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**THE PRACTICAL ASPECTS
OF ALLERGEN MANAGEMENT
IN MEAT MANUFACTURING
IN THE UNITED KINGDOM**

Abstract: Food allergies can cause unusual reactions from the immune system which presents incidences of various clinical symptoms. The symptoms have the same character and occur always after eating food of which the person is allergic to. Allergens can be vegetable protein molecules or of animal origin. Food manufacturers have legal requirements to inform customers on labels about all allergens present in any product offered for sale. While in the case of allergen-free products they have to make every effort to avoid cross contamination with allergens which are present in meat factories. The proper management of allergens has the benefit of allowing a company to avoid losses relating to the withdrawal of the product from the market; loss of position in the industry and reduces the risk of having to defend cases in UK courts. The context of this article is the study of the legal regulations and voluntary standards introduced by a company. The aim of this article is to discuss the most important factors for the successful management of allergens by the example of a meat manufacturer in the UK. A group of these factors include food labelling, employee training, risk analysis of cross contamination, audits and the checks of suppliers, validation and verification of the cleaning process and the process of new products in development. The second part of the article is a detailed research into the issue that such a large number of hospitalizations (4,500) and deaths (10) from food allergies still occur every year in the UK, despite all the safety procedures and legislation that is currently in force. These numbers indicate that the legal regulations and the requirements of voluntary standards must continue to improve the management of allergens in food manufacturing.

Keywords: food allergy, allergen management.

JEL classification: L15.

PRAKTYCZNE ASPEKTY ZARZĄDZANIA ALERGENAMI W PRZEMYSŁE MIĘSNYM W WIELKIEJ BRYTANII

Streszczenie: Alergia pokarmowa to nieprawidłowa odpowiedź systemu immunologicznego powodująca występowanie różnych objawów klinicznych. Objawy te zawsze przyjmują tę samą postać i zawsze występują po spożyciu tego pokarmu, na który dana osoba jest uczulona. Alergenem mogą być cząsteczki białkowe pochodzenia roślinnego lub zwierzęcego. Przedsiębiorstwa produkujące żywność są zobowiązane wymaganiami prawnymi do informowania klienta na etykiecie o alergenach występujących w oferowanym produkcie. Z kolei w przypadku produkcji żywności bez alergenów muszą dolożyć wszelkich starań, aby uniknąć ryzyka skażenia produktu alergenami, które mogą występować w zakładzie. Prawidłowe zarządzanie alergenami pozwala przedsiębiorstwu na uniknięcie strat związanych z wycofaniem produktu z rynku, utratą pozycji w branży oraz ograniczenie ryzyka toczenia spraw sądowych o odszkodowania. Artykuł nawiązuje do uregulowań prawnych oraz dobrowolnych standardów wprowadzanych przez przedsiębiorstwa. Celem artykułu jest omówienie najważniejszych czynników wpływających na skuteczne zarządzanie alergenami na przykładzie przedsiębiorstwa przetwórstwa mięsnego w UK. Do grupy tych czynników zalicza się znakowanie żywności, szkolenia pracownicze, analizę ryzyka zagrożenia skażenia krzyżowego, ocenę dostawców, walidację i weryfikację procesu mycia oraz powstawanie nowych produktów. W drugiej części artykułu został poruszony problem wciąż dużej liczby hospitalizacji (4500) i wypadków śmiertelnych (10) w UK, których przyczyną były alergie żywnościowe. Liczby te świadczą o tym, że pomimo uregulowań prawnych i wymogów określonych w standardach dobrowolnych nadal należy poprawiać i ciągle doskonalić zarządzanie alergenami w przedsiębiorstwach.

Słowa kluczowe: alergeny w żywności, zarządzanie alergenami.

