

Food manufacturing initiatives to protect the allergic consumer

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Food allergy is one of the most problematic issues that food manufacturers must confront. It is important because consumption of certain food proteins by certain individuals can cause serious reactions, including death. The magnitude of the outcome requires that food manufacturers take special steps to minimize the possibility of food allergy. Manufacturing operations must be carefully analysed for potential problems, and an allergen-prevention plan should be established.

Although many food ingredients may provoke allergic reactions, severe and potentially fatal reactions are generally limited to only a very few of the huge number of proteins present in a typical diet. The most common causes of food allergy are proteins present in cow's milk, eggs, soya, peanuts, certain tree nuts, fish, and Crustacea (1, 2).

Since only a small minority of the population suffers from any particular food allergy, prevention must be based on the avoidance of the specific allergen. In order to avoid specific dietary allergens, allergic consumers need sufficient and correct information on the nature and composition of each product. Consequently, adequate and accurate food labelling is considered the primary means of the prevention of food allergy.

The prevention of food allergy is the combined responsibility of the allergic consumer and the food manufacturer. Consumers should use available ingredient information to select their diet, and should be suspicious of any food that does not carry an ingredient statement. In cases where consumers do not prepare their own food, they must ensure that those who select and prepare their food (e.g., school canteens, hospital caterers, etc.) are fully

informed of their condition and take appropriate action. Food manufacturers are responsible for taking various initiatives during food processing in order to ensure adequately and accurately labelled finished products.

Allergens in food processing

Food processing practices can lead to the presence of hidden allergens which are not indicated on the product label. For example, these may arise from use of shared processing equipment, use of rework, use of contaminated raw materials, presence of allergenic proteins as carryover in ingredients such as natural flavours and starches, mistakes in formulation, use of the wrong packaging with resultant inaccurate labelling, and switching of ingredients without alteration of labels. A number, albeit small, of severe hypersensitivity reactions, including deaths, have occurred as a consequence of hidden allergens.

Product formulation

Understanding the formulation of a product in order to identify allergenic ingredients is a primary responsibility of the manufacturer. A process control check to verify that known allergens are listed on the ingredient label is essential. It is also important to verify that the food product is placed in the appropriately labelled package and/or that the appropriate label is placed on the product.

Ingredient control

A close working relationship with ingredient suppliers is imperative for ensuring that allergens are not inadvertently introduced into the production line. The raw material specification should include the statement that the ingredient being purchased is free of allergens that are not listed. Formulated products, or compound ingredients, are of special concern because of the use of multiple components. Raw materials milled or processed on lines that are also used for other allergenic raw materials are another concern. An on-site audit is recommended to verify that proper practices and procedures are in place to ensure the use of safe and properly labelled raw materials.

Rework

Rework refers to partially finished products that are reincorporated into the manufacturing line. Rework that is isolated in storage bins, drums, or other containers to be added back into a product stream must be clearly identified and specifically considered with respect to allergenic components. To avoid cross-contamination, containers used for holding rework should not be reused unless they are designated for a specific product type or unless a documented and approved container-cleaning protocol is followed.

System design and cleaning

The introduction of food allergens can occur at almost any level of the manufacturing process as a result of cross-contamination. Process flow diagrams help in identifying the key points for control of allergens.

The optimum situation would be to manufacture allergen-containing products in a separate factory or to have physically separated dedicated lines that manufacture one product from formulation to packaging. However, this is generally impractical for economic reasons. Nevertheless, whenever possible, systems should be designed to minimize allergy-related problems; e.g., by facilitating thorough cleaning and providing easy access to verify the absence of food residues. Enclosed systems or systems in which products are well contained also play an important role in allergen control, and line crossovers should be avoided where possible to prevent ingredients from falling from one belt to another. Air drafts or the practice of washing down or blowing off equipment can produce aerosols that may spread allergens throughout the facility. Thus, the impact of airflow

and cleaning practices on allergen contamination should be considered.

Cleaning between product runs is an integral part of the manufacturing operation and is particularly important after the manufacture of an allergen-containing product. Some equipment may need to be disassembled and cleaned manually. Verification that a system is allergen clean should begin with a visual inspection, although several laboratories are now developing methods, such as rapid immunoassays, that can be used as an overall verification test for the cleaning procedures.

If the allergen line contains dry particulates, it is important to determine whether there are any areas where particulates may accumulate in the system and then contaminate the next product. If these areas cannot be cleaned sufficiently, it may be possible to engineer these dead spots out of the system. Alternatively, it may be necessary to dedicate lines or pieces of equipment that are very difficult to clean to the manufacture of specific products.

Dust from an allergen-containing product is a potential source of concern. Dust could be on the floor, on the top of enclosed equipment, on utensils, on employee uniforms, etc. Enhanced cleaning may be necessary in certain situations. Utensils and equipment should be dedicated to specific products or thoroughly cleaned between-allergen containing and non-allergen-containing products.

Appropriate production scheduling is one of the most practical and easiest approaches to reduce the risk of allergen contamination. Allergen-containing products should be scheduled at the end of a production cycle, after the production of products which do not contain the allergen. For example, egg noodles should be run after rather than before plain noodles.

Measures taken by food manufacturers

All factories using a critical allergen as an ingredient must take reasonable precautions to avoid contamination of products that do not normally contain these allergens and that do not carry a specific mention in the ingredient statement. These precautionary measures, which include efficient cleaning of production lines and equipment, strict separation of materials that may contain critical allergens, and formal procedures for rework, as well as employee-training programmes, should form part of an allergen-prevention plan.

A correctly implemented allergen-prevention plan can minimize the possibility of hidden allergens (3). Identifying the allergenic materials of concern and the potential points where cross-

contamination may occur during food manufacture is critical to this process. Furthermore, the allergen-prevention plan must be re-evaluated as system or equipment modifications are made, and if new ingredients are introduced into the factory.

Two complementary approaches are generally used in order to deal with food allergy: good manufacturing practices (GMP) and labelling.

GMP and HACCP

The GMP approach entails the establishment of a prevention plan to avoid the inadvertent presence of critical allergens in all products in which they are not regular ingredients. All factories using a critical allergen as an ingredient must carry out a special HACCP (hazard analysis of critical control points) study for all of their products that do not mention the allergen in the ingredient statement in order to assess the contamination risk. The HACCP team is made up of personnel who are close to the day-to-day operation of the factory since the study is facility-, product-, and line-specific. The aim of the HACCP study is to identify those critical points in product manufacture where measures can be taken to minimize the presence of hidden allergens in finished products. Where the study shows that measures can be taken to prevent any potential contamination, an appropriate monitoring plan should be established for each of the critical control points.

In many cases, allergy prevention can be achieved through compliance with GMP, good housekeeping, suitable production scheduling, and efficient cleaning. However, there are clearly limits to what can be achieved at reasonable cost, depending upon the contamination levels that can be tolerated. Consequently, in cases where the HACCP study indicates that GMP and the implementation of additional reasonable measures cannot exclude the possibility of contamination of a product by a critical allergen, then the finished food product must be labelled appropriately.

Labelling

Labelling is the primary means a manufacturer has to inform the consumer about the potential allergens in a product. Having the correct label on a food product is imperative; consequently, verification that the carton or package label matches the finished product formulation is critical. A key issue is the determination of which procedure best informs the allergic consumer of the possible presence of hidden allergens. Several approaches have been used for the labelling of inadvertent allergens that may be present in a food

where GMP cannot avoid, with certainty, the presence of the allergen. The method selected is usually dependent upon the regulatory situation in the country in which the product is marketed.

Unresolved issues for food manufacturers

Key allergens

Almost any food protein may be a food allergen, and a recent review indicated that more than 170 different foods have been reported in the scientific literature as being responsible for allergy (4). The implementation of successful allergen-prevention plans by food manufacturers may require the implementation of specific new procedures within manufacturing facilities. Consequently, it is not feasible for food manufacturers to control for the possible inadvertent presence of all potential food allergens in finished products. The initiatives taken by the FAO (1) and other international and national agencies to define a manageable list of "critical" food allergens requiring specific control measures are of great importance in this regard. Such a list must be based on strong scientific criteria, such as prevalence and severity, to be of value to both food manufacturers and allergic consumers alike.

Maximal acceptable level (threshold levels)

There is a wide variation in the sensitivity of food-allergy sufferers to specific food allergens. In part, this is because the tolerance for an offending food differs from one food to another, differs from one individual to another, and varies according to the state of health of a particular individual. Some individuals with food allergies respond with severe adverse reactions to extremely low levels of the offending food. Although the lowest dose of a food allergen that is likely to provoke an adverse reaction cannot be calculated with any degree of certainty for all individuals, it is nevertheless important to obtain information allowing an estimation of allergen doses unlikely to elicit severe reactions in the vast majority of sensitive individuals. For example, such a value is necessary in order to have an idea of the degree of sensitivity required by the analytic methods used to confirm that cleaning procedures for production lines are sufficient to avoid cross-contamination. At the present time, adequate cleaning is based on visual inspection and sometimes also on the arbitrary limit of sensitivity of any allergen assays that may be used.

The best estimates of the lowest tolerated dose in most individuals for various allergenic foods can

probably be derived from carefully taken histories of actual allergic reactions and extrapolations based on experiments with carefully controlled double-blind food challenges. In a recent review, Kjelkevik et al. (5) provided an estimate of the doses of allergenic ingredients leading to reactions. A total of 6 mg hazelnut in chocolate, 50 mg corylin (hazelnut) in a cookie, milk corresponding to 10 mg casein, and egg corresponding to 10 and 190 mg ovalbumin caused reactions requiring medication. A meal containing a cow's milk equivalent of about 60 mg casein resulted in fatal anaphylaxis. Peanut allergies appear to be in a class of their own, and several fatalities related to peanut allergy are reported each year. Following a series of double-blind, placebo-controlled food challenges, Hourihane et al. (6, 7) indicated that as little as 100 µg peanut protein may provoke reactions in some subjects with peanut allergy.

Detection and quantitation of food allergens

Traces of allergenic proteins can be detected in foods through the use of immunologic methods (8, 9). These may involve the use of sera from allergic individuals that contain allergen-specific IgE antibodies. However, due to their more reliable availability, immunologic assays using polyclonal or monoclonal antibodies from animals are more widely used for such analyses. For example, sensitive assays have been developed for the detection and quantitation of milk (10), peanut (11; [Peanut Protein Test Kit, Cortecs Diagnostics, Deeside, UK]), and egg proteins (10, 12). Analytic checks of samples taken along the production line are useful for the determination of critical points where contaminations may occur and for assessing the adequacy of cleaning procedures. However, these tests may be of limited value if the offending allergen is not evenly distributed within the batch (e.g., peanuts in chocolate).

Conclusions

Allergens can enter food products in various ways. The presence of even trace amounts of food allergens can pose a serious problem for sensitive

individuals. Food manufacturers are responsible for the control of food allergens in their products and for providing adequate and accurate information concerning their presence to the allergic consumer. The principal means of dealing with this issue are through GMP, the establishment of an allergy-prevention plan integrating the HACCP concept, and appropriate labelling.

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