

Allergenicity Assessment of new proteins - Discussion Paper

Committee Paper for Discussion - ACNFP/171/06

Advisory Committee For Novel Foods and Processes

Next Steps for Allergenicity Assessment of new proteins following the Allergenicity workshop in February 2024

Issue

A workshop on the allergenicity of new foods was held in February 2024 to explore the state-of-the-art knowledge on the assessment of allergenicity. Following this work, the Committee is asked to explore how this knowledge can apply to the assessment of applications for market authorisations it considers, in particular novel foods. Specifically, what information or advice could be provided to applicants to support the robust and timely assessment of the allergenicity of the foods subject to review for market authorisations.

Background

1. Under the novel food regulation, there are an increasing number of applications for foods to be used as a source of protein. These range from cell cultivated products from mammalian cells, new plant proteins, microbial proteins, and extracts of foods for their protein content. With an increased interest in the consumption of non-animal-based diets for environmental and health reasons, it is appropriate to consider further whether new considerations or approaches should be taken into account in the review of this aspect of novel food dossiers.
2. At present there is no consensus internationally on the assessment of allergenicity. The focus traditionally, in both the UK and the EU, has been on the potential for cross reactivity with existing food allergens. However, the review for potential new allergens has not been possible.

3. The workshop in February 2024 brought together experts in food allergy and allergenicity with a range of backgrounds and expertise to explore the current knowledge. The focus was agreed to be the assessment of the potential for allergenicity and clinically relevant IgE mediated food allergic reactions from exposure to new food sources. The report of the discussions is provided in Annex A. This outlines the key points raised in the discussion. It will be published on the ACNFP website once finalised.

4. In summary, participants had recommendations in four areas.

- The first was on the bioinformatic analysis and literature data how this could be improved to provide more meaningful data for assessment.
- Linked to the work of the WHO expert consultation, whether further safety assessment is always needed when considering the level of protein present in the novel food.
- Making better use of digestion studies for nutrition and allergenicity assessment, and;
- Making use of other sources of evidence to support the assessment such as clinical data or data from other species.

5. The key message was the need for a tiered assessment with clear triggers for when further information is needed. The objective was to support applicants in developing their data packages to produce information that was informative and useful for the novel food under review. This informed development of a decision tree Annex B to support applicants and assessors in navigating the allergenicity assessment.

6. We note that since the workshop, there have been a number of publications in this space and are keen to ensure any ongoing work takes account of the developments in the interim.

7. Using the views shared at the workshop as a basis, this paper seeks to explore with members three key areas:

- The objective for further work in this space – specifically if the focus should be supporting applicants to improve the quality of the allergenicity sections of the dossier?
- Is the decision tree a good basis for supporting the assessment and is there any additional information to be added or information to be removed?
- How can this paper and other resources that are now available on allergenicity be used to advice applicants on how to navigate the

assessment process?

8. To facilitate discussion on these points members are asked to review the decision tree to support applicants navigate the allergenicity assessment, that was developed from the discussion at the workshop Annex B.

Committee Actions Required

- The Committee are asked to review the output of the allergenicity workshop and note the recommendations identified.
- Comment on the draft decision tree developed based on the discussion.
- Discuss whether there are additional resources that have become available in the last year that could inform the development of this section of the dossier by applicants and support the ACNFP review.
- Comment on the next steps for this work and how it can be used to support applicants in providing information in the allergenicity that is tailored and relevant to the nature of the novel food seeking authorisation.

ACNFP Secretariat

April 2024

Annexes

Annex A – Draft Report of the Allergenicity workshop held in February 2024.

Annex B – Draft flow chart for structuring information and assessment of the potential for allergenicity of new foods based on the discussion at the allergenicity workshop.