Buying food means a close study of ingredients and warning labels and where food is made on-site, questioning staff about its preparation. Inaccurate information can lead to serious consequences.

The situation has improved since the introduction of the **Food Information Regulations** in 2014. Consumers can now expect accurate information on allergenic ingredients (14 allergens are covered) in all types of food, whether packaged or served as a meal or snack.

Unfortunately this is not the end of the problem for consumers with food allergies or intolerances. There is still the issue, due to cross-contamination, of unintentional presence of allergenic material.

Voluntary measures are in place to warn vulnerable consumers of risks, in the form of precautionary allergen labelling, such as 'may contain'. Deciding when to use a 'may contain' statement, however, is not straightforward. It requires food businesses to understand the potential allergen cross-contamination risks on their premises and also the potential risks posed by products received from suppliers. In addition, research suggests that consumers with food allergies often find it difficult to interpret and understand 'may contain' statements.

The Institute of Food Safety, Integrity and Protection (TiFSiP) and the **Chartered Institute of Environmental Health** (CIEH) work with the food industry to provide advice and guidance on food safety. In discussions, a number of food businesses have raised questions about the best way to address

uncertainties around 'may contain' statements. As a result, TiFSiP and the CIEH have brought key stakeholders together to discuss the issues and how they could be addressed.

This paper considers concerns raised at the industry events, in particular the concerns voiced at an expert roundtable held in June 2015. The roundtable was attended by representatives from the food service and manufacturing sectors, from a body representing consumers with food allergies, a toxicologist with specific experience of allergen control, an environmental health professional and a regulatory specialist with expertise in UK and European Union allergen legislation.

The focus of this paper is on the 'may contain' issues raised by the roundtable attendees. It identifies measures that could reduce uncertainty related to the provision and interpretation of 'may contain' statements, identifies key guidance documents and suggests areas for improvement.

Aims and objectives

The aim of the paper is to stimulate a debate between food service operators and consumers with food allergies about the use of precautionary 'may contain' allergen statements. In particular, the paper is intended to highlight issues related to food service operators passing on 'may contain' statements from manufacturers to consumers. By doing so, TiFSiP and the CIEH hope to make it easier for consumers with food allergies and intolerances, and their friends and families, to more easily choose food unlikely to cause an adverse reaction.

The paper does not address issues related to 'gluten free' statements. TiFSiP and the CIEH recognise the issue's importance and it may form part of future work programmes.



The context

The Food Information Regulations (FIRs 2014) came into effect in December 2014 and apply to all food businesses. The most significant change required by the Regulations is for food businesses to provide information about allergenic ingredients in all types of food, packed and loose.

Providing accurate information on allergenic ingredients is extremely important because it allows consumers with allergies to decide on which foods are safe for them to eat. The 14 allergens specified in the Regulations include:



Celery, and products thereof



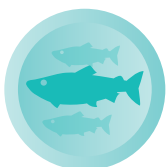
Cereals, containing gluten, namely wheat, rye, barley, oats, and products thereof



Crustaceans, and products thereof



Eggs and products thereof



Fish, and products thereof



Lupin, and products thereof



Milk, and products thereof (including lactose)



Molluscs, and products thereof



Mustard, and products thereof



Nuts, namely almond, hazelnut, walnut, cashew, pecan nut, brazil nut, pistachio nut and macadamia nut



Peanuts, and products thereof



Sesame seeds, and products thereof



Soybeans, and products thereof



Sulphur dioxide and sulphites

Complying with the requirement to provide accurate allergen ingredients information for a dish is a significant undertaking but is possible due to the clear rules-based framework for businesses to follow. Providing accurate declarations about allergens present due to cross-contamination is more problematic. There is no rules-based framework for provision of information about trace allergens, that is, allergens present which are not ingredients.

There is no mandatory requirement to provide information about the unintentional presence of allergens in a food. There is, however, a requirement to let consumers know if a food could adversely affect a specific health condition. For example, if a consumer declares their allergy or intolerance to a food business, the business has a duty to inform the consumer if the level of unintentional allergens is known to be at a level that could cause an allergic reaction. Providing this information to consumers enables food choices that reflect individual sensitivity levels.

