



The new and improved EU rules on novel foods

An overview of Regulation (EU) 2015/2283

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A Leatherhead Food
Research white paper

Number 62

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January 2018 saw the introduction of new measures to centralise and streamline the process by which EU manufacturers apply to use novel foods. One of our Senior Regulatory Consultants, Annie-Laure Robin, spotlights the changes.

Updates to the European Union (EU) legislation¹ on novel foods have rationalised the assessment process and increased the number of categories from four to ten. The changes reflect scientific and technical developments across the global food industry since the legislation was first introduced in 1997.

Revised novel food definition

As with the previous novel food EU legislation², any foods³ which have no significant history of consumption in the EU before 15 May 1997 are considered novel and must undergo a rigorous pre-market safety assessment. Now, the definition of 'novel' also includes traditional foods, whole insects and engineered nanomaterials.

Traditional foods

Foods with more than 25 years of safe consumption outside the EU now benefit from a simpler authorisation procedure. Examples

include haskap berries and fonio seeds, traditionally eaten in Japan and West Africa respectively. Food business operators providing evidence of historic consumption can access the EU market within five months under the new notification procedure.

Edible whole insects

Regulations for consumption of insects are fragmented across the EU. Some member states allow it, whereas others consider whole insects as novel. The new legislation clarifies the situation⁴.

In the UK, whole insects were not previously considered novel. So, the Food Standards Agency has requested data demonstrating history of consumption for any insects being supplied in the UK⁵.

Engineered nanomaterials

Food produced using new technologies is clearly defined as novel under the new rules. This includes explicit reference to engineered

¹ Regulation (EU) 2015/2283 of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Official Journal of the European Union (OJ), L 327, 11.12.2015, p 1-22).

² Regulation (EC) No 258/97 of 27 January 1997 concerning novel foods and novel food ingredients (OJ, L 43, 14.2.1997, p 1, as amended).

³ As defined in Article 2 of Regulation (EC) 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031, 1.2.2002, p 1, as amended).

⁴ See recital 8 of Regulation (EU) 2015/2283 '*should cover whole insect and their parts*'.

⁵ See at <https://www.food.gov.uk/news-updates/news/2015/14264/edible-insects>.

nanomaterials, which involves the manipulation of food particles to deliver benefits such as improved nutritional content or fat reduction.

The novel food definition of 'engineered nanomaterials' mirrors that of the EU 'food information to consumer' Regulation⁶ for labelling. Interestingly, the definition has not been updated in light of the 2011 Commission Recommendation⁷ on this matter. It suggested that a material would not be classified as containing nanomaterials if 50% or fewer of its particles were sized between 1 to 100nm. Although where environment, health, safety or competitiveness concerns exist, this threshold could be reduced to between 1 and 50%.

Simpler, more centralised process

There are no changes in the demands for scientific data in novel food dossiers under the new rules. However, requirements are now clearer, as outlined in European Food Safety Authority (EFSA) guidance⁸ and supported by Implemented Acts^{9,10}.

A Union list of authorised novel foods has also been published. This makes it easier to research which foods were authorised under the previous or current novel food regime, as

well as any conditions of use and specifications¹¹.

All authorisation of novel food is non-applicant specific, including items on the Union list. So, under the new rules there is no exclusivity on novel food authorisation, unless a company applies for five year data protection of newly developed scientific evidence and proprietary data¹².

Two new authorisation procedures

A two-tier process has been introduced to differentiate new novel foods from those that have a safe history of consumption outside the EU:

1. **General procedure** – applications are now submitted direct to the EU Commission via an e-portal rather than via member states. The expectation is that the authorisation process should take 18-24 months, a great improvement on the previous 2.5 to three year timeframe.
2. **Notification procedure** – this applies to traditional foods only and the process can be completed in as little as five months if no safety concerns are raised. This simplified procedure should enable better access to the EU market for third country foods.

⁶ See Article 2(2)(t) of Regulation (EU) No.1169/2011 of 25 October 2011 on the provision of food information to consumers (OJ, L 304, 22.11.2011, p 18, as amended).

⁷ Commission Recommendation of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p 38-40).

⁸ EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.

⁹ Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 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 (OJ, L 351, 30.12.2017, p 64-71).

¹⁰ Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ, L 351, 30.12.2017, p 55-63).

¹¹ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 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 (OJ, L 351, 30.12.2017, p. 72-201)

¹² See Article 26 of Regulation (EU) 2015/2283.

Transitional measures

Some foods sold in parts of the EU before January 2018 – such as whole insects – are now classified as novel. They can be still marketed until 2020, and a novel food application can be submitted in the interim.

Conclusion

The new EU regulation on novel foods represents a significant evolution from the previous regime. Numerous important changes have resulted in benefits such as:

- More clarity over what constitutes a novel food
- Quicker and simpler pre-market assessment procedures, especially for third country traditional foods, reducing trade barriers
- No application fees (the previous model involving national authorities could incur administrative fees)
- Better efficiency – a single risk assessment is carried centrally by EFSA, replacing the previous two-stage process involving national authorities and EFSA.

As with any new regime, it will take some time for the full impact to be felt by food business operators. It will be interesting to see if the revised procedures deliver on their promises. The stage could be set for a surge in new novel foods over the coming years.

How Leatherhead can help

If you need to check the status of an ingredient would be considered novel in the EU, and need support on getting an official view, contact our regulatory team who would be happy to help provide information and support: legislation@leatherheadfood.com.

About the author

Annie-Laure is a Senior Regulatory Consultant at Leatherhead. She has a MSc in food science from the University of Reading and has 15 years' EU food regulatory experience in government, the food supplement industry and consultancy services. This includes seven years working at the UK Food Standards Agency (food labelling, food authenticity, novel food/food supplements) immediately prior to joining Leatherhead in 2007. In her role as Senior Regulatory Consultant, Annie-Laure provides regulatory advice and training on French and EU food law to Leatherhead's broad membership, mentors a team of experts covering the European territories and contributes to the management of the department. Annie-Laure has an in-depth knowledge on labelling, novel foods and food additives, amongst many other food law subjects.

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Leatherhead Food Research provides expertise and support to the global food and drinks sector with practical solutions that cover all stages of a product's life cycle from consumer insight, ingredient innovation and sensory testing to food safety consultancy and global regulatory advice. Leatherhead operates a membership programme which represents a who's who of the global food and drinks industry. Supporting all members and clients, large or small, Leatherhead provides consultancy and advice, as well as training, market news, published reports and bespoke projects. Alongside member support and project work, our world-renowned experts deliver cutting-edge research in areas that drive long-term commercial benefit for the food and drinks industry. Leatherhead Food Research is a trading name of Leatherhead Research Ltd, a Science Group (AIM:SAG) company.

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