Commission Implementing Regulation (EU) 2020/917 of 1 July 2020 authorising the placing on the market of infusion from coffee leaves of Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Implementing Regulation (EU) 2017/2470 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/917

of 1 July 2020

authorising the placing on the market of infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending 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 15(4) 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. Traditional food from a third country is a novel food defined in Article 3(2)(c) of Regulation (EU) 2015/2283.

(2) Commission Implementing Regulation (EU) 2017/2468[(2)] lays down administrative and scientific requirements concerning traditional foods from third countries.

(3) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470[(3)] establishing a Union list of authorised novel foods was adopted.

(4) Pursuant to Article 15(4) of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a traditional food from a third country.

(5) On 27 November 2018, the company AM Breweries (‘the applicant’) submitted a notification to the Commission of the intention to place infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner on the Union market as a traditional food from a third country in accordance with Article 14 of Regulation (EU) 2015/2283. The applicant requests for infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* to be used as such or as an ingredient in other beverages by the general population.

(6) Pursuant to Article 7(2) of Implementing Regulation (EU) 2017/2468, the Commission requested additional information from the applicant as regards the validity of the notification. The requested information was submitted on 4 June 2019, 21 June 2019, 29 August 2019 and 30 August 2019.

(7) The data presented by the applicant demonstrate that infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* as such has a history of safe food use in Africa, Asia and North America.

(8) Pursuant to Article 15(1) of Regulation (EU) 2015/2283, on 11 September 2019, the Commission forwarded the valid notification to the Member States and to the European Food Safety Authority ('the Authority').

(9) No duly reasoned safety objections to the placing on the market within the Union of infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* were submitted to the Commission by the Member States or the Authority within the four-months period laid down in Article 15(2) of Regulation (EU) 2015/2283.

(10) On 3 February 2020, the Authority published its 'Technical Report on the notification of infusion from coffee leaves (*Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner) as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283'[(4)].

(11) In that report, the Authority noted that the leaves of *Coffea arabica* contain Epigallocatechin gallate (EGCG) and therefore, the presence of EGCG in the infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* cannot be excluded. On that basis, the Authority established a maximum level of 700 mg of EGCG per litre of the infusion. It is therefore appropriate to establish maximum levels of 700 mg/L of EGCG in the specifications of the traditional food in the Union list of authorised novel foods.

(12) The Authority concluded that the available data on composition and history of use of the infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* do not raise safety concerns.

(13) In addition to the infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* to be used as such, the applicant requested the infusion to be used as an ingredient in other beverages for the general population. The applicant has submitted documented data demonstrating history of safe use in a third country in accordance with Article 14(1)(e) of Regulation (EU) 2015/2283 only for the infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* as such, while no evidence on the use of the infusion as ingredient in other beverages was submitted. The applicant was invited to provide clarification, and possibly revision, of the proposed uses of the infusion, which correspond to the foods in which the infusion is traditionally consumed and for which a history of safe use should have been submitted. However, the applicant did not change the proposed uses and did not provide evidence demonstrating the history of safe food use in a third country of the infusion as ingredient in other beverages. Consequently, in the absence of the required documented data, the Commission is of view that the history of safe food use in a third country has been demonstrated by the

applicant only for the infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* as such. Therefore, the notification for the authorisation of the infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora*, as far as it concerns its use as an ingredient in other beverages, is considered not valid.

(14) The Commission should therefore authorise the placing on the market within the Union of infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* as such and update the Union list of novel foods accordingly.

(15) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

1 The infusion from coffee leaves of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A. Froehner, 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 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 Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

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, 1 July 2020.

For the Commission

The President

Ursula VON DER LEYEN