Well-informed food businesses will have a good understanding of allergen cross-contamination issues which could occur on their premises and typically use appropriate HACCP (Hazard Analysis and Critical Control Point) systems to eliminate or control such hazards.

Numerous food businesses have spoken to TiFSiP and the CIEH to express concern about the consistency and reliability of supplier declarations regarding unintentional trace presence of allergens. Inconsistent and unreliable declarations means it can be difficult, when producing complex products made from multiple ingredients, to determine what allergen contamination information should be passed on to final consumers.

Consumer demand is driving menu content and the provision of information about potential allergens. There is anecdotal evidence that some food businesses may be using allergen-free labelling for competitive advantage, without the evidence to support their claims. Food businesses are concerned that the current approach to 'may contain' allergen labelling could put customers at risk, and damage the sector's reputation.



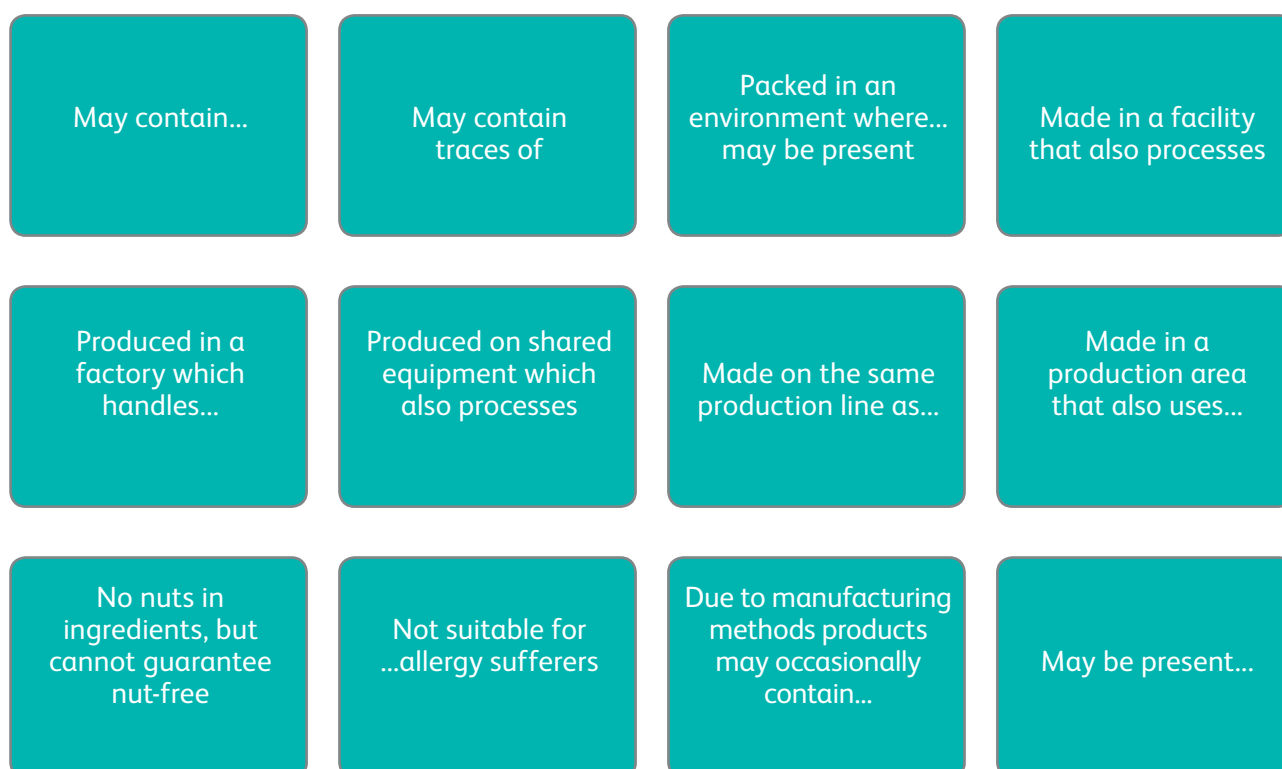
What is ‘may contain’ labelling?