Introduction

Food allergies are an abnormal response of the immune system which causes the occurrence of different clinical symptoms. These symptoms always take the same form and always occur after the eating of food to which a person is allergic to [Jarosz and Dzieniszewski 2005, pp. 25–26]. An allergen is

a substance that the human body recognizes as being foreign. It produces an abnormal reaction of the antiserum [Respondek and Ryżko-Skiba 2005, pp. 23–24]. The allergen may be the protein molecules of vegetable or of animal origin. Depending on the way in which the allergen enters the body, there are:

- inhaled allergens – inhaled along with air this may affect a person that has been sensitised, to have asthma attacks or allergic rhinitis;
- contact allergens – acting after contact with the skin;
- food allergens – causing rashes, diarrhoea, and respiratory symptoms;
- allergens are injected directly into the body, causing a variety of symptoms, from swelling at the injection site to the risk of death from anaphylactic shock [Respondek and Ryżko-Skiba 2005, pp. 23–24].

Food allergies are divided into three types, depending on the symptoms and when they occur.

1. IgE-mediated food allergy – the most common type, triggered by the immune system producing an antibody called immunoglobulin E (IgE). Symptoms occur a few seconds or minutes after eating. There is a greater risk of anaphylaxis with this type of allergy.
2. Non-IgE-mediated food allergy – these allergic reactions are not caused by immunoglobulin E, but by other cells in the immune system. This type of allergy is often difficult to diagnose as symptoms take much longer to develop (up to several hours).
3. Mixed IgE and non-IgE-mediated food allergies – some people may experience symptoms from both types [National Health Service 2015].

In accordance with regulation of the European Parliament and of the Council (EU) no 1169/2011 of 21.10.2011 annex II to substances or products causing allergies or intolerances include:

1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut 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.

In the meat industry in the UK, there are food additives which typically include the following allergenic substances: gluten, eggs, soy, milk, sulphur dioxide and derivatives of these components.

1. Materials and methods

The treatment of allergens to be discussed are based on the example of selected company production and processing of poultry in the UK, named for the purposes of this article company X. The company is a leading producer of meat and poultry products, supplying products to retail chains such as for

example Marks and Spencer, Tesco, Sainsbury's, Aldi, and Lidl. The manufacturer produces retail branded products and under its own brand.

On 13th December 2014 the entry into force of the amendment for a regulation of the European Parliament and of the Council (EU) no 1169/2011 of 21.10.2011, which strictly defines the method of marking the presence of food additives, catalysts in processing and other substances or products, that are scientifically proven to cause allergies or intolerances. Article 21 of the said regulation specifies how to label substances or products causing allergies or intolerances. The list of ingredients shall be headed or preceded by a suitable heading which consists of or includes the word 'ingredients'. It shall include all the ingredients of the food, in descending order of weight, as recorded at the time of their use in the manufacture of the food. Another requirement is the name of the substance or product containing 14 allergens listed in regulations using script clearly distinctive from the rest of the list of ingredients. For example, using the type, style, or colour of the background. The name of the substance or product must include the 14 allergens listed in Annex II of Regulation (EU) No 1169/2011 of the European Parliament and of the Council, which shall be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour. Figure shows an example of a label with the listed allergens.

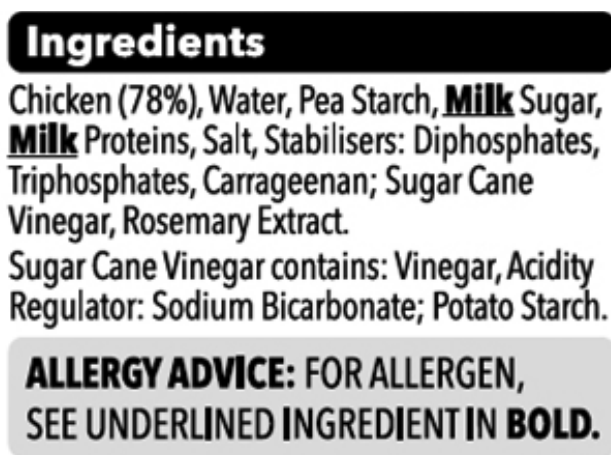


Figure 1. Examples of allergen indications on the labelling of a foodstuff

Source: Developed by the author

BRC (The British Retail Consortium) Global Standard for Food Safety is a voluntary standard that certifies companies in the food industry to implement, among others, to meet the requirements of customers, to reduce the number of customer's audits, and to maintain an adequate level of GMP/GHP (Good Manufacturing Practice/Good Hygienic Practice). The number of establishments certified for compliance with the standard BRC in the UK and Poland are presented in Table 1 (at 1.05.2015).

