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DRAFT

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

authorising the placing on the market of dried coffee cherry husk (cascara) from *Coffea arabica* L. as a novel food 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 1852/2001¹, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470² has established a Union list of novel foods.
- (3) On 21 June 2017, the company Panama Varietals GmbH ('the applicant') made a request to the competent authority of Austria to place dried *Coffea arabica* L. coffee cherry husk ('cascara'), as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council³. The application requests for the dried coffee cherry husk from *Coffea arabica* L. to be used as in herbal and other non-tea infusions and non-alcoholic beverages intended for the general population. The dried cherry husk of *Coffea arabica* L. can contain all what remains of the coffee cherry (skin, pulp, parchment, mucilage, and some of the silver skin covering the coffee beans) after the beans have been removed.
- (4) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (5) While the request for placing dried coffee cherry husk ('cascara') from *Coffea arabica* L. on the market as a novel food within the Union was submitted to a Member State in

¹ OJ L 327, 11.12.2015, p. 1.

² 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).

³ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.

- (6) On 6 February 2020, the applicant also made a request to the Commission for the protection of proprietary data on the detailed description of the production process⁴, analytical data on the composition of the novel food⁵, and data on the novel food stability⁶, submitted in support of the application.
- (7) On 7 July 2020, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of dried coffee husk ('cascara') from *Coffea arabica* L. as a novel food.
- (8) On 16 December 2021, the Authority adopted its scientific opinion 'Safety of dried coffee husk ('cascara') from *Coffea arabica* L. as a novel food pursuant to Regulation (EU) 2015/2283⁷ in accordance with Article 11 of Regulation (EU) 2015/2283.
- (9) In its scientific opinion, the Authority concluded that dried coffee cherry husk ('cascara') from *Coffea arabica* L. is safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that dried coffee cherry husk ('cascara') from *Coffea arabica* L., when used as in herbal and other non-tea infusions and non-alcoholic beverages intended for the general population, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (10) 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 Council⁸. 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.
- (11) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the scientific data on the detailed description of the production process, the analytical data on the composition of the novel food, and on the novel food stability data, without which it could not have assessed the novel food and reached its conclusion.
- (12) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those data and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (13)

⁴ Panama Varietals GmbH (2020 and 2021, unpublished)

⁵ Panama Varietals GmbH (2020 and 2021, unpublished)

⁶ Panama Varietals GmbH (2020 and 2021, unpublished)

⁷ EFSA Journal 2022; 20(2):7085.

⁸ 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 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p.18).

- (14) The applicant declared that they held proprietary and exclusive rights of reference to the scientific data, at the time they submitted the application.
- (15) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific data on the detailed description of the production process, the analytical data on the composition of the novel food, and on the novel food stability data, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place dried coffee cherry husk ('cascara') from *Coffea arabica* L., on the market within the Union during a period of five years from the entry into force of this Regulation.
- (16) However, restricting the authorisation of dried coffee cherry husk ('cascara') from *Coffea arabica* L., and the reference to the scientific data contained in the applicant's file for the sole use by them does not prevent subsequent 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 an authorisation.
- (17) The Commission considers appropriate that for the coffee cherry husk placed on the market as such for the preparation of infusions, a labelling should be provided to properly inform the consumers on their preparation.
- (18) It is appropriate that the inclusion of dried coffee cherry husk ('cascara') from *Coffea arabica* L., as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (19) Dried coffee cherry husk ('cascara') from *Coffea arabica* L., should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (20) 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 coffee cherry husk ('cascara') from *Coffea arabica* L., are authorised to be placed on the market within the Union.

Dried coffee cherry husk ('cascara') from *Coffea arabica* L., shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.
2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 2

Only the company Panama Varietals GmbH⁹ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from the date of entry into force of this Regulation [*OP please insert the date*], unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of Panama Varietals GmbH.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 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 Panama Varietals GmbH.

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,

For the Commission

The President

Ursula VON DER LEYEN

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