There are currently around 40 different ways used to express ‘may contain’. For example:

- ‘May contain traces of...’
- ‘Produced on lines handling...’
- ‘Manufactured in a facility where [...] are present’ (Figure 1)

This range of descriptors can be differently interpreted by consumers with food allergies leading them to incorrectly assign more significance to some phrases than others¹. This may result in inadvertent engagement in risky behaviours or unnecessary restrictions in food choices².

Figure 1: Examples of precautionary allergen statements



The Food Standards Agency (FSA) examined the level of allergen contamination in prepacked foods with and without precautionary allergen statements³. A wide variety of different statements were used across product categories. The most frequently used advisory label was ‘may contain traces’ (38 per cent (418/1106)). The second most frequently used was ‘may contain’ (20.6 per cent (228/1106)). The research found that the wording of advisory labels did not reflect the level of cross-contamination. FSA guidance recommends the use of ‘may contain X’ or ‘not suitable for someone with X allergy’. These two statements were found on 20.6 per cent and 7.2 per cent (80/1106) of products, respectively.

Source: Allen et al. *World Allergy Organization Journal* 2014, 7:10 ([available here](#))

1 Barnett et al. *BMC Public Health* 2011, 11:734 ([available here](#))

2 Dunn Galvin et al. *Allergy* 2015, DOI: 10.1111/all12614 ([available here](#))

3 FSA, 2014. Survey of Allergen Advisory Labelling and Allergen Content of UK Retail Pre-Packaged Processed Foods. FS241038 ([available here](#))

Consumers with food allergies and intolerances need to be confident that the information provided about their food is accurate and reliable. They want to be sure that food businesses have systems and processes in place to prevent, reduce or warn of allergen presence, whether arising from ingredients or as a result of cross-contamination. They need to know if allergens are present and if allergens might be present.

The vast majority of food businesses work hard to ensure that food is safe both in terms of hygiene and in the accurate declaration of the presence of allergens. Despite their best efforts, some businesses struggle to provide consistent, accurate and reliable information about the allergen risks present due to cross-contamination in their supply chain.

A business may have good systems in place to control allergen cross-contamination in its own operations but is reliant on its suppliers to manage risks within their operations. Particular difficulties are created by the widespread and inconsistent use of precautionary 'may contain' labelling by suppliers.

The current use of precautionary allergen labelling is a source of great frustration and concern for consumers with food allergies and the businesses that supply them. Research^{4,5}, has shown that many consumers with food allergies consider precautionary warnings to be overused, and as a result they are often ignored or mistrusted, defeating the object of providing better quality allergy advice and improving (vulnerable) consumers' choice. Food service businesses that pass on all 'may contain' statements, without being confident they are accurate,

can 'devalue' the warning, reduce choice, and potentially provide false impressions about the allergy risks. Similarly, blanket approaches that ignore all 'may contain' declarations could provide false assurances to consumers with food allergies.

Precautionary allergen labels would be more meaningful to food service businesses, and consumers, if they provided consistent and reliable warnings of allergen cross-contamination risks. Reliable warnings would help food service businesses to provide the information needed by consumers with food allergies to make well-informed and safe food choices.

Providing allergen information

The provision of accurate information about allergenic ingredients to consumers is mandatory under the Food Information Regulations 2014. The Regulations require that consumers are told whether any of **14 specified allergens** have been used as ingredients⁶. To enable the provision of information to consumers, food businesses should pass mandatory information about the presence of any of the 14 listed allergens (and products thereof) to other food businesses.

Many well-informed food businesses consider the Regulations relatively straightforward to implement. Although significant effort is necessary to comply with requirements to provide accurate information about allergenic ingredients, it can be achieved due to the clear rules-based framework that has been established by the Regulations.