Table 1. Number of establishments with the BRC Global Standard for Food Safety

Field of audit	Category no.	Category description	Numbers of sites in United Kingdom	Number of sites in Poland
Raw products of animal or vegetable origin that require cooking prior to consumption	01	Raw red meat	145	68
	02	Raw poultry	130	61
	03	Raw prepared products (meat, fish and vegetarian)	383	89
Processed foods	08	Cooked meat/fish products	152	92
	09	Raw cured and/or fermented meat and fish	34	34

Source: A study based on <http://www.brcdirectory.com/> [access: 1.05.2015].

From 1.07.2015 all plants in the UK were certified in accordance with the release of the seventh BRC Global Standard for Food Safety, where the area requirements in section 5.3 Allergen Control is still a primary requirement. The obligation on the producer is to implement an effective system of management of allergens to minimise the risk of the contamination of products [The BRC 2015]. Also companies certified according to IFS since April 2014 are forced to comply with the requirements for the management of food allergens in the manufacturing process.

BRC requirements are much more stringent in terms of managing allergens than standard IFS. First of all, the BRC standard specifies what should be included in a procedure to maintain the effective control of allergens used in that establishment, as well as specifying the need for the validation of cleaning methods. All the requirements of a BRC standard in the management of food allergens must be met by the company tested. It has been assessed in how it reaches the Standard in this regard.

Table 2. The requirements of BRC and IFS in the management of food allergens

BRC Global Standard For Food Safety Issue 7, 2015	IFS Food Version 6, 2014
<p>5.3. Allergen control</p> <p>The site shall have a system for the management of allergenic materials which minimises the risk of contamination of products and meets legal requirements for labelling in the country of sale</p>	<p>4.20. Allergens and specific conditions of production</p> <p>4.20.1. Raw material specifications identifying allergens requiring declaration that are relevant to the country of sale of the finished product shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which such raw materials containing allergens are added</p>
<p>5.3.1. The site shall carry out an assessment of the raw materials to establish the presence and likelihood of contamination of allergens. This shall include review of raw material specifications and, where required, obtain additional information from suppliers, for example through questionnaires to understand the allergen status of the raw material, its ingredients and the factory in which it is produced</p>	<p>4.20.2. The manufacturing of products which contain allergens requiring declaration shall be carried out as to ensure cross contamination is minimised as far as possible</p>
<p>5.3.2. The company shall identify and list allergen-containing materials handled on site. This shall include raw materials, processing aids, intermediate and finished products, and any new product development ingredients or products</p>	<p>4.20.3. Finished products containing allergens requiring declaration shall be declared in accordance with current legal requirements. For the adventitious or unintentional presence, the labelling of legally declared allergens and traces shall be based on hazard analysis and assessment of associated risks</p>
<p>5.3.3. A documented risk assessment shall be carried out to identify routes of contamination and establish documented policies and procedures for handling raw materials, intermediate and finished products to ensure cross-contamination is avoided. This shall include:</p> <ul style="list-style-type: none"> - consideration of the physical state of the allergenic material (i.e. powder, liquid, solid particulate) - identification of potential points of cross-contamination through the process flow - assessment of the risk of allergen cross-contamination at each process step - identification of suitable controls to reduce or eliminate the risk of cross-contamination or its elimination 	<p>4.20.4. Where customers specifically require that products are “free from” certain substances or ingredients (e.g. gluten, pork, etc.), or that certain methods of treatment or production are excluded, verifiable procedures shall be in place</p>

