

Guidance on “Free-From” Allergen Claims

Guidance to manufacturers and caterers on the **appropriate use of “free-from” claims** in relation to food allergens.



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FOREWORD

“The Food Standards Agency welcomes the BRC and FDF’s efforts to achieve greater consistency in “free-from” allergen claims. This consistent approach will make it easier for consumers with food allergies and intolerances to find and understand “free-from” allergen information to help them make safer food choices.”

Food Standards Agency
Chief Executive
Catherine Brown

EXECUTIVE SUMMARY

A growing number of food business operators, including manufacturers, retailers and caterers are making “free-from” allergen or “allergen-free” claims for their food products. This document provides guidance to food business operators on the appropriate use of “free-from” claims in relation to food allergens. Terms such as “free-from artificial colours/preservatives” and “meat-free” are outside the scope of this guidance.

With the exception of “gluten-free”, there is no specific UK or EU legislation covering “free-from” claims. “Free-from” claims are therefore regulated in accordance with the provisions of General Food Law (Regulation (EC) No 178/2002), as amended.

A “free-from” allergen claim is an absolute claim unless a regulatory threshold has been set and should only be used following a rigorous assessment of the ingredients, process and environment.

To make a “free-from” claim the following principles should be followed:

1.

The product recipe does not use any ingredients or compound ingredients (including additives and processing aids) containing the specified “free-from” allergen. (See sections 3 and 6 for exceptions)

2.

The product is made in an environment (e.g. a factory or catering facility) strictly following good manufacturing practices (GMP) and allergen management practices. (See sections 4 and 5)

3.

A robust sampling and testing programme (using a fully validated analytical method) suitable for the specified allergen must be in place. (See sections 4 and 5)

4.

The communication of a “free-from” claim to consumers, including labelling, of the product must comply with the relevant legal requirements. For catering in particular, since foods will be provided in a non-prepacked format, effective communication practices (between customer, front and back of house) are imperative.

1) INTRODUCTION

A growing number of food business operators, including manufacturers, retailers and caterers are making “free-from” or “allergen-free” claims for their food products. The food industry is committed to providing accurate and consistent food labelling and communication.

Consumers likely to purchase “free-from” food products fall into two groups. The first group of consumers are those suffering from, or caring for someone with, an intolerance or allergy to a particular food ingredient. For these people, the presence of even very small amounts of the allergen can be detrimental or, in the case of food allergy, possibly fatal. The second group comprises those for whom the avoidance of a particular ingredient is a lifestyle choice. Regardless of the reason for purchase the standard of a “free-from” food must be the same.

This industry guidance provides information to food business operators on the appropriate use of “free-from” food allergens claims. Relevant to both prepacked and non-prepacked foods, it provides useful guidance for food manufacturers and caterers, particularly smaller enterprises considering making “free-from” claims. This guidance should not be used as an enforcement tool but will nevertheless be helpful for enforcement bodies, who advise food businesses on best practice.

The guidance is an overview of the key considerations for making accurate and reliable “free-from” claims, and

the preparatory work needed to substantiate them. This aims to ensure “free-from” is applied both accurately and consistently across the whole food industry. Some food companies may have additional requirements that go beyond legal compliance.

A “free-from” allergen claim is an absolute claim unless a regulatory threshold has been set.