4 Barnett et al. BMC Public Health 2011, 11:734 ([available here](#))

5 Dunn Galvin et al. Allergy 2015, DOI: 10.1111/all12614 ([available here](#))

6 The 14 allergens are listed in a free TiFSiP guide for food businesses ([available here](#))

Managing allergen cross-contamination

Even these well-informed food businesses struggle with the provision of accurate and reliable information about potential cross-contamination associated with products provided by suppliers. Passing on ‘may contain’ allergen information to consumers is not straightforward due to the variety of language used in suppliers’ ‘may contain’ warnings, its inconsistent application between suppliers and the lack of transparency about the level of risk behind ‘may contain’ warnings.

Allergen cross-contamination can occur on-site during food preparation or may be ‘brought in’ through products and ingredients.

Allergen cross-contamination on-site

Allergen control during on-site preparation is typically addressed as part of a business’ HACCP system. The HACCP system will include identification of allergenic hazards from cross-contamination and, in a systemised and logical manner, will set out how they can be managed to reduce associated risks. For example, this could result in the establishment of separate food preparation areas for allergenic ingredients and the implementation of appropriate cleaning procedures to remove allergen contaminants from surfaces and utensils.

Guidance for food businesses, intended for prepacked rather than non-prepacked foods, is available on ways to manage allergen cross-contamination and to determine

whether a ‘may contain’ statement is required^{7,8,9}. Guidance for non-prepacked foods is available from FSA Northern Ireland¹⁰ and Safefood¹¹. Existing food safety system certification schemes, such as the BRC Global Standard and ISO 222000, can help to test the quality of HACCP systems, including the management of allergen-hazards.

Allergen contamination in ‘incoming supplies’

Dealing with supply chain allergen cross-contamination risks is more complex. Food businesses report that it is difficult to interpret and summarise information provided by suppliers about potential allergen contamination. This is particularly problematic when there are multiple components bearing ‘may contain’ labels that will be used to create a single final product. Providing consumers with meaningful information is extremely difficult due to the large numbers of ingredients and the large range of meal variants.

Many food businesses report that they are not confident in the accuracy of the ‘may contain’ information provided by their suppliers. There are suspicions that the ‘may contain’ warnings could be a form of ‘defensive labelling’, that is, labels are based on concerns about potential claims rather than accurate assessments of ‘real’ or quantified risks. Operators in the food service sector have expressed particular concerns about the difficulty of trusting the accuracy of ‘may contain’ information when purchasing dishes and products from distribution companies rather direct from a manufacturer.

7 FSA, 2006. Guidance on Allergen Management and Consumer Information ([available here](#))

8 FDE, 2013. Guidance on Food Allergen Management for Food Manufacturers ([available here](#))

9 Campden BRI, 2013. Guideline 71: Food Allergens: practical risk analysis, testing and action levels ([available here](#))

10 FSA Northern Ireland, 2015. Safe catering – your guide to making food safely ([available here](#))

11 Safefood, 2015. Food Allergy and Intolerance. Guidance for the Catering Industry ([available here](#))

As a consequence, food businesses expressed significant uncertainty about when to pass on 'may contain' information provided by suppliers. Their rationale is that allergic consumers' food choices will not be more informed if they are told products could potentially contain a wide range of allergens as a result of cross-contamination risks.

Legal liability and the provision of precautionary ('may contain') allergen information

Although the majority of deaths reported from allergic reactions to food are associated with undeclared ingredients rather than as a result of cross-contamination, concerns have been expressed about legal liabilities if a consumer were to have an allergic reaction caused by trace presence of allergens. The question of liability is of particular concern in situations where a food business decides not to pass on 'may contain' information in the belief that the precautionary labelling is unreliable, does not reflect actual risk and has the potential to confuse consumers.



'May contain' labelling is voluntary but the legal requirement to provide safe food is fundamental. All food business operators are required to carry out risk assessments and to have suitable risk management measures in place to ensure they provide 'safe food'.

Allergic reactions to the presence of known allergens are a foreseeable risk and, as such, consumers with food allergies are entitled to expect the provision of accurate and reliable information about allergen presence. That expectation will apply generally to the presence of allergens whether as ingredients or as a result of cross-contamination. Such information enables safer food choices by consumers with food allergies.

