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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 23.7.2024 amending Annex II to Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the polymers in Component Material Category 11

Delegations will find attached document C(2024) 5128 final.

Encl.: C(2024) 5128 final



EUROPEAN
COMMISSION

Brussels, 23.7.2024

C(2024) 5128 final

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

of 23.7.2024

amending Annex II to Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the polymers in Component Material Category 11

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

On 5 June 2019, the European Parliament and the Council adopted Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products¹. EU fertilising products may contain polymers, in the conditions laid down in Component Material Categories (CMCs) 8 and 9 in Annex II to the Regulation. The Commission has to assess biodegradability criteria for certain polymers belonging to CMC 9 controlling the release of nutrients ('coating agents') or increasing the water retention capacity or the wettability of the products ('water retention polymers').

On 23 June 2021, the Commission adopted Delegated Regulation (EU) 2021/1768² adding certain categories of polymers in Component Material Categories 1 and 11. Such polymers are normally used as technical additives, to increase the agronomic efficiency or the safety of the products. In order to identify which polymers do not cause any environmental concern and therefore include them in CMCs 1 and 11, the Commission took into account the scientific opinion issued by the Risk Assessment Committee and the Committee for Socio-Economic Analysis³ of the European Chemical Agency in accordance with Regulation (EC) No 1907/2006⁴ on intentionally added microplastic particles to consumer or professional use products of any kind.

Based on the same scientific opinion, the Commission adopted Regulation (EU) 2023/2055⁵ which introduces a general restriction in Regulation (EC) No 1907/2006 of placing on the market of synthetic polymer microparticles. Specific categories of polymers (such as natural polymers not chemically modified) and polymers meeting certain biodegradability or solubility criteria are not covered by the general restriction and may continue to be placed on the market.

EU fertilising products are excluded from the scope of that restriction, pending the outcome of the assessment on biodegradability criteria for coating agents and water retention polymers.

The polymers which may be used as materials belonging to CMC 11 should follow the same general rules set out in Delegated Regulation (EU) 2023/2055.

¹ Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003, OJ L 170, 25.6.2019, p. 1.

² Commission Delegated Regulation (EU) 2021/1768 of 23 June 2021 amending, for the purpose of its adaptation to technical progress, Annexes I, II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products, OJ L 356, 8.10.2021, p. 8.

³ RAC ECHA. 2020. Opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics (ECHA/RAC/RES-O -0000006790-71-01/F).

⁴ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1.

⁵ Commission Regulation (EU) 2023/2055 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles (OJ L 238, 27.9.2023, p. 67, ELI: <http://data.europa.eu/eli/reg/2023/2055/oj>).

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States have been consulted in the Commission expert group on fertilising products (E01320) according to the rules of the Interinstitutional Agreement on Better Law-Making of 13 April 2016⁶.

Details of these consultations can be found in the minutes of the meetings held on 27-28 November 2023 and 15-16 April 2024, as well as in the various position papers of interested stakeholders publicly available on the CIRCABC page of the group, at the following link:

<https://circabc.europa.eu/ui/group/36ec94c7-575b-44dc-a6e9-4ace02907f2f/library/b8e01334-4d39-445d-bf4e-589356d55b1f>

Member States and interested stakeholders were largely supportive of the adoption of this delegated Regulation.

The draft delegated Regulation has been published for feedback on the Better Regulation portal together with four other draft delegated Regulations. 49 contributions have been submitted in total. Three stakeholders supported this delegated Regulation.

One stakeholder was of the view that the definition of natural polymer is too restrictive. No change has been introduced in the draft as the intention is to keep the notions aligned with the definitions in Regulation (EC) No 1907/2006.

The draft delegated Regulation has also been notified based on Article 2(9)(2) of the Agreement on Technical Barriers to Trade and no comments have been received.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends Annex II to Regulation (EU) 2019/1009. The legal basis of this delegated act is Article 42(1) of Regulation (EU) 2019/1009.

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⁶ OJ L 123, 12.5.2016, p. 1.

Commission Delegated Regulation (EU) .../... of 23.7.2024 amending Annex II to Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the polymers in Component Material Category 11

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003¹, and in particular Article 42(1) thereof,

Whereas:

- (1) Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. Pursuant to the requirements related to the component material categories ('CMCs') 8 and 9 laid down in Part II of Annex II to this Regulation, EU fertilising products may contain certain polymers.
- (2) The ubiquitous presence of tiny fragments of synthetic or chemically modified natural polymers, which are insoluble in water, degrade very slowly and can easily be ingested by living organisms, raises concerns about their general impact on the environment and, potentially, on human health. That is particularly valid for polymers intentionally added to EU fertilising products which are subsequently released to the environment.
- (3) Therefore, Regulation (EU) 2019/1009 set out an obligation for the Commission to assess by 16 July 2024 the biodegradability criteria of two categories of polymers belonging to CMC 9: polymers controlling the water penetration into nutrient particles and thus the release of nutrients ('coating agents') and polymers increasing the water retention capacity or wettability of the product ('water retention polymers').
- (4) On 23 June 2021, the Commission adopted Delegated Regulation (EU) 2021/1768² adding new categories of polymers in Component Material Categories 1 and 11. Such polymers are normally used as technical additives, to increase the agronomic efficiency or the safety of the products. In order to identify which polymers do not cause any environmental concern and therefore should be included in CMCs 1 and 11, the Commission took into account the scientific opinions issued by the Risk Assessment Committee³ and the Committee for Socioeconomic Analysis of the European Chemical Agency in accordance with Regulation (EC) No 1907/2006 of the

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¹ OJ L 170, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1009/oj>.

² Commission Delegated Regulation (EU) 2021/1768 of 23 June 2021 amending, for the purpose of its adaptation to technical progress, Annexes I, II, III and IV to Regulation (EU) 2019/1009 of the European Parliament and of the Council laying down rules on the making available on the market of EU fertilising products, OJ L 356, 8.10.2021, p. 8.

³ RAC ECHA. 2020. Opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics (ECHA/RAC/RES-O -0000006790-71-01/F).

European Parliament and of the Council⁴, on intentionally added microplastic particles to consumer or professional use products of any kind. Thus, only natural polymers, which have not been chemically modified, biodegradable polymers or soluble polymers may be used as materials belonging to CMCs 1 or 11.

- (5) Subsequently, the Commission adopted Regulation (EU) 2023/2055⁵ which introduces a general restriction in Regulation (EC) No 1907/2006 of placing on the market of synthetic polymer microparticles ('the general restriction'). Certain categories of polymers and polymers meeting biodegradability or solubility criteria set out in Regulation (EC) No 1907/2006 are excluded from the general restriction.
- (6) EU fertilising products are excluded from the scope of the general restriction, waiting for the outcome of the assessment on biodegradability criteria for coating agents and water retention polymers. However, the requirements for polymers belonging to CMC 11 typically used as technical additives should be aligned to the requirements for polymers exempted from the general restriction. Firstly, the materials belonging to CMC 11 are already subject to some provisions of Regulation (EC) No 1907/2006, specifically adapted to their use as component materials in EU fertilising products. Secondly, the polymers which may be used as materials belonging to CMC 11, typically technical additives, such as anti-dusting or anti-caking agents, are not fulfilling a specific function during a certain period after their application to soils, like coating agents and water retention polymers, they do not have to slowly degrade and there is no justification to introduce or maintain specific biodegradation rules for them. Thirdly, the general restriction in Regulation (EC) No 1907/2006 applies to similar polymers in national fertilising products, except for coating agents or water retention polymers which are to meet the same criteria as the ones to be laid down in accordance with Regulation (EU) 2019/1009. Aligning the requirements for materials belonging to CMC 11 to those in Regulation (EC) No 1907/2006 is thus needed both to ensure coherence by applying the same rules to similar materials contained in either harmonized or non-harmonised products, and to achieve the objectives pursued by introducing the general restriction in Regulation (EC) No 1907/2006, which could be jeopardized by maintaining more lenient rules in Regulation (EU) 2019/1009.
- (7) Regulation (EU) 2019/1009 should therefore be amended accordingly.
- (8) Regulation (EU) 2023/2055 is to start applying to national fertilising products from 17 October 2028. For coherence reasons and to allow sufficient time to adapt to the requirements introduced by this Regulation, the same transitional period should apply,

⁴ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1.

⁵ Commission Regulation (EU) 2023/2055 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles (OJ L 238, 27.9.2023, p. 67, ELI: <http://data.europa.eu/eli/reg/2023/2055/oj>).

HAS ADOPTED THIS REGULATION:

Article 1

Point 1 in section ‘CMC 11: BY-PRODUCTS WITHIN THE MEANING OF DIRECTIVE 2008/98/EC’ in Part II of Annex II to Regulation (EU) 2019/1009 is amended as follows:

(1) point (b) is replaced by the following:

‘(b) polymers, other than:

- (i) polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted and which are not chemically modified substances within the meaning of Article 3, point (40), of Regulation (EC) No 1907/2006;
- (ii) polymers that are degradable in accordance with Appendix 15 of Annex XVII to Regulation (EC) No 1907/2006;
- (iii) polymers that have a solubility greater than 2 g/L in accordance with Appendix 16 of Annex XVII to Regulation (EC) No 1907/2006; or
- (iv) polymers that do not contain carbon atoms in their chemical structure,’;

(2) the following point (ba) is inserted:

‘(ba) polymers covered by CMC 8 and CMC 9,’.

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 apply from 17 October 2028.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23.7.2024

For the Commission
The President
Ursula VON DER LEYEN