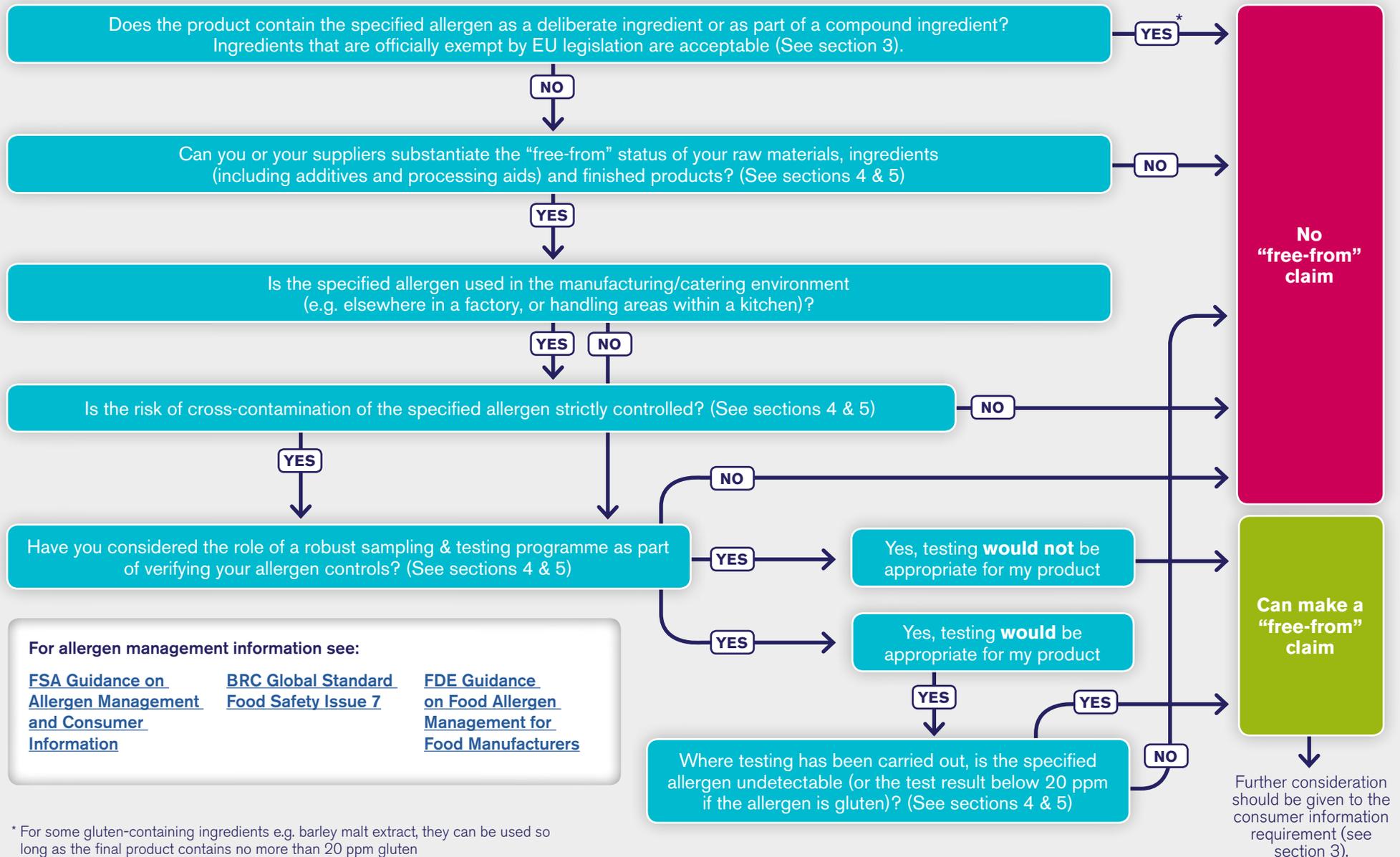
This guidance is not an exhaustive allergen management guide. It does not address the use of ‘may contain’ advisory statements, or alternative statements to “free-from” or “allergen-free”. Terms such as “free-from artificial colours/preservatives” and “meat-free” are out of the scope of this guidance.

The claim “free-from” should only be used following a rigorous assessment of the ingredients, process and environment.

From a consumer perspective “free-from” means a complete absence of the specified allergen in the product. However, in practice it is the scientific demonstration on an ongoing basis that the specified allergen in the food product is at a level that ensures safety and takes into account the analytical limit of detection (LoD) for a recognised and accepted laboratory test method. Scientific research is beginning to point towards levels of allergens (thresholds) below which adverse reactions are improbable. However, only those for gluten, sulphur dioxide and/ or sulphites (and lactose for infant formula only in the United Kingdom and European Union) have been transferred into regulatory limits. For true allergens, the focus is on limits for precautionary allergen labelling, rather than “free-from”.

