

(2) the following Appendices 15 and 16 are added:

Appendix 15

Entry 78 – Rules on proving degradability

This appendix lays down the rules for proving degradability of polymers for the purposes of entry 78, namely the permitted test methods and the pass criteria for those methods. The test methods were designed to measure biotic degradation, although it cannot be excluded that some abiotic degradation takes place during the test and contributes to the test results.

The tests shall be conducted by laboratories complying with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency or accredited to ISO 17025.

1. Test methods

The permitted test methods are organised into five groups, on the basis of their design and underlying rationale. Meeting the pass criteria in any of the permitted test methods in groups 1 to 3 is sufficient to demonstrate that