Meeting

Risk Assessment of Food Allergenicity Round Table Discussion

COMMITTEE PAPER FOR DISCUSSION ACNFP/163/05

ADIVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

RISK ASSESSMENT OF FOOD ALLERGENICITY ROUND TABLE DISCUSSION

Issue

The Committee is asked to consider the proposed structure for a workshop of experts to consider and further develop the approached to the assessment of allergenicity for new proteins.

The feedback on the proposal will be used to refine the agenda for a 1-day round table discussion to take place in February 2024.

Background

Purpose

Recently, the FSA has received a number of novel food applications based on protein products and the expectation is that this trend will continue in future. The ACNFP previously highlighted the need to consider the issue of the potential allergenicity to consumers from these types of novel food.

At the 153rd ACNFP meeting, the Committee discussed wider issues surrounding the allergenicity assessment process and the move towards alternative proteins as novel foods. Allergenicity risk assessment was considered an area of high importance by ACNFP. The work of the Science Council on the topic of Net Zero

indicated the potential for innovation of novel protein sources and recent dossiers reviewed the ACNFP have highlighted that further research is needed, along with the potential for revised guidance based on this evolving science.

The further guidance that could be provided to the applicant was considered in depth by Committee members. The ACNFP indicated that the need for the FSA to provide improved and consistent guidance on the assessment of the allergenicity of new proteins and develop a clearer framework for review was a high priority.

State of play

The 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 EFSA Panel of Genetically Modified Organisms (GMO Panel) first published the “Risk assessment of genetically modified plants and derived food and feed” in 2006. This guidance has been periodically updated in response to scientific and technological developments in this field.

In 2017, a Working Group from the EFSA GMO Panel was tasked with developing supplementary guidance for the allergenicity assessment of genetically modified (GM) plants. The resulting publication addressed three main topics:

1. non IgE-mediated adverse immune reactions to food (celiac disease)
2. *in vitro* protein digestibility tests
3. endogenous allergenicity

The GMO Panel reviewed the scientific and regulatory developments in each of these areas and then considered how these approaches could be implemented into the risk assessment of GM plants. Recommendations were made to supplement the previous guidance documents for points (i) and (iii). In the case of *in vitro* protein digestibility tests, the GMO Panel indicated that further research was needed before additional guidance could be provided.

In 2021, the GMO Panel updated its advice from their 2017 publication concerning *in vitro* protein digestibility tests in allergenicity and protein safety assessments. The Panel concluded that there was a need for more reliable systems to predict the fate of the proteins in the gastrointestinal (GI) tract, further work was needed to fully understand the complexity of digestion and absorption of dietary protein, and develop approaches so that this information can be integrated into a weight-

of-evidence approach.

In June 2021, EFSA organised an Allergenicity Risk Assessment event to support the drafting of a Scientific Opinion on the current gaps and future development needs for allergenicity and protein safety assessment. This meeting considered issues relating to IgE cross-reactivity and *de novo* sensitisation prediction, which were not addressed by the GMO Panel in 2017.

Based on the prior experience gained by risk assessors, and new developments in the field, there was a recognition that certain key aspects of food allergenicity assessment needed to be updated. These were identified as:

1. better standardisation on the use of the available knowledge on the source of the gene and the protein itself – context of clinical relevance, route of exposure and potential threshold values of food allergens;
2. modernisation of *in silico* tools used with more targeted databases;
3. better integration of *in vitro* testing, with clear guidance on how protein stability and digestion inform the assessment and on the use of human sera;
4. better clarity on the use of the overall weight-of-evidence approach for protein safety and the aspects needed for expert judgement.

In 2023, the FAO/WHO published their reports on the risk assessment of food allergens. Part 1 reviewed and validated the Codex Alimentarius priority allergen list through risk assessment, and Part 2 reviewed and established threshold levels in foods for the priority allergens.

Part 1 included a review of the criteria for exempting foods that are on the priority allergen list from labelling. The following considerations were identified:

1. is the level of protein likely to cause a reaction (above threshold value)?
2. is the type of protein likely to cause a reaction (not all protein in food may be allergenic)?
3. does the production process reduce the allergenicity of the food?
4. is their an absence of a clinical/biological reactivity in affected individuals?
5. is the food derivative well-characterised and specified?

Proposal for workshop

Currently, the Committee is using the principles of the EFSA Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 as the basis for allergenicity risk

assessment. These guidelines incorporate the key principles from the allergenicity risk assessment of GMO products used as food or feed. This guidance recognises that “food allergens are mostly protein” and the basis for allergenicity assessment is “the default assumption for novel foods containing proteins is that they have allergenic potential.”

This proposed workshop would be an expert elicitation session to identify and refine the allergenicity risk assessment process used by the Committee, so that consumers, clinicians and regulators can be confident that the outcome is appropriate and proportionate. The recommendations should also be able define the data requirements from industry more clearly.

The proposed meeting would comprise of invited guests with a range of expertise associated with food allergenicity. A provisional date for this 1-day round table discussion in February 2024. The outcome would be guidance for applicants in the form of statement drafted after the workshop and agreed with participants. Opportunity would be given for the ACNFP to input and comment to ensure it would support the Committees work.

To inform the further refinement of the Agenda for the workshop, the Committee is asked to consider the current approach for assessing the potential allergenicity of novel foods. This will be an informal review of the relevant recommendations in the Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.

Members are asked to provide feedback around key areas or questions that will be used to refine the meeting agenda. This agenda will then be presented to a panel of experts for further discussion at a future round table discussion.

Committee Action Required

● The Committee is asked to comment on the approach described in this paper and provide comments on the proposed agenda

● Members are asked to identify further candidates with the appropriate expertise who could be invited for the workshop in February 2024.

● The Committee is asked to review the recommended steps in the food allergenicity risk assessment process as described in the EFSA guidance and identify key questions that could be presented to a workshop on food allergenicity issues for further discussion.

ACNFP Secretariat

November 2023