

Editorial

Post-marketing surveillance of novel foods

Clinicians are very familiar with the concept of post-marketing surveillance of new pharmaceutical products. Once a new drug has cleared all the statutory hurdles in relation to safety and efficacy in clinical trials, the statutory authorities allow its release on to the market. However, a program of surveillance is then essential to pick up rare side-effects and longer-term complications that might, in the final analysis, result either in its withdrawal from the market or in a modification of recommendations for use. Unfortunately there is no such requirement for a similar procedure to be employed in relation to the release of new foods on to the market.

Novel foods undergo a scrutiny by regulatory authorities but, once approved, there appears to be little control over their continued marketing irrespective of any problems that might arise. This is of particular concern to allergists. I have written in a previous editorial about genetically modified foods that have caused enormous public disquiet and certainly do have some implications for the pediatric allergist (1). The British Society for Allergy & Clinical Immunology has produced a working party report on the potential allergenicity of genetically modified (GM) foods. The report is very balanced and I believe an excellent contribution to the debate (2). However, concerns about novel foods and their potential allergenicity extend beyond GM foods.

It is interesting to note that as a consequence of the public disquiet about GM soy, food manufacturers have been seeking a guaranteed GM-free alternative. The focus latterly has been on sweet lupin. The flour has a similar protein content to soy and therefore theoretically could be used as an alternative. Indeed, it is now on the market in many European countries. However, it is becoming clear that a percentage of peanut-allergic individuals react to lupin and some have had severe reactions (3). Reports of allergic reactions have not resulted in any changes to the regulations in relation to the marketing of sweet lupin-containing products. A post-marketing surveillance program would have picked up the progressively increasing reports of allergic reaction to lupin, particularly in peanut-allergic

individuals. One would hope and expect that this would have led to, at the very least, a recommendation to change the labeling to warn peanut-allergic consumers that there is a potential for problems.

Research is required to understand the way in which allergies to novel foods evolve in a community. It is very apparent from the experience with both the sweet lupin and, indeed, before that with kiwi fruit, that the first reports of reactions tend to occur in adults where it is clear that cross-reactivity is the problem. This ought to be predictable on the basis of taxonomic relationships between the new food and foods already on the market. At the same time, reports appear of individuals being exposed in an occupational situation; this has certainly been the case for sweet lupin (4). It is only very much later that cases of isolated primary sensitization to the food develop in younger individuals. This, in part, will relate to the slow introduction of new foods into younger and younger individuals' diets but may also reflect the way in which primary sensitization occurs in very early life. Provided research can characterize the pattern of evolution of allergic problems, it should then be possible to devise post-marketing surveillance strategies targeted at particular sections of the population, which might shorten the period between detection of a problem and appropriate action being taken.

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References

1. WARNER JO. Genetically modified food and the pediatric allergist. *Pediatr Allergy Immunol* 2002; 13: 73–4.
2. BSACI. Working Party Report on the potential allergenicity of genetically modified organisms and their products. *Clin Exp Allergy* 2002; 32: 1131–43.
3. MONERET-VAUTRIN DA, GUERIN L, KANNY G, et al. Cross allergenicity of peanut and lupin: the risk of lupin allergy in patients allergic to peanuts. *J Allergy Clin Immunol* 1999; 104: 883–8.
4. PARISOT L, APARICIO C, MONERET-VAUTRIN DA, GUERIN L. Allergy to lupin flour. *Allergy (Net)* 2001; 56: 918–9.