EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards certain botanical species containing hydroxyanthracene derivatives

(Text with EEA relevance)

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amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards certain botanical species containing hydroxyanthracene derivatives

(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), first subparagraph, thereof,

Whereas:

(1) Commission Regulation (EU) 2021/468[2] placed under Union scrutiny and included in Part C of Annex III to Regulation (EC) No 1925/2006, preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing hydroxyanthracene derivatives, preparations from the leaf or fruit of *Cassia senna* L. containing hydroxyanthracene derivatives and preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. containing hydroxyanthracene derivatives. The term 'preparation' covers all preparations obtained from botanical materials by various processes[3]. The preparations were placed under scrutiny in accordance with Article 8(2), first subparagraph, point (b), of Regulation (EC) No 1925/2006, taking into account the possible harmful effects on health associated with the use in foods of those substances and the persisting scientific uncertainty. The opinion of the European Food Safety Authority, hereinafter referred to as "the Authority" on the safety of hydroxyanthracene derivatives for use in food,[4] on which the placement under scrutiny was based, had concluded that the hydroxyanthracenes individually listed in Part A of Annex III to Regulation (EC) No 1925/2006, in particular aloe-emodin and emodin, are genotoxic in vitro and that aloe-emodin had shown to be genotoxic in vivo.

(2) Pursuant to Article 8(5), first subparagraph, of Regulation (EC) No 1925/2006, a decision is to be taken either to allow the use of a substance listed in Part C of Annex III

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1 OJ L 404, 30.12.2006, p. 26, ELI: http://data.europa.eu/eli/reg/2006/1925/oj.

2 Commission Regulation (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards botanical species containing hydroxyanthracene derivatives (OJ L 96, 19.3.2021, p. 6, ELI: http://data.europa.eu/eli/reg/2021/468/oj).

3 Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. *EFSA Journal* 2009; 7(9):1249.

4 *EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Younes, M., Younes, M., Aggett, P., Aguilar, F., Crebelli, R.,Filipič, M., Frutos, M. J., Galtier, P., Gott, D., Gundert-Remy, U., Kuhnle, G. G., Lambré, C., Leblanc, J. C., Lillegaard, I. T., Moldeus, P., Mortensen, A.,Oskarsson, A., Stankovic, I., … Wright, M. (2018). Safety of hydroxyanthracene derivatives for use in food. EFSA Journal, 2018 16(1), 5090.*

thereto or to list it in Part A or B of that Annex, taking into account the opinion of the Authority on files submitted for evaluation.

(3) Two interested parties submitted such files for evaluation to the Authority, within the period provided for in Article 5(2) of Commission Implementing Regulation (EU) No 307/2012[5].

(4) On the basis of those two files, the Authority consulted stakeholders and the public, in accordance with Article 5c, point (b), of Implementing Regulation (EU) No 307/2012. During the public consultation, 11 additional genotoxicity studies on the relevant preparations were submitted to the Authority. In its assessment, the Authority considered the studies submitted within the period provided for in Article 5(2) of Regulation (EU) No 307/2012 and those submitted during the public consultation. No studies on carcinogenicity were submitted.

(5) In its opinion of 20 March 2024[6], the Authority noted that the studies submitted during the scrutiny period and in the framework of the public consultation confirm the presence of genotoxic hydroxyanthracene derivatives listed in Part A of Annex III to Regulation (EC) No 1925/2006 in the plant preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids, from the leaf or fruit of *Cassia senna* L. and from the bark of *Rhamnus frangula* L. and *Rhamnus purshiana* DC.

(6) The Authority further noted that all the submitted genotoxicity tests were conducted with plant preparations containing low concentrations of hydroxyanthracene derivatives listed in Part A of Annex III to Regulation (EC) No 1925/2006 and other hydroxyanthracene derivatives.

(7) The Authority explained that in this situation the absence of genotoxic results in the submitted studies cannot be used to rule out the genotoxicity concern originating from the presence of a genotoxic component in the plant preparation. The Authority further explained that this is in line with the EFSA Scientific Committee statement on the genotoxicity assessment of chemical mixtures[7] that considers that chemically defined substances have to be assessed individually for their potential genotoxicity and that '[i]f a mixture contains one or more chemical substances that are individually assessed to be genotoxic in vivo, the mixture raises concern for genotoxicity'.

(8) Considering the presence of a compound that was genotoxic in vivo, the Authority concluded that the plant preparations containing hydroxyanthracene derivatives have to be considered of concern for genotoxicity. The Authority further concluded that the safety of plant preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids, from the leaf or fruit of *Cassia senna* L. and from

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5 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, ELI: http://data.europa.eu/eli/reg_impl/2012/307/oj).

6 Scientific opinion on additional scientific data related to the safety of preparations of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids, *Rhamnus purshiana* DC., *Rhamnus frangula* L. and *Cassia senna* L., submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006. *EFSA Journal* 2024; 22(5):e8766.

7 EFSA Scientific Committee, More, S., Bampidis, V., Benford, D., Boesten, J., Bragard, C., Halldorsson, T., Hernandez-Jerez, A., Hougaard-Bennekou, S.,Koutsoumanis, K., Naegeli, H., Nielsen, S. S., Schrenk, D., Silano, V., Turck, D., Younes, M., Aquilina, G., Crebelli, R., Gürtler, R., Schlatter, J. (2019).Statement on the genotoxicity assessment of chemical mixtures. EFSA Journal, 17(1), 5519.

the bark of *Rhamnus frangula* L. and *Rhamnus purshiana* DC., containing hydroxyanthracene derivatives, could not be established based on the submitted studies.

(9) Considering that the safety of the plant preparations placed under evaluation could not be established by the Authority based on the submitted scientific data, those plant preparations should be included in Part A of Annex III to Regulation (EC) No 1925/2006 and be deleted in Part C of that Annex.

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

(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 inserted after the entry 'Ephedra herb and its preparations originating from *Ephedra* species':

'Preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. containing hydroxyanthracene derivatives';

(2) in Part A, the following entries are inserted after the entry 'Preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives':

'Preparations from the leaf or fruit of *Cassia senna* L. containing hydroxyanthracene derivatives

Preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing hydroxyanthracene derivatives';

(3) in Part C, the following entries are deleted:

'Preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. containing hydroxyanthracene derivatives

Preparations from the leaf or fruit of *Cassia senna* L. containing hydroxyanthracene derivatives

Preparations from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing hydroxyanthracene derivatives'.

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
Ursula VON DER LEYEN