New developments in the allergenicity assessment of food derived from biotechnology

Antonio Fernandez¹, Regina Selb¹, Philippe Egenmann², Michelle Epstein³, Karin Hoffmann-Sommergruber³, Frits Koning⁴, Martinus Lovik⁵, Clare Mills⁶, Javier F. Moreno⁷, Henk van Loveren⁸, Jean-Michel Wal⁹

¹European Food Safety Authority, Parma, Italy; ²University Hospitals of Geneva, Switzerland; ³Medical University of Vienna, Austria; ⁴Leiden University Medical Center (LUMC), the Netherlands; ⁵Norwegian University of Science and Technology (NTNU), Trondheim, Norway; ⁶The University of Manchester (UNIMAN), United Kingdom; ⁷Consejo Superior de Investigaciones Científicas (CSIC), Madrid, Spain; ⁸Maastricht University, the Netherlands; ⁹Institut National de la Recherche Agronomique (INRA), Paris, France

The European Food Safety Authority (EFSA) and other international bodies (Codex) define approaches for allergenicity assessment of food and feed derived from biotechnology. As an outcome of the allergenicity assessment, risk assessors estimate whether the novel protein is likely to be allergenic and whether the food derived from biotechnology is likely to be more allergenic than that derived from its appropriate comparator(s). Because it is challenging to predict the allergenicity of novel proteins, a weight-of-evidence approach is used to provide the assessor with a cumulative body of evidence to a) reduce the uncertainty linked to the allergenicity assessment and, b) enhance the reliability of predictions regarding the allergenic potential of novel protein(s). Currently, EFSA is developing supplementary guidance to better define and clarify specific aspects of the allergenicity assessment requirements. In particular, i) non-IgE-mediated immune adverse reactions to foods; ii) in vitro protein digestibility; and iii) endogenous allergenicity, are addressed. Firstly, celiac disease is a well characterised non-IgE-mediated adverse immune reaction to food, and the food proteins involved, as well as the underlying molecular mechanisms, have been described in detail. Consequently, EFSA is working on defining a strategy to be followed for the assessment of novel proteins’ potential to cause celiac disease. Secondly, the outcome of in vitro protein digestibility studies is considered relevant information in the weight-of-evidence approach. To date, the “pepsin resistance test” is commonly accepted for the safety assessment considerations by risk assessors. However, EFSA has previously highlighted its limitations for the allergenicity assessment as well as for its capacity to reflect in vivo digestion conditions. Consequently, EFSA is proactively developing a complementary strategy in order to reduce the resulting uncertainty in the allergenicity assessment. This strategy will be based on state-of-the-art in science, aiming at proposing an enhanced and refined in vitro gastroduodenal digestion test where different physiological conditions will be taken into consideration and more informative read-out procedures will be recommended. Thirdly, high performance methodologies for protein identification and quantification will be proposed as complementary/alternative methods to those based on human sera for the assessment of endogenous allergenicity within the comparative assessment analysis.