



Plenary sitting

B10-0465/2026

5.10.2026

MOTION FOR A RESOLUTION

pursuant to Rule 115(2) and (3), and (4)(c) of the Rules of Procedure

on the draft Commission regulation 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
(D099926/03 – 2026/2839(RPS))

Committee on the Environment, Climate and Food Safety

Member responsible: Pascal Arimont

European Parliament resolution on the draft Commission regulation 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 (D099926/03 – 2026/2839(RPS))

The European Parliament,

- having regard to the draft Commission regulation 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 (D099926/03),
 - 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 foods¹, and in particular Article 8(5), first subparagraph, thereof,
 - having regard to the opinion delivered on 1 July 2026 by the Standing Committee on Plants, Animals, Food and Feed,
 - having regard to Article 5a(3)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission²,
 - having regard to Rule 115(2) and (3), and (4)(c) of its Rules of Procedure,
 - having regard to the motion for a resolution of the Committee on the Environment, Climate and Food Safety,
- A. whereas the draft Commission regulation would prohibit in foods preparations obtained from specified *Rheum*, *Cassia senna* and *Rhamnus* species (the ‘botanical species concerned’) where those preparations contain hydroxyanthracene derivatives (HADs);
- B. whereas Commission Regulation (EU) 2021/468³ placed those same categories of preparations under Union scrutiny in Part C of Annex III to Regulation (EC) No 1925/2006; whereas the draft Commission regulation would move them from Part C to Part A, resulting in a complete prohibition;
- C. whereas the draft Commission regulation is a new measure adopted at the end of the scrutiny procedure under Article 8(5) of Regulation (EC) No 1925/2006 and is therefore not formally identical to Regulation (EU) 2021/468; whereas it nevertheless concerns the same categories of preparations, and continues to rely, in part, on the European Food Safety Authority (EFSA) scientific opinion adopted on 22 November 2017 and published on 23 January 2018 on the safety of hydroxyanthracene derivatives for use in

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

² OJ L 184, 17.7.1999, p. 23, ELI: <http://data.europa.eu/eli/dec/1999/468/oj>.

³ Commission Regulation (EU) 2021/468 of 18 March 2021 amending Annex III to Regulation (EC) No 1925/2006 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>).

food⁴;

- D. whereas preparations from the botanical species concerned have a long history of use in foods and food supplements across the Union; whereas national law in several Member States expressly permits the use of at least some of those botanical species or preparations, subject to compositional requirements, conditions of use and warnings designed to manage identified risks raised by EFSA; whereas, for the full breadth of products and uses captured by the draft Commission regulation, the Commission has not set out a distinct assessment showing why Member State's enforcement and targeted national risk-management measures would be insufficient pending a fully evidenced harmonised measure, or why the scale or effects of the identified risk require an immediate absolute Union-wide prohibition;
- E. whereas the General Court annulled⁵ the provisions of Regulation (EU) 2021/468 placing the preparations from the botanical species concerned under Union scrutiny; whereas those judgments are subject to pending appeals before the Court of Justice and the implications of the final judgments should therefore be fully taken into account in order to ensure legal certainty and a stable regulatory framework;
- F. whereas the relevant provisions have been annulled on the ground that the conditions laid down in Article 8 of Regulation (EC) No 1925/2006 for empowering the Commission to exercise delegated powers to amend the list of substances set out in Annex III were not met;
- G. whereas EFSA has identified concerns regarding the genotoxicity of HAD-containing botanical preparations although uncertainty persists; whereas the European Medicines Agency (EMA) recognises certain medicinal uses of HAD-containing herbal substances under defined conditions, restrictions and warnings;
- H. whereas EFSA and EMA carry out assessments under different legal frameworks, for different purposes and in relation to different conditions of use; whereas, while their assessments are therefore not directly comparable, their respective conclusions concerning HAD-containing botanicals merit careful consideration when determining the appropriate risk-management measures for foods;
- I. whereas Article 30 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁶ provides for a mechanism for addressing relevant divergences in scientific opinions; whereas the Commission should clarify whether that provision is applicable to the respective EFSA and EMA assessments in this case and, if so, how it has been used;
- J. whereas EFSA's assessment itself recognises that specific data may lead to different

⁴ EFSA 'Scientific Opinion on the safety of hydroxyanthracene derivatives for use in food', *EFSA Journal*, 2018, 16(1):e5090, <https://doi.org/10.2903/j.efsa.2018.5090>.

