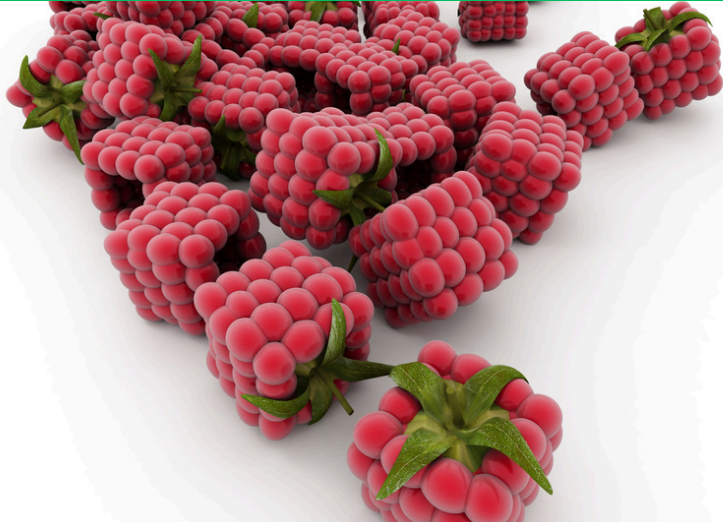


NewsLetter



What about GB novel foods authorisations?

Whilst the EFSA guidance is only applicable to applications for novel foods to be placed on the market in the EU and Northern Ireland, the Food Standards Agency has previously urged applicants who wish to place such products on the GB market to follow the parts of the EFSA guidance that relate to the development of dossiers only and not the application process.

The “Regulated Products” section of the Food Standards Agency website currently directs novel food authorisation applicants to the 2021 EFSA guidance. At the time of writing it is not clear whether the FSA will adopt the new guidance and so applicants are advised to seek clarification from the FSA regarding the format of dossiers submitted on or after the 1st February.

What are the main changes to the guidance?

Amendments to the dossier requirements for full Novel Foods applications include those relating to:

- Cell cultures
- Production process
- Analytical methods and sampling practices
- Composition
- Stability testing
- Impact of processing
- Specifications
- Proposed use and use levels
- Estimate of exposure to substances of safety concern
- Absorption, distribution, metabolism and excretion
- Specific considerations for new nutrient sources
- Tiered approach to conducting toxicological studies
- Repeated-dose toxicological studies
- Nutritional information
- Allergenicity

More Information

- [Novel and Traditional Food applications and notifications](#)

New EFSA Novel Food Authorisation Guidance

The European Food Safety Authority (EFSA) has revised its “Administrative guidance for the preparation of novel food applications...” for full applications and those relating to traditional foods from third countries. This updates the 2021 version of the guidance.

The new guidance comes into effect from 1st February 2025 and all new applications for relevant authorisation made to EFSA should use the new guidance from this date.

The new EFSA guidance has been produced to bring the Novel Foods application processes in line with the duties for transparency introduced by [Regulation \(EU\) 2019/1381](#) “the Transparency Regulation”.

However, in addition to changes in the application process, the guidance also amends and updates the scientific dossier requirements for novel food applications.

Relevant ABC Food Law resources:

Webinars:

- [Novel Foods](#)