Defining the targets for the assessment of IgE-mediated allergenicity of new or modified food proteins - DTU Orbit (11/08/2019)

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Many food innovations rely on the introduction and use of new or modified proteins. New or modified food proteins may lead to major health risks due to their inherent potential to cause food allergy. Currently, the pre-market allergenicity assessment for new or modified food proteins and protein sources relies on methods for identifying allergenic hazards based on characteristics of known allergens. However, there is no general consensus on the allergenicity parameters to use and the criteria that should apply for the evaluation and decisions to be made. In this paper, we propose that the strategy for allergenicity risk assessment of new or modified food proteins and the methodologies applied should be governed by the risk management questions to be answered, reflected in the information needed by risk managers to enable their informed decision making. We generated an inventory of health outcome-related assessment parameters and criteria potentially important for risk management decision-making and we discuss the implications of selecting different optional criteria (e.g. cut-off values) for what could be accepted as safe with regards to the health outcomes in the (at risk) population. The impact of these various options on both method development and risk management practices was investigated.

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