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COMMISSION IMPLEMENTING REGULATION (EU) 2026/391

of 23 February 2026

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use and the specific labelling requirements of the novel food pasteurised *Akkermansia muciniphila*

(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 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) Commission Implementing Regulation (EU) 2022/168 ([3]) authorised, in accordance with Regulation (EU) 2015/2283, the placing on the market of pasteurised *Akkermansia muciniphila* as a novel food to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([4]) and in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([5]), intended for the adult population, excluding pregnant and lactating women.

(4) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 therefore includes pasteurised *Akkermansia muciniphila* as an authorised novel food.

(5) On 19 December 2023, the company 'the Akkermansia Company SA' ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the conditions of use for 'pasteurised *Akkermansia muciniphila*'. The applicant initially proposed extending the conditions of use of the novel food to use as an ingredient in a broad range of foods, in food supplements as defined in Directive 2002/46/EC and food for special medical purposes as defined in Regulation (EU) No 609/2013 intended for the general population from 12 to less than 18 years of age, and to pregnant and lactating women. During the risk assessment process, the applicant withdrew the part of the request concerning the use of the novel food as an ingredient in a broad range of foods. The applicant requested for the novel food to be used in food supplements and

([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]) Commission Implementing Regulation (EU) 2022/168 of 8 February 2022 authorising the placing on the market of pasteurised *Akkermansia muciniphila* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 28, 9.2.2022, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2022/168/oj).

([4]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/oj).

([5]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35, ELI: http://data.europa.eu/eli/reg/2013/609/oj).

food for special medical purposes for the general population from 12 to less than 14 years of age at a maximum use level of $2{,}1\times10^{10}$ cells/day. For food supplements and food for special medical purposes intended for the general population from 14 to less than 18 years of age, the applicant proposed a maximum use level of $3{,}0\times10^{10}$ cells/day. For food supplements and food for special medical purposes intended for pregnant and lactating women, the applicant proposed a maximum use level of $3{,}4\times10^{10}$ cells/day. Finally, the applicant requested to amend the existing additional labelling requirements, as the statement indicating that food supplements containing pasteurised *Akkermansia muciniphila* should be consumed by adults only, excluding pregnant and lactating women is no longer appropriate as the level of pasteurised *Akkermansia muciniphila* will be harmonised across all population groups.

(6) Following a request by the Commission, the applicant provided legal documentation demonstrating that the existing authorisation holder 'A-Mansia Biotech S.A' for pasteurised *Akkermansia muciniphila* has changed its name to the applicant's name, the Akkermansia Company SA. It is therefore appropriate to update the name of the authorisation holder in the Annex to Implementing Regulation (EU) 2017/2470.

(7) On 19 December 2023, the applicant submitted to the Commission a request for the protection of proprietary data for the study 'Intake assessment report', which supported the proposed use of the novel food as an ingredient in a broad range of foods, in accordance with Article 26 of Regulation (EU) 2015/2283. During the risk assessment process, the applicant withdrew this request for data protection, as that proposed use was no longer within the scope of the application.

(8) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 12 February 2024, requesting it to provide a scientific opinion on the changes of the conditions of use of 'pasteurised *Akkermansia muciniphila*' as a novel food.

(9) On 27 August 2025, the Authority adopted its scientific opinion on the 'Safety of an extension of use of pasteurised *Akkermansia muciniphila* as a novel food' ([6]) in accordance with Article 11 of Regulation (EU) 2015/2283.

(10) In its scientific opinion, the Authority concluded that the proposed changes are safe for the general population from 12 to less than 18 years of age. However, the Authority also concluded that the safety of the novel food in the case of pregnant and lactating women cannot be established. Therefore, it is appropriate to amend the conditions of use of 'pasteurised *Akkermansia muciniphila*' to include the general population from 12 to less than 18 years of age.

(11) The information provided by the applicant and the Authority's opinion give sufficient grounds to establish that the changes to the conditions of use of 'pasteurised *Akkermansia muciniphila*' are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

(12) It is also appropriate to amend the labelling requirements of the novel food pasteurised *Akkermansia muciniphila*, in line with the changed conditions of use and the findings of the Authority's opinion.

(13) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.

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

([6]) *EFSA Journal* 2025; 23:e9632 (https://doi.org/10.2903/j.efsa.2025.9632).

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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, 23 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470, the entry for '*Akkermansia muciniphila (pasteurised)*' is replaced by the following:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other require-ments	Data Protection
	Specified food category	*Maximum levels*			
'***Akkermansia muciniphila* (pasteurised)**	Foods for special medical purposes as defined under Regulation (EU) No 609/2013, excluding foods for special medical purposes intended for infants, children younger than 12 years of age, pregnant and lactating women	In accordance with the particular nutritional requirements of the persons for whom the products are intended, but no higher than: — $2{,}1 \times 10^{10}$ cells/day for the general population older than 12 years of age, — $3{,}0 \times 10^{10}$ cells/day for the general population older than 14 years of age. — $3{,}4 \times 10^{10}$ cells/day for the adult population	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'pasteurised *Akkermansia muciniphila*'. The labelling of food supplements containing pasteurised *Akkermansia muciniphila* shall bear a statement that those food supplements should not be consumed by: a) pregnant and lactating women; b) by infants and children under 12 years of age / infants, children and adolescents under 14 years of age/ infants, children and adolescents under 18 years of age depending on the age groups the food supplement is intended for.		Authorised on 1 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/ 2283. Applicant: the Akkermansia Company SA., rue Granbonpré, 11, Bâtiment H, 1435 Mont-Saint-Guibert. Belgium. During the period of data protection, the novel food pasteurised Akkermansia muciniphila is authorised for placing on the market within the Union only by the Akkermansia Company SA, 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 the Akkermansia Company SA. End date of the data protection: 1 March 2027.'
	Food supplements as defined in Directive 2002/46/EC, excluding infants and children younger than 12 years of age, pregnant and lactating women	$2{,}1 \times 10^{10}$ cells/day for the general population older than 12 years of age, $3{,}0 \times 10^{10}$ cells/day for the general population older than 14 years of age. $3{,}4 \times 10^{10}$ cells/day for the adult population			

ELI: http://data.europa.eu/eli/reg_impl/2026/391/oj