A “free-from” claim stating the absence of a specific food allergen in any food, including prepacked and non-prepacked food (e.g. food sold loose or a menu item), must be relevant and based on a comprehensive risk assessment accompanied by rigorous controls (which may include analytical testing) to ensure that the claim is valid and not misleading. It is important that good manufacturing and/or handling practices are observed at all times with regard to the production and serving of these specialised foods.

2) CONSIDERATIONS FOR MAKING A 'FREE- FROM' CLAIM?



3) LEGISLATION

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Overarching legislation

With the exception of gluten, there is no specific UK or EU legislation covering “free-from” claims. “Free-from” claims are regulated in accordance with the provisions of General Food Law, to make sure the food is safe for consumption; and the regulations on food information, to make sure product information is not misleading and is accurately communicated.

General Food Law, Regulation (EC) No 178/2002,

Article 14 on Food Safety Requirements establishes that:

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

- (a) injurious to health;
- (b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:

- (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
- (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

Food Information to Consumers, Regulation (EU) No 1169/2011,

Article 7 on Fair Information Practices establishes that:

Food information shall not be misleading, particularly:

- (a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition...
- (b) by attributing to the food effects or properties which it does not possess;
- (c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics.

Points (a) and (b) mean:

If your product is not produced to the principles laid down in this guidance and to the specified criteria, your product is unlikely to be free from the specified allergen and therefore you should be careful not to present it in such a way that may mislead the consumer into believing the product is free from the specified allergen and therefore suitable for them. In this case, phrases that could have a similar meaning to “free-from” or pictorials that can give the impression that the product is suitable for those allergic to an allergen, should be avoided.

Point (c) means:

You cannot claim “free-from” on a product when all similar products would be “free-from”

3) LEGISLATION contd

Specific allergen legislation

For the purpose of this guidance, gluten and, sulphur dioxide have specific rules pertaining to them. Only infant formula has thresholds for lactose in the United Kingdom and European Union.

Gluten

Currently in the EU the only “free-from” claim which is covered by specific legislation relates to gluten i.e. “gluten-free”, “suitable for people intolerant to gluten” or “suitable for coeliacs”. In addition to gluten, there are other proteins within gluten-containing cereals that are allergenic. Consequently a wheat, barley or rye allergy should be considered differently to coeliac disease.

The statement “gluten-free” may only be made where the food as sold to the final consumer contains no more than 20 mg/kg of gluten

Since there is a legislative limit for claiming “gluten-free”, there are exceptional circumstances where some gluten-containing ingredients may be added to “gluten-free” products providing the final product has a level of gluten

below the threshold of 20 ppm. Barley malt extract is an example of this exception.

Commission Regulation (EC) No 41/2009 established the rules for the use of terms concerning the absence of gluten. From this date, rules relating to gluten will be governed by Regulation (EU) No 1169/2011 and set out in Commission implementing Regulation (EU) No 828/2014.

This regulation is explicit in permitting only these statements to be used to provide information to consumers on the absence of gluten in food. Furthermore, if you are using the statements, the conditions and compositional requirements laid out in the regulation must be complied with.

It is misleading to suggest that a food possesses special characteristics when in fact all similar foods possess such characteristics, therefore you cannot claim “gluten-free” on water and similar products.

For more information on gluten see [FDG Gluten Labelling Guidance](#)

For more information about claiming gluten-free in a catering environment see [Coeliac UK](#)

Sulphur dioxide and sulphites

There is no specific legislation for “free-from” sulphur dioxide/sulphites claims; however the Food Information to Consumers Regulation states that the allergen must be listed in the ingredients list and emphasised when the total SO₂ for sulphur dioxide and sulphites is above 10ppm.

For more information on sulphites see [BRC Allergen Labelling Guidance \(2013\) Section 7](#)

Lactose

In EU legislation, thresholds for making a “lactose-free” claim have only been defined for infant and follow-on formula, which prescribes that the lactose content should be ≤ 10 mg/100 kcal (2.5 mg/100 kJ). A number of European countries have specific guidance thresholds for lactose however a level has not been adopted in general EU legislation.

Exempt ingredients derived from allergenic foodstuffs

Some specific ingredients derived from allergenic foodstuffs are not allergenic themselves and have been officially exempted in legislation from mandatory labelling (See section 6 glossary under ‘EU Regulated Allergens’ for these exemptions).