⁵ Judgment of the General Court of 13 November 2024, *Aloe Vera of Europe BV v European Commission*, T-189/21, ECLI:EU:T:2024:802; *Ortis v European Commission*, T-271/21, ECLI:EU:T:2024:804; *Synadiet and Others v Commission*, T-274/21, ECLI:EU:T:2024:806; and *Aboca and Others v Commission*, T-302/21, ECLI:EU:T:2024:808.

⁶ OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>.

conclusions for particular HADs, citing rhein as an example; whereas the scientific assessment therefore does not treat every HAD identically;

- K. whereas HADs comprise a heterogeneous group of compounds; whereas the draft Commission regulation would prohibit any preparation obtained from the botanical species concerned containing any HAD, irrespective of the particular HAD present, its concentration and dose, the manufacturing process, the conditions of use or the consumer group concerned, and even where the particular component underlying EFSA's concern is absent; whereas the draft Commission regulation should further set out why more targeted measures, including maximum levels, compositional requirements, conditions of use or mandatory warnings, would not provide an equivalent high level of consumer protection, in accordance with the principle of proportionality;
 - L. whereas a complete prohibition will have economic consequences for farmers, herb growers and food business operators and should not be imposed before the differences in scientific risk assessment have been clarified and it is confirmed that a complete prohibition is the only means to manage the risk.
 - M. whereas in the light of the foregoing protecting public health, ensuring legal certainty and adopting proportionate measures are complementary objectives; whereas an objection would not replace scientific assessment with political judgment, but would provide time for the outstanding legal and scientific questions to be properly considered;
1. Opposes adoption of the draft Commission regulation;
 2. Considers that the draft Commission regulation exceeds the implementing powers provided for in Regulation (EC) No 1925/2006, in so far as it treats the inability to establish safety on the submitted data as sufficient to justify a complete prohibition provided for in Part A of Annex III to that Regulation, extends a concern based on a particular component to every preparation containing any HAD, and does not sufficiently demonstrate the identification of a harmful effect for each of the broad categories of preparation and use covered by the prohibition;
 3. Calls on the Commission to withdraw the draft regulation or defer its adoption until the Court of Justice has delivered final judgment in the pending appeals and, if the cases are referred back, until the Commission has duly assessed and explained the implications of the pleas remaining to be examined;
 4. Emphasises that legal certainty and the effective and orderly exercise of judicial review warrant institutional restraint; notes that the Commission is not legally barred from acting, but considers that adopting the proposed prohibition before final disposal of the pending appeals and before the unexamined pleas have been duly addressed risks parallel proceedings, inconsistent outcomes, irreversible adaptation costs and reduced practical effectiveness of the pending judicial review;
 5. Calls on the Commission, before proposing any new measure, to obtain a complete, transparent and up-to-date scientific assessment covering the individual HADs and preparations concerned, hazard characterisation, exposure and dose, manufacturing processes, duration and conditions of use and vulnerable groups; further calls on the

Commission to ensure that the methodological questions raised regarding pivotal evidence and any material divergences between EFSA, EMA and other competent scientific bodies are formally examined and explained, and to clarify whether Article 30 of Regulation (EC) No 178/2002 applies in this context and, if so, how its mechanism has been used;

6. Calls on the Commission to set out the basis on which a complete prohibition is considered necessary and proportionate, to further examine whether less restrictive measures under Part B of Annex III to Regulation (EC) No 1925/2006 could provide an equivalent high level of consumer protection and to define any regulated category by reference to sufficiently precise botanical, compositional, analytical and concentration criteria to ensure legal certainty and effective enforcement;
7. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.