Council of the European Union

Brussels, 15 July 2026
(OR. en)

11964/26

DENLEG 80
FOOD 106
SAN 600

COVER NOTE

From:	European Commission
date of receipt:	15 July 2026
To:	General Secretariat of the Council
No. Cion doc.:	D099926/3
Subject:	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

Delegations will find attached document D099926/3.

Encl.: D099926/3

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/1196/2024 Rev.3
(POOL/A1/2024/1196/1196R3-EN.docx) D099926/3
[…](2024) XXX draft

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)

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)

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 added to food and used in their manufacturing obtained by various processes[3] from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids containing hydroxyanthracene derivatives, from the leaf or fruit of *Cassia senna* L. containing hydroxyanthracene derivatives and from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC. containing hydroxyanthracene derivatives. In its scientific opinion of 22 November 2017 on the safety of hydroxyanthracene derivatives for use in food[4], on which Regulation (EU) 2021/468 was based, the European Food Safety Authority ('the Authority') had concluded that hydroxyanthracene derivatives were to be considered as genotoxic and carcinogenic unless there are specific data to the contrary, such as for rhein, and that there was a safety concern for extracts containing hydroxyanthracene derivatives although uncertainty persisted. In line with the Authority's scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment[5], which considered that no exposure level to genotoxic substances is to be considered without risk, the Authority was unable to provide advice on a daily intake of hydroxyanthracene derivatives that does not give rise to concerns about harmful effects to health.

---

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., Aggett, P., Aguilar, F., Crebelli, R., Filipič, M. et al., Safety of hydroxyanthracene derivatives for use in food. EFSA Journal 2018; 16(1), 5090.

5 EFSA Scientific Committee; Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379. [69 pp.] doi:10.2903/j.efsa.2011.2379.

(2) Two interested parties submitted files for evaluation to the Authority, within the period provided for in Article 5(2) of Commission Implementing Regulation (EU) No 307/2012[6]. All the documents submitted by each interested party are listed in Section 2.1 of the Authority`s scientific opinion of 20 March 2024[7].

(3) 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, eleven additional genotoxicity studies on the relevant preparations were submitted to the Authority. All the documents submitted by each interested party during the public consultation are listed in Appendix A of the scientific opinion of 20 March 2024.

(4) In its opinion of 20 March 2024, the Authority considered the studies submitted within the period provided for in Article 5(2) of Implementing Regulation (EU) No 307/2012 and those submitted during the public consultation.

(5) The Authority noted that those studies confirmed the presence of a hydroxyanthracene derivative shown to be genotoxic in vivo 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 studies showed negative results. However, the Authority explained that all the submitted genotoxicity studies had been conducted with plant preparations containing low concentrations of hydroxyanthracene derivatives and considered that the absence of genotoxic results in these studies could not be used to rule out the genotoxicity concern, originating from the presence of a component shown to be genotoxic in vivo in the plant preparations. The Authority further explained that this is in line with its Scientific Committee statement on the genotoxicity assessment of chemical mixtures[8] 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'.

(7) Considering the presence of a compound that was shown to be genotoxic in vivo, the Authority concluded that the plant preparations used in the submitted studies must be considered of concern for genotoxicity. Therefore, 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 the bark of *Rhamnus frangula* L. and *Rhamnus purshiana* DC., containing hydroxyanthracene derivatives, could not be established based on the submitted studies.

(8) Considering that the safety of the plant preparations placed under scrutiny could not be established by the Authority based on the submitted scientific data, those plant

---

6 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).

7 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.

8 EFSA Scientific Committee, More, S., Bampidis, V., Benford, D., Boesten, J., Bragard, C. et al., Statement on the genotoxicity assessment of chemical mixtures. EFSA Journal 2019; 17(1), 5519.

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.

(9) A reasonable period should be provided to allow food business operators to adapt to the new requirements set out in this Regulation. Considering the safety concerns, such period should concern only products already lawfully placed on the market before the entry into force of this Regulation.

(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 'Monacolins from red yeast rice':

'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

Foodstuffs lawfully placed on the market before the entry into force of this Regulation and in the manufacture of which preparations from the bark of *Rhamnus frangula* L., *Rhamnus purshiana* DC., from the leaf or fruit of *Cassia senna* L. or from the root or rhizome of *Rheum palmatum* L., *Rheum officinale* Baillon and their hybrids, containing hydroxyanthracene derivatives, were used or to which such preparations were added may remain on the market until [*entry into force + 12 months*].

Article 3

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