4) RISK ASSESSMENT FOR PREPACKED FOODSTUFFS

A rigorous, stringent and comprehensive risk assessment of the product, its ingredients and production is an essential pre-requisite for proposing to apply a “free-from” label to any product. It should cover all elements from raw materials to packing, assessing the probability of contamination by the allergen from various sources. It must be proportionate to the increased probability of harming consumers, at whom those products are specifically targeted. If an allergenic ingredient is present (e.g. used in other product lines), then the risk of cross-contamination from the specified allergen must be strictly controlled with GMP or as part of the site's HACCP system.

The scope of the risk assessment should consider the following factors for prepacked foods:

1. Supplier quality assurance, raw material approval controls & supply agreements

- Can the supplier consistently demonstrate that all raw materials are “free-from” the specified allergen and is this covered in the terms of supply agreement?
- Has the raw material supplier been initially approved and regularly audited to assess their ability to reliably maintain the “free-from” status of the supplied raw materials?

2. Facility design

- Is the production facility dedicated to exclude the allergen for which the “free-from” claim is made?
- If the production facility is not wholly dedicated, is it sufficiently physically or time segregated to eliminate the risk of cross-contamination (change of work clothing, storage, production scheduling, warehousing, material flows etc.)?

3. Production controls

- Are defined control measures in place at the manufacturing facility and have these controls been validated?
- Are these controls periodically verified and continuously monitored?
- If those controls include cleaning and sanitation, have these been demonstrated reliably to remove the allergen(s) of concern to the required extent?

4. Product testing

- Testing for the specified allergen in the product can be an effective way to verify allergen management controls. It is never a substitute for good allergen management. The necessity to test and how to implement a robust programme depends on a number of considerations. These include the way the product is produced, the type of product and the type and form of the allergen being tested for. Have you considered the role and purpose of testing and whether it would effectively verify allergen management controls?

- Where testing is considered appropriate and necessary, have you considered:
 - What will be tested?
 - Where in the production process will the samples be taken?
 - What test method is most appropriate?
 - Based on risk, how frequently should samples be tested?
 - How much a sample should be and whether this is representative?
 - What action will be taken following results? Have you considered positive release procedures to assure the “free-from” status of the product?

5. Distribution & transport practices

- Have distribution and transport practices been assessed in the risk assessment (considering off-site storage or third party hauliers)?

For information on allergen management see [FSA Guidance on Allergen Management and Consumer Information](#), [BRC Global Standard Food Safety Issue 7](#) and [FDE Guidance on Food Allergen Management for Food Manufacturers](#).

5) RISK ASSESSMENT FOR NON-PREPACKED FOODSTUFFS AND CATERING

The risk assessment for non-prepacked food should generally consider the same factors for prepacked (section 4). For catering and in-store production there needs to be specific considerations for the kitchen and preparation environment and staff communication. Foods provided in a non-prepacked format will require effective communication practices between the staff (preparation and sales or front and back of house) and customers.

If in doubt these products should not make a “free-from” claim or any claim consumers would understand as “free-from”.

Special attention needs to be given to the following activities:

1. Catering environment

- Are there segregated areas in the kitchen/ preparation environment or scheduled production times where allergens can be controlled or absent?
- Can key equipment be segregated or made bespoke for making allergen-free recipes (e.g. colour coding)?
- Consider separate equipment such as mixers or toasters.
- Consider storage environment of ingredients and finished dishes.
- Is there an effective cleaning regime in place that is validated and verified to consistently remove the specified allergen?
- Consider change of work clothing and hygiene practices.

2. Ingredients

- Have you considered the allergen status of all ingredients in your recipe?
- Ingredient suppliers may only tell you what allergens are in a product. Note this is NOT the same as an ingredient being “free-from” a specific allergen. “Free-from” status needs to be assured by you or your supplier.
- Ideally, select products which are already manufactured to meet “free-from” criteria.

3. Staff training

- Have all staff had suitable allergen training and do they understand the importance of cross contamination controls and their relevance to allergenic consumers?
- Do you have a member of staff with sufficient knowledge to validate and audit the controls?
- Is there effective communication between the customer and relevant staff?

