## **Novel Food Assessments**

#### What is a Novel Food?

A Novel Food is defined as food that had not been consumed to a significant degree by humans in the UK before 15 May 1997, as defined by UK legislation. Such foods are subject to a pre-market safety assessment before a decision is made on UK-wide authorisation.

# Placing your product on the market in Great Britain

The FSA and Food Standards Scotland (FSS) will use our <u>risk analysis process</u> to assess the safety of novel foods and provide advice to ministers, who will decide whether the product can be placed on the market in England, Wales and Scotland. When a decision is made to authorise a product, this will mean a change to the legislation. The legislation will set out how the product can be used and any associated conditions of use.

In assessing the safety of novel foods, the FSA and FSS shall, where appropriate, consider the following:

- Whether the novel food concerned is as safe as food from a comparable food category already existing on the market within the UK;
- Whether the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the UK;
- A novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

#### **Authorisation process**

Our risk assessment will be carried out in accordance with the requirements of retained EU law and the guidance previously developed by the European Food Safety Authority (EFSA). For more details on what you'll need to supply with your application for a novel food or novel process application, <u>read our guidance for</u> regulated product applicants.

After you submit your application, the FSA will carry out initial checks to make sure it contains all the necessary information. The ACNFP will then carry out an assessment to decide if the product or process is safe to be placed on the market in England, Wales and Scotland. We may request advice from other experts or Committees to help us with our assessment.

Based on this evidence, The FSA will consider possible risk management options and make a recommendation to ministers. The ministers will then decide whether the product should be authorised for use in Great Britain. There will be an opportunity to comment on the application by taking part in a consultation during the risk analysis process and before the final recommendation is made. If a decision is taken to support an authorisation, the legislation will be updated to reflect the change.

The timing of the full risk analysis process will depend on how complex the application is and on the type of product. It is likely to be at least a year. For novel foods the deadlines are set in legislation.

Throughout the process, the FSA will keep in touch to clarify any elements of the application or to seek additional information if needed. If more information is needed to complete the evaluation, the FSA will be able 'stop the clock' on an assessment and start it again once they receive the required information.

## **The Application Process**

#### Before you start

Read the FSA <u>advice on the authorisation process</u>, including what types of products need to be approved, and the guidance on the application requirements.

You will need to apply using the Regulated Product Application Service

If you have any questions on the process or the requirements, you can contact us at regulatedproducts@food.gov.uk.

Questions for the ACNFP can be sent to the Secretariat at acnfp@food.gov.uk

## **Historic Full Applications**

For a full list of all full applications submitted to the UK before the 1st January 2018 please refer to the archived ACNFP Novel Food Assessment page.

The listed applications will either have a status of Authorised, Rejected, Withdrawn or Passed to the European Commission under regulation 2015/2283.

Please note that historic archived content may not meet current accessibility standards.

## **Northern Ireland**

The EU law that applies to Northern Ireland after the transition period is specified in Annex II to the <u>Northern Ireland Protocol</u>. This means that if you're seeking an authorisation for an extraction solvent to be placed on the Northern Ireland market you will have to continue to follow EU rules and its <u>authorisation</u> procedures.