ACNFP/142/01

COMMITTEE PAPER FOR DISCUSSION

# ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

# ASSESSMENT OF THE GUIDANCE FOR GENETICALLY MODIFIED FOOD/FEED APPLICATIONS

## Issue

As previously highlighted to the Committee, handling of genetically modified (GM) food/feed applications will be subject to the nature of the future relationship with the EU. However, it is anticipated that the UK and therefore the Committee would have a role in assessing applications for authorisation of GM food and feed to be marketed in the UK.

In light of future UK GM food and feed authorisations, this item is to seek the Committee's input on scientific technical guidance for UK applicants. This meeting provides an opportunity to discuss and explore the European Food Safety Authority (EFSA) guidance documents clarifying to EU applicants the scientific data requirements they must meet when submitting their scientific dossier for assessment.

## Background

1. Currently, applications submitted for GM food and feed for use within the EU are risk assessed by EFSA under Regulation (EC) 1829/2003. This includes genetically modified plants, animals and microorganisms.

2. As part of EU Exit preparations, the relevant EU legislation has been transposed and amended to operate effectively in UK law. This will be available in UK law from day 1 (1 January 2021). This retains the current legal requirements for GM foods including the requirements on applications. The legislation stipulates that the risk assessment and evidence gathering aspects previously undertaken by EFSA are to be undertaken by the FSA, risk management previously undertaken by the Commission to be undertaken by the FSA, whilst responsibility for the final decision on authorisations will sit with Ministers.

3. Assessment of GM food and feed applications has not been requested of the ACNFP committee since 2003, therefore the Secretariat are working with the Committee to develop future working practices to ensure robust risk assessments are produced post EU Exit.

4. Successful authorisations for food/feed containing GM organisms must meet the following criteria:

    - it does not have adverse effects on human health, animal health or the environment;
    - it does not mislead the consumer;
    - it does not differ from the food/feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer/animals/humans.

5. To support applicants, EFSA have produced both administrative and scientific guidance documents on areas including application format, general risk assessment, allergenicity, literature searches, sequencing data, agronomic and phenotypic data and post market monitoring. They are intended to provide a common format for applications to follow so that they fulfil the legal requirements of Regulation (EC) No 1829/2003 and Regulation (EU) No 503/2013 (Annex A).

6. At the 135th ACNFP meeting in November 2018, the Committee agreed to continue to use the EFSA guidance as long as it remains relevant to the UK situation. To support the Committee's consideration of the information needed for risk assessments, the Secretariat have compiled the current EFSA guidance in Annex B. These will be examined over a series of ACNFP meetings as detailed in Annex C to identify areas which require amendment to conform to the UK system.

7. At the 126th ACNFP meeting in 2016 the Committee assessed the draft Guidance Document on Allergenicity Assessment of GM Plants as part of an EFSA public consultation.

8. To support the Committee in assessing the guidance the Secretariat have provided the technical scientific dossier of an authorised GM food/feed. This is provided in Annex D and contains commercially sensitive information.

9. Furthermore, the Secretariat has collated the EFSA guidance summaries into a single document (Annex E) to provide the Committee with an overview of each of guidance documents to be discussed.

## Committee Action Required

The Committee is asked to consider the questions outlined below, with respect to each of the guidance documents within Annexes F to L. A summary is provided in Annex E.

- Does the guidance document meet the minimum needs of the Committee and provide a suitable basis for the Committee to review and assess dossiers within the UK system?
- Do the Committee consider the relevant information is included and that the technical information is provided at the right level of detail?
- Are there sections of the guidance that the Committee feel would need changing to support a UK risk assessment in light of scientific advancements?

Additionally, the Committee are asked to examine the ACNFP comments submitted to EFSA during public consultation on the draft Guidance Document on Allergenicity Assessment of GM Plants (Annex M) and answer the question below.

- Do the Committee consider that the comments made are still in line with current Committee views?

Secretariat
June 2020

## **Annexes attached**:

**Annex A:** Commission Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed

**Annex B:** Summary of EFSA Administrative and Scientific Guidance

**Annex C:** ACNFP GM strategic plan (Reserved Business).

**Annex D:** Authorised GMO food and feed application dossier (Reserved business).

**Annex E:** EFSA GM guidance summaries

**Annex F:** EFSA Scientific Opinion. Guidance on the agronomic and phenotypic characterisation of genetically modified plants.

**Annex G:** EFSA Technical Report. Explanatory note on the determination of newly expressed protein levels in the context of genetically modified plant applications for EU market authorisation.

**Annex H:** EFSA Technical Report. Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials.

**Annex I:** EFSA Technical Report. Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms.

**Annex J:** EFSA Statement. Human dietary exposure assessment to newly expressed proteins in GM foods.

**Annex K:** EFSA Scientific Opinion. Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed.

**Annex L:** EFSA Scientific Opinion. Guidance on allergenicity assessment of genetically modified plants.

**Annex M:** ACNFP public consultation response to EFSA on draft Guidance on allergenicity assessment of genetically modified plants (Reserved Business).