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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.

As regards point (a) of this point, the results shall be considered to be valid, if:

- (i) the percent mortality observed in the control (i.e. blank soil) is less than 10 %; and
- (ii) the average loss of biomass (mean weight) of the worms in the blank soil does not exceed 20 %.

As regards point (b) of this point, the results shall be considered to be valid, if the average loss of offspring in the control (i.e. blank soil) is less than 20 %.’;

(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 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:
 - (i) 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
 - (ii) 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, ultimate degradation of at least 30 % relative to the degradation of the reference material in 12 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) 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) 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;
 - (c) 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.’.

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:

- (i) 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;
- (ii.) an instruction not to apply the product within at least 3 meters of surface water bodies, while respecting any national rules setting more stringent requirements;
- (iii) an instruction to incorporate in soil the product after its functionality period and maintain it buried;’.