EFFECTIVE ALLERGEN MANAGEMENT

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BRCGS
Second Floor
7 Harp Lane
London EC3R 6DP

Tel: +44 (0) 20 3931 8150
Email: publishing@brcgs.com
brcgs.com

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Part I
Introduction

Managing allergens provides a significant challenge for suppliers across the food, packaging and consumer goods supply chains.

An allergic reaction occurs when the immune system of a susceptible individual adversely reacts to a food or substance (usually a protein) that is harmless for most individuals. Food allergies represent a significant health hazard for an increasing percentage of the world's population. Therefore, the correct management of allergenic materials throughout the food supply chain is a paramount aspect of food safety.

In addition to allergies, there are a number of conditions (that are considered to be food hypersensitivities) producing adverse symptoms in susceptible individuals. This includes food intolerance such as lactose intolerance and auto-immune conditions such as coeliac disease. While the main focus of this guidance is food the tools and techniques discussed can be applied to the manufacture of any food or non-food product and packaging.

Incorrect allergen management has resulted in a considerable number of product withdrawals and is the most common cause of recall. A root cause analysis of these recalls has suggested that the main causes can be summarised as:

- Unintentional presence of an allergen. This could be due to allergen cross-contact[2] of a raw material or product during production, or the accidental addition of an allergen by using the wrong recipe.
- Mis-packing – where the wrong packaging is used, e.g. due to insufficient changeover controls or a lack of training of packing line staff.
- Wrongly labelled packaging. This could be due to specification errors, a failure to transfer all information during packaging development, ineffective change management (such as when a recipe changes) or printing controls and sign-off of new packaging.

An allergen management plan is a documented system that serves to identify, control, educate and communicate the risk and presence of allergens on the site, from raw materials through to finished products. This includes a risk assessment of allergen cross-contact and the implementation of controls to minimise or eliminate the risk of contamination to and/or from the final product.

How this publication is organised

This guidance has been designed to provide further explanation of the allergen management requirements of several BRCGS Standards (referred to as 'the Standard') and to aid individuals and companies in the development of robust allergen management systems and procedures that adequately meet requirements. While the guidance concentrates on food safety, allergen management features in requirements in our global standards on storage and distribution, packaging materials, gluten-free and consumer products.

Allergen management affects all aspects of the Standard. Even if allergens are not specifically mentioned in the wording of the requirement a failure to meet the requirement could lead to an allergen issue in the production cycle.

This guideline will concentrate on five themes:
- Materials and allergens – understanding the raw materials that arrive on site.
- Risk assessment – the significance of any process, activity or ingredient should be evaluated by accurate cross-contact risk assessments to determine the control or action required.
- Control procedures – the segregation of allergens and activities to reduce the risk of allergen cross-contact.

[2] The terms cross-contact and cross-contamination are used interchangeably in guidance about allergen management. Within this document the terms are used to mean the transfer of any material from one surface or food to another surface, food or product.

- Cleaning regimes – cleaning controls and on-going monitoring to remove or reduce the risks of allergen cross-contact.
- Packaging and labelling – understanding raw materials used in packaging, packaging controls in production and keeping the consumer informed.

The guidance will look at these themes in detail and consider their part in a comprehensive allergen management system (see Figure 1). The guidance should be read in conjunction with those parts of a Standard that specifically reference allergen management.

Figure 1 Core elements of an allergen management system

Whether systems implemented comply with the Standard will be a decision made by the auditor during a BRCGS audit. The auditor will refer to evidence collected and observations made during the audit.

Legislative considerations

There are an estimated 180-200 foods that can cause adverse reactions. Legislation in many countries identifies the foods or ingredients that are most likely to cause a reaction in that geographic region and which must therefore be managed in the supply chain. Some of these ingredients must be declared on packaging where it is present in a product because customers must be informed before they make a purchase. Examples of such legislation include European Union Regulation (EU) No. 1169/2011, as amended, on the provision of food information to consumers and the US Food Allergen Labeling and Consumer Protection Act 2004.

Companies must ensure they understand the full legislative definitions of the allergens they are handling, as this may vary from country to country or region to region. For example, 'tree nuts' in some regions include products that are not botanically defined as tree nuts, such as coconuts, pine nuts or almonds.
National legislation in place in the country of sale as well as in the country of production must be used to identify

those substances that must be managed as allergens. Where products are both produced and sold in countries where there are no legal requirements for the labelling of allergens, refer to the list of allergens as defined in the Codex Alimentarius General Standard for Labelling of Pre-packaged Foods. This list should be used as the basis for assessing compliance to the Global Standard Food Safety.

Good practice and legislative requirements change routinely as new research is published. It is important that sites have a mechanism to remain up to date, so that they consistently meet requirements.

Some examples of the different legislative allergen lists are given in Appendix 1.

Customer considerations

Some customers, such as brand owners or large retailers, have very detailed allergen requirements. Manufacturing sites need to ensure they are aware of these requirements when developing and reviewing their allergen management systems.

Reviewing the allergen management plan
The allergen management system needs to be reviewed based on risk, including when there:

- is a change in raw materials or suppliers
- is a change to the manufacturing process
- will be an introduction of new machinery or equipment
- is a change to cleaning practices and procedures

BRCGS
Floor 2
7 Harp Lane
London EC3R 6DP

T: +44 (0)20 3931 8150
E: enquiries@brcgs.com
W: brcgs.com
W: brcgsbookshop.com
W: brcgsparticipate.com