Meeting

Review of the updated EFSA Novel Food Guidance (2024) - Discussion Paper

Committee Paper for Discussion - ACNFP/175/02

Advisory Committee For Novel Foods and Processes

Review of the updated EFSA Novel Food Guidance (2024)

Issue

The Advisory Committee on Novel Foods and Processes (ACNFP) and the Food Standards Agency (FSA) / Food Standards Scotland (FSS) use technical guidance developed by the European Food Safety Authority (EFSA) in 2016 to support the risk assessment of full novel food applications in Great Britain (GB).

In 2024, EFSA published an updated version of the novel food guidance, with some significant differences to the 2016 version. The Committee is asked to review the 2024 version and advise whether the updated guidance is appropriate to provide the basis for assessment of GB novel food applications.

Background

1. Full novel food (‘Article 10’) applications submitted to the FSA are evaluated in line with the requirements laid out in assimilated Regulation (EU) 2015/2283 and technical guidance previously developed by EFSA in 2016 and retained by the FSA/FSS when the UK left the EU. The ACNFP advise the FSA on the safety assessment of full novel food applications within this assessment framework.

2. While the UK is not planning to produce its own guidance in the short term, it recognises that the nature of the novel foods under review have evolved since the original EFSA guidance was produced in 2016. To address this, the FSA has

published several supplementary technical guidance documents, including recent guidance for cell-cultivated product (CCP) applications. However, in light of the new EFSA guidance in 2024, it is appropriate to consider whether a move to the new guidance to underpin the assessment of full novel foods in GB is needed.

3. The technical guidance was updated by EFSA in 2021 as part of the practical implementation of the new provisions introduced by the General Food Law (Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain). These changes were not relevant to GB applications. The administrative parts of the guidance were updated but the scientific part of the guidance remained unchanged from the 2016 version.

4. The guidance was further updated in 2024 to reflect the change in the scientific understanding and advances in technology since it was first published, alongside EFSA's experience of assessing novel foods. The updated guidance includes additional information regarding novel foods derived from new sources, such as cell culture-derived products, or foods derived from new production methods, such as precision fermentation.

5. There are important changes to the type and quality of the scientific information required to demonstrate that a novel food is safe under the proposed conditions of use. Some significant changes included in the updated version of the EFSA guidance are:

- Removal of administrative guidance to applicants, as this is now covered in a separate guidance document (not relevant to GB applications). The 2024 version focuses on the scientific and technical requirements only.
- Reference to new and updated cross-cutting EFSA documents, such as the 2021 'Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles'.
- Reference to other new and updated documents, including several OECD test guidelines which have been updated since the guidance was first published.
- Reference to new and updated EFSA tools, such as the new Dietary Exposure (DietEx) tool for exposure assessment.
- Significant changes to the identity requirements for different classes of novel foods, and changes to the sub-sections/classes of novel foods.
- A clearer description of the tiered testing strategies to be used for ADME, genotoxicity and repeated dose toxicity, and the triggers that may cause

escalation to a higher tier. Flowcharts are used to illustrate the tiered approaches and the inter-relationships between the three.
- A new, tiered approach for assessing allergenicity.
- Further emphasis on the need to minimise animal testing. Applicants are required to perform a comprehensive literature search prior to conducting any studies with animals, and validated methods based on new-approach methodologies are encouraged.
- Emphasis on integrating and interpreting data from different sections to provide overall considerations on the safety of the novel food.

6. Using the EFSA updated novel food guidance document (Annex B) as a basis, this paper seeks to explore with members four key areas:

- Do members agree with the scientific principles underpinning the updated guidance?
- Are there any aspects of the guidance that are not relevant or appropriate to GB applications? Conversely, are there aspects of the risk assessment for GB applications that the guidance doesn't adequately address?
- Do members have any concerns that the guidance references a number of cross-cutting EFSA guidance documents that haven't been formally reviewed by ACNFP?
- Would it be appropriate to use the updated guidance to assess the risk of novel foods for the GB population?

7. To facilitate discussion on these points, a breakdown of the key changes by each section of the scientific part of the guidance has been provided in Annex A. Where members have comments on specific sections (such as identity, allergenicity, etc.), they are kindly requested to leave written comments in the appropriate section of Annex A.

Committee Action Required

- The Committee is asked to review the 2024 EFSA novel food guidance (Annex B), noting the key changes outlined in Annex A.
- The Committee is asked to advise whether the EFSA 2024 guidance is appropriate for assessing GB applications and should be incorporated into the current FSA assessment framework.

Secretariat

Annexes

Annex A – Overview of changes to the 2024 EFSA novel food guidance

Annex B – EFSA NDA Panel, 2024. Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.

Annex C – EFSA NDA Panel, 2016. Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.