Caterers should only make a “free-from” claim if:

- The incoming goods are already marketed by a manufacturer as “free-from” and are sold in their original packaging or;
- A full risk assessment has been completed for the production of a “free-from” meal, specific to their kitchen, that demonstrates they are capable of assuring “free-from” status for the specified allergen.

For more information about claiming gluten-free in a catering environment see Coeliac UK [accreditation](#) and [training](#) resources.

6) GLOSSARY

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Compound ingredient

An ingredient that is itself the product of more than one ingredient.

(Regulation (EU) No 1169/2011)

Cross-contamination

The unintentional presence of another substance in the final product. In the context of allergens, it usually refers to trace amounts of allergenic foods which, whilst not of themselves unwholesome, may be problematic for those suffering from particular allergies. (FSA Guidance on Allergen Management, 2006)

EU regulated allergens

The 14 substances listed in Annex II of the Food Information to Consumers Regulation (EU) No 1169/2011 (as amended by Commission Delegated Regulation No 78/2014) recognised across Europe as the most common ingredients or processing aids causing food allergies and intolerances:

1. Cereals containing gluten namely wheat (such as spelt and Khorasan wheat), rye, barley, oats and 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. Egg 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 a 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-α-tocopherols, natural D-α-tocopherol acetate and natural D-α-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 almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut and Macadamia nut (Queensland nut)) 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/ or sulphites at concentrations of more than 10mg/kg or 10mg/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

Food allergen

This is the substance in a food that can cause an allergic reaction. Allergens are normally proteins and in some people, the immune system thinks allergens are foreign or dangerous. The immune response to these allergenic proteins is what leads to allergic reactions. The EU states 14 specific foods which are of public health importance (most potent and prevalent food allergens in Europe) which

are listed in Annex II to the EU FIC. (FSA Allergens Technical Guidance, 2015)

Food allergy

An adverse reaction to a food that involves the immune system and can be a potentially life threatening condition. Symptoms can appear within minutes, or up to several hours after a person has eaten a food they are allergic to. There is no cure for food allergy. An allergic individual must avoid the food which makes them ill. (FSA Allergens Technical Guidance, 2015)

Food intolerance

Most food intolerances do not involve the immune system and are generally not life-threatening. However, they can make someone feel very ill or affect their long-term health. Examples of food intolerance include lactose and gluten intolerance. (FSA Allergens Technical Guidance, 2015)

glossary contd...

6) GLOSSARY contd

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Free-from

Foods made without certain common allergenic ingredients, such as milk, egg or cereals containing gluten in a controlled environment which have been scientifically demonstrated to be below the analytical limit of detection of a testing method. (FSA Allergy: What to consider when labelling food, 2015)

Gluten

A protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and which is insoluble in water and 0,5 M sodium chloride solution. (Regulation (EU) No 828/2014)

Gluten-free

The statement “gluten-free” may only be made where the food as sold to the final consumer contains no more than 20 mg/kg of gluten. (Regulation (EU) No 828/2014)

Good manufacturing practices (GMP)

Implemented procedures and practices undertaken using best practice principles. (BRC Global Standard Food Safety Issue 7)

Hazard analysis and critical control points (HACCP)

A system that identifies, evaluates and controls hazards which are significant for food safety. (BRC Global Standard Food Safety Issue 7)

Lactose

A disaccharide of glucose and galactose and the primary sugar of mammalian milk. Lactose intolerance is not to be confused with intolerance or allergy to (cow's) milk proteins. (EFSA Lactose Opinion, 2010)

Limit of detection

The smallest measure that can be detected with reasonable certainty for a given analytical procedure. (IUPAC Goldbook online)

Positive release

Ensuring a product or material is of an acceptable standard prior to release for use. (BRC Global Standard Food Safety Issue 7)

ppm

Parts per million

Physical segregation

To keep one food or food ingredient separate from another through managing

space. The segregated area should be designed to a high standard of hygiene, where practices relating to personnel, ingredients, equipment, packaging and environment aim to prevent product contamination. (BRC Global Standard Food Safety Issue 7)

