COMMITTEE PAPER FOR DISCUSSION **ACNFP/142/04**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

ASSESSMENT OF THE GUIDANCE FOR APPLICATIONS FOR NOVEL FOODS AND NOTIFICATIONS FOR TRADITONAL FOODS FOR THIRD COUNTRIES (Reserved Business)

Issue

1. Since the 1st of January 2018, when regulation (EU) 2015/2283 came into full effect, the ACNFP Committee has been handling the safety assessment of notifications for Traditional Novel Foods for Third Countries and has not been completing the safety assessment for Applications for Novel Food Assessments.

2. Due to EU-Exit, the ACNFP Committee will have a future role in completing the safety assessments for Novel Food Applications and continue completing the safety assessment for Notifications of Traditional from third countries. However, these processes will form part of the UK's legal and regulatory frameworks. For this, 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, which is the 1st January 2021.

3. Since the 1st January 2018, The ACNFP Committee has five new members, a new secretariat team, a new administrative team and new team leader. The secretariat, therefore considered that it would be useful for the Committee to review the requirements for assessments of full applications under the Novel Foods Regulations.

4. Members are, therefore, asked to review the legislation, technical guidance and implementing acts. The secretariat would appreciate the committee's views and input on the legislation and technical guidance for applications for novel foods and notifications for traditional foods for third countries

5. Committee members are asked to consider the sections of the guidelines provided in **annexes A to G** to: reach a common understanding of the Committee's role in delivering the risk analysis process; raise points of clarification; and; comment on the approach suggested in relation to the standard reporting framework for risk assessments.

Background

1. On the 1st of January 2018, regulation (EU) 2015/2283 came into full effect in the EU. Under this regulation, all authorisations for novel food applications became generic applications as opposed to the applicant specific. Further to this, this regulation means that novel food application safety assessment became centralised at the European level. This means that the safety evaluation of novel foods has been carried out by the European Food Safety Authority (EFSA). The European Commission consults EFSA on the applications and bases its authorisation decisions on the outcome of the EFSA's evaluation. If appropriate, within 9-months, EFSA may submit to the commission, duly reasoned safety concerns to the European Commission on the Novel Food applications.

2. Since the 1st of January 2018, regulation (EU) 2015/2283 introduced a simplified process to facilitate the assessment of notifications for traditional foods from third countries. This process has streamlined data requirements and focuses on whether the safety assessment can be established based on evidence of a history of consumption in the third country, and there are no safety concerns raised. In the safety assessment of traditional foods from third countries, the European Commission forwards the valid notification to the EU countries and to EFSA. Within four months, member states or EFSA may consider the notification to submit to the commission duly reasoned safety concerns on the notification.

3. As the assessment of full Novel Food applications has not been requested of the ACNFP committee since 2018, the Secretariat are working with the Committee to develop future working practices to ensure robust risk assessments are produced post EU Exit.

4. Assessment of Traditional food applications has been requested of the ACNFP committee since 2018, the Secretariat are working with the Committee to ensure that future working practices are robust post EU Exit.

5. To support applicants in producing applications and notifications, EFSA have developed scientific and technical guidance for the preparation and presentation of applications for authorisation of Novel Foods and authorisations for traditional foods from Third countries. These guidance documents present a common format for the organisation of the information in order to assist an applicant in the preparation of a well structure application, and outlines the data need to carry the safety assessment, so that they fulfil the legal requirements of Regulation (EC) No 2015/2283.

