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Scientific Summary Paper on Food Allergies

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Prepared by the AIFST Scientific Affairs Committee

Introduction

Food allergies affect a small proportion of the population, but in some cases an allergic reaction can be life-threatening or fatal. It is generally estimated that in the Australian community the prevalence of true food allergies is of the order of 1-2% of the overall population; however it is higher in children (5-8%). Many children have outgrown allergies such as those to milk and eggs by the time they have reached 5-7 years of age.

Food allergies need to be distinguished from food intolerances, which are generally caused by chemical agents, eg. sulphites or certain genetic deficiencies, eg. lactose intolerance. True food allergies are an unusual immunological response to the ingestion of the offending food, usually mediated by immunoglobulin E (IgE). Virtually all known food allergens are proteins, and an individual must first be sensitised by exposure to the protein to develop antibodies, which then react to further exposures. Allergenic proteins are usually not denatured under food processing conditions, and are resistant to digestion in the intestinal tract. Allergies are characterised by the rapid release of powerful cellular chemicals such as histamine by the antibodies, which cause the symptoms of the allergic reaction within minutes to an hour after ingestion.

Symptoms can range from mild to severe, with most individuals suffering from just a few of the many possible symptoms. These can range from problems with

- the respiratory tract (rhinitis, asthma, throat swelling),
- the gastrointestinal tract (nausea, vomiting, diarrhoea, abdominal cramping), or
- the skin (hives, itching, dermatitis, eczema).

In some cases a more severe *systemic* reaction can occur which results in a rapid loss of blood pressure, severe obstruction of the airways, a generalised shock reaction and multiple organ failure. This is known as anaphylactic shock, and can be fatal if not treated within minutes. Although only a few people with food allergies are at risk of such serious consequences, there are many documented cases of death resulting from accidental ingestion of an offending food.

It is estimated that about 90% of all food allergies are attributable to eight common foods –

- cows' milk,
- eggs,
- fish,
- crustaceans,
- peanuts,
- soybeans,

- tree nuts* and
- wheat.

However over 160 additional foods have been documented as having caused allergies. The frequency and potential severity of reactions to some of these eight major allergens is a reason why the Australia New Zealand Food Standards Code now requires the food industry to pay particular attention to their control and labelling.

**Note: Tree nuts is a group consisting of almonds, Brazil nuts, cashews, chestnuts, hazelnuts, hickory nuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts. From an allergenic perspective, coconuts and more unusual nuts such as shea nuts or kola nuts are not classed as tree nuts and are rarely allergenic.*

Control of food allergens in manufacturing and processing

Whilst mandatory labelling of the most common and serious allergens will provide information to sensitive consumers about the presence of these substances in foods, an area of concern is when one or more of these allergens may be present through incidental means such as cross-transfer during production. This may occur either in the final production processes, or may be a risk factor with one or more ingredients. This situation poses great problems for both food manufacturers and sensitive consumers.

Food manufacturers have an obligation to employ good manufacturing practices to minimise the possible contamination of foods with serious allergens. Practices such as arranging production schedules to reduce the risk of cross-transfer, control of rework material, cleaning procedures, good equipment design and plant layout should be examined to minimise the risk of consumers being exposed to incidental allergens.

The Australian food industry has recently issued a *Food Industry Guide to Allergen Management and Labelling.* Copies are available from the Australian Food and Grocery Council and the guide is also available on their website <www.afgc.org.au>.

Label advisory statements

In some cases, despite the best endeavours of processors, a risk of unintended presence of some of these allergens may still exist. An increasingly common means of conveying that risk to consumers is to employ advisory labelling statements such as “may contain traces of ….”. However allergy support groups and allergic consumers have indicated that this type of statement is unhelpful and does not provide sensitive consumers with an adequate indication of the risk of an allergen being present.

The AIFST Scientific Affairs Committee recommends that food processors determine the real level of potential contamination by regular testing of their food products for the presence of the likely allergens. Sensitive ELISA test kits are now available for the most common food allergens, and more are being developed. Currently available kits have a qualitative sensitivity of about 1ppm of the offending allergenic protein, a level which is generally regarded as not of concern for most allergic consumers (Taylor et al, 2002). A risk assessment approach based on reliable testing will allow food processors to indicate the level of risk to consumers, and assist in decisions about whether to apply advisory label statements.

Sensitivity of allergy sufferers

Although cases of exquisite sensitivity have been reported anecdotally, there is now some foundation work available to suggest that an absolute zero threshold is not necessary, and good work is in progress to discover safe threshold levels for most consumers.

There is now rapidly growing evidence that most allergy sufferers can tolerate small amounts of the offending proteins, although the threshold levels vary between individuals and also between sources of the same allergen (Hourihane, 2001). Commercially refined edible oils have no allergenicity (Hefle & Taylor, 1999), and in a challenge study even peanut allergic subjects did not react to refined peanut oil (Hourihane et al, 1997a). This illustrates the maxim "no protein, no problem" (Taylor, 2000).

