Commission Implementing Regulation (EU) 2019/1976 of 25 November 2019 authorising the placing on the market of Phenylcapsaicin 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) 2019/1976

of 25 November 2019

authorising the placing on the market of Phenylcapsaicin 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 1852/2001[(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) 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 7 February 2018, the company aXichem AB ('the applicant') made a request to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place Phenylcapsaicin obtained by chemical synthesis on the Union market as a novel food. The application concerns the use of Phenylcapsaicin in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council[(3)] excluding those intended for infants young children and children under the age of 11 years, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council[(4)] intended for the general population above the age of 11 years.

(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, an *in vivo* absorption, distribution, metabolism, and excretion ('ADME') study with Phenylcapsaicin in rats[5], an *in vivo* ADME study with Capsaicin in rats[6], a bacterial reverse mutation test with Phenylcapsaicin[7], an *in vitro* mammalian cell micronucleus test with Phenylcapsaicin[8], a 90-day oral toxicity study in Wistar rats with Phenylcapsaicin[9], and a TRPV1 activation test using the HEK293 cell line with Phenylcapsaicin and Capsaicin[10].

(6) On 27 August 2018, the Commission consulted the European Food Safety Authority ('the Authority'), asking it to carry out an assessment of Phenylcapsaicin as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283.

(7) On 15 May 2019, the Authority adopted its scientific opinion 'Safety of Phenylcapsaicin as a novel food pursuant to Regulation (EU) 2015/2283'[11]. That scientific opinion is in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283.

(8) In its opinion, the Authority concluded that Phenylcapsaicin is safe under the proposed conditions of use. Therefore the scientific opinion gives sufficient grounds to establish that Phenylcapsaicin, under the proposed uses and uses levels, when used in foods for special medical purposes excluding those intended for infants, young children, and children under the age of 11 years, and when used in food supplements intended for the general population above the age of 11 years, complies with Article 12(1) of Regulation (EU) 2015/2283.

(9) In its opinion on Phenylcapsaicin, the Authority considered that the data from the *in vivo* ADME study with Phenylcapsaicin in rats, the *in vivo* ADME study with Capsaicin in rats, the bacterial reverse mutation test with Phenylcapsaicin, the *in vitro* mammalian cell micronucleus tests with Phenylcapsaicin, the 90-day oral toxicity study in rats with Phenylcapsaicin, and the TRPV1 activation test using the HEK293 cell line with Phenylcapsaicin and Capsaicin served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of Phenylcapsaicin 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 *in vivo* ADME study with Phenylcapsaicin in rats, the *in vivo* ADME study with Capsaicin in rats, the bacterial reverse mutation test with Phenylcapsaicin, the *in vitro* mammalian cell micronucleus tests with Phenylcapsaicin, the 90-day oral toxicity study in rats with Phenylcapsaicin, and the TRPV1 activation test using the HEK293 cell line with Phenylcapsaicin and Capsaicin, 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 the safety of Phenylcapsaicin, 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 Phenylcapsaicin 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 Phenylcapsaicin should be authorised without prejudice to that Directive.

(15) Regulation (EU) No 609/2013 lays down requirements on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The use of Phenylcapsaicin should be authorised without prejudice to that Regulation.

(16) 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 Phenylcapsaicin 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: aXichem AB;

Address: Södergatan 26, SE 211 34, Malmö, Sweden,

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 aXichem AB.

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 (EC) No 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 aXichem AB.

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, 25 November 2019.

For the Commission

The President

Jean-Claude JUNCKER