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## COVER NOTE

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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2024) 4826 final, ANNEXES
Subject:	ANNEXES to the Commission Delegated Regulation amending Regulation (EU) 2019/1009 of the European Parliament and of the Council as regards biodegradability criteria for coating agents and water retention polymers

Delegations will find attached document C(2024) 4826 final, ANNEXES.

Encl.: C(2024) 4826 final, ANNEXES



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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 biodegradability criteria for coating agents and water retention polymers**

## 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) in point 1, the introductory wording is replaced by the following:  
‘An EU fertilising product may contain polymers where the purpose of the polymers is:’;
- (2) point 2 is replaced by the following:  
‘2. From 17 October 2028, the polymers referred to in point 1(a) and (b) shall be:
  - (a) polymers that are the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted and which are not chemically modified substances within the meaning of Article 3, point (40), of Regulation (EC) No 1907/2006; or
  - (b) polymers that are biodegradable in accordance with the criteria set out in Appendix 1 to this Annex.’;
- (3) the following Appendix 1 is added:

### *‘Appendix 1*

#### **Biodegradability criteria for polymers referred to in section CMC 9, point 1(a) and (b)**

1. The biodegradability of polymers referred to in section CMC 9, point 1(a) and (b) shall be demonstrated in the following two environmental compartments:
  - (a) Compartment 1: soil; and
  - (b) Compartment 2: fresh, estuarine or marine water.
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 48 months plus the functionality period (FP) as indicated on the label; or
    - (2) mineralisation of at least 90 %, measured as evolved CO<sub>2</sub>, over a maximum of 48 months plus the functionality period (FP) as indicated on the label;
  - (b) in compartment 2, ultimate degradation relative to the degradation of the reference material in 12 months as set out in the following table:

Criterion assessed	Pass criterion (FP=0)	Pass criterion (FP=1 month)	Pass criterion (FP=2 months)	Pass criterion (FP=3 months)	Pass criterion (FP≥6 months)
Minimum target degradation after 12 months	≥ 43,8 %	≥ 41,0 %	≥ 38,1 %	≥ 35,1 %	≥ 25,0 %

For functionality periods of less than 6 months, other than the ones set out in this table, the pass criteria shall be calculated using the following exponential decay formula:

$$TD12m = 1 - \exp(-\lambda * (12 - FP))$$

where:

TD12m = the minimum target degradation after 12 months (expressed as a percentage),

$\lambda$  = the degradation rate calculated as  $\lambda = -\ln(0,1) / t_{90}$ ,

$t_{90}$  = the time for 90% biodegradation, which is 48 months,

FP = the functionality period (expressed in 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) 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) or (b) 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 20 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 20 months plus the functionality period as indicated on the label; or

(ii) mineralisation of at least 90 %, measured as evolved CO<sub>2</sub>, over a maximum of 20 months plus the functionality period 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.
- 6. For polymers referred to in section CMC 9, point 1(a), the test shall be performed on a material consisting of:
  - (a) the polymer or polymers contained in or building a continuous coating on particles ('polymer particles') comparable in terms of composition, form, size and surface area to the coating agent present in the EU fertilising product;
  - (b) the isolated coating; or
  - (c) the polymer or the polymers in the form placed on the market where the core of the material is replaced by an inert material such as glass.
- 7. For polymers referred to in section CMC 9, point 1(b), the test shall be performed on a material consisting of the polymer in the form placed on the market.
- 8. 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

Part I of Annex III to Regulation (EU) 2019/1009 is amended as follows:

(1) in point 1, subpoint (f) is replaced by the following:

‘(f) for products containing a polymer referred to in Part II, section CMC 9, point 1(a) or (b), of Annex II:

(i) the time period following use during which the nutrient release is being controlled or the water retention capacity is being increased (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 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;’;

(2) point 7 is replaced by the following:

‘7. The end-user shall be instructed not to use the product in contact with soil, and in collaboration with the manufacturer, to make sure of a sound disposal of the product after end of use where the EU fertilising product:

a. is a growing medium as referred to in Part II, section PFC 4, point 2a, of Annex I; or

b. contains a polymer with the purpose of binding material in the product as referred to in Part II, section CMC 9, point 1(c) of Annex II, which does not meet any of the requirements in Part II, section CMC 1, point 1(f)(i), (ii), (iii) or (iv) of that Annex.’.