In a landmark challenge study to determine a peanut protein threshold in sensitive individuals (Hourihane et al, 1997b), the lowest dose to elicit a reaction was 2mg, but some subjects tolerated up to 50mg, and this is still well below other published levels of reactivity. In other challenges reported from double-blind, placebo-controlled food challenges (the "gold standard"), minimum levels of 55mg for codfish and 88mg for soy were established. For milk and egg protein, some subjects reacted to levels below 100mg, which was the lowest level tested, but the majority tolerated this level (Hourihane, 2001). A report from France (Rance et al, 2000) on a challenge series with 125 subjects showed that 6 (4.8%) reacted to 1mg peanut protein, and a further 45 (36.2%) reacted to cumulative doses below 100mg.

More recently still, a forum of allergy clinicians and other experts shared information on their clinical observations (Taylor et al, 2002), and the lowest observed provoking doses were reported as 0.25mg peanut protein, 0.1mg egg protein, 0.6mg milk protein, 5mg fish (protein level unknown) and 0.3 mg mustard protein. However variability in experimental designs and food types used did not allow the forum to recommend thresholds for these food proteins. The major reason was that most of the tests had been conducted for diagnostic purposes rather than for establishing threshold levels, and therefore in most cases a no-observed-adverse-effect level (NOAEL) was not established.

In risk assessments for food additives to establish acceptable daily intakes (virtually safe doses), for instance, a NOAEL is first established on the basis of tests on animals or from human observations. Uncertainty factors are then applied to account for extrapolation from animal data to humans, and also to account for possible differences between individual humans. Although the forum results showed the lowest provoking doses for the individuals observed, in risk assessment terms these would be the *lowest-observed-adverse effect levels* (LOAEL). This does not allow the determination of a NOAEL or a scientific recommendation on acceptable levels of allergenic protein, however the forum concluded that for peanut, egg and cow's milk the threshold levels appear to be in the low milligram range or higher for most individuals with allergies to those particular foods.

Work is at present underway in the USA on the evaluation of a specific anti-IgE antibody (TNX-901), and initial observations show a substantially increased threshold of sensitivity in subjects with peanut hypersensitivity, eg. in one study from a 178mg peanut flour base-line threshold (about half a peanut) to 2805mg (almost nine peanuts). The initial conclusions are that injections could provide protection against most unintended ingestions of peanuts (Leung et al, 2003).

Summary

Although threshold levels have not been definitively established for common food allergens, it appears that for all but the most exquisitely sensitive allergy sufferers, protein levels in the low milligram range are able to be tolerated. Therefore a zero threshold is not strictly necessary, however it is the duty of food processors and manufacturers to adopt appropriate manufacturing controls and practices to minimise the incidental inclusion of allergens in foods where the allergen is not otherwise identified in ingredient lists. In this respect it must be realised that there is a small proportion of allergy sufferers who are severely sensitive to minute amounts of food allergens. However the use of blanket allergen advisory label statements is not helpful to most allergic consumers, and where used should be based on a thorough risk assessment, which of necessity includes testing products regularly for the possible presence of allergenic proteins.

References

- Hefle SL & Taylor SL 1999, Allergenicity of edible oils, Food Technology, 53, 62-70
- Hourihane JO'B, Bedwani SJ, Dean TP & Warner JO 1997a, Randomised double-blind crossover challenge study of allergenicity of peanut oils in subjects allergic to peanuts, Br Med J, 314, 1084-1088
- Hourihane JO'B, Kilburn SA, Nordlee JA, Hefle SL, Taylor SL & Warner JO 1997b, An evaluation of the sensitivity of subjects with peanut allergy to very low doses of peanut protein: A randomized, double-blind, placebo-controlled food challenge study, J Allergy Cli Immunol,100, 596-600
- Hourihane JO'B 2001, The threshold concept in food safety and its applicability to food allergy, Allergy, 56, Suppl. 67:86-90
- Leung DYM, Sampson HA, Yunginger JW, Burks Jr AW, Schneider LC, Wortel CH, Davis FM, Hyun JD & Shanahan Jr WR 2003, Effect of anti-IgE therapy in patients with peanut allergy, New England J Med, 348, 977-985
- Rance F, Abbal M & Dutau G 2000, Peanut allergy in children: skin prick test, specific IgE and dose response by double-blind placebo-controlled food challenge, Allergy, 55, Suppl. 63:55 (abstract)
- Taylor SL 2000, Food Allergens: Issues and solutions for the food industry, workshop held in Sydney, October 2000
- Taylor SL, Hefle SL, Bindslev-Jensen C, Bock SA, Burks Jr AW, Christie L, Hill DJ, Host A, Hourihane JO'B, Lack G, Metcalfe DD, Moneret-Vvautrin DA, Vadas PA, Rance F, Skrypec DJ, Trautman TA, Yman IM & Zeiger RS 2002, Factors affecting the determination of threshold doses for allergenic foods: How much is too much?, J Allergy Clin Immunol, 109, 24-30.