Unigrains – In Brief
Regulation (EU) 2015/2283 on novel foods

New Regulation (EU) 2015/2283 on the introduction of novel foods on the European market comes into force on 1st January 2018. It will replace Regulation (EC) 258/1997, also known as the '*Novel Food* Regulation', the purpose of which is to guarantee a balance between industrial innovation and consumer protection, particularly in health and nutritional terms, by regulating the introduction of foods on the European market.

What is a 'novel food'?

The term *novel food* applies to '**food that has not been consumed to a significant degree by humans in the EU prior to 15 May 1997**'.

The novel aspect may lie in the product itself (e.g. a new plant species, such as chia seeds) or in the manufacturing process (e.g. UV pasteurisation). 'Novel food' status is determined by food sector operators, who may consult the Member States for an opinion. In practice, there are very few consultations of this type, because the process requires a publication (at least indicating the name of the company and the subject of their application), which is seen as impeding industrial secrecy.

Why introduce a new regulation?

The current regulation includes a presumption of harmfulness, which is a major constraint to innovation: a novel food can only be introduced onto the European market once its safety has been established.

The current authorisation procedures are national: each member state handles the applications it receives, even though the resulting marketing authorisation applies to the entire Union.

The cumbersome procedures, their cost and the lengthy processing time (**an average five years**) resulted in a low number of applications: approximately **250 for the entire Union since 1997, or seven to ten applications per year.** Around half, i.e. **125 novel foods and ingredients, have been authorised**.

The European regulation has thus been undergoing reform since 2008, and this new regulation is the outcome of lengthy discussions in the European institutions.

What are the main changes?

The new regulation mainly concerns the following points:

- Extension of the notion of 'novel food' to cover the development of new technologies -> **More foods will now be concerned by an authorisation procedure.**
- A streamlining of the procedure -> **Authorisation applications will now be less expensive and faster (about 18 months).**
- A standardised authorisation procedure sent to the Commission and no longer to the Member States -> **Applications from all EU countries will be processed in the same way.**
- Generic authorisations resulting in a **positive list of permitted *novel foods*** -> In theory, if an authorisation is granted to one company for a certain food, it may also be adopted by another company. However, in practice, the right of use is very often exclusive and restricted to specific conditions.

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In November 2016, the EFSA (European Food Safety Agency) published the guidelines for companies looking to market novel foods.

Traditional foods from third countries

'Exotic' foods traditionally consumed in third countries benefit from a simplified procedure, with a **straightforward notification to the EFSA**. However, companies wishing to introduce these foods to the European market must demonstrate that the foods have been consumed in at least one third country for at least 25 years as a part of the customary diet of a significant number of people.

Authorisation and data protection

Companies that submit *novel food* authorisation applications may request data protection, especially with regard to scientific data (manufacturing process, results of studies proving product safety), on condition that the data is proprietary and it is substantive for the evaluation and authorisation process.
Data protection is granted for **five years** as from the date on which the novel food is approved.

Unigrains' opinion

Technology makes it possible to create innovative foods, but the impact of these foods on our health remains unknown. Generally speaking, the introduction of new products on food markets always incurs some degree of risk. Food law is the outcome of the health crises of the 1990s and is designed to guarantee public health in a context of constant innovation.
In the harsh economic climate of the late 2000s, innovation became a key factor in differentiating the food offering. The new Novel Food Regulation modernises European food law by simplifying and streamlining the authorisation procedure that governs the marketing of new foods.

It should boost food innovation while stimulating research and encouraging assessments of the impact of new foods on our health, an area in which we still have much to learn.

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