

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 (Text with EEA relevance)

*Article 5*

**Scientific data requirements**

1 The dossier submitted in support of an application for the authorisation of a novel food shall enable a comprehensive risk assessment of the novel food.

2 Where the application for the authorisation of a novel food involves the use of engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283, the applicant shall provide detection and characterisation test methods in compliance with the requirements of Article 10(4) of that Regulation.

3 The applicant shall provide a copy of the documentation on the procedure and strategy followed when gathering the data.

4 The applicant shall provide a description of the safety evaluation strategy and the corresponding toxicological testing strategy and shall justify the inclusion or exclusion of specific studies or information.

5 The applicant shall provide on request the raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, to support their application. This information includes data used to generate the conclusions of the individual studies and results of examinations.

6 Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups.

7 For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration.

Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC or, if they are carried out outside the territory of the Union, they shall follow the OECD Principles of Good Laboratory Practice. The applicant shall provide evidence of compliance with those requirements and shall justify any deviation from the standard protocols.

8 The applicant shall propose an overall conclusion on the safety of the proposed uses of the novel food. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

**Status:**

Point in time view as at 20/12/2017. This version of this provision has been superseded.

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2469, Article 5.