

Ad hoc meeting with Industry _16 Nov 2022



Protein safety assessment

GMO Unit

Trusted science for safe food

Regulation 503 requirements

❖ **Toxicity assessment of NEPs:**

- Case by case approach. Depending on knowledge on protein's source, function or activity and history of human or animal consumption
- If history of safe consumption is duly documented, specific toxicity studies not needed
- Where specific testing is required, the applicant shall provide
 - Molecular and biochemical characterisation of the NEP
 - Bioinformatics searching for homology to proteins known to cause adverse effects
 - Stability of the protein, e.g. influences of temperature, pH
 - Degradation of the NEP to proteolytic enzymes (pepsin test)
 - 28 day toxicity study, depending on the outcome additional targeted investigation may be needed

❖ **Allergenicity assessment of NEPs:**

- Case by case approach. The approach shall include:
 - Bioinformatics searching for homology with know allergens
 - Specific serum screening, cases where there is a sequence homology or structure similarity and where the source of the gene is considered allergenic
 - Pepsin resistance and *in vitro* digestibility tests
 - Additional studies, if needed

Where are these principles coming from?

GUIDELINES FOR PREDICTION

Codex Alimentarius 2003-2009

EFSA GMO Panel (2011, 2017)



Foods derived from modern biotechnology

Second edition

SCIENTIFIC OPINION

Guidance for risk assessment of food and feed from genetically modified plants¹

EFSA Panel on Genetically Modified Organisms (GMO)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

This document provides updated guidance for the risk assessment of food and feed containing, consisting or produced from genetically modified (GM) plants, submitted within the framework of Regulation (EC) No 1829/2003 on GM food and feed. The risk assessment strategy for GM plants and derived food and feed proposed seeks to deploy appropriate approaches to compare GM plants and derived food and feed with their respective comparators. The underlying assumption of this

SCIENTIFIC OPINION

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Guidance on allergenicity assessment of genetically modified plants

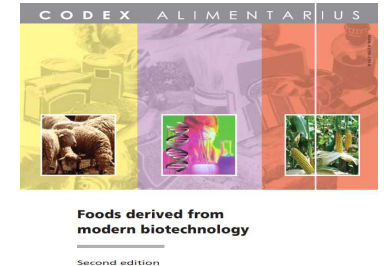
EFSA Panel on Genetically Modified Organisms (GMO), Hanspeter Naegeli, Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Elsa Ebbesen Nielsen, Fabien Nogue, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal, Philippe Eigenmann, Michelle Epstein, Karin Hoffmann-Sommergruber, Frits Koning, Martinus Lovik, Clare Mills, Francisco Javier Moreno, Henk van Loveren, Regina Selb and Antonio Fernandez Dumont

Abstract

This document provides supplementary guidance on specific topics for the allergenicity risk assessment of genetically modified plants. In particular, it supplements general recommendations outlined in previous EFSA GMO Panel guidelines and Implementing Regulation (EU) No 503/2013. The topics addressed are non-IgE-mediated adverse immune reactions to foods, *in vitro* protein digestibility tests and endogenous allergenicity. New scientific and regulatory developments regarding these three topics

Challenges in the assessment:

- Complexity in the testing of some proteins
- When there is a large number of individual proteins to test
 - The need to minimize use of animals
- Proteins with hits to allergens and toxins (very low % of similarity to allergens/toxins and/or of dubious relevance)
-



Ongoing developmental projects on the topic:

- Protein toxicity prediction

<https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8841>
<https://etendering.ted.europa.eu/cft/cft-display.html?cftId=10487>

- Protein allergenicity prediction

<https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8829>

- HLA-DQ peptide modelling software

<https://etendering.ted.europa.eu/cft/cft-display.html?cftId=4505>

- AOP-celiac disease

<https://www.efsa.europa.eu/en/call/outsourcing-external-report-preparatory-work-development-adverse-outcome-pathways-relevant>

■ Allergenicity doc

SCIENTIFIC OPINION



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Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology

EFSA Panel on Genetically Modified Organisms (GMO),
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Fabien Nogué, Nils Rostoks, Jose Juan Sánchez Serrano, Giovanni Savoini, Eve Veromann,
Fabio Veronesi, Antonio Fernandez Dumont and Francisco Javier Moreno

Abstract

This Scientific Opinion addresses the formulation of specific development needs, including research requirements for allergenicity assessment and protein safety, in general, which is urgently needed in a world that demands more sustainable food systems. Current allergenicity risk assessment strategies are based on the principles and guidelines of the Codex Alimentarius for the safety assessment of foods derived from 'modern' biotechnology initially published in 2003. The core approach for the safety assessment is based on a 'weight-of-evidence' approach because no single piece of information or experimental method provides sufficient evidence to predict allergenicity. Although the Codex Alimentarius and EFSA guidance documents successfully addressed allergenicity assessments of single/

■ Synthetic bio doc

SCIENTIFIC OPINION



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Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of genetically modified plants obtained through synthetic biology

EFSA Panel on Genetically Modified Organisms (GMO),
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Michelle M Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko,
Francisco Javier Moreno, Fabien Nogue, Nils Rostoks, Jose Juan Sanchez Serrano,
Giovanni Savoini, Eve Veromann, Fabio Veronesi, Josep Casacuberta, Matias D Zurbriggen,
Antonio Fernandez, Jose Angel Gomez Ruiz, Andrea Gennaro, Nikoletta Papadopoulou,
Anna Lanzoni and Hanspeter Naegeli

Abstract

Synthetic biology (SynBio) is an interdisciplinary field at the interface of molecular engineering and biology aiming to develop new biological systems and impart new functions to living cells, tissues and organisms. EFSA has been asked by the European Commission to evaluate SynBio developments in agri-food with the aim of identifying the adequacy and sufficiency of existing guidelines for risk assessment and determine if updated guidance is needed. In this context, the GMO Panel has previously adopted an Opinion evaluating the SynBio developments in agri-food/feed and the adequacy and sufficiency of existing guidelines for the molecular characterisation and environmental risk assessment of genetically modified plants (GMPs) obtained through SynBio and reaching the market in the next decade. Complementing the above, in this Opinion, the GMO Panel evaluated the adequacy

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