COMMISSION IMPLEMENTING REGULATION (EU) 2022/47
of 13 January 2022


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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 Société 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.

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. Société 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.

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.

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').

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.

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.

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.

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.

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.

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 (6). 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.

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.

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

<table>
<thead>
<tr>
<th>Authorised novel food</th>
<th>Conditions under which the novel food may be used</th>
<th>Additional specific labelling requirements</th>
<th>Other requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Coffea arabica' L. and/or 'Coffea canephora' Pierre ex A. Froehner dried cherry pulp and its infusion (Traditional food from a third country)</td>
<td>Specified food category and Maximum levels</td>
<td>The designation of the novel food on the labelling of the foodstuffs containing it shall be “coffee cherry pulp” and/or “cascara (coffee cherry pulp)”, and/or “coffee cherry pulp infusion” and/or “coffee cherry pulp dried infusion”. If the product containing the novel food contains more than 150 mg/l of caffeine (as such or after reconstitution), it shall be labelled with the following indication: “High caffeine content. Not recommended for children or pregnant or breast-feeding women” in the same field of vision as the name of the food, followed by the caffeine content expressed in mg per 100 ml. Typical infusion preparations are prepared with up to 6 g of coffee cherry pulp per 100 ml of hot water (&gt; 75 °C). For the coffee cherry pulp placed on the market as such for the preparation of infusions, instructions shall be given to the consumer on the preparation.</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Authorised Novel Food</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Coffea arabica' L. and/or 'Coffea canephora' Pierre ex A. Froehner dried cherry pulp and its infusion (Traditional food from a third country)</td>
<td>Description/Definition: The traditional food consists of the dried unroasted coffee cherry pulp of Coffea arabica L. and/or Coffea canephora Pierre ex A. Froehner (genus: Coffea 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”.</td>
</tr>
</tbody>
</table>
Typically, the infusion is prepared by mixing up to 6 g of cascara pulp or husk in 100 ml of hot water (> 75 °C) for a few minutes and then pouring through a strainer, or using corresponding amounts in dried or instant infusions.

**Composition of the dried coffee cherry pulp:**
- 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: < 10$^4$ 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: ≤ 0.02 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 μg/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