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Invited Review

Development and evolution of risk assessment for food allergens

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ABSTRACT

The need to assess the risk from food allergens derives directly from the need to manage effectively this food safety hazard. Work spanning the last two decades dispelled the initial thinking that food allergens were so unique that the risk they posed was not amenable to established risk assessment approaches and methodologies. Food allergens possess some unique characteristics, which make a simple safety assessment approach based on the establishment of absolute population thresholds inadequate. Dose distribution modelling of MEDs permitted the quantification of the risk of reaction at the population level and has been readily integrated with consumption and contamination data through probabilistic risk assessment approaches to generate quantitative risk predictions. This paper discusses the strengths and limitations of this approach and identifies important data gaps, which affect the outcomes of these predictions. These include consumption patterns among allergic individuals, analytical techniques and their application, severity-dose relationships, and the impact of extraneous factors which alter an individual's physiology, such as infection or exercise. Nevertheless, application of these models has provided valuable insights, leading to further refinements and generating testable hypotheses. Their application to estimate the risk posed by the concurrent consumption of two potentially contaminated foods illustrates their power.

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1. Introduction

The need to assess the risk from allergenic constituents or residues in manufactured food products arose very soon after food allergy was identified as a public health issue and mandatory food allergen source labelling as well as voluntary precautionary allergen statements on products ensued. It became apparent that failure to assess risk would lead to excessive warnings of unintended allergen presence on products and reduced food choices for people with food allergy. A pioneering piece of work demonstrated the feasibility of conducting allergen risk assessments when it showed to a standard higher than that required of hypoallergenic formulae that highly refined (N/RBD) peanut oil did not trigger reactions in people with peanut allergy, whereas crude peanut oil, which contained up to 100 times more protein, could do so (Hourihane et al., 1997a).

However, assessing the risk arising from the presence of allergenic constituents in products remained challenging. Initially the question was raised whether allergic reactions even obeyed classical toxicological principles, such as dose–response relationships. As data built up on reactivity within populations of people with food allergies (Taylor et al., 2004), it became clear that the range of reactivity to allergens is extremely wide, spanning at least 6 orders of magnitude, based on the results of controlled food challenge studies. The lack of knowledge about the distribution of this reactivity added to the perception generated by anecdotal case reports that most reactions occurred in response to extremely small amounts that would be difficult to measure, let alone manage in ordinary food manufacturing facilities.

Over the last decade or so, much progress has been made in filling a number of the data and knowledge gaps that prevented an adequate assessment of the risk. Food challenge data from studies designed to identify and characterise low dose reactors have become available in sufficient quantity to derive dose distributions for a large number of the more significant allergenic constituents. These data, on their own, would have been of much more limited value if the tools to analyse them had also not developed in parallel. Thus statistical modelling of dose distributions has become a widely accepted approach to characterising allergenic hazard (Bindslev-Jensen et al., 2002; Crevel et al., 2007). Similarly, probabilistic approaches to estimating the likely consequences of a particular pattern of allergen contamination are gaining currency (Spanjersberg et al., 2007), although gaps remain. These include inadequate data to characterise the hazard with confidence for some allergenic foods, but perhaps the most significant is understanding the background frequency of reactions that occur from day to day among allergic consumers and the associated pattern of severity. This background will in part be influenced by the food choices of allergic consumers (e.g. avoidance of certain food types, brands, etc.) and their acceptance of certain types of reaction (e.g. the milder variety). Inadequate knowledge about these food choices together with limited understanding of the frequency and range of product contamination point to an important data gap around the exposure component of the risk posed by food allergens.

Notwithstanding the remaining data and knowledge gaps, the progress to date, as well as initiatives such as the Allergen Bureau's of Australia and New Zealand VITAL initiative, demonstrated that allergen management could be placed on a sounder, evidence-based footing, based on robust risk assessment. This would improve the safety of allergic consumers, while providing the food industry with a clear set of standards towards which they could work. This paper presents the results of the work by the ILSI-Europe Food Allergy Task Force's Expert Group and the discussions with stakeholders concerning risk assessment of allergenic foods.

2. Evolution of risk assessment for food allergens

Allergens in food pose a health risk to humans who may become sensitised or are already sensitised to these proteins. Terminologies and methodologies for food risk and safety assessment and management developed and evolved largely in response to the threats to public health from chemical or microbiological contaminants that may be present in food. For a long time, it was questioned whether classical toxicological risk assessment principles could be applied to allergy and allergenic foods. However, with better understanding of reactions to allergens, together with increasing volumes and quality of data, it is now widely accepted that the broad principles and approaches of chemical toxicology risk assessment can be applied to food allergens (Madsen et al., 2009; Spanjersberg et al., 2007, 2010), as can the same terminologies and methodologies. This section describes the concepts and terminology in (mainly chemical) food safety and risk assessment and their applicability to allergens. In addition, practical approaches that have been developed for food allergen risk assessment are described.

2.1. Concepts and terminology in risk assessment for foods

Clarity of thought and communication among risk assessors and managers are critical in ensuring good management of risk and much effort has been expended on international harmonisation of terminologies. In this paper, terminology is based on definitions set out by the INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY (IPCS) in 2009 in their "Alphabetical list of selected key generic terms in hazard and risk assessment and their definitions" (INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY HARMONIZATION PROJECT). This terminology has been harmonised across the different disciplines covered by the Codex Alimentarius Commission and thus also applies to microbiological risk assessment