

COMMISSION IMPLEMENTING DECISION

of **XXX**

terminating the procedure for authorising the placing on the market of dried biomass powder of *Chlamydomonas reinhardtii* THN 6 (NF-2022-8410) as a novel food without updating the Union list of novel foods

(Only the English text is authentic)

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 1852/2001¹, and in particular Article 10(6) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods ('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 has established the Union list.
- (3) On 28 April 2023, the company Triton Algae Innovations, Ltd. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283, to place dried biomass powder of *Chlamydomonas reinhardtii* THN 6 (NF/2022/8410) on the Union market as a novel food. The applicant requested the dried biomass powder of *Chlamydomonas reinhardtii* THN 6 to be used as an ingredient in a number of foods intended for the general population.
- (4) On 31 July 2023, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of dried biomass powder of *Chlamydomonas reinhardtii* THN 6 as a novel food.

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).

- (5) On 24 March 2025, the Authority adopted its scientific opinion ‘Safety of dried biomass powder of *Chlamydomonas reinhardtii* THN 6 as a novel food pursuant to Regulation (EU) 2015/2283³’ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (6) The Authority identified a number of data gaps, which needed to be addressed by the applicant over the course of the risk assessment period about the identity, the production process, compositional data, specifications, history of use, proposed uses and use levels, nutritional information, genotoxicity and allergenicity of the novel food. Despite being contacted several times, the applicant did not reply to the Authority's requests for additional data. Owing to these deficiencies, the Authority concluded that, based on the available data, the safety of dried biomass powder of *Chlamydomonas reinhardtii* THN 6 cannot be established.
- (7) It follows from the above that, in the absence of sufficient evidence to conclude on the safety of dried biomass powder of *Chlamydomonas reinhardtii* THN 6, the Commission cannot proceed with the update of the Union list. Moreover, the opinion of the Authority does not give sufficient grounds to establish that the novel food at the proposed uses and use levels complies with the requirements of Article 7 of Regulation (EU) 2015/2283.
- (8) Therefore, based on the Authority's opinion, the Commission considers that the authorisation of dried biomass powder of *Chlamydomonas reinhardtii* THN 6 as a novel food as requested by the applicant is not justified and the procedure should be terminated in accordance with Article 10(6) of Regulation (EU) 2015/2283 without the update of the Union list.
- (9) In accordance with Regulation (EU) 2015/2283, the Commission is to inform the applicant, and all the Member States of the reasons provided in this Decision for not considering the update to be justified. The Commission is also to add this application to the list of applications for which the update of the Union list was considered as not justified,

HAS ADOPTED THIS DECISION:

Article 1

The procedure for authorising the placing on the market within the Union of dried biomass powder of *Chlamydomonas reinhardtii* THN 6 (NF/2022/8410) as a novel food is terminated without the update of the Union list.

Article 2

This Decision is addressed to Triton Algae Innovations, Ltd., 11760 Sorrento Valley Road, Suite R San Diego, CA 92121, United States of America.

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This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material

Done at Brussels,

*For the Commission
Olivér VÁRHELYI
Member of the Commission*

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