Using the 'due diligence' defence

In the event of a death or serious harm arising from the presence of undeclared allergen contamination, the voluntary nature of precautionary allergen labelling might provide a reasonable defence in a criminal court if supported by appropriate risk assessment and other due diligence measures. However, in a civil court the burden of proof is lower ('on the balance of probability') and an effective defence may be more problematic.

A robust 'due diligence' defence would require a robust risk assessment of likely cross-contamination hazards. Detailed information from suppliers on the steps taken to avoid allergen cross-contamination would be expected to support a risk assessment. Obtaining and verifying such information from suppliers should provide a sufficient basis for decisions about the need to withhold or communicate 'may contain' information to consumers. Such an informed risk assessment might well be considered evidence of 'reasonable and proportionate' steps to ensure food safety. Failure to assess the robustness of suppliers' 'may contain' statements might leave food business operators liable if the statements are not communicated to consumers.

Working with suppliers to improve the quality of ‘may contain’ information

It may be operationally or commercially problematic to conduct detailed risk assessments across a broad supplier base. Alternative ‘reasonable and proportionate’ steps may be available to improve the usefulness of supplier ‘may contain’ information.

In developing their own ‘may contain’ risk assessments food service sector businesses could ask their suppliers questions about allergen management. For example:

- What is the basis of the precautionary allergen statement for ‘X’?
- Do you have [name of allergen] on site?
- Was [name of allergen] handled on the same line?
- Do you have products that contain [name of allergen] on site?
- Do you actively monitor for the unintentional presence of [name of allergen] in the finished product?

Such questions would facilitate the testing and probing of suppliers’ risk assessments and consequently, the robustness of any precautionary allergen statements they have applied.

However, the resource requirements for suitably qualified expertise could be significant, especially across a large supplier base. Food businesses could consider less burdensome approaches, but applicability should be determined on a case by case basis. For example, a food business dealing with suppliers that provide long lists of ‘may contain’ information could ask suppliers:

- To explain and provide supporting evidence for the ‘may contain’ statements. The additional detail could help to improve

the quality of allergen information provided to consumers.

- Whether they follow the [FSA Guidance on Allergen Management and Consumer Information](#). The FSA Guidance provides advice on the use of precautionary allergen statements, and also includes information about what should be included in allergen risk assessment and management. Of particular value is the decision tree on page 11, which could be used as the basis for a supplier-form to better determine the likely extent of allergen contamination.
- Or other guidance on allergen management.

Ultimately, consideration might need to be given to replacing suppliers that cannot or will not provide more detailed information.

What next?

Provision of safe food is a fundamental requirement of food legislation and consumers with food allergies reasonably expect to be provided with information about the safety of food for their specific circumstances. Providing accurate and reliable information about potential allergen contaminants is not straightforward. It requires technical competence and cooperation across the food supply chain. There are a number of measures that could improve the situation, some are currently available but more could be sought for the future. Suggestions from attendees at the roundtable included:

1. Consistent use of authoritative guidance to obtain better information from suppliers

FSA Guidance¹² on allergens identifies ways in which a food business can determine whether or not a supplier’s ‘may contain’ information

12 FSA, 2006. Guidance on Allergen Management and Consumer Information ([available here](#))

is based on reasonable evidence, or is merely a precautionary statement intended to provide a blanket assurance or limit the (remote) likelihood of future liabilities.

Knowing that 'may contain' statements are evidence-based would help food businesses to more confidently pass on information to customers and provide greater assurance to those with food allergies.

2. Limit and simplify the range of 'may contain' descriptors

Terminology is important, labelling should be consistent. Consensus on the use of a more limited range of 'may contain' descriptors, across the food manufacturing and food service sectors, would assist in simplifying the situation, particularly if backed up by consumer education campaigns. The FSA Guidance recommends the use of two phrases 'may contain' or 'not suitable for'.

