The relevance of a digestibility evaluation in the allergenicity risk assessment of novel proteins. Opinion of a joint initiative of COST action ImpARAS and COST action INFOGEST

The current allergenicity assessment of novel proteins is based on the EFSA GMO guidance. Recently, EFSA launched a new guidance document on allergenicity assessment of GM plants (2017). This document describes, amongst other topics, the new scientific and regulatory developments on in vitro protein digestibility tests. The EFSA GMO Panel stated that for in vitro protein digestibility tests, additional investigations are needed before any additional recommendation in the form of guidance can be provided. To this end, an interim phase is considered necessary to evaluate the revisions to the in vitro gastrointestinal digestion test, proposed by EFSA. This prompted the establishment of a joint workshop through two COST Action networks: COST Action ImpARAS and COST Action INFOGEST. In 2017, a workshop was organised to discuss the relevance of digestion in allergenicity risk assessment and how to potentially improve the current methods and readouts. The outcome of the workshop is that there is no rationale for a clear readout that is predictive for allergenicity and we suggest to omit the digestion test from the allergenicity assessment strategy for now, and put an effort into filling the knowledge gaps as summarized in this paper first.

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