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COMMISSION DELEGATED REGULATION (EU) 2024/2787

of 23 July 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) 2019/1009. 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 forward proposals concerning the biodegradability criteria for mulch films in soils and in water.

⁽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.

- (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 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.
- (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 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) the following point 1a is inserted:

'1a. An EU fertilising product belonging to PFC 3 may contain a polymer in the form of a mulch film.;

(2) the following point 2a is inserted:

'2a. The polymer in a mulch film referred to in point 1a shall comply with the biodegradability criteria set out in Appendix 2 to this Annex.;

(3) in point 3, the introductory wording is replaced by the following:

'For the polymers referred to in point 1(a) and (b) and in point 1a, neither the polymer, nor its degradation by-products, shall show any overall adverse effect on animal or plant health, or on the environment, under reasonably foreseeable conditions of use in the EU fertilising product. The polymers referred to in point 1(a) and (b) and point 1a shall pass a plant growth acute toxicity test, an earthworm acute toxicity test and a nitrification inhibition test with soil micro-organisms as follows:;

(4) the following point 4 is added:

'4. The polymer referred to in point 1a shall pass an earthworm chronic toxicity test so that:

- (a) after an incubation period of 28 days, the observed mortality and the biomass of surviving adult earthworms in a soil exposed to the test material shall not differ by more than 10 % compared to those from the corresponding blank soil not exposed to the test material;
- (b) after an incubation period of 56 days, the observed number of offspring in a soil exposed to the test material shall not differ by more than 10 % compared to those from the corresponding blank soil not exposed to the test material.

The results shall be considered to be valid only if in the controls (i.e. blank soil):

- (a) after an incubation period of 28 days, the observed adult mortality is no more than 10 %;
- (b) after an incubation period of 56 days each replicate (containing 10 adults) produces at least 30 offspring; and
- (c) the coefficient of variation of reproduction is no more than 30 %.;

(5) the following Appendix 2 is added:

'Appendix 2

Biodegradability criteria of polymers for mulch films referred to in section CMC 9, point 1a

1. The biodegradability of polymers in mulch films referred to in section CMC 9, point 1a, shall be demonstrated in the following two environmental compartments:
 - (a) compartment 1: soil;
 - (b) compartment 2: fresh, estuarine or marine water, or water sediment interface.
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 24 months plus the functionality period of the product as indicated on the label; or
 - (2) mineralisation of at least 90 %, measured as evolved CO₂, over a maximum of 24 months plus the functionality period of the product as indicated on the label:

- (b) in compartment 2:
 - (1) ultimate degradation of at least 30 % relative to the degradation of the reference material in 12 months; or
 - (2) ultimate degradation of at least 90 % relative to the degradation of the reference material in 24 months plus the functionality period of the product as indicated on the label.
- 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) ISO/CD 23517:2021. Plastics – Soil biodegradable materials for mulch films for use in agriculture and horticulture;
 - (c) 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), (b) and (c) 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 10 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 10 months plus the functionality period of the product as indicated on the label; or
 - (ii) mineralisation of at least 90 %, measured as evolved CO₂, over a maximum of 10 months plus the functionality period of the product 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;
 - (d) EN/ISO 19679:2020 Plastics – Determination of aerobic biodegradation of non-floating plastic materials in a seawater/sediment interface – Method by analysis of evolved carbon dioxide;
 - (e) EN/ISO 18830:2017 Plastics – Determination of aerobic biodegradation of non-floating plastic materials in a seawater/sandy sediment interface – Method by measuring the oxygen demand in closed respirometer.
- 6. Polymers may be tested in any of the following forms:
 - (a) in the form of the film placed on the market;
 - (b) in a powder form of the milled film.

7. 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

In Part I, point 1, of Annex III to Regulation (EU) 2019/1009, the following point (fa) is inserted:

- ‘(fa) for products belonging to PFC 3 containing a polymer referred to in Part II, section CMC 9, point 1a, of Annex II:
- (a) the time period following use during which the soil improver will fulfil its function (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;
 - (b) 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;
 - (c) an instruction to follow the national measures on handling mulch films after their functionality period or, in the absence of such measures, to incorporate in soil the product after its functionality period and maintain it buried;’.
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