Precautionary allergen labelling

Voluntary advisory labelling on possible cross-contamination with allergens. (FSA Guidance on Allergen Management, 2006)

Prerequisite

The basic environmental and operational conditions in a food business that are necessary for the production of safe food. These control generic hazards covering good manufacturing practice and good hygienic practice and shall be considered within the HACCP study. (BRC Global Standard Food Safety Issue 7)

Risk assessment

The identification, evaluation and estimation of the levels of risk involved in a process to determine an appropriate control process. (BRC Global Standard Food Safety Issue 7)

Threshold

The term refers to the amount needed to elicit an allergic reaction in a sensitive individual within a given population. (FSA Guidance on Allergen Management, 2006)

Validation

Obtaining evidence to demonstrate the effectiveness that a control or measure, if properly implemented, is capable of delivering the specified outcome. (BRC Global Standard Food Safety Issue 7)

Verification

The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control or measure is or has been operating as intended. (BRC Global Standard Food Safety Issue 7)



7) REFERENCES

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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, applied from 21 February 2002.

Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, repealed from end of 2015 by Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children.

Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten, repealed from 20 July 2016.

Regulation (EU) No 1169/2011 of the European Parliament and of the

Council of 25 October 2011 on the provision of food information to consumers, as amended, applied from 13 December 2014.

Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food, applies from 20 July 2016.

Commission Delegated Regulation (EU) No 78/2014 of 22 November 2013 amending Annexes II and III to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards certain cereals causing allergies or intolerances, applied from 19 February 2014.

EFSA Scientific Opinion on lactose thresholds in lactose intolerance and galactosaemia. (EFSA Journal 2010;8(9):1777)

→ [Opinion](#)

BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011 (in partnership with FDF) (March 2013)

→ [Guidance](#) → [Addendum](#)

FDE Guidance on Food Allergen Management for Food Manufacturers (January 2013)

→ [Guidance](#)

FDF Gluten Labelling Best Practice: How to Label Pre-Packed Foods Which Include Cereals Containing Gluten (in partnership with BRC, Anaphylaxis Campaign and Coeliac UK) (June 2015)

→ [Guidance](#)

FSA Technical Guidance Food Allergen Labelling and Information Requirements under the EU Food Information for Consumers Regulation No. 1169/2011 (April 2015)

→ [Guidance](#)

FSA Guidance on Allergen Management and Consumer Information (2006)

→ [Guidance](#)

FSA Guidance on Composition and Labelling of Foodstuffs Suitable for People Intolerant to Gluten (January 2012)

→ [Guidance](#)

FSA Allergy: What to consider when labelling food (2015)

→ [Guidance](#)

FSA The impact of Food Allergy

→ [Training](#)

International Union of Pure and Applied Chemistry (IUPAC)

→ [Goldbook Online](#)

BRC Global Standard Food Safety Issue 7 and Understanding Allergen Management (2015)

→ [Standard](#)

Coeliac UK

→ [Accreditation](#) → [Training](#)

ABOUT FDF

The Food and Drink Federation is the voice of the UK food and drink industry, the largest manufacturing sector in the country. Our sector directly employs around 400,000 people and accounts for almost 16% of the UK's total manufacturing sector by value. We are an essential partner to UK farmers, buying the bulk of what they produce.

Our membership comprises manufacturers of all sizes as well as trade associations dealing with specific sectors of the industry. In representing the interests of our members, we focus on the following core priorities:

- **Food Safety and Science**
 - **Health and Wellbeing**
 - **Sustainability**
 - **Competitiveness**
-

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ABOUT BRC

Retail is an exciting, diverse and dynamic industry undergoing transformational change. The BRC is at the forefront – enhancing, assisting, informing and shaping. Our mission is to make a positive difference to the industry and to the customers it serves. Our broad range of stakeholders demonstrates how retailing touches almost every aspect of our culture.

The BRC leads the industry and works with our members to shape debates and influence issues and opportunities that will help make that positive difference. We care about the careers of people who work in our industry, the communities retail touches and competitiveness as a fundamental principle of the industry's success – our 3Cs.

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