

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES**ISSUE**

With the introduction of the new assessment processes under 2015/2283 EU for the first time the Committee is considering notification dossiers for traditional foods from third countries. This provides an opportunity to explore with the Committee the approach to assessing these dossiers as part of the role for Member States to raise safety objections where safety concerns are identified.

Background

In the Novel Food Regulation (2015/2283) EU a simplified process is provided for novel foods that have 25 years continuous use in the customary diet of a significant number of people in at least one country outside the EU. The process for these foods is summarised in the diagram in Annex A.

This process was intended to address concerns raised by third countries that the novel food regulation was acting as a barrier to trade in traditional foods that had long been consumed by humans. The approach for the notification system is intended to strike a balance between gaining from the experience of third countries use of these foods and recognising that traditional foods will need some assessment under the novel food regulation to take account of the different diet and food behaviours seen in the EU.

Member States along with EFSA have a role in reviewing the notifications under the traditional food process. Within a four-month period Member States and EFSA can make reasoned safety objections through the Commission's electronic portal which would trigger further assessment of the novel food before it could be marketed.

For the first 3 months Member States are encouraged to raise concerns for discussion. However, there is not an opportunity in the system as outlined in the basic regulation for applicants to provide further information. Objections in the form of a description of the foods and a summary of the safety objections identified can be submitted at any time within the 4-month period. It will be important to be as clear as possible where objections are raised, to allow applicants to respond to these in their traditional foods dossier that would be subject to EFSA evaluation.

EU requirements

The requirements for notifications are detailed in the basic regulation (2015/2283) and an implementing act for traditional foods application (2017/2468) provided in Annex B. To support applicants EFSA have produced guidance on the information to

be provided this is provided in Annex C. This is intended to provide a common format for notifications for applicants to follow.

As for all novel foods, successful notifications must meet the criteria for authorised novel foods i.e. that they are safe, not misleading and if replacing another food that they are not nutritionally disadvantageous.

The requirements for the notification broadly relate to the following categories of information:

- Administrative data
- Characterisation of the food
- Information about the safe use of the food in the third country; and
- The risk management measures proposed including any labelling.

The guidance suggests the type of food i.e. chemical, microorganism, isolated from a plant, isolated from an animal or isolated from cell and tissue culture, will inform the information needed to establish the novel food is safe.

Assessment

The FSA is intending to utilise the expertise of the ACNFP to assist in identifying any issues with traditional food notifications that may need to be raised as reasoned safety objections. This is a new process for all Member States and EFSA. The EFSA guidance provides some insight into the common information that all notification dossiers will need to provide. This provides insight into the elements that will be considered by EFSA in assessing these foods, however we feel it is important to discuss with the Committee the approach in the UK.

The Secretariat has identified the following questions to discuss with the Committee.

- How far can a risk based assessment be taken in this context when there may be limited data and a 4-month period for assessment?
- Given the range of traditional foods, what are the key aspects that need to be considered for these types of foods to ensure their safety for an EU population?
 - Perhaps consider how the assessment might need to be different for baobab fruit, cascara and a kombucha like product that had not been used previously in the EU.
- How does the “History of safe use” contribute to understanding the risks posed by the traditional food?
- To what extent does the history of safe use address deficiencies in composition data for complex products that are difficult to characterise such as whole foods?
- To what extent can an estimate of the potential intake of these foods help in assessing the safety of these foods

- How can the potential for new risks for a food that only emerge in a new population be taken into account in assessing these foods – e.g. allergenicity.

Openness

As part of the discussion of how this process will be considered by the ACNFP the Secretariat is seeking the view on the Committee on the issue of transparency of the Committee's work.

The information on the traditional foods notifications are considered confidential and are subject to limitations on what can be shared as outlined in the basic regulation and the implementing acts. Under new regulations on data protection personal information this type of information cannot be shared. Sharing information on notifications on request would continue to be subject to the relevant information access laws in the Member State e.g. the Freedom of Information Act in the UK.

The Commission is publishing non-confidential summaries of the notifications to make public the applications under consideration. While objections from Member States will be shared with the applicant, there has been no suggestion of making these public. This is similar to the approach to assessments made by other Member States which were subject to a 60-day consultation process under the previous regulation (258/97 EC).

Considerations of EFSA are normally open in the form of publication of their opinions. While they have not stated their approach for traditional food notifications, it is possible that they and some Member States may put their objections in the public domain for transparency.

The Secretariat proposed to continue to summarise the discussion of the Committee on traditional food dossiers in minutes that would be publicly available and would continue to put the papers of the Committee on the ACNFP website. The intention remains to maintain the principles of openness that the Committee has applied in the past, while protecting the information necessary for the assessment that is commercially sensitive. To inform the Agency's approach on this issue the views of members are sought.

COMMITTEE ACTION REQUIRED

- The Committee is asked to consider the questions raised and how this influences how the assessment process is conducted in the UK.
- Members are asked to share their views on maintaining the principle of openness in the ACNFP's work in the context of the Committee's and the Agency's obligations under data management law.

**Secretariat
April 2018**

Annexes attached:

- Annex A** **Summary diagram of the traditional food process.**
- Annex B** **Implementing act outlining requirements for notifications and applications under the traditional foods authorisation process.**
- Annex C** **EFSA guidance for applicants on preparing a traditional food dossier**