EUROPEAN
COMMISSION

Brussels, XXX
[…](2024) XXX draft

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

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)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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 products[1]. Regulation (EU) 2019/1009 sets out an obligation for the Commission to assess biodegradability criteria for certain polymers used in EU fertilising products to control the release of nutrients ('coating agents') or to increase the water retention capacity or the wettability of the products ('water retention polymers').

This delegated Regulation sets out biodegradability criteria for coating agents and water retention polymers, based on the conclusion of an external study[2].

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 2016[3] .

Details of these consultations can be found in the minutes of the meetings held on 24 October 2022, 18-19 April 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. [to fill in]

The draft delegated Regulation has been published for feedback on the Better Regulation portal [to fill in].

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 [to be confirmed].

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act amends Annexes II and III 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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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 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.

3 OJ L 123, 12.5.2016, p. 1.

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(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

[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 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).

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.

(3) 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 No 1907/2006.

(4) 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].

(5) 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.

(6) 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.

(7) 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 that 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.

(8) 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

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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).

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.

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 Delegated 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.

(9) 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 the degradation in soils due to factors such as erosion and ultraviolet radiation. 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.

(10) 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.

(11) 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.

(12) 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,

For the Commission
The President
Ursula von der Leyen