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Delegations will find attached document D036045/02.

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COMMISSION REGULATION (EU) No …/..

of XXX

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

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

of XXX

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards *Ephedra* species and 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(2) thereof,

Whereas:

(1) Pursuant to Article 8(2) of Regulation (EC) No 1925/2006, a Member State may request the Commission to initiate a procedure to include a substance or an ingredient containing a substance other than a vitamin or a mineral in Annex III to Regulation (EC) No 1925/2006 listing the substances whose use in foods is prohibited, restricted or under Union scrutiny, if that substance is associated with a potential risk to consumers as defined by Article 8(1) of Regulation (EC) No 1925/2006.

(2) On 7 September 2009, Germany sent a request to the Commission regarding the possible harmful effects associated with the intake of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) and *Ephedra* species and their preparations, and asked the Commission to initiate the procedure under Article 8 of Regulation (EC) No 1925/2006 for those two substances.

(3) The request by Germany fulfilled the necessary conditions and requirements laid down in Articles 3 and 4 of Commission Implementing Regulation (EU) No 307/2012[2].

(4) On 9 September 2011, the Commission asked the European Food Safety Authority (hereafter 'the Authority') to evaluate the safety in use of *Ephedra* and Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) species in food.

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1 OJ L 404, 30.12.2006, p. 26.

2 Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).

(5) On 3 July 2013, the Authority adopted a scientific opinion on the evaluation of the safety in use of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille)[3]. It concluded that the chemical and toxicological characterisation of yohimbe bark and its preparations used in food originating from Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) are not adequate to conclude on their safety as ingredients of food. Therefore, it was not possible for the Authority to provide advice on a daily intake of yohimbe bark and its preparations that does not give rise to concerns for human health.

(6) On 6 November 2013, the Authority adopted a scientific opinion on the safety evaluation of *Ephedra* species for use in food[4]. It found that although the marketing of foods containing Ephedra herb and its preparations in retail outlets is not documented in Europe, food supplements containing Ephedra herbs or their preparations that are typically used for weight loss and athletic performance can easily be purchased via the internet. The Authority concluded that it cannot be excluded that consumers may purchase herbal tea from Ephedra herb via the internet. Given that Ephedra herb and its preparations are marketed almost exclusively as food supplements, the Authority calculated potential exposure levels to the herb from food supplements. It concluded that Ephedra herb and its preparations in food supplements may result in exposure to total ephedra alkaloids or ephedrine which falls within or may exceed the therapeutic dose ranges for the individual ephedra alkaloids or ephedrine, in medicinal products.

(7) The Authority concluded that due to the absence of adequate toxicity data, it could not provide advice on a daily intake of Ephedra herb and its preparations from all foods that does not give rise to concerns for human health. Nevertheless, it concluded that exposure to total ephedra alkaloids or ephedrine in foods, mainly in food supplements could lead to severe adverse effects on the cardiovascular and central nervous systems (such as hypertension and stroke), which may be enhanced in combination with caffeine. Therefore, the use of Ephedra herb and its preparations containing ephedra alkaloids in food is of significant safety concern for human health.

(8) The Commission received no comments from interested parties following publication by the Authority of its opinions on *Ephedra* species and on Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille).

(9) As there is a possibility of harmful effects on health associated with the use of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) and its preparations in foods, but scientific uncertainty persists, the substance should be placed under Union scrutiny and therefore, should be included in Part C of Annex III to Regulation (EC) No 1925/2006. Consequently, during the period of Union scrutiny and pending a decision on whether to allow the use of the substance or to place it in Part A or Part B of Annex III to Regulation (EC) No 1925/2006 at the end of the scrutiny period, national provisions regulating the use of Yohimbe (*Pausinystalia yohimbe* (K. Schum) Pierre ex Beille) in food should still apply.

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[3] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the evaluation of the safety in use of Yohimbe (*Pausinystalia yohimbe* (K.Schum.)Pierre ex Beille). EFSA Journal 2013;11(7):3302.

[4] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on safety evaluation of *Ephedra* species for use in food. EFSA Journal 2013;11(11):3467.

(10) Considering the significant safety concern associated with the use of Ephedra herb and its preparations in foods, in particular with regard to exposure to ephedra alkaloids present in food supplements, and considering that no daily intake of Ephedra herb and its preparations that does not give rise to concerns for human health could be set, the use of that substance in foods should be prohibited. Therefore, Ephedra herb and its preparations should be included in Annex III, Part A of Regulation (EC) No 1925/2006.

(11) 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:

"Ephedra herb and its preparations originating from Ephedra species"

(2) In Part C, the following entry is added:

"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,

For the Commission
The President
Jean-Claude JUNCKER