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Delegations will find attached document D067676/03.

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Brussels, **XXX**  
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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 botanical species containing hydroxyanthracene derivatives**

(Text with EEA relevance)

# COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards 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<sup>1</sup>, and in particular Article 8(2)(a)(i) and (b) thereof,

Whereas:

- (1) Pursuant to Article 8(2) of Regulation (EC) No 1925/2006, on its own initiative or on the basis of information provided by Member States, the Commission may 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) Plants containing hydroxyanthracene derivatives are numerous and belong to different botanical families and genera. They are widely used in food supplements.
- (3) In its Scientific Opinion of 9 October 2013 on the scientific substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function<sup>2</sup>, the European Food Safety Authority ('the Authority') concluded that hydroxyanthracene derivatives in food can improve bowel function, but advised against long-term use and consumption at high doses due to potential safety concerns such as the danger of electrolyte imbalance, impaired function of the intestine and dependence on laxatives.
- (4) In view of that opinion, and of the concerns raised by Member States, during the discussion on the health claim under consideration in 2013 about the possible harmful effects associated with the consumption of foods containing hydroxyanthracene derivatives and preparations thereof, the Commission in 2016 requested the Authority to deliver a scientific opinion on the evaluation of safety in use of hydroxyanthracene derivatives in food in accordance with Article 8 of Regulation (EC) No 1925/2006.

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<sup>1</sup> OJ L 404, 30.12.2006, p. 26.

<sup>2</sup> EFSA Journal 2013;11(10):3412

- (5) The information provided by the Member States to the Commission fulfilled the necessary conditions and requirements laid down in Articles 3 and 4 of Commission Implementing Regulation (EU) No 307/2012<sup>3</sup>.
- (6) On 22 November 2017, the Authority adopted a scientific opinion on the evaluation of the safety of hydroxyanthracene derivatives for use in food<sup>4</sup>. The hydroxyanthracene derivatives considered relevant for this risk assessment were those found in the root and rhizome of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids; leaves or fruits of *Cassia senna* L.; bark of *Rhamnus frangula* L., bark of *Rhamnus purshiana* DC. and in leaves of *Aloe barbadensis* Miller and/or various *Aloe* species, mainly *Aloe ferox* Miller and its hybrids.
- (7) The Authority found that the hydroxyanthracene derivatives aloe-emodin and emodin and structurally related substance danthron have been shown to be genotoxic in vitro. Aloe extracts have also been shown to be genotoxic in vitro most likely due to hydroxyanthracene derivatives present in the extract. Furthermore, aloe-emodin was shown to be genotoxic in vivo. The whole leaf aloe extract and structural analogue danthron were shown to be carcinogenic.
- (8) Given that aloe-emodin and emodin may be present in the extracts, the Authority concluded that hydroxyanthracene derivatives should be regarded as genotoxic and carcinogenic unless there are specific data to the contrary and that there is a safety concern for extracts containing hydroxyanthracene derivatives although uncertainty persists. The Authority was unable to provide advice on a daily intake of hydroxyanthracene derivatives that does not give rise to concerns for human health.
- (9) Considering the severe harmful effects on health associated with the use of aloe-emodin, emodin, danthron and aloe extracts containing hydroxyanthracene derivatives in food, and that no daily intake of hydroxyanthracene derivatives that does not give rise to concerns for human health could be set, such substances should be prohibited. Therefore, aloe-emodin, emodin, danthron and aloe preparations containing hydroxyanthracene derivatives should be included in Annex III, Part A of Regulation (EC) No 1925/2006.
- (10) During manufacture, hydroxyanthracene derivatives can be removed from the botanical preparations through a series of filtering processes resulting in products that contain those substances only at trace levels as impurities.
- (11) As there is a possibility of harmful effects on health associated with the use of *Rheum*, *Cassia* and *Rhamnus* and their preparations in food, but scientific uncertainty persists about whether such preparations contain the substances listed in Annex III, Part A of Regulation (EC) No 1925/2006, such substances should be placed under Union scrutiny and therefore, should be included in Part C of Annex III to Regulation (EC) No 1925/2006.
- (12) Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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<sup>3</sup> 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).

<sup>4</sup> The Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the safety of hydroxyanthracene derivatives. EFSA Journal 2018;16(1):5090.

HAS ADOPTED THIS REGULATION:

*Article 1*

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

- (1) in Part A, the following entries are added in alphabetical order:
  - ‘aloe-emodin and all preparations in which this substance is present’;
  - ‘emodin and all preparations in which this substance is present’;
  - ‘preparations from the leaf of *Aloe* species containing hydroxyanthracene derivatives’;
  - ‘danthron and all preparations in which this substance is present’.
- (2) in Part C, the following entries are added in alphabetical order:
  - ‘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’;
  - ‘preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. 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*