Commission Regulation (EU) 2019/650 of 24 April 2019 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) (Text with EEA relevance)

COMMISSION REGULATION (EU) 2019/650

of 24 April 2019

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[(1)], and in particular Article 8(5) thereof,

Whereas:

(1) In accordance with Article 8(2) of Regulation (EC) No 1925/2006, taking into account the possible harmful effects on health associated with the use of Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) and its preparations in foods, and the persisting scientific uncertainty, this substance has been placed under Union scrutiny and was included in Part C of Annex III to Regulation (EC) No 1925/2006 by means of Commission Regulation (EU) 2015/403[(2)].

(2) Pursuant to Article 8(5) of Regulation (EC) No 1925/2006, within four years from the date a substance has been listed in Part C of Annex III, a decision shall be taken to generally allow the use of a substance listed in Part C of Annex III or to list it in Part A or B of Annex III, as appropriate, taking into account the opinion of the European Food Safety Authority ('the Authority') on any files submitted for evaluation by food business operators, or any other interested parties as mentioned in Article 8(4).

(3) Pursuant to Article 5(2) of Commission Implementing Regulation (EU) No 307/2012[(3)], only files submitted within 18 months from the entry into force of a decision that includes a substance to Part C of Annex III to Regulation (EC) No 1925/2006 shall be taken into account by the Authority as being a valid file for the purposes of a decision as laid down in Article 8(5) of Regulation (EC) No 1925/2006.

(4) Considering that interested parties have not submitted any scientific data to the Authority to demonstrate the safety of Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex Beille) within the time limit referred to in Article 5(2) of Implementing Regulation (EU) No 307/2012, Yohimbe (Pausinystalia yohimbe (K. Schum) Pierre ex

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2019/650. (See end of Document for details)*

Beille) and its preparations should be included in Part A of Annex III to Regulation (EC) No 1925/2006, which means that their use in food will be prohibited.

(5) Regulation (EC) No 1925/2006 should therefore be amended accordingly.

(6) 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

Annex III to Regulation (EC) No 1925/2006 is amended as follows:

(1) in Part A, the following entry is added:

Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille);

(2) in Part C, the following entry is deleted:

Yohimbe bark and its preparations originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille).

Article 2

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, 24 April 2019.

For the Commission

The President

Jean-Claude JUNCKER