Improving the consistency of 'may contain' statements, and ensuring they are appropriate for allergic consumers, would require food businesses to work with organisations representing consumers with food allergies, such as Anaphylaxis Campaign and Allergy UK. The work could link to EU proposals on voluntary labelling (Article 36.3 of Regulation 1169/2011, EU Food Information for Consumers Regulation).

3. Establish threshold levels for allergen contaminants to improve risk management and communication

In Australia and New Zealand the food manufacturing sector uses the VITAL system (Voluntary Incidental Trace Allergy Labelling) to determine the need for 'may contain' labelling, it has proven successful. There have been long running discussions, at EU level, about setting reference doses to inform threshold levels for declaration of food allergen contaminants, but to date little progress has been made.

Agreeing reference doses for allergen contaminant threshold levels for application of 'may contain' statements would facilitate more effective risk management and risk communication between manufacturers (suppliers) and their food service customers. While set reference doses could help, the food service sector would still have to determine when the thresholds were likely to be reached and when 'may contain' warnings should be provided. For example, a small amount of product with trace allergen could be significantly diluted in a final meal and so not reach the set threshold. Decisions around thresholds would be complex as they would require complex dose / impact risk assessments that would be impracticable for most food service businesses.

The issue requires further work to explore whether it would be possible to establish a simplified decision-tree or 'rule of thumb' to guide food service businesses about whether 'may contain' statements are required. Any future work would have to establish whether such a proposal would be helpful to food service businesses and consumers with food allergies, whether it is likely to be feasible, and if not, what other options are available to improve the consistency of allergen risk management and risk communication.

In summary, an EU wide, consistent, threshold based approach for precautionary labelling would be of great value. However, it is unlikely to be achieved in the short term as it would require consensus at a European level. Clarity and consistency would be improved by rationalising 'may contain' descriptors, ensuring their application is based on a real evidence of risk, and clearer more effective communication of their significance to consumers with food allergies. Most importantly, it would assist vulnerable consumers in making well informed allergen management decisions to protect their health.

Additional resources

The documents listed below contain useful information about the provision of allergy information to consumers.

FSA, 2006. Guidance on Allergen Management and Consumer Information [\(available here\)](#)

Good practice guidance on managing food allergens with particular reference to avoiding cross-contamination and using appropriate advisory labelling ('may contain' labelling).

It is intended as voluntary best practice advice to help food producers and retailers assess the risks of cross-contamination of a food product with an allergenic food or food ingredient, and then to determine whether or not advisory labelling is appropriate.

The approach described is relevant to any size food business, although some of the management techniques are not appropriate for smaller businesses.

FDE, 2013. Guidance on Food Allergen Management for Food Manufacturers [\(available here\)](#)

A guidance document prepared by FoodDrinkEurope to provide evidence-based and consistent information on good practice in risk management of allergenic foods. It sets out general principles for managing specific foodstuffs causing allergy or intolerances.

The focus of the guidance is the production of pre-packed foods, however the general principles also apply to non-prepacked foods.

FDf, 2015. Gluten Labelling Best Practice: How to Label Pre-Packed Foods Which include Cereals Containing Gluten. Version 1 [\(available here\)](#)

A best practice guide by the Food and Drink Federation for manufacturers about how to label food products containing gluten, with special reference to gluten-free foods.

Although intended primarily for food manufacturers, the guide provides information that would be useful to any food business considering the labelling of food products containing gluten. The guide may also assist food businesses to understand and interpret information provided by suppliers about gluten-containing products.



FSA, 2010. Composition and labelling of foodstuffs suitable for people intolerant to gluten: Guidance ([available here](#))

Guidance from the Food Standards Agency to help food businesses understand and comply with the legislation concerning the composition and labelling of food products containing gluten. It covers both foods sold pre-packed and non-pre-packed (loose).

The guidance is intended for food manufacturers, producers, retailers, caterers, enforcement authorities, and other parties interested in claims which highlight the suitability of foods for people intolerant to gluten (coeliac disease).

BDA, 2014. Allergen Toolkit for Healthcare Catering ([available here](#))

The British Dietetic Association, in conjunction with the Hospital Caterers Association, have published a toolkit about the steps to comply with the Food Information Regulations.

