COMMISSION IMPLEMENTING REGULATION (EU) 2022/47

of 13 January 2022

authorising the placing on the market of Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner dried cherry pulp and its infusion as a traditional food from a third country 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 15(4),

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, a Union list of authorised novel foods was established by Commission Implementing Regulation (EU) 2017/2470 (3).
- (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 6 May 2020, the company Societé de Produits Nestlé SA ('the applicant') submitted a notification to the Commission of their intention to place *Coffea arabica* L. and *Coffea canephora* Pierre ex A.Froehner dried cherry pulp and its infusion on the Union market as a traditional food from a third country in accordance with Article 14 of Regulation (EU) 2015/2283. The applicant requested that *Coffea arabica* L. and *Coffea canephora* Pierre ex A.Froehner dried cherry pulp and its infusion to be used as an ingredient for infusions (including ready-to-drink beverages) and flavoured drinks intended for the general population.
- (6) On 13 November 2020, the company Luigi Lavazza SpA ('the applicant') submitted a notification to the Commission of their intention to place Coffea arabica L. and Coffea canephora Pierre ex A.Froehner dried cherry pulp and its infusion on the Union market as a traditional food from a third country in accordance with Article 14 of Regulation (EU) 2015/2283. The applicant requested that Coffea arabica L. and Coffea canephora Pierre ex A.Froehner dried cherry pulp and its infusion to be used as an ingredient for infusions and flavoured drinks intended for the general population.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries 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. 55).

⁽³⁾ 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).

- (7) Pursuant to Article 7(2) of Implementing Regulation (EU) 2017/2468, the Commission requested additional information from the applicants as regards the validity of the notification. Societé de Produits Nestlé SA submitted the requested information on 17 July 2020, 17 November 2020 and 23 December 2020, while Luigi Lavazza SpA submitted the requested information on 2 April 2021.
- (8) The data presented by the applicants demonstrate that *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner dried cherry pulp and its infusion has a history of safe food use in Yemen, Ethiopia and Bolivia.
- (9) Pursuant to Article 15(1) of Regulation (EU) 2015/2283, on 4 January 2021 and 6 April 2021, the Commission forwarded the valid notifications to the Member States and to the European Food Safety Authority ('the Authority').
- (10) No duly reasoned safety objections to the placing on the market within the Union of *Coffea arabica* L. and/or *Coffea canephora* Pierre ex A.Froehner dried cherry pulp and its infusion were submitted to the Commission by the Member States or the Authority within the 4-month period laid down in Article 15(2) of Regulation (EU) 2015/2283.
- (11) On 27 May 2021, the Authority published its 'Technical Report on the notification of the coffee cherry pulp from *Coffea arabica* L. and *Coffea canephora* Pierre ex A.Froehner as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283' (4), based on the notification from Société de Produits Nestlé SA.
- (12) On 2 September 2021, the Authority published its 'Technical Report on the notification of dried cherry pulp from *Coffea arabica* L. and *Coffea canephora* Pierre ex A.Froehner as a traditional food from a third country pursuant to Article 14 of Regulation (EU) 2015/2283' (5), based on the notification from Luigi Lavazza SpA.
- (13) In those reports, the Authority concluded that the available data on the composition and the history of the proposed use of *Coffea arabica* L. and *Coffea canephora* Pierre ex A.Froehner dried cherry pulp and its infusion do not raise safety concerns.
- (14) The Commission should therefore authorise the placing on the market within the Union of Coffea arabica L. and/or Coffea canephora Pierre ex A.Froehner dried cherry pulp and its infusion as a traditional food from a third country and update the Union list of authorised novel foods accordingly.
- (15) The Authority in its opinion noted that the consumption of beverages containing caffeine is not recommended to children or pregnant or breast-feeding women if the caffeine content exceeds 150 mg/l, as stipulated by Regulation (EU) No 1169/2011 of the European Parliament and of the Council (°). Therefore, if the product containing the novel food contains more than 150 mg/l of caffeine, a labelling should be provided in order to properly inform the consumers of the caffeine content and that the product is not recommended for children, pregnant and breast-feeding women.
- (16) For the coffee cherry pulp placed on the market as such for the preparation of infusions, a labelling should be provided to properly inform the consumers on the preparation of the product.
- (17) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly,

(5) EFSA Supporting publications, https://doi/10.2903/sp.efsa.2021.EN-6808

⁽⁴⁾ EFSA Supporting publications, https://doi.org/10.2903/sp.efsa.2021.EN-6657

⁽⁹⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

HAS ADOPTED THIS REGULATION:

Article 1

Coffea arabica L. and/or Coffea canephora Pierre ex A.Froehner dried cherry pulp and its infusion as specified in the Annex to this Regulation, shall be included as a traditional food from a third country in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

The entry in the Union list referred to in paragraph 1 shall include the conditions of use and the 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, 13 January 2022.

For the Commission The President Ursula VON DER LEYEN The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the following entry is inserted in Table 1 (Authorised novel foods):

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Authorised novel food 'Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner dried cherry pulp and its infusion (Traditional food from a third country)		Maximum levels		Other requirements
	coffee substitutes, coffee mixes and instant mixes for hot beverages (and their flavoured counterparts). Flavoured and unflavoured non-alcoholic ready-to-drink beverages			ed

(2) the following entry is inserted in Table 2 (Specifications):

Authorised Novel Food	Specifications	
'Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner dried cherry pulp and its infusion (Traditional food from a third country)	Description/Definition: The traditional food consists of the dried unroasted coffee cherry pulp of <i>Coffea arabica</i> L. and/or <i>Coffea canephora</i> Pierre ex A. Froehner (genus: <i>Coffea</i> family: Rubiaceae) and its infusion. The infusion can be used as such or concentrated or dried.	
	Ripe coffee cherries are collected, and then the coffee beans are mechanically removed, prior or after a drying process, leaving the dried coffee cherry pulp, which can be milled to a powder. The separated coffee cherry pulp is also known as "cascara", from the Spanish "cáscara", meaning "husk".	

Composition of the dried coffee cherry pulp:

Typically, the infusion is prepared by mixing up to 6 g of cascara pulp or husk in 100 ml of hot water (> $75 \,^{\circ}\text{C}$) for a few minutes and then pouring through a strainer, or using corresponding amounts in dried or instant infusions.

Water: < 18 %

Water activity (a_w) : ≤ 0.65

Ash: < 10,4 % DM

Protein: < 15 % DM

Fat: < 5 % DM

Carbohydrates: < 85 % DM

Microbiological criteria:

Aerobic Plate Count: < 104 CFU/g

Total yeasts and moulds: < 100 CFU/g

Enterobacteriaceae: < 50 CFU/g

Salmonella: Absence in 25 g

Bacillus cereus: < 100 CFU/g

Mycotoxins:

Ochratoxin A: < 5,0 μg/kg

Aflatoxin B1: < 2,0 μg/kg

Aflatoxin B1, B2, G1, G2 (as sum): < 4,0 μg/kg

Heavy metals:

Cadmium (Cd): < 0,05 mg/kg

Lead (Pb): < 1,0 mg/kg

Copper: ≤ 50 mg/kg

Mercury: $\leq 0.02 \text{ mg/kg}$

Arsenic: ≤ 0,2 mg/kg

Impurities:

Benzo(a)pyrene: < 10,0 μg/kg

Sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene: $< 50.0 \mu g/kg$

Pesticides:

Pesticide levels in the traditional food shall comply with levels set by Regulation (EC) No 396/2005 for "0639000" for "Herbal infusions from any other parts of the plant".

CFU: Colony Forming Units DM: Dry Matter'