



Council of the  
European Union

193854/EU XXVII. GP  
Eingelangt am 24/07/24

Brussels, 24 July 2024  
(OR. en)

12565/24  
ADD 1

ENT 147  
MI 729  
COMPET 831  
IND 391  
ENV 815  
AGRI 590  
SAN 468  
DELECT 144

#### COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 July 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2024) 5113 final, ANNEXES 1 to 2
Subject:	ANNEXES to the Commission Delegated Regulation 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, ANNEXES 1 to 2.

Encl.: C(2024) 5113 final, ANNEXES 1 to 2



EUROPEAN  
COMMISSION

Brussels, 23.7.2024

C(2024) 5113 final

ANNEXES 1 to 2

## **ANNEXES**

**to the**

### **Commission Delegated Regulation**

**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**

## 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 CO<sub>2</sub>, 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:
    - (a) 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
    - (b) mineralisation of at least 90 %, measured as evolved CO<sub>2</sub>, 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- $\beta$ -hydroxybutyrate;
  - (b) negative controls: non-biodegradable polymers such as polyethylene or polystyrene.’.

## **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;’.