# Questions and Answers: New Novel Food Regulation

Brussels, 3 January 2018

The new Novel Food Regulation (EU) 2015/2283 entered into force on 1 January 2018. It aims to improve the conditions, so that businesses can bring new and innovative food to the EU market more easily, while still maintaining a high level of food safety for European consumers. The regulation offers European consumers the benefit of a broader choice of food and a more favourable environment for Europe's agri-food industry – the second largest employment sector in Europe – to benefit from innovation, which is good for growth and jobs.

**What is novel food?**

Novel food is defined as food that has not been consumed to any significant degree in the EU before 15 May 1997 (when the first novel food legislation entered into force). This can be newly developed, innovative food or food produced using new technologies and production processes, as well as food traditionally eaten outside of the EU. This definition has not changed with the new Novel Food Regulation.

**What are the main changes?**

The new Novel Food Regulation defines ten separate categories of novel foods (Article 3).

The authorisation procedure is more efficient and safe, innovative food can be delivered to market more quickly and without unnecessary trade barriers, whilst ensuring a high level of food safety.

The new regulation creates a **centralised authorisation system,** giving the applicants greater certainty, simplicity and speed during the authorisation process.

The **European Food Safety Authority (EFSA)** will conduct a scientific risk assessment for the novel food application, while the Commission will manage the files of each applicant and put forward a proposal for the authorisation of a novel food which is found to be safe.

The new Novel Food Regulation also introduces a **more appropriate assessment procedure for traditional foods coming to the EU from third countries**. If the traditional food in question can be demonstrated as being historically safe and there are no safety concerns raised by EU Member States or EFSA, that traditional food will be allowed to be placed on the market on the basis of a notification by the food business operator. An e-submission system has been developed to facilitate the on-line submission of novel foods applications and/or traditional foods notifications.

The regulation also includes **data protection provisions,** which guarantee that newly developed scientific evidence and proprietary data cannot be used for the benefit of another application for 5 years after the novel food has been authorised. Data protection is not applicable to notifications or applications to place traditional foods in the European Union market.

**Are insects covered by the new Novel Food Regulation?**

Yes, in the EU, insects fall within the definition of novel food as food ingredients isolated from animals. Parts of insects (such as legs, wings, head, etc.), as well as whole animals, fall within this definition.

The new Regulation clarifies that also whole animals had not been consumed to a significant degree by humans in the EU prior to 15 May 1997 (cut-off date of the Regulation), they also fall under the definition of novel food.

**How are nanomaterials defined in the new Novel Food regulation?**

The definition of nanomaterials in the novel food regulation concerns intentionally produced ('engineered') nanomaterials with one or more dimensions of 100 nm or composed of distinct parts which may have dimensions of 100 nm or less. The definition also includes engineered nanomaterials with structures, aggregates, and agglomerates which may have dimensions over 100 nm, but which retain nanoscale characteristics such as large specific surface area and specific physic-chemical properties. The novel food regulation calls for the revision of the definition of engineered nanomaterials on the basis of new scientific evidence and knowledge and/or internationally agreed definition. The current revision of the definition of engineered nanomaterials is on-going.

**Who holds the primary responsibility for determining the novel food status of a food?**

Economic operators are responsible for determining whether or not the food they intend to place on the European Union market is novel. In case of doubt, they should check the status of their food in the Member State in which they plan to place the food on the market first.

**What happened to the existing authorised novel foods in the EU?**

Under the current novel food regulation, although specific authorisations and the conditions of use of a food remain valid, they are no longer applicant-specific, but become generic following their inclusion in the Union list. This means that any economic operator can place authorised novel foods on the European Union market.

**What is the European Union list of novel foods?**

This is a positive list containing all authorised novel foods which can be placed on the European Union market under the new Regulation.

**What is the difference between an application for the authorisation of a novel food and a notification for the authorisation of a traditional food from a third country?**

In terms of submission and processing the two are similar as the new Regulation requires the applicant to submit an application for a novel food or a notification for a traditional food to the Commission via the on line e-submission portal. They differ extensively in the data and information requirements establishing the safety of the novel or of the traditional food. The application for the authorisation of a novel food must contain extensive safety data and (toxicological) studies supporting the safety of the novel food. The notification of a traditional

food puts weight and emphasis on establishing the safety of the traditional food on the history of consumption of the traditional food in a third country.

**What are the conditions for authorisation?**

Novel food will only be authorised for use in the EU if it does not present a risk to public health, is not nutritionally disadvantageous when replacing a similar food and does not misleading to the consumer. It must undergo a **scientific assessment prior to authorisation to ensure its safety**. The authorisation sets out the conditions for its use, its designation as a food, specific labelling requirements (where appropriate) and post-market monitoring requirements (where appropriate).

**What happens to novel foods applications that have not been finalised by 1 January 2018?**

Those applications, which have not finalised by the time the new Novel Food Regulation came into force, will be treated as applications under the new Regulation. This Commission will take care of the finalisation of those requests.

**What about confidentiality in the new novel food regulation?**

Article 23 of the novel food Regulation sets out the conditions and requirements for applicants requesting confidential treatment of certain information submitted with applications for authorisation. As with data protection, the Commission must assess and decide on each request and inform the applicant and Member State. Some information (name of applicants, novel food, conditions of use, summaries of studies, analysis methods, etc.) cannot be claimed as confidential and in case of disagreement with the Commission's position on their request; applicants may choose to withdraw their application.

**Will the new Novel Food Regulation affect innovation in the food sector?**

The new Novel Food Regulation aims to help innovators and economic operator develop and put on the European Union market new food while maintaining a high level of consumer safety. Moreover, the data protection provisions will help to protect the interests of companies which produce new, innovative products, and should help to encourage innovation in the food sector, help create new job and growth opportunities, and strengthen the competitiveness of the European Union food industry.