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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 Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the inclusion of mulch films in Component Material Category 9

Delegations will find attached document C(2024) 5113 final.

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EUROPEAN
COMMISSION

Brussels, 23.7.2024
C(2024) 5113 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 23.7.2024

amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the inclusion of mulch films in Component Material Category 9

(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 products[1]. Regulation (EU) 2019/1009 sets out an obligation for the Commission to assess biodegradability criteria for mulch films to determine if to include such component materials in Component Material Category 9 in Annex II to that Regulation.

This delegated Regulation adds mulch films in Component Material Category 9 and sets out the relevant biodegradability criteria and test methods, as determined with the support 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.

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. The draft delegated Regulation was widely supported by contributing stakeholders.

Four stakeholders found the 24 months for achieving the biodegradation as being too long. Two of them were of the view that the criteria should be aligned with the ones set out in Regulation (EC) No 1907/2006[4], as amended by Commission Regulation (EU) 2023/2055[5],

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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.

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 of 25 September 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration,

hereafter referred to as the REACH restriction on intentionally added microplastics. No change has been introduced in this delegated Regulation. Firstly, the 24 months strikes a good balance between the need to ensure that mulch films are able to fulfil their function during their functionality period, and also that they would biodegrade in a reasonable period of time, so that to avoid the accumulation of polymers in soils. Secondly, mulch films are out of the scope of the REACH restriction on intentionally added microplastics.

One stakeholder expressed concerns regarding the temperature at which polymers are to biodegrade, explaining that the average temperature in soils in some Member States is well below the 25 degrees Celsius temperature mentioned in the draft delegated act. No change has been introduced as that temperature is only relevant for the testing in laboratory conditions of materials. The supporting study assessed the behaviour of polymers and found that they are to biodegrade in various types of EU soils and climatic conditions.

One stakeholder expressed strong concerns regarding the biodegradability in aquatic environments. A change has been introduced to introduce a new biodegradability requirement subject to the development of stable testing methods. While the available test methods may only produce reliable results for a maximum of 12 months, based on the findings of the supporting study, such limitation is not expected in real life conditions, and it is safe to assume that the biodegradation in aquatic environments would continue beyond the period of 12 months.

Based on the contribution of a stakeholder, a new requirement has been introduced for polymers in mulch films to pass an earthworms chronic toxicity test, in addition to the ecotoxicity tests already set out for polymers belonging to Component Material Category 9 in Regulation (EU) 2019/1009.

Various opinions have been expressed as regards the need to introduce labelling requirements concerning the application of mulch films close to water surface bodies. Some were of the view that such a labelling requirement is not needed as there is no risk, some were of the view that it is not an efficient way of addressing the risk of polymers' leaching in water. Based on the contributions received, the labelling requirement has been slightly revised to refer to the national rules setting out buffer zones for the use of fertilisers. A minimum buffer zone should be indicated on the label, to be complied with in case there are no corresponding national rules.

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 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.

Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles, OJ L 238, 27.9.2023, p. 67.

Commission Delegated Regulation (EU) …/... of 23.7.2024 amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards the inclusion of mulch films in Component Material Category 9

(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. EU fertilising products may contain only materials belonging to one of the Component Material Categories (CMCs) in Annex II to Regulation (EU) 2019/2009. That Regulation sets out an obligation for the Commission to assess biodegradability criteria for mulch films with the purpose of including them as a component material belonging to CMC 9. The Commission performed that assessment with the support of an external study ('the study')[2].

(2) Mulch films are used to maintain, improve or protect the physical or chemical properties, the structure or the biological activity of the soil. They could contribute to keeping water in soils and increase the soil temperature with positive impact on the development of crops. Given that the application of mulch films does not allow weeds to grow, the crops will no longer compete with weeds on sunlight and nutrients. Therefore, the use of mulch films could lead to a more efficient use of fertilisers. Mulch films also would reduce the use of herbicides, thus contributing to achieving the target set out in the Communication on the Farm to Fork Strategy to reduce the overall use and risk of chemical pesticides by 50 % by 2030.

(3) The study showed that there are both biodegradable and non-biodegradable mulch films on the market, used as national fertilising products. Appropriate requirements should be laid down to include biodegradable polymers in the form of mulch films within the scope of Regulation (EU) 2019/1009. The biodegradation should be assessed both in soils and in aquatic environments.

(4) 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

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

[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.

forward proposals concerning the biodegradability criteria for mulch films in soils and in water.

(5) As regards biodegradability criteria in soils, given that mulch films imply the application of large quantities of polymers to soils, their biodegradation should be proven within maximum 24 months. 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.

(6) The biodegradability criteria for aquatic environments should take into account both the function of mulch films and the available testing methods. On the function, the mulch films are applied to soils to improve or protect the physical or chemical properties, the structure or the biological activity of the soil for 12 months in average. So, mulch films are designed to slowly degrade when exposed to various environmental factors, in particular sunlight and rain. The biodegradation which unavoidably occurs during that functionality period should be limited so that the mulch film can still fulfil its function. As regards the available test methods for biodegradability in water, they are reliable during a period of 12 months. Therefore, biodegradability criteria in aquatic environments should be set out at a level during the testing period that would allow them to fulfil their function and would also 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 24 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. However, given the ongoing work on developing the testing methods for biodegradation in aquatic environments and to support innovation, mulch films for which the same biodegradation criteria for soil can be proven in aquatic environment should also be included in the scope of the EU harmonisation rules.

(7) In real life conditions, mulch films are to be applied to soil. They are not supposed to reach aquatic environments. While the transport of parts of mulch films to aquatic environment 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. 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 zones, in accordance with national measures on the use of fertilisers. In the absence of such rules, a minimum buffer zone of 3 m should be complied with. In addition, to avoid leaching to water bodies and encourage the biodegradation in soils, the labelling of mulch films should also include an instruction to incorporate the product in the soil after the functionality period.

(8) To ensure equal conditions for competition, 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.

(9) Polymers already included in CMC 9 have to pass a plant growth acute toxicity test, an earthworm acute toxicity test and a nitrification inhibition test with soil micro-organisms. To ensure a high level of protection of human health and the environment, the same tests should also apply to polymers in mulch films. In addition, as mulch films are used in larger quantities compared to the other polymers in CMC 9, the mulch film polymers should also pass an earthworm chronic toxicity test.

(10) Regulation (EU) 2019/1009 should therefore be amended accordingly.

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*.

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