The toolkit provides useful information about allergen management applicable to anyone working in a care setting.

TiFSiP, 2015. Allergen Information: Guidance for food businesses ([available here](#))

TiFSiP produced an interactive guide to help food service businesses better understand the Food Information Regulations (2014).

The guide sets out how to comply with the legislation, manage food allergens, and develop food allergen awareness in a food service business.

Campden BRI, 2013. Guideline 71: Food Allergens: practical risk analysis, testing and action levels ([available here](#))

The guidance provides an overview of allergen management with reference to food safety management systems, including a systematic approach to aid identification of risk factors. It discusses the risks in relation to threshold levels, 'the smallest amount of an allergen likely to have a significant effect on the majority of allergic consumers', and the need or otherwise to include a 'may contain' statement on food packaging.

FSA Northern Ireland, 2015. Safe catering – your guide to making food safely ([available here](#))

The guide is for catering businesses and retailers who have a catering function within their business. The guide is based on the principles of HACCP and includes a chapter about managing allergen cross-contamination.

Safefood, 2015. Food Allergy and Intolerance. Guidance for the Catering Industry ([available here](#))

The guide is intended as an educational resource for caterers, offering a practical guideline for serving customers who may have a food allergy, food intolerance, coeliac condition or who may wish to avoid a particular food for other reasons. The guide can be used as part of training for catering staff knowledge and awareness on the issue.

About TiFSiP

The Institute of Food Safety Integrity & Protection (TiFSiP) is an inclusive membership organisation for individuals and organisations that work to keep food safe, healthy and trustworthy. It facilitates collaboration among the food community and keeps members informed about new ways of working and protecting consumers

TiFSiP works to ensure members have information to underpin the development of the skills and capabilities necessary to deliver safe food by:

- Helping members to understand food safety and integrity requirements, through provision of analysis of issues and case studies.
- Facilitating Continuing Professional Development e.g. through webinars and events (currently UK based), as well as through development of knowledge from the online information provision.

- Providing opportunities for networking online, through TiFSiP's private and public communities.
- Encouraging collaborative working, formal or informal, with peers and experts across the food community (for example, updating professional colleagues or developing good practice advice).

See more at: www.tifsip.org



About the CIEH

Chartered Institute of Environmental Health (CIEH)

The roots of the CIEH go back to the 1840s. Over the centuries it has established a reputation as a trusted and respected institute, awarding and campaigning organisation and membership body.

The CIEH set standards, accredit courses and develop qualifications.

Awarding organisation

Its global network of 10,000 Registered Trainers and Centres are supported through events and training materials to ensure qualifications are delivered to the highest standard.

To assist employers comply with legal requirements and best practice, a range of safety and compliance training solutions are available from CIEH. These include, for example, qualifications, eLearning, qualification development, professional consultancy and project delivery, and assurance to complement existing in-house training. The CIEH portfolio includes; health and safety, food safety, first aid, fire safety, environmental management and education and training and many more.

Campaigning

Information, evidence and policy advice are provided to local and national government, and also to environmental and public health practitioners in the public and private sectors.

Charitable objectives

All profits made by the CIEH are channelled back into its charitable objectives, funding research and policy development in the pursuit of advancing public and environmental health worldwide.

Reputation and accreditation

The organisation's Royal Charter requires the CIEH to: 'secure and justify the confidence of the public' in our members and in the environmental health sector.

CIEH qualifications are internationally recognised, and are regulated by OFQUAL, Welsh Government, Department for Education and Skills (DfES) and the Council for the Curriculum Examinations and Assessment (CCEA). The CIEH is certified under ISO 17024 in Dubai by the Dubai Accreditation Centre (DAC). ISO 14001 registered Environmental Management. BS 8900-2 registered Sustainable Development.

www.cieh-corporate.com



May
contain...

www.cieh-corporate.com

www.tifsip.org

September 2015

MAR1811

TiFSiP
The Institute of Food Safety
Integrity & Protection

Chartered
Institute of
Environmental
Health

