COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Commission 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 authorised novel foods.

(3) Commission Implementing Regulation (EU) 2022/168[3] authorised 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.

(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 and for a change of the specific labelling requirement for the novel food 'pasteurised *Akkermansia muciniphila*'. The applicant proposed extending the conditions of use of the novel

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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

food in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[4] and food for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[5] intended for the general population from 12 to less than 18 years of age, and in addition to pregnant and lactating women. The applicant requested for the novel food to be used in food supplements and food for special medical purposes for the general population from 12 to less than 14 years of age a maximum use level of $2{,}1\times10^{10}$ cells/day. For food supplements and food for special medical purposes that are 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 that are 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) 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.

(7) 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.

(8) 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 pregnant and lactating women cannot be established. Therefore, it is appropriate to amend the conditions of use of 'pasteurised *Akkermansia muciniphila*' for the general population from 12 to less than 18 years of age.

(9) 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.

(10) It is also appropriate to amend the labelling requirements of the novel food pasteurised *Akkermansia muciniphila*, in line with the proposed conditions of use, as the statement that food supplements containing pasteurised *Akkermansia muciniphila* consumed by adults only, excluding pregnant and lactating women does no longer apply.

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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).

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

(11) The information provided in the application gives sufficient grounds to establish that the changes to the conditions of use and to the specific labelling requirements of the novel food pasteurised *Akkermansia muciniphila* are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.

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

(13) 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

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,

For the Commission
The President
Ursula VON DER LEYEN