



Abstract

## Assessment of Protein Quality in Novel Foods by the European Food Safety Authority: Methodology and Challenges †

Reinhard Ackerl <sup>1,\*</sup>, Vânia Mendes <sup>1</sup>, Andrea Germini <sup>1</sup>, Harry J. McArdle <sup>2</sup>, Monika Neuhäuser- Berthold <sup>3</sup>, Ruth Roldán-Torres <sup>1</sup> and Ermolaos Ververis <sup>1,4</sup>

- European Food Safety Authority (EFSA), 43126 Parma, Italy; vania.mendes@ext.efsa.europa.eu (V.M.); ruth.roldan@efsa.europa.eu (R.R.-T.); ermolaos.ververis@efsa.europa.eu (E.V.)
- <sup>2</sup> Rowett Research Institute, University of Aberdeen, Aberdeen AB24 3FX, UK; h.mcardle@abdn.ac.uk
- Department of Nutritional Science, Justus Liebig University, 35392 Giessen, Germany; monika.neuhaeuser-berthold@ernaehrung.uni-giessen.de
- School of Medicine, National and Kapodistrian University of Athens, 34400 Psachna, Greece
- \* Correspondence: reinhard.ackerl@efsa.europa.eu
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Abstract: Background: An increasing number of novel protein sources have been developed in recent years, seeking approval to access the European Union (EU) food market. Consequently, the protein quality of these foods and food ingredients could become more relevant to the nutritional status and health of the EU population. Objectives: To provide an overview of the protein quality of novel foods assessed by EFSA and to identify the potential for further advancements of the methodological approach followed during the safety assessment. Methods: A search was carried out using the EFSA library portal to identify all the EFSA scientific opinions published under the EU regulatory frameworks for novel foods (NF) (Regulation (EC) 258/97; Regulation (EU) 2015/2283). Outputs addressing novel foods having 5 g of protein/100 g of NF for solids and 2.5 g/100 mL for liquids (FAO, 2013) or more were included in the study. Data extraction comprised information on the identity of the NF, protein content, digestibility, and anticipated protein intake. Results: Since 2004, 45 EFSA scientific opinions on the safety of novel proteins and their sources have been published [2004–2013: 9 and 2014-2023: 36]. The products comprised whole foods with substantial protein content, protein concentrates, and protein hydrolysates, with 45% being plant-derived, 29% animal-derived, and 11% of fungal origin. The intended uses were mainly as ingredients in foods (67%) and/or food supplements (56%). A high variability was noted regarding the approaches followed by applicants to assess protein quality. An increasing trend for the use of the Digestible Indispensable Amino Acid Score (DIAAS) was noted. The major challenges identified in the protein quality assessment of novel sources were related to the use of appropriate nitrogen-to-protein conversion factors for each NF, the robustness and validity of digestibility assessment methods, and its approach. Discussion: These findings indicate that there may be an opportunity to harmonize further the principles and methodologies used in NFs protein quality assessment within the EU food regulatory environment. This will allow accommodating recent trends in human protein nutrition whilst ensuring foods entering the EU market will not be nutritionally disadvantageous for consumers.

Keywords: novel foods; alternative proteins; protein quality; protein digestibility



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