

Regulation (EU) 2015/2283 of the European Parliament and of the Council 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 (Text with EEA relevance)

CHAPTER V

DATA PROTECTION

Article 28

Authorisation procedure in case of a parallel application for the authorisation of a health claim

- 1 The [^{F1}appropriate authority must], on request by the applicant, stay an authorisation procedure for a novel food started following an application, where the applicant has submitted:
- a a request for data protection in accordance with Article 26; and
 - b an application for the authorisation of a health claim on the same novel food in accordance with Article 15 or 18 of Regulation (EC) No 1924/2006, in conjunction with a request for data protection in accordance with Article 21 of that Regulation.

The stay of the authorisation procedure shall be without prejudice to the assessment of the food by the [^{F2}Food Safety Authority] in accordance with Article 11.

- 2 The [^{F1}appropriate authority must] inform the applicant about the date of effect of the stay.

- 3 While the authorisation procedure is stayed, time shall cease to run for the purposes of the time-limit laid down in Article 12(1).

- 4 The authorisation procedure shall resume when [^{F3}the opinion has been received] on the health claim pursuant to Regulation (EC) No 1924/2006.

The [^{F1}appropriate authority must] inform the applicant about the date of resumption of the authorisation procedure. From the date of resumption, time shall begin to run afresh from the beginning for the purposes of the time-limit laid down in Article 12(1) of this Regulation.

- 5 In the cases referred to in paragraph 1 of this Article, where data protection has been granted in accordance with Article 21 of Regulation (EC) No 1924/2006, the period of data protection granted in accordance with Article 26 of this Regulation shall not exceed the period of data protection granted in accordance with Article 21 of Regulation (EC) No 1924/2006.

- 6 The applicant may withdraw at any time the request for staying the authorisation procedure submitted in accordance with paragraph 1. In that case, the authorisation procedure shall resume and paragraph 5 shall not apply.

Changes to legislation: This version of this Regulation was derived from EUR-Lex on IP completion day (31 December 2020 11:00 p.m.). It has not been amended by the UK since then. Find out more about legislation originating from the EU as published on legislation.gov.uk. (See end of Document for details)

Textual Amendments

- F1** Words in Art. 28 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **34(a)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(10)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F2** Words in Art. 28(1) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **34(b)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(10)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F3** Words in Art. 28(4) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/702), regs. 1, **reg. 34(c)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(10)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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