

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 1	Scope and subject matter
Article 2	Definitions
Article 3	Structure, content and presentation of an application
Article 4	Administrative data requirements
Article 5	Scientific data requirements
Article 6	Verification of the validity of an application
Article 7	Information to be included in the opinion of the Authority
Article 8	Transitional measures
Article 9	Entry into force and application
	Signature

ANNEX I

Template cover letter accompanying an application for novel food

EUROPEAN COMMISSION
Directorate General
Directorate
Unit
Date: ...
Subject: Application for authorisation of a novel food in accordance...
(Please indicate clearly by ticking one of the boxes)
Application for an authorisation of a new novel food.
Application...
The Applicant(s) or their Representative(s) in the Union
(name(s), address(es)...) ...
...
...
submit(s) this application in order to update the Union list...
Identity of the novel food (information on the identity of...
...
...
Confidentiality. Where appropriate, state whether the application includes confidential data...
Yes No
Data Protection. Where appropriate, state whether the application includes a...
Yes No
Yours sincerely,
Signature ...

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2469. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

Enclosures:

Complete dossier Summary of the dossier List of the parts...

Food categories, conditions of use and labelling requirements

ANNEX II

Justification for confidential information

This Annex shall be updated during the application procedure each...

Where the production process contains confidential data, a non-confidential summary...

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2469. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- (1) [OJ L 327, 11.12.2015, p. 1.](#)
- (2) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances ([OJ L 50, 20.2.2004, p. 44](#)).
- (3) OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Number 1. OECD Principles on Good Laboratory Practice (as revised in 1997) ENV/MC/CHEM(98)17.

Changes to legislation:

There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2469. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- Annex 1 word omitted by [S.I. 2019/702 reg. 60\(c\)](#)
- Annex 1 word omitted by virtue of S.I. 2019/702, reg. 60(c) (as substituted) by [S.I. 2020/1504 reg. 15\(15\)](#)
- Annex 1 words substituted by [S.I. 2019/702 reg. 60\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 60 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(15))
- Annex 1 words substituted by [S.I. 2019/702 reg. 60\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 60 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(15))
- Annex 1 words substituted by S.I. 2019/702, reg. 60(a) (as substituted) by [S.I. 2020/1504 reg. 15\(15\)](#)
- Annex 1 words substituted by S.I. 2019/702, reg. 60(b) (as substituted) by [S.I. 2020/1504 reg. 15\(15\)](#)
- Art. 3(1) words substituted by [S.I. 2019/702 reg. 53](#)
- Art. 5(7) words omitted by [S.I. 2019/702 reg. 55](#)
- Art. 6 substituted by [S.I. 2019/702 reg. 56](#)
- Art. 7(2) words substituted by [S.I. 2019/702 reg. 57](#)
- Art. 8 substituted by [S.I. 2019/702 reg. 58](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/702 reg. 59](#)
- Art. 4(b) words substituted by [S.I. 2019/702 reg. 54](#)