<p>5.3.4. Documented procedures shall be established to ensure the effective management of allergenic materials to prevent cross-contamination into products not containing the allergen. This shall include as appropriate:</p> <ul style="list-style-type: none"> – physical or time segregation while allergen-containing materials are being stored, processed or packed – the use of separate or additional protective overclothing when handling allergenic materials – use of identified, dedicated equipment and utensils for processing – scheduling of production to reduce chances between products containing an allergen and products not containing the allergen – systems to restrict the movement of airborne dust containing allergenic material – waste handling and spillage controls – restriction of food brought onto site by staff, visitors, contractors and for catering purposes 	
<p>5.3.5. Where rework is used, or reworking operations are carried out, procedures shall be implemented to ensure rework containing allergens is not in products that do not already contain the allergen</p>	
<p>5.3.6. Where the nature of the production process is such that cross-contamination from an allergen cannot be prevented, a warning should be included on the label. National guidelines or codes of practice shall be used when marking such a warning statement</p>	
<p>5.3.7. Where a claim is made regarding the suitability of a food for allergy or food sensitivity sufferers, the site shall ensure that the production process is fully validated to meet the stated claim and the effectiveness of the process is routinely verified. This shall be documented</p>	
<p>5.3.8. Equipment or area cleaning procedures shall be designed to remove or reduce to acceptable levels any potential cross-contamination by allergens. The cleaning methods shall be validated to ensure they are effective and that the effectiveness of the procedure routinely verified. Cleaning equipment used to clean allergenic materials shall either be identifiable and specific for allergen use, single use, or effectively cleaned after use</p>	

Source: BRC and IFS.

2. Results and discussion

The first step in dealing with allergens in factory X is the identification of allergenic substances that can be delivered to the plant, along with supplies of additives or packaging from the supplier. To that end, the manufacturer evaluates all of its suppliers. Questionnaires with answers are evaluated in order to determine the need to carry out an audit at the supplier. The manufacturer is not required to audit all suppliers. In company X they work on the principle that by possessing BRC at A/A + B/B + it allows them to qualify as a safe supplier, exempt from the need for auditing. It should be added that regulatory requirements do not impose the way its suppliers qualify operators. Trader X also carries out an analysis of the risk of cross contamination on their suppliers, especially if one of the vendors in the production of food additives has more types of allergens than company X. Suppliers who have the production of nuts or their derivatives are automatically rejected because company X has a “free from nut” policy.

The next step is to identify all materials containing allergens at the premises. Companies that produce branded products or already have a system (BRC Global Standard for Food Safety) in place must keep up to date a list of all raw materials containing allergens used in their premises. Companies benefit most from specific computer programs where the list of raw material inventory have specified allergens contained in the material already assigned, with an indication of the location in the warehouse. In the simpler versions they use excel. This is typically in the form a table which shows a list of all materials, suppliers, the type of allergen, the method of storage and the form of allergen such as liquid, powder, granulate, or constant mass.

The most difficult and at the same time the most important process in the management of food allergens is to carry out a risk analysis of potential cross-contamination of the product in the factory. Manufacturer X appointed a multidisciplinary team composed of managers from different departments such as hygiene, purchasing, technical, production and engineering. All members of the team have knowledge and skills in the management of food allergens. A very important part is choosing the leader of the group, which has the greatest knowledge and has the ability to direct the team. During regular meetings the team must determine the flow of raw materials, intermediates and finished products at the plant. The easiest way to do this is to track the allergen on a map of the plant. This allows them to show the possible crossing paths of different types of allergens.

Analysis of the risk of cross-contamination covers all stages of the manufacture of the product. The Food Standard Agency in 2004 published a guide which listed the following factors to be taken into consideration during the process of risk analysis:

- treatment of raw materials,
- storage of raw materials,
- transport,
- employees,
- cleaning process,
- the use of common equipment during the production of a variety of allergens,
- packaging,
- supply chain,
- air in production areas,
- reuse of material,
- new product development.