Novel Food and Traditional Novel Food legislation

6. Regulation (EU) 2015/2283 provides the legal basis for the safety assessment of novel foods. For novel foods, it defines and establishes:
    a. The placing of novel foods on the market within the union
    b. Provides the legal definition of a novel food and its associate categories
    c. Procedure for determination of novel food status
    d. The Implementing power concerning the definition of novel foods
    e. Union list of authorised novel foods,
    f. General conditions for inclusion of novel foods in the Union list
    g. Procedure for authorising the placing on the market within the Union of a novel food and updating the Union list
    h. Opinion of the Authority
    i. Authorisation of a novel food and updates of the Union list
    j. Implementing acts laying down administrative and scientific requirements for applications
7. Regulation (EU) 2015/2283 provides the legal basis for the safety assessment of Traditional Novel Foods from Third Countries. For novel foods, it defines and establishes:
    a. Procedures for notifying the placing on the market within the Union of a traditional food from a third country
    b. Application for the authorisation of a traditional food from a third country
    c. Opinion of the Authority on a traditional food from a third country
    d. Authorisation of a traditional food from a third country and updates of the Union list
    e. Updates to the Union list as regards authorised traditional foods from third countries
    f. Implementing acts laying down administrative and scientific requirements concerning traditional foods from third countries

Novel Food and Traditional Novel Food Implementing Acts

9. Implementing acts are legally binding acts that enable the Commission, under the supervision of committees consisting of EU countries' representatives, to set conditions that ensure that EU laws are applied uniformly. For Novel and traditional foods, the implementing acts include:

    a. Commission Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

    b. Commission Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283

    c. Commission Implementing Regulation (EU) 2017/2470 on establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods (see also chapter 3.3)

    d. Commission implementing acts that update the union list of Novel Foods. E.g. Commission Implementing Regulation IEU) 2020/24

Novel Food and Traditional Novel Food Guidance's

10. To assist applicants in preparing applications, EFSA has produced two guidance documents that provide scientific and technical guidance for submitting Novel Food Applications and Traditional Foods from Third Country notifications.

11. Guidance on the preparation and presentation of an application of a novel food in the context of Regulation (EU) 2015/2283

    a. This guidance includes; identify of the food; production process; compositional data; specifications; history of use; proposed uses and levels of anticipated intake; adsorption, distribution, metabolism and excretion; nutritional information, toxicological information; and conclusions

12. Guidance on the preparation and presentation of an application of a traditional food from third countries in the context of Regulation (EU) 2015/2283

    a. This guidance includes, identify of the food, production process, compositional data, specifications, data from experience of continuous use, other data, proposed use in the EU market and conclusions

Committee Action Required

13. The Committee is asked to consider the questions outlined below, with respect to legislation, implementing acts and guidance contained within **annex's B-G.**

14. The FSA requests that the Committee focuses on reviewing the guidance for applicability for future ACNFP assessment, as they are of greatest direct relevance to the Committee's work.

15. It should also be noted that the union list of novel foods has been added. This is to show members what the list looks like, but this document itself does not need to be fully reviewed, simply looking at one or two examples will suffice.

16. The FSA ask the Committee to consider annex's **B to G** and answer the following questions:

    a. Does the guidance document meet the needs of the Committee and provide a suitable basis for the Committee to review and assess dossiers within the UK system?

    b. Do the Committee consider that relevant information is included and that the technical information is provided at the right level of detail?

    c. Are there sections of the guidance that the Committee feel would need changing to support a UK risk assessment considering scientific advancements? What could we improve going forwards?

    d. What does the Committee consider demonstrates a history of safe use, and what are the boundaries for this and what evidence would need to be supplied to convince the Committee of a history of safe use?

    e. What would the Committee see as a circumstance for allowing a product through with post-market monitoring? What outstanding concerns would they have, and how would they revisit this in the future?

    f. What is the Committees understanding of being nutritionally disadvantageous?

Annexes

Annex A – Committee Paper for Discussion

Annex B – Summary of FSA work plan and Summary flow chart

Annex C – Regulation (EU) 2015/2283

Annex D – Novel Food Application Guidance

Annex E - Traditional Food Application Guidance

Annex F – Union List of Novel Foods

Annex G– Committee implementing regulation for administrating Novel Foods on the union list

Annex H – Committee implementing regulation for administrating traditional Foods on the union list

Annex I – Committee implement regulation for union list update (Ribose Cl)

Secretariat

June 2020