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COMMISSION IMPLEMENTING REGULATION (EU) 2026/1219

of 9 June 2026

authorising the placing on the market of inulin-propionate ester as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 12(1) thereof,

Whereas:

(1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.

(2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ([2]) has established a Union list of novel foods.

(3) On 14 February 2018, Imperial College Hammersmith Campus ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place inulin-propionate ester on the Union market as a novel food. The applicant requested for the novel food to be used in cereal bars and fruit smoothies intended for the general population.

(4) On 14 February 2018, the applicant also made a request to the Commission for the protection of the following proprietary data: batch-to-batch analyses, including quantification of inulin and propionate and in-house analytical methods ([3]), and a human trial study ([4]).

(5) On 16 July 2018, the Commission requested the European Food Safety Authority ('the Authority') to provide a scientific opinion on inulin-propionate ester as a novel food.

(6) On 25 June 2025, the Authority adopted its scientific opinion on the 'Safety of inulin-propionate ester as a novel food pursuant to Regulation (EU) 2015/2283' ([5]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(7) In its scientific opinion, the Authority concluded that that the novel food, inulin-propionate ester, is safe under the proposed conditions of use.

(8) The scientific opinion of the Authority covers the compositional data of the novel food, including chemical and microbiological parameters. However, in the Authority's opinion, these parameters are not reflected in the specifications of the novel food. To ensure the safety of the novel food, it is necessary that the specifications of the novel food include relevant chemical and microbiological parameters.

(9) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the proprietary data concerning batch-to-batch analyses, including quantification of inulin and propionate and in-house analytical methods, without which it could not have assessed the novel food and reached its conclusion.

([1]) OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj.
([2]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).
([3]) Annex A – Batch analyses reports, Annex B – In-house analytical methods, Quantification of Inulin and Propionate (Section 2.c.1.3 of the dossier).
([4]) Section 2.i.6.3 of the dossier.
([5]) *EFSA Journal*, 2025;23:e9534.

(10) The Commission requested the applicant to further clarify the justification provided with regard to its proprietary claim over those data and studies and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2), point (b), of Regulation (EU) 2015/2283.

(11) The applicant declared that they held proprietary and exclusive rights of reference to the relevant studies, at the time they submitted the application, and that third parties cannot lawfully access, use or refer to those data.

(12) The Commission assessed all the information provided by the applicant and considers that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, batch-to-batch analyses, including quantification of inulin and propionate and in-house analytical methods, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place inulin-propionate ester on the market within the Union during a period of five years from the entry into force of this Regulation.

(13) However, such restriction of the authorisation and the reference to the data contained in the applicant's file for their sole use does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.

(14) It is appropriate that the inclusion of inulin-propionate ester as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.

(15) Inulin-propionate ester should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Inulin-propionate ester is authorised to be placed on the market within the Union.

Inulin-propionate ester shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the Imperial College Hammersmith Campus ([6]) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 30 June 2026, unless a subsequent applicant obtains an authorisation for the novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of the Imperial College Hammersmith Campus.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from the date of entry into force of this Regulation without the agreement of the Imperial College Hammersmith Campus.

([6]) DuCane Road, London W12 0NN, United Kingdom.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in *the Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 9 June 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods) the following entry is inserted in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'**Inulin-propionate ester**	*Specified food category*	*Maximum levels*	The designation of the novel food on the labelling of the foodstuffs containing it shall be "inulin-propionate ester".		Authorised on 30 June 2026. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Imperial College Hammersmith Campus, DuCane Road, London W12 0NN, United Kingdom. During the period of data protection, the novel food inulin-propionate ester is authorised for placing on the market within the Union only by Imperial College Hammersmith Campus, 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 of Regulation (EU) 2015/2283 or with the agreement of Imperial College Hammersmith Campus. End date of the data protection: 30 June 2031'
	Cereal bars	17 g/100 g			
	Fruit smoothies	3 g/100 ml			

(2) in Table 2 (Specifications), the following entry is inserted in alphabetical order:

Authorised Novel Food	Specifications
'**Inulin-propionate ester**	**Description/Definition**: The novel food, inulin-propionate ester, is obtained by synthesis from inulin and propionic anhydride. **Physical and chemical properties**: Appearance: white to off-white powder **Composition**: Inulin (% w/w): 65-95 Free propionic acid (% w/w): < 1 Esterified propionate (% w/w): 5-35

Authorised Novel Food	Specifications
	Inulin-propionate ester (% w/w) after hydrolysis: 100-112 Total nitrogen (g/100 g): < 0,1 Total fat (g/100g): < 0,5 Sodium (% w/w): < 0,1 **Chemical parameters**: Arsenic: < 0,1 mg/kg Cadmium: < 0,01 mg/kg Lead: < 0,05 mg/kg Mercury: < 0,05 mg/kg **Microbiological parameters**: Total Aerobic Count: < 1 000 CFU/g *Listeria* spp.: ND/25 g *E. coli*: < 10 CFU/g Enterobacteriaceae: < 10 CFU/g CFU: Colony Forming Units'