



2024/2770

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COMMISSION DELEGATED REGULATION (EU) 2024/2770

of 15 July 2024

amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards biodegradability criteria for coating agents and water retention polymers

(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 2003/2003 ⁽¹⁾, 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 for Component Material Category 9 in Annex II to that Regulation, EU fertilising products may contain polymers to control the release of nutrients ('coating agents'), to increase the water retention capacity or wettability of the EU fertilising product ('water retention polymers') or as binding materials. Coating agents are used in particular in the production of controlled release fertilisers. Their purpose is to slowly and timely release nutrients to plants and thus, reduce nutrients leaching. The use of such products is very important to reach the target set out in the Commission Communication on the Farm to Fork Strategy ⁽²⁾ to reduce nutrient losses by at least 50 %, while ensuring that there is no deterioration in soil fertility. Water retention polymers may be used in other categories of EU fertilising products, too, such as soil improvers and growing media. They directly contribute, among others, to a sustainable use of water in agriculture. Polymer-based binding materials may be used in growing media. Such products are not to be used in contact with soils.
- (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. To address this general concern, the Commission adopted Regulation (EU) 2023/2055 ⁽³⁾ which introduces a general restriction in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁴⁾ of placing on the market of synthetic polymer microparticles. Some types of polymers (such as natural polymers which are not chemically modified) and polymers which meet specific biodegradability or solubility criteria are not concerned by the general restriction and may continue to be placed on the market.

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

⁽²⁾ Communication of the Commission on 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' (COM(2020) 381 final of 20 May 2020).

⁽³⁾ Commission Regulation (EU) 2023/2055 of 25 September 2023 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>).

⁽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, ELI: <http://data.europa.eu/eli/reg/2006/1907/2014-04-10>).

Regulation (EU) 2019/1009 sets out an obligation for the Commission to assess by 16 July 2024 the biodegradability criteria for coating agents and water retention polymers used as component materials in EU fertilising products. Therefore, EU fertilising products are excluded from the scope of that general restriction in Regulation (EC) No 1907/2006.

The Commission assessed with the support of an external study the biodegradability criteria for coating agents and water retention polymers and test methods to verify compliance with those criteria ('the study')⁽⁵⁾.

- (3) The study built a tool to predict the biodegradability behavior of polymers by using a mathematical model and showing the correlation between biodegradability under test conditions and natural environments representative of the different regions of the Union. Thus, the study assessed various factors such as soil temperature, soil pH, water content in soil, water temperature and other factors linked to the polymer characteristics (chemical structure, crystallinity, surface and thickness). The study put forward proposals concerning the biodegradability criteria in soils and in water.
- (4) The biodegradability criteria should be laid down both for soil (the main compartment, where the products are applied) and aquatic (in case of leaching or other accidental presence in surface water bodies) environments.

As regards biodegradation in soils, only polymers which can reach the ultimate degradation or mineralisation within 48 months after the functionality period should be allowed as component materials. To reduce the testing period, an accelerated testing method should be permitted. The study showed an adequate correlation between real life conditions and temperatures higher than 25 °C which is the temperature used in testing conditions. Testing at a higher temperature such as 37 °C accelerates biodegradation, while it is still considered acceptable in terms of microbiology and environment-dependent factors in real life conditions. The results obtained by the soil tool developed in the study showed that the testing period could be reduced in specific cases. Therefore, an accelerated testing at 37 °C under specific conditions should be introduced as an alternative option to demonstrate 90 % ultimate degradation or mineralisation.