The treatment of materials covers all stages, ranging from transport to the start of the production process. Even at the transport stage it is extremely important to prevent the cross-contamination of raw materials. Company X does checks of deliveries to see if there has been any contamination of raw materials. Particularly in the event of a joint transport of several raw materials containing various allergens in its composition. Company X is a manufacturer of products declaring an absence of specific allergens in a product, for example gluten free. In order to confirm the absence of cross-contamination on the vendor company X uses rapid tests for the presence of gluten in the acceptance of delivery. The storage of raw materials must take place in conditions which preclude any possibility of infection. The raw materials are stored on racks, abiding to the principle of raw materials with one type of allergen may not be stored above raw materials from other allergens. In general, labels are affixed to pallets, containers or other packaging of raw materials. These labels are the names of the allergens present in the processing. A person is responsible for the acceptance of raw materials and puts a cross on the label which means that the allergen is present in the raw material taken to the warehouse.

All employees (including temporary workers and subcontractors) taking part in the use of ingredients, equipment, utensils, packaging and product are aware of the presence of food allergens and consequently their consumption by sensitive people. Employees are trained in the prevention of cross-contamination of food allergens. Appropriate procedures for the management of food allergens are available and/or posted everywhere that

can be observed in connection with the compliance of the quality policy in the company. All employees are informed about allergens and how to deal with them during the initial training sessions, which precedes the offer to work. Company X applies the practice at the introduction level before the acceptance of production workers, it is necessary to pass the initial training and to pass the final test of the so-called “basic principles of hygiene”, which corresponds to the CIEH (Chartered Institute of Environmental Health) Level 2. During the training sessions the employees are also informed about anaphylactic shock. This course is repeated at intervals of at least two years for each production employee. Company X also carries more advanced courses for employees dealing with materials containing allergens. The type of course and degree of sophistication depends on the work to be done and the level of contact with allergenic materials. Temporary workers and subcontractors must read and sign a form to confirm consent to the application of the policy on the management of food allergens on the premises before they go on site. Company X has very restrictive rules in respect of all persons entering the premises. The entrance gate has a sign – “nut free site”. Non-employees are informed by security personnel about the allergenic policy within the factory. All persons visiting the plant prior to introduction into the company must sign the form about all the allergens present in the establishment, with information as regarding the anaphylactic shock risk and in accordance with company policy. The supervisor delegated to visitors, assesses the person to be sure he/she understands the policy management of food allergens in the company. In the absence of doubt the supervisor signs the form and the visitor is permitted entry into the premises in the presence of the supervisor.

Cleaning processes are considered to be the first line of defence against contact with allergens. Checking the cleaning process ensures that the defined procedure for cleaning is efficient and allows for the removal of allergens from the production line or equipment. Cleaning programs should be developed and approved prior to the start of production of the products containing a specific allergen. Cleaning systems, production lines and equipment must be verified in accordance with the timetable laid down on the basis of a risk analysis. The most commonly used analytical methods in the validation is ELIZA (Enzyme linked immuno-sorbent assays) based on the protein database [Food Drink Europe 2013]. Company X always performs a clean system validation in the event of a change in the supplier of chemical products or, in the case of a new allergen not yet used in the plant. A system of validation is done on the basis of a risk analysis of the most vulnerable places of cross-contamination

