

Brussels, 15 July 2026
(OR. en)

11900/26

DENLEG 78
FOOD 104
SAN 593

COVER NOTE

From:	European Commission
date of receipt:	14 July 2026
To:	General Secretariat of the Council

No. Cion doc.:	D115964/02
----------------	------------

Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
----------	--

Delegations will find attached document D115964/02.

Encl.: D115964/02



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2025/1804
(POOL/E2/2025/1804/1804-
EN_REV1.docx) D115964/02
[...](2026) **XXX**

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

of **XXX**

**amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles
intended to come into contact with food**

(Text with EEA relevance)

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

of **XXX**

amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

(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 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC¹, and in particular Article 5(1), second subparagraph, points (a), (d), (e), and (i), and Article 11(3) thereof,

Whereas:

- (1) Commission Regulation (EU) No 10/2011² lays down specific rules as regards plastic materials and articles intended to come into contact with food. In particular, Annex I to Regulation (EU) No 10/2011 establishes a Union list of authorised substances that may be intentionally used in the manufacture of plastic materials and articles intended to come into contact with food.
- (2) On 25 November 2021, the European Food Safety Authority ('the Authority') adopted a scientific opinion³ on the substance chopped carbon fibres, from carbonised polyacrylonitrile (FCM No 1086), intended to be used as a filling and reinforcement material in plastic food contact materials and articles. The Authority concluded that the substance chopped carbon fibres from carbonised polyacrylonitrile, with a minimum carbon content of 95% w/w and at sizes not at the nanoscale in any dimension, is not of safety concern for the consumer, when used in contact with all food types and under all conditions of use, at up to 40% w/w for polyether ether ketone (PEEK) polymer. It is therefore appropriate to authorise the substance accordingly.
- (3) On 26 January 2022, the Authority adopted a scientific opinion⁴ on the substance nano precipitated calcium carbonate (FCM No 1087). The Authority concluded that a

¹ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4, ELI: <http://data.europa.eu/eli/reg/2004/1935/oj>).

² Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1, ELI: <http://data.europa.eu/eli/reg/2011/10/oj>).

³ EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2022). Scientific Opinion on the safety assessment of the substance chopped carbon fibres, from carbonised polyacrylonitrile, for use in food contact materials. EFSA Journal 2022;20(1):7003, 8 pp. <https://doi.org/10.2903/j.efsa.2022.7003>

⁴ EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2022). Scientific Opinion on the safety assessment of the substance nano precipitated calcium carbonate for use in plastic food contact materials. EFSA Journal 2022;20(2):7135, 8 pp. <https://doi.org/10.2903/j.efsa.2022.7135>

specific assessment of the particles in nanoform is not required as the particulate form of the substance dissolved rapidly under simulated gastric conditions and the substance is not of safety concern for the consumer when used as a filler in all types of polymers for all types of food. However, the Authority could not conclude on its safety in contact with infant formulae. Considering that coated particles of this substance could have modified properties and that the application did not cover such particles, the use of the substance should be restricted to uncoated particles in the nanoform. The Authority further observed that the overall migration in acidic foods from a material containing the substance may exceed the limit laid down in Article 12 of Regulation (EU) No 10/2011. In light of this opinion, it is therefore appropriate to authorise the use of uncoated particles of the substance in the nanoform for the manufacture of plastic materials and articles intended to be in contact with all kind of food except infant formulae. Furthermore, in order to ensure that the risk of exceedance of the overall migration in acidic foods is considered as part of the verification of compliance, a note on the verification of compliance as regards this substance should be added in Table 3 in Annex I to Regulation (EU) No 10/2011.

- (4) On 8 June 2023, the Authority adopted a scientific opinion⁵ on the substance poly(2-hydroxypropanoic acid), n-octyl/n-decyl esters (FCM No 1088). The applicant intends to use the substance for single use food contact articles, including films, trays or containers, for fresh foods such as fruits, vegetables, slightly acidic foods and watery based materials, such as water and non-alcoholic beverages. The Authority concluded that the substance is not of safety concern for the consumer when it is used as an additive up to 15% w/w in the manufacture of polylactic acid (PLA) food contact materials and articles intended to be in contact for up to 10 days at 40 °C with foods simulated by 3% acetic acid (simulant B), provided that the migration of the substance does not exceed 0.05 mg/kg food. Furthermore, it results from the opinion that the specific migration limit ('SML') is exceeded when testing is done in food simulants 10% ethanol, 95% ethanol and isooctane or when starch is added to PLA, thereby potentially increasing the migration of the substance. In light of the Authority's opinion and in order to minimise the risk that the migration of the substance into food exceeds the SML, it is appropriate to authorise the use of the substance only as an additive up to 15% w/w in materials and articles made from PLA which do not contain starch (FCM No 564) or other additives with a function similar to starch, and which are intended to be in contact for up to 10 days at 40°C with water included in food category 01.01, or with food included in categories 04.01 (fruit, fresh or chilled), 04.04 (vegetables, fresh or chilled) and 08.01 (vinegar), as specified in Table 2 of Annex III. It is also appropriate to add a note on verification of compliance indicating that there is a risk that the specific migration limit may be exceeded.
- (5) On 12 March 2024, the Authority adopted a scientific opinion⁶ on the mixture of 1,9-nonanediamine (NMDA) and 2-methyl-1,8-octanediamine (MODA) (FCM No 1090). The Authority concluded that the mixture of NMDA and MODA is not of safety concern for the consumer when used as a co-monomer with terephthalic acid, to

⁵ EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2023). Scientific Opinion on the safety assessment of the substance poly(2-hydroxypropanoic acid), n-octyl/n-decyl esters, for use in food contact materials. *EFSA Journal* 2023;21(7):8100, 9 pp. <https://doi.org/10.2903/j.efsa.2023.8100>

⁶ EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2024). Safety assessment of mixtures of 1,9-nonanediamine (NMDA) and 2-methyl-1,8-octanediamine (MODA), for use in food contact materials. *EFSA Journal*, 22(4), e8703. <https://doi.org/10.2903/j.efsa.2024.8703>

manufacture polyamide materials and articles intended for contact with all types of food, except for infant formula and human milk, if the sum of the migration of NMDA and MODA does not exceed 0.05 mg/kg food and if the migration into food of the fraction with molecular weight below 1000 Da consisting of NMDA/MODA-related species, namely oligomers of the substances NMDA, MODA, terephthalic acid and benzoic acid formed during manufacturing of the polyamide, does not exceed 5 mg/kg food. It is therefore appropriate to authorise the mixture accordingly.

- (6) Regulation (EU) No 10/2011 should therefore be amended accordingly.
- (7) 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 I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

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