Commission Implementing Regulation (EU) 2020/1820 of 2 December 2020 authorising the placing on the market of dried Euglena gracilis 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1820

of 2 December 2020

authorising the placing on the market of dried *Euglena gracilis* 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 20 December 2018, the company Kemin Foods L.C. (‘the applicant’) introduced an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place dried whole cell *Euglena gracilis* on the Union market as a novel food. The application requested for dried whole cell *Euglena gracilis* to be used as a novel food in a number of food categories for the general population as follows: breakfast, granola and protein bars; yoghurt; yoghurt beverages; fruit juices, smoothies and nectars, vegetable juices; fruit-flavoured drinks; meal replacement beverages. The applicant also requested for dried whole cell *Euglena gracilis* to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(3)], excluding food supplements for infants, and in total diet replacement for weight control as defined by Regulation (EU) No 609/2013 of the European Parliament and of the Council[(4)], excluding total diet replacement for weight control for infants.

(4) 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, *in vitro* fermentation studies[5], bacterial reverse mutation test[6], *in vivo* micronucleus test[7], acute toxicity study in rats[8], 14-day dietary toxicity/palatability study in rats[9], 90-day dietary toxicity study in rats[10].

(5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 13 May 2019, asking it to provide a scientific opinion by carrying out an assessment for dried *Euglena gracilis* as a novel food.

(6) On 25 March 2020, the Authority adopted the scientific opinion on the "Safety of dried whole cell *Euglena gracilis* as a novel food pursuant to Regulation (EU) 2015/2283"[11]. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.

(7) In that opinion, the Authority concluded that dried *Euglena gracilis* is safe at the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that dried *Euglena gracilis* under the specific conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.

(8) In accordance with Commission Delegated Regulation (EU) 2017/1798[12] total diet replacement for weight control are foods intended for healthy overweight or obese adults who intend to achieve weight reduction. Therefore, dried *Euglena gracilis* may be authorised for use in total diet replacement for weight control only for adults, excluding infants, children and adolescents.

(9) In its opinion, the Authority considered that the data from the 90-day dietary toxicity study in rats served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of dried *Euglena gracilis* could not have been reached without the data from the unpublished report of that study.

(10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the 90-day dietary toxicity study in rats, and to clarify its claim to an exclusive right of reference to that study, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.

(11) The applicant declared that, at the time of the submission of the application, it held proprietary and exclusive right of reference to that study under national law, and that therefore third parties cannot lawfully access or use that study or refer to that data.

(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 90-day dietary toxicity study in rats contained in the applicant's file 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. Accordingly, the placing on the market within the Union of dried *Euglena gracilis* should be restricted to the applicant for that period.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1820. (See end of Document for details)*

(13) However, restricting the authorisation of dried *Euglena gracilis* and of the reference to the study 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 legally obtained information supporting such authorisation under Regulation (EU) 2015/2283.

(14) 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

1 Dried *Euglena gracilis* 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: Kemin Foods L.C.,

— Address: 2100 Maury Street Des Moines, IA 50317, USA,

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 of this Regulation or with the agreement of Kemin Foods L.C.

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.

Article 2

The data 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 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 Kemin Foods L.C.

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, 2 December 2020.

For the Commission

The President

Ursula VON DER LEYEN