to which is included transport belts, gloves, inlays, the tables employees will be using to prepare a product, injectors, cases, etc. Places that have obtained the highest score in the risk analysis shall be tested. Validation involves taking a sample of the surface during the production of the product to a specific allergen for example eggs. The sample will be accompanied by the last few packs of the product. Swabs of the product are sent to an independent laboratory to determine the level of allergen. The production process is carried out after cleaning and disinfecting the production line. Then the production line can be certain that the product does not contain egg allergen. The swabs, together with a few packs of finished product are sent to a laboratory to determine the level of allergen using the method ELIZA. This process is repeated three times in order to compare the results. Validation is subject to annual review, even in the case when there is no change in the supplier of chemical agents. In the case of verification, this company uses quick tests (the most common are Neogen and Romer), that in a few minutes, gives a positive or negative result in respect of that equipment. Company X applies the verification of cleaning once a week. More restrictive reviews are applied in the case of products referred to as allergens absent, declaring gluten free. In the case of a product referred to as “gluten free” being produced on the production line following a product containing gluten, then the testing procedures are executed in several places in order to eliminate the possibility of cross contamination of the product. The production of a product with the lack of this allergen will not be started until a negative test has been obtained, releasing the line by the quality control department.

The next step in the management of food allergens is to carry out a risk analysis with regard to the equipment. Small movable equipment such as scoops, scrapers, brushes, sieves, etc. use colours each of which is assigned to a particular allergen. All scoops, sieves etc. (weighing room additions) to gluten are red, green soybeans, egg yellow etc. In the case of fixed equipment such as machines and equipment it is necessary to carry out a risk analysis on the basis of the order of the individual products in the production process. Company X uses a system in which products are produced in the first place, which in its composition does not have gluten as an allergen. In the meat industry this is considered to be one of the most feared.

The management of food allergens is very important in the case of the use of the finished product or products that are stored in the form of a partly completed product. In both cases, it is vital for the proper identification of all allergens contained in the product. Re-use of the product should be carried out only in respect of the same product and allergens.

The proper management of food allergens is important at the stage of the formation of a new product. Section technologists, before drawing up new products contact the management of food allergens in the establishment and analyse the risk of introducing new allergens into the manufacturing plant. It is necessary to specify the data management capabilities of allergens in the plants. In the case of the high risk of cross-contamination of a specific allergen, the production of the product is rejected.

Conclusions

It is estimated that 21 million people in the UK suffer from at least one type of allergy. Up to 8% of children and 2% of adults are diagnosed with food allergies and at least 1 in 100 people have celiac disease [FSA 2014]. The FSA says that every year there are 4,500 hospital admissions and 10 deaths due to food allergies. Discussing the topic of managing allergens in the food industry is spearheading most of the magazines and organizations dealing with nutrition. An example of this might be an extensive article in the Food Safety Magazine in December 2014 for Allergen Management: challenges and trends, that refers to The Global Food Safety Conference (GFSC) in Anaheim, CA. Any of the persons referred to in the article shows different results regarding irregularities in the management of food allergens and ways to repair them. One of the more interesting statements is a misunderstanding between academic knowledge and the reality of production in industrial plants. R. Craing Wilson states: “there are two reasons for error 1) a thorough understanding of what is an allergen, and 2) appropriate marking for the sake of the consumer” [Food Safety Magazine 2014]. In the above mentioned article it also points out other causes of errors in the management of food allergens. These include: errors in understanding acceptable levels of allergens and the introduction of a better understanding than the level of ppm, insufficient education of workers in manufacturing plants and errors in the marking of food additives on labels.

In the current situation it is difficult to give one specific factor which would have a decisive influence on the proper management of food allergens. In the above mentioned article it is suggested that the introduction of a uniform standard would have a positive impact on the effectiveness of the management of food allergens. Although manufacturing plants, producing under the name of the retailer for a long time, implement the standards imposed by brands such as M&S, Tesco or BRC, IFS standards, unfortunately this does not mean that you cannot find them on the list of establishments

which have had to withdraw a product from the market. Despite ever more complex procedures, continuing training for workers, laboratory tests of raw materials and the product management of food allergens it continues to be a major challenge for manufacturing plants. Therefore, every effort should be made to increase the effectiveness of operations under this serious problem of potential cross-contamination of the product by an allergen. Manufacturing plants producing food should follow the practice set out in the FSA guidelines, as well as guidelines set out by leading commercial retailers, since the fulfilment of such requirements should, to a large extent, increase the effectiveness of the management of allergens within the company.

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