

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 26

Authorisation procedure in case of data protection

1 On request by the applicant, and where supported by appropriate and verifiable information included in the application provided for in Article 10(1), newly developed scientific evidence or scientific data supporting the application shall not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food without the agreement of the initial applicant.

2 The data protection shall be granted by the Commission under Article 27(1) where the following conditions are met:

- a the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;
- b the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and
- c the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

However, the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used.

3 Paragraphs 1 and 2 shall not apply to notifications and applications concerning the placing on the market within the Union of traditional foods from third countries.

Article 27

Authorisation of a novel food and inclusion in the Union list based on protected proprietary scientific evidence or scientific data

1 Where a novel food is authorised and included in the Union list pursuant to Articles 10 to 12 based on proprietary scientific evidence or scientific data that are granted data protection as provided for in Article 26(1), the entry of that novel food in the Union list shall indicate, in addition to the information referred to in Article 9(3):

- a the date of inclusion of the novel food in the Union list;
- b the fact that that inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26;
- c the name and address of the applicant;

- d the fact that during the period of data protection the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c) of this paragraph, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 or with the agreement of the initial applicant;
- e the end date of the data protection provided for in Article 26.

2 Scientific evidence or scientific data protected in accordance with Article 26 or for which the protection period under that Article has expired shall not be granted renewed protection.

Article 28

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

1 The Commission shall, 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 Authority in accordance with Article 11.

2 The Commission shall 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 the Commission has received the opinion of the Authority on the health claim pursuant to Regulation (EC) No 1924/2006.

The Commission shall 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.