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

(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 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]) establishing a Union list of authorised novel foods was adopted.

(3) On 24 October 2019, the company A-Mansia Biotech S.A. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place pasteurised *Akkermansia muciniphila* on the Union market as a novel food. The applicant requested for pasteurised *Akkermansia muciniphila* bacteria to be used as a novel food at levels not exceeding 5×10^{10} cells per day in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ([3]) and in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([4]), intended for the adult population, excluding pregnant and lactating women.

(4) On 24 October 2019, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, a bacterial reverse mutation test ([5]), an *in vitro* mammalian cell micronucleus test ([6]), a 14-day dose ranging oral toxicity study in rats ([7]), a 90-day oral toxicity study in rats ([8]), the published toxicity data ([9]), a flow cytometry validation study ([10]), and an antimicrobial resistance study ([11]).

([1]) OJ L 327, 11.12.2015, p. 1.
([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).
([3]) 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).
([4]) 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).
([5]) Brient, 2019a (unpublished).
([6]) Brient, 2019b (unpublished).
([7]) Bracken, 2019a (unpublished).
([8]) Bracken, 2019b (unpublished).
([9]) Druart C., Plovier H., Van Hul M., Brient A., Phipps K.R., de Vos W.M., and Cani P.D., 2020. Toxicological Safety evaluation of pasteurized *Akkermansia muciniphila*. Journal of Applied Toxicology, 41:276-290.
([10]) Jensen, 2019 (unpublished).
([11]) Gueimonde, 2019 (unpublished).

(5) On 19 May 2020, the Commission requested, in accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Food Safety Authority ('the Authority') to carry out an assessment of pasteurised *Akkermansia muciniphila* as a novel food.

(6) On 7 July 2021, the Authority adopted its scientific opinion on the safety of pasteurised *Akkermansia muciniphila* as a novel food pursuant to Regulation (EU) 2015/2283 ([12]).

(7) In its scientific opinion, the Authority concluded that pasteurised *Akkermansia muciniphila* is safe under the proposed conditions of use for the proposed target populations at levels not exceeding $3{,}4 \times 10^{10}$ cells/day. Therefore, that scientific opinion gives sufficient grounds to establish that pasteurised *Akkermansia muciniphila*, when used at levels not exceeding $3{,}4 \times 10^{10}$ cells/day in food supplements and in foods for special medical purposes intended for the adult population, excluding pregnant and lactating women, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.

(8) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on the data from the bacterial reverse mutation test, the *in vitro* mammalian cell micronucleus test, the 14-day dose ranging oral toxicity study in rats, the 90-day oral toxicity study in rats, the method validation study for the formulation analysis for the 90-day oral toxicity study in rats, and the antimicrobial resistance study.

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

(10) The applicant declared that they held proprietary and exclusive rights of reference to the data from the bacterial reverse mutation test, the *in vitro* mammalian cell micronucleus test, the 14-day dose ranging oral toxicity study in rats, the 90-day oral toxicity study in rats, the published toxicity data, the flow cytometry validation study, and the antimicrobial resistance study at the time they submitted the application and therefore third parties could not lawfully have access to or use those studies.

(11) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the data from the bacterial reverse mutation test, the *in vitro* mammalian cell micronucleus test, the 14-day dose ranging oral toxicity study in rats, the 90-day oral toxicity study in rats, the published toxicity data, the flow cytometry validation study, and the antimicrobial resistance study contained in the applicant's file on which the Authority based its conclusion on the safety of the novel food and without which it could have not assessed the novel food, should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, only the applicant should be authorised to place pasteurised *Akkermansia muciniphila* on the market within the Union during that period.

(12) However, restricting the authorisation of pasteurised *Akkermansia muciniphila* and the reference to the data contained in the applicant's file for the sole use by the applicant does not prevent other 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 authorisation.

(13) The Annex to 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,

([12]) Safety of pasteurised Akkermansia muciniphila as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283; EFSA Journal 2021:19(9):6780.

HAS ADOPTED THIS REGULATION:

Article 1

1. Pasteurised *Akkermansia muciniphila* as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the initial applicant:

company: A-Mansia Biotech S.A.;

address: rue Granbonpré, 11 Bâtiment H 1435 Mont-Saint-Guibert, Belgium,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected pursuant to Article 2 or with the agreement of A-Mansia Biotech S.A.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The scientific data contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of A-Mansia Biotech S.A.

Article 3

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

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, 8 February 2022.

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:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	Specified food category	*Maximum levels*			
'***Akkermansia muciniphila* (pasteurised)**	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 for the adult population, excluding pregnant and lactating women	$3,4 \times 10^{10}$ cells/day	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 they should be consumed by adults only, excluding pregnant and lactating women.		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: A-Mansia Biotech S.A., 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 A-Mansia Biotech S.A., 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 Mansia Biotech S.A.. End date of the data protection: 1 March 2027.'
	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	$3,4 \times 10^{10}$ cells/day			

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

Authorised novel food	Specification
'***Akkermansia muciniphila* (pasteurised)**	**Description:** Pasteurised *Akkermansia muciniphila* (strain ATCC BAA-835, CIP 107961) is produced by anaerobic growth of the bacteria followed by pasteurisation, concentration of the cells, cryopreservation, and freeze drying. **Characteristics/Composition:** Total *A. muciniphila* cell count (cells/g): $2,5 \times 10^{10}$ to $2,5 \times 10^{12}$ Viable *A. muciniphila* cell count (CFU/g): < 10 (LoD)(*) Water activity: ≤ 0,43 Moisture (%): ≤ 12,0 Protein (%): ≤ 35,0 Fat (%): ≤ 4,0 Crude ash (%): ≤ 21,0 Carbohydrates (%): 36,0 – 86,0 **Microbiological criteria:** Aerobic mesophilic total count: ≤ 500 CFU(**)/g Sulphite reducing anaerobes: ≤ 50 CFU/g Coagulase^{+} Staphylococci: ≤ 10 CFU/g Enterobacteriaceae: ≤ 10 CFU/g Yeast: ≤ 10 CFU/g Mould: ≤ 10 CFU/g *Bacillus cereus*: ≤ 100 CFU/g *Listeria* spp.: Absence in 25 g *Salmonella* spp.: Absence in 25 g *Escherichia coli*: Absence in 1 g (*) LoD: Limit of Detection; (**) Colony Forming Units.'