- (5) The biodegradability criteria for aquatic environments should take into account both the function of the polymer and the available testing methods. On the function of the polymer, the coating agents or water retention polymers are to release nutrients in soils slowly or to increase the water retention, for 6-9 months in average. So, those polymers are designed to slowly degrade when exposed to various factors in soils, such as water. The biodegradation in soil which unavoidably occurs during that functionality period should be limited so that the polymer can still fulfil its function. As regards the available test methods for biodegradability in water, they are reliable during a period of 12 months. Thus, stringent criteria for aquatic environment as set out in Regulation (EU) 2023/2055 would negatively affect the primary function of soil-biodegradable coating agents and water retention polymers. Therefore, biodegradability in aquatic environments should be set out at a lower level during the testing period but still high enough to ensure that there would not be an accumulation of polymers in aquatic environments. It is assumed that the biodegradation process will continue after the 12-month testing period and will reach the 90 % within 48 months after the functionality period. While that ultimate degradation cannot be proved with the existing test methods, it is nevertheless a safe assumption as the material already proved a biodegradation potential and it will continue to be exposed to the same environmental factors.
- (6) In real life conditions, coating agents and water retention polymers are contained in EU fertilising products to be applied to soil. They are not supposed to reach aquatic environments. While leaching cannot be totally excluded, the potential risks to the aquatic environment are reduced because the polymers concerned would reach water bodies only after having already started their degradation in soils. To further limit the potential risks, a labelling requirement should be set out, warning end-users not to use the product close to surface water bodies and to maintain buffer strips, in accordance with national measures on the use of fertilisers. In the absence of such rules, a minimum buffer strip of 3 m should be complied with.

⁽⁵⁾ Study to assess biodegradability criteria for polymers used in EU fertilising products as coating agents or to increase water retention capacity or wettability and of mulch films, ISBN 978-92-68-05051-7; doi:10.2873/23399.

- (7) To ensure equal conditions for competition and in accordance with the requirements for the criteria set out in Article 42(6) of Regulation (EU) 2019/1009, the test methods to prove compliance with the biodegradability criteria should be listed. Such test methods are set out in European or international standards and are thus reliable and reproducible.
- (8) As regards polymers used as binding materials, the Commission received information on the use of biodegradable polymers as binding materials. If such polymers fulfill the conditions set out for polymers belonging to CMC 1, then they do not raise environmental concerns and the specific labelling requirements concerning the use and the disposal of EU fertilising products containing such polymers are not justified and should not apply.
- (9) 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 concerning the biodegradability of polymers, the same transitional period should apply.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/1009 is amended as follows:

- (1) Annex II is amended in accordance with Annex I to this Regulation;
- (2) Annex III is amended in accordance with Annex II 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*.

Annex I and point 1 of Annex II shall apply from 17 October 2028.

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

Done at Brussels, 15 July 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Part II, section ‘CMC 9: POLYMERS OTHER THAN NUTRIENT POLYMERS’, of Annex II to Regulation (EU) 2019/1009 is amended as follows:

- (1) in point 1, the introductory wording is replaced by the following:

‘An EU fertilising product may contain polymers where the purpose of the polymers is:’;
- (2) point 2 is replaced by the following:

‘2. From 17 October 2028, the polymers referred to in point 1(a) and (b) shall be:

 - (a) 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; or
 - (b) polymers that are biodegradable in accordance with the criteria set out in Appendix 1 to this Annex.’;
- (3) the following Appendix 1 is added:

‘Appendix 1

Biodegradability criteria for polymers referred to in section CMC 9, point 1(a) and (b)

- 1. The biodegradability of polymers referred to in section CMC 9, point 1(a) and (b) shall be demonstrated in the following two environmental compartments:
 - (a) Compartment 1: soil; and
 - (b) Compartment 2: fresh, estuarine or marine water.
- 2. The polymer shall achieve:
 - (a) in compartment 1:
 - (1) ultimate degradation of at least 90 % relative to the degradation of the reference material within 48 months plus the functionality period (FP) as indicated on the label; or
 - (2) mineralisation of at least 90 %, measured as evolved CO₂, over a maximum of 48 months plus the functionality period (FP) as indicated on the label;
 - (b) in compartment 2, ultimate degradation relative to the degradation of the reference material in 12 months as set out in the following table:

Criterion assessed	Pass criterion (FP = 0)	Pass criterion (FP = 1 month)	Pass criterion (FP = 2 months)	Pass criterion (FP = 3 months)	Pass criterion (FP ≥ 6 months)
Minimum target degradation after 12 months	≥ 43,8 %	≥ 41,0 %	≥ 38,1 %	≥ 35,1 %	≥ 25,0 %

For functionality periods of less than 6 months, other than the ones set out in this table, the pass criteria shall be calculated using the following exponential decay formula:

$$TD12m = 1 - \exp(-\lambda * (12 - FP))$$

where:

TD12m = the minimum target degradation after 12 months (expressed as a percentage),

λ = the degradation rate calculated as $\lambda = -\ln(0,1) / t90$,

t90 = the time for 90 % biodegradation, which is 48 months,

FP = the functionality period (expressed in months).

3. To demonstrate the biodegradability criteria in point 2(a), one of the following test methods shall be used:
 - (a) EN ISO 17556:2019. Plastics – Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved;
 - (b) ASTM D5988-96:2018. Standard Test Method for Determining Aerobic Biodegradation in Soil of Plastic Materials.
4. When there is no phase transition (glass transition or melting transition) between 25 °C and 37 °C, the temperature during testing in accordance with points 3(a) or (b) may be adjusted at 37 °C.

In such a case, the relevant criterion in point 2(a) shall be considered as being demonstrated if the polymer achieves:

- (a) at least 45 % ultimate degradation or mineralisation as referred to in point 2(a) in a separate test at 25 °C in 20 months, whereby degradation or mineralisation shall be progressing, and the plateau phase shall not have been reached, unless the degradation or mineralisation is at least 90 %; and
 - (b) one of the following criteria:
 - (i) ultimate degradation of at least 90 % relative to degradation of the reference material within 20 months plus the functionality period as indicated on the label; or
 - (ii) mineralisation of at least 90 %, measured as evolved CO₂, over a maximum of 20 months plus the functionality period as indicated on the label.
5. To demonstrate the biodegradability criteria in point 2(b), one of the following test methods shall be used:
 - (a) EN/ISO 14851:2019 Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium. Method by measuring the oxygen demand in a closed respirometer;
 - (b) EN/ISO 14852:2021. Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium. Method by analysis of evolved carbon dioxide;
 - (c) ASTM D6691:2018 Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in the Marine Environment by a Defined Microbial Consortium or Natural Sea Water Inoculum.
6. For polymers referred to in section CMC 9, point 1(a), the test shall be performed on a material consisting of:
 - (a) the polymer or polymers contained in or building a continuous coating on particles ('polymer particles') comparable in terms of composition, form, size and surface area to the coating agent present in the EU fertilising product;
 - (b) the isolated coating; or
 - (c) the polymer or the polymers in the form placed on the market where the core of the material is replaced by an inert material such as glass.

7. For polymers referred to in section CMC 9, point 1(b), the test shall be performed on a material consisting of the polymer in the form placed on the market.
 8. The following materials may be used as reference materials:
 - (a) positive controls: biodegradable materials such as micro-crystalline cellulose powder, ashless cellulose filters or poly- β -hydroxybutyrate;
 - (b) negative controls: non-biodegradable polymers such as polyethylene or polystyrene.'.
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ANNEX II

Part I of Annex III to Regulation (EU) 2019/1009 is amended as follows:

- (1) in point 1, subpoint (f) is replaced by the following:
 - ‘(f) for products containing a polymer referred to in Part II, section CMC 9, point 1(a) or (b), of Annex II:
 - (i) the time period following use during which the nutrient release is being controlled or the water retention capacity is being increased (the “functionality period”), which shall not be longer than the period between two applications in accordance with the use instructions referred to in point (d) of this point;
 - (ii) an instruction to apply the product in compliance with the buffer zones required for fertilising products in accordance with the relevant national rules or, in the absence of such rules, to apply the product at least 3 m from any surface water body;’;
- (2) point 7 is replaced by the following:
 - ‘7. The end-user shall be instructed not to use the product in contact with soil, and in collaboration with the manufacturer, to make sure of a sound disposal of the product after end of use where the EU fertilising product:
 - (a) is a growing medium as referred to in Part II, section PFC 4, point 2a, of Annex I; or
 - (b) contains a polymer with the purpose of binding material in the product as referred to in Part II, section CMC 9, point 1(c) of Annex II, which does not meet any of the requirements in Part II, section CMC 1, point 1(f)(i), (ii), (iii) or (iv) of that Annex.’.