This paper, commissioned by the ILSI Europe Food Allergy Task Force and published in the peer-reviewed journal Food and Chemical Toxicology, outlines a risk analysis framework to underpin decision-making in the area of allergen cross-contact. The latter may arise for a number of reasons, for instance the presence of residues in inaccessible shared equipment and airborne dust. The paper identifies challenges relevant to each component of the risk analysis framework. These are risk assessment, risk management and risk communication. It concludes that risk management decisions must be informed by a clear understanding of the risk assessment’s outputs and limitations. Clear, consistent and trustworthy communications involving all stakeholders underpin these activities. This is the third paper in a three-part series.

Risk assessment endpoint – Understanding the model outputs

The previous papers in this series have described the model used to assess the risk posed by the unintentional presence of allergens, arising from cross-contact, in manufactured food. Risk assessment is a prerequisite for risk management; therefore, a clear understanding of the limitations and outputs of the risk assessment is required to inform risk management measures. Two important challenges are outlined below:

1. Data gaps: The risk assessment model described in earlier papers focuses solely on the probability or likelihood of a reaction occurring without any regard to the nature of those effects (i.e. severity, duration or reversibility). However, the latter is an important consideration for stakeholders when determining the acceptable level of risk and the risk management measures to be implemented. This limitation is a reflection of a lack of data on the relationship between dose and severity and highlights an important area for future research.

2. Output interpretation: Typically, the result of a risk assessment is expressed as the likelihood of a reaction such as 1%, 1 in a million, etc. However, a risk assessment includes intake data which are expressed as intake over a specified period of time. Thus the resulting expression of risk, at the very least, should indicate the time denominator or, where appropriate, the number of predicted reactions per unit of product.

Risk management – Translating the risk assessment to protection of public health

Risk management can only take place effectively if its objectives are clearly defined and understood from the outset. A clear description of risk management objectives should therefore precede any risk assessment as they will guide the collection of the appropriate data. The biggest challenges are in the setting of clear and realistic objectives.

1. Clear Objectives: To ensure clarity, the objectives should outline: i) The scope of the risk
management activity, ii) The individuals or population to be protected and iii) The adverse reaction to be mitigated.

2. Realistic Objectives: The objectives must be feasible and achievable, grounded in a level of risk accepted by the different stakeholders, thereby avoiding unintended detrimental consequences. For example, a low threshold may result in a lower risk of allergic reactions. However, compliance with a low threshold may not be technologically and/or economically feasible for food businesses. Potential consequences include an increase in the prevalence of precautionary labelling, a reduction in food choice for allergic consumers and an increase in risk-taking behaviour.

Risk Communication – Establishing a common understanding of the risk

Risk communication is the third component of the risk analysis framework. It is not a passive process of transmitting information, but an interactive one encompassing all stakeholders, including allergic consumers, clinicians and other health professionals. Restoring confidence in precautionary labelling will require explanation of the benefits that the risk analysis framework will bring and the active engagement of all stakeholder groups, in reaching agreement on the level of risk that can be accepted. A critical aspect will be to explain how the application of such a framework to precautionary labelling will help reduce the anxiety experienced by allergic consumers and those caring for such consumers.

Although it is clear that certain challenges exist with the risk analysis framework, the authors conclude that clear, quantitative action levels based on sound science form the basis for allergen management and labelling. This will mitigate current confusion and uncertainty surrounding precautionary labelling. This conclusion which integrates the perspectives of different stakeholders (i.e. allergic consumers, health professionals, food industry and public health authorities) recognises that the proposed framework must be adaptable to new and emerging evidence.

For further information please see: