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DRAFT

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

authorising the placing on the market of heat-killed *Mycobacterium setense manresensis* bacteria 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 and Commission Regulation (EC) No 1852/2001¹, 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) 2017/2470² establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.
- (4) On 2 February 2018, the company Laboratorio Reig Jofre, S.A. ('the applicant') made a request to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place heat-killed *Mycobacterium setense manresensis* bacteria on the Union market as a novel food. The application concerns the use of heat-killed *Mycobacterium setense manresensis* bacteria in food supplements as defined in Directive No 2002/46/EC of the European Parliament and of the Council³ intended for the general population above the age of 18 years and excluding pregnant and lactating women. The proposed conditions of use entail the intake of one capsule a day of the food supplement containing up to 1 x 10⁵ heat-killed *Mycobacterium setense manresensis* bacteria for 14 consecutive days, followed by a minimum period of six months during which food supplements containing the heat-killed *Mycobacterium setense manresensis* should not be consumed before another 14 day consumption period is initiated.

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).

- (5) The Applicant also submitted a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, the production process⁴, the batch to batch compositional analysis⁵, the scientific evidence to characterise the product⁶, the bioinformatics study to investigate the potential virulence of *Mycobacterium setense manresensis*⁷, the mice study to investigate the potential virulence of *Mycobacterium setense manresensis*⁸, the study to examine the horizontal antimicrobial resistance gene transfer potential of *Mycobacterium setense manresensis*⁹, the study to investigate the antimicrobial susceptibility of *Mycobacterium setense manresensis*¹⁰, and the double blind, randomised, placebo-controlled clinical trial in humans¹¹.
- (6) On 25 June 2018, the Commission consulted the European Food Safety Authority ('the Authority'), asking it to carry out an assessment of heat-killed *Mycobacterium setense manresensis* as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.
- (7) On 19 September 2019, the Authority adopted its scientific opinion "Safety of heat-killed *Mycobacterium setense manresensis*' as a novel food pursuant to Regulation (EU) 2015/2283"¹². That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (8) In that opinion, the Authority concluded that heat-killed *Mycobacterium setense manresensis* is safe under the proposed conditions of use entailing the intake of one capsule a day of the food supplement containing up to 1×10^5 heat-killed *Mycobacterium setense manresensis* bacteria for 14 consecutive days, followed by a minimum period of six months during which food supplements containing the heat-killed *Mycobacterium setense manresensis* should not be consumed, before another 14 day consumption period is initiated. Therefore the scientific opinion gives sufficient grounds to establish that heat-killed *Mycobacterium setense manresensis*, when used in food supplements intended for the general population above the age of 18 years and excluding pregnant and lactating women, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (9) In its opinion on heat-killed *Mycobacterium setense manresensis*, the Authority considered that the data from the production process, the batch to batch compositional analysis, the scientific evidence to characterise the product, the bioinformatics study to investigate the potential virulence of *Mycobacterium setense manresensis*, the mice study to investigate the potential virulence of *Mycobacterium setense manresensis*¹³, the study to examine the horizontal antimicrobial resistance gene transfer potential of

⁴ Applicant unpublished data

⁵ Manresana de Microbiologia, S.L. 2017 (unpublished)

⁶ Rech G., et al. 2015. Draft genome sequences of *Mycobacterium setense* type strain DSM-45070 and the non-pathogenic strain Manresensis isolated from the bank of the Cardener River in Manresa, Catalonia, Spain. *Genome Announcements*, 3, e01485-14. <https://doi.org/10.1128/genomeA.01485-14>.

⁷ Comas 2016a (unpublished)

⁸ Vilapana, 2014 (unpublished)

⁹ Comas, 2016b (unpublished)

¹⁰ Esteban, 2015 (unpublished)

¹¹ Montané E. et al, 2017. Pilot, double-blind, randomized, placebo-controlled clinical trial of the supplement Nyaditum resae® in adults with or without latent TB infection: safety and immunogenicity. *PLoS ONE*, 12, e0171294. <https://doi.org/10.1371/journal.pone.0171294>.

¹² EFSA Journal 2019;17(6):5718

¹³ Vilapana, 2014 (unpublished)

Mycobacterium setense manresensis, the study to investigate the antimicrobial susceptibility of *Mycobacterium setense manresensis*, served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of heat-killed *Mycobacterium setense manresensis* could not have been reached without the data from the report of these studies.

- (10) Following the receipt of the Authority's opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary data from the production process, the batch to batch compositional analysis, the scientific evidence to characterise the product, the bioinformatics study to investigate the potential virulence of *Mycobacterium setense manresensis*, the mice study to investigate the potential virulence of *Mycobacterium setense manresensis*¹⁴, the study to examine the horizontal antimicrobial resistance gene transfer potential of *Mycobacterium setense manresensis*, the study to investigate the antimicrobial susceptibility of *Mycobacterium setense manresensis*, and to clarify their claim to an exclusive right of reference to these reports and studies, as referred to in Article 26(2) of Regulation (EU) 2015/2283.
- (11) The Applicant declared that, at the time the application was submitted, they held proprietary and exclusive rights of reference to the study under national law and that therefore third parties could not lawfully access or use those studies.
- (12) 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 studies contained in the Applicant's file which served as a basis for the Authority's conclusion establishing the safety of the novel food and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.
- (13) However, restricting the authorisation of heat-killed *Mycobacterium setense manresensis* and of the reference to the studies contained in the Applicant's file for the sole use of 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 lawfully obtained information supporting the authorisation under this Regulation.
- (14) Directive 2002/46/EC lays down requirements on food supplements. The use of heat-killed *Mycobacterium setense manresensis* should be authorised without prejudice to that Directive.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

¹⁴ Vilapana, 2014 (unpublished)

HAS ADOPTED THIS REGULATION:

Article 1

1. Heat-killed *Mycobacterium setense manresensis* 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 Applicant:
Company: Laboratorio Reig Jofre, S.A.;
Address: Gran Capitan, 10, 08970 Sant Joan Despi, Barcelona, Spain
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 the novel food without reference to the data protected pursuant to Article 2 or with the agreement of Laboratorio Reig Jofre, 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 to this Regulation.
4. The authorisation provided for in this Article shall be without prejudice to the provisions of Regulation (EU) No 609/2013 and to the provisions of Directive 2002/46/EC.

Article 2

The studies and reports contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the Applicant as fulfilling the requirements laid down in Article 26(2) of Regulation 2015/2283, 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 Laboratorio Reig Jofre, 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,

For the Commission
The President
Ursula von der LEYEN