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EDITORIAL

Testing of genetically modified novel proteins for allergenicity in food and feed: a toxicological and regulatory challenge

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Toxicological aspects of food safety have been a scientific matter for Archives of Toxicology for more than 30 years (Preussmann 1978; Netsch et al. 1980; Miller 1987; Pascal 1992; Bakhiya and Appel 2010). Up to now, topics of carcinogenicity and mutagenicity of food ingredients have been predominating (Preussmann 1978; Bakhiya and Appel 2010). This mostly referred to classical food constituents and additives. However, since the late 1980s new questions arose of toxicological evaluation strategies for so-called "novel food" (Solomons 1987) or for food end-products derived from biotechnology processes (Wilson 1987).

In this context, a matter of recent concern is the allergenicity of genetically modified plant- and microorganism-derived food and feed. Genetically modified food and feed contain quantities of new or existing proteins, which might cause allergies in people and/or animals. For instance, the legislation of the European Union requires that allergenicity of such products should be assessed before these can be placed on the market.

Very recently, the Genetically Modified Organisms (GMO) Panel of the European Food Safety Authority (EFSA) has published an official "Scientific Opinion on strategies for assessing risk of allergenicity of genetically modified plants and microorganisms and derived food and feed" (EFSA 2010). This publication took into consideration a total of 181 comments, received from national assessment bodies, non-governmental organizations, business associations, universities, and individuals during a consultation period. The comments widely addressed the issue of how to implement the general approach for assessing the allergenicity, as well as how to interpret the results of methods discussed in the Opinion. In vitro and cell-based tests for assessing the allergenicity of newly expressed proteins are covered in Annex 4, and animal models in Annex 6 of the Opinion. On the one hand, Annex 6 stresses that animal models in general are not validated and therefore inconclusive for the assessment of the sensitizing potential of a novel protein. But on the other hand, it acknowledges that such models could provide useful information on mechanisms underlying the induction and development of an allergic reaction, when there are indications of a sensitizing or adjuvant potential of newly expressed proteins. In essence, it appears that hierarchical approaches to allergenicity determination are needed for an integrated assessment.

In the present issue of Archives of Toxicology, Ahuja et al. (2010) provide an up-to-date review of the progress made in this particular field of development of in vivo models, and of possible ways of integration of such models into a science-based hierarchical assessment of novel proteins in food.

By this publication, Archives of Toxicology intends to foster the present discourse between scientists and regulators in this specific field, in order to balance innovation and safety of both food and feed.

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