Introduction
The prevalence of people with life-threatening food allergies is increasing. It is now believed as many as 1-2% of adults and 5-8% of children are affected. Avoidance of allergen-containing foods by the individuals affected is the only reliable way to prevent an allergic reaction. Therefore, preventing cross-contamination of an ‘allergen-free’ food is essential. In factories where the allergen is present in some formulations but not others, it means ensuring that processing lines are thoroughly and effectively cleaned between runs. The food industry needs to control allergens to prevent cross-contamination to products that should not contain them. Good hygiene, awareness of allergens and their risk of being cross-contaminated and effective cleaning are essential. HACCP audits should be undertaken to identify the critical control points (ccps) to control allergens and controls and checks put in to ensure that the ccps are effectively controlled.

This document looks at the measures that can be taken to reduce cross contamination risks and what tests can be done after the cleaning to show that the allergen has been removed. It also discusses the limitations of what can be done, bearing in mind that there is no lower limit known for levels of allergen that can provoke a response in sensitive individuals. For some individuals, it is believed that contact and/or ingestion of minute amounts of an allergen can result in a serious anaphylactic reaction and may even result in anaphylactic shock and even death.

Food Allergens
A food allergen is a globular protein having specific sequences of amino acids, usual in the molecular weight range 10,000 - 70,000. A food allergy is an immunologically based response causing selective production of specific antibodies. These antibodies cause a release of powerful cellular chemicals, (messenger molecules -- Histamine, Serotonin & Protease) which in turn cause the symptoms of allergic reactions.

As food allergens are proteins, they have a high affinity for stainless steel and attach themselves to these types of surfaces. They are also hydrophobic and therefore not soluble in water. This makes them more difficult to remove.
Legislation
EU labelling legislation regarding food allergens is now implemented and enforced. It has raised awareness in the food industry of the potential for cross-contamination of allergenic ingredients in the food supply chain. As of January 1st 2006, food manufacturers are required to list food allergens on food packaging to alert consumers with allergies of the potential risk of any food product.

Directive 2003/89/EC, as amended by 2007/68/EC, sets out requirements for the fuller listing of ingredients on the labels of pre-packed foods, including specific allergenic ingredients and their derivatives (subject to exemptions). The Directive establishes a list of ingredients liable to cause allergies or intolerances namely: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds and sulphur dioxide. Commission Directive 2006/142/EC added molluscs and lupin to this list, following advice from The European Food Safety Authority (EFSA).

There are no legal requirements for the labelling of the possible adventitious presence of allergens but food manufacturers voluntarily use ‘may contain’ advisory labelling where there is a demonstrable risk of the presence of trace amounts of allergen from cross-contamination within the ingredient supply chain or from manufacturing operations. Currently, food manufacturers often “err on the safe side” with regard to the labelling, if they consider that there is even the slightest risk of allergens in the food. There is, however, agreement between the food industry, consumer groups and enforcement bodies that unjustified use of advisory labelling unnecessarily restricts consumer choice and devalues the impact of the warnings. There are ongoing discussions as to how labelling can be improved to make it more accurate and informative to those susceptible to allergens.

Cleaning to reduce cross contamination of allergens
Very small amounts of some allergens, such as nuts, can cause adverse reactions, including potentially fatal anaphylactic shock. Therefore, thorough cleaning that is effective in reducing the risks of allergen cross contamination is essential. A ‘visually and physically clean’ standard, and assurance that “difficult to clean” areas in the production line are thoroughly cleaned, may be adequate for many food products. However, when there is a risk, even the slightest risk, of allergens being present, this standard is likely to be inadequate. Allergens may still be present and it is necessary to check for residual allergens. Even surfaces
that have low ATP counts (or proven to be microbiologically satisfactory) could still have significant quantise of antigen.

Complex equipment must be dismantled and manually cleaned to ensure hard to clean areas are free from allergen residues. Particular food materials (for example, powders, seeds, pastes and particulates) present significant cleaning problems and any relevant industry guidance, where this has been developed, should be followed. Adequate procedures should be in place for cleaning both production and packaging machinery. Where adequate cleaning is not possible, then the risk of allergen cross-contamination should be assessed and advisory labelling used, if appropriate.

Care is needed in cleaning to ensure that the cleaning of one line does not contaminate another (for example, by use of compressed air cleaning or water pressure cleaning), or an area which has already been cleaned. Always clean dry mix areas from the top down.

Any spillage that occurs during production, storage and transportation should be cleaned up immediately to ensure that there is minimum risk of allergen cross-contamination. Where known allergen contamination has occurred, the contaminated material should be labelled and physically moved away from the non-contaminated ingredients and work-in-progress.

Consideration should be given to maintenance activities, such as the use of dedicated tools or adequate cleaning procedures where tools are not dedicated. All cleaning equipment should be thoroughly cleaned and checked from time to time to ensure that it is free of allergens.

Where adherence to a cleaning regime is part of a separation system, it should be validated as ‘fit for purpose’ and compliance should be monitored.

Investment in developing and following appropriate cleaning regimes will help to minimise food allergen cross-contamination and can reduce the likelihood of needing costly product recalls. The basic principles of cleaning to prevent cross-contamination may be summarised as follows:

- Ensure that cleaning equipment itself is cleaned after use to minimise the risk that it may carry and transfer allergen traces.
• Establish appropriate cleaning regime including laundering of protective clothing.
• Validate cleaning regimes.
• Monitor that cleaning is being done properly.
• Keep records of cleaning.

Where dedicated production facilities are not available, cleaning provides the break between allergen and non-allergen containing production runs. However, cleaning in itself cannot be considered as a control measure, and it needs to be integrated into the site’s overall allergen management programme. Moreover, the effectiveness of cleaning must be assessed and cleaning validation should be included as part of the prerequisite programme.

Validation of cleaning
The types of samples taken for cleaning validation can vary depending on the production environment and accessibility of a given process or piece of equipment, but may include surface swabs, purge material samples, rinse waters, air and finished product. Whatever type of sample is selected, samples should be taken immediately after the product containing the nominated allergen is produced and before any cleaning is undertaken – this effectively acts as a positive control. Once cleaning has been undertaken (usually to a visible clean) using the standard documented regime, samples should then be collected for analysis. The non-allergen containing product should be run post cleaning and samples of finished product (usually first off line) should be sent for analysis by a competent and accredited laboratory using validated methods of detection.

Initial cleaning validation should be repeated at least 3 times to ensure the consistent removal of allergens. If the cleaning regime is changed in any way (e.g. the temperature of the environment or cleaning chemicals; the time taken for the clean; there is a change of cleaning product or its concentration; or there is any other change to the cleaning schedule) then the effectiveness of cleaning should be validated again, preferably three times. It is also good practice, even if there have been no changes to the cleaning regime, the validation process should be repeated at least annually. A valuable tool for ensuring standards are maintained is trend analysis. It is therefore important to review results so that even minor changes can be identified and their significance assessed. As in all cleaning procedures, there must be regular reviews and improvements made to ensure that the cleaning standards are the best possible.
Testing for residual allergens

Traditional testing taking swabs and then analysing in the Chemical Laboratory is laborious and time consuming. In recent years, rapid test kits have been developed. ATP Test kits are ideal for assessing the residual hygiene of a surface. However, a surface with a low ATP assessment could still have sufficient allergen, albeit it at a very low level, to contaminate subsequent food touching the surface and thus be a potential risk to an allergen sensitive consumer.

More recently, rapid tests have been developed for different allergens: peanut, almond, egg, milk products, gluten, soy, etc. These have detection limits as low as 1-2ppm and results can be obtained within 30 minutes. This rapid detection enables remedial steps to be taken. These tests can be used on food ingredients, cleaned equipment, the environment, equipment used in cleaning (brushes, buckets, etc), Cleaning in place (CIP) rinse solutions and the end food product.

Both quantitative and qualitative “rapid test kits” are available. Probably, the most prevalent Quantitative test is the Elisa (enzyme linked immunosorbent assay) which can give a reasonably accurate estimate of the amount of most antigens present. In contrast, tests such as the PCR (polymerase chain reaction) will indicate the presence of an antigen but cannot tell you how much of it is present.

Conclusion

The amount of allergen that can cause an allergic reaction is not defined although it is known that it can vary from person to person. It is therefore important for food businesses to adopt a qualitative approach to allergen management and risk assessment. It must be remembered that effective cleaning and cleaning validation, although important, is part of the business of allergen management. Good allergen management involves awareness of the issues; segregation, wherever possible, of allergens from other food ingredients and parts of the factory where non-allergen foods are made; training of personnel; testing ingredients and final product for allergens; and, of course, an EFFICIENT CLEANING REGIME including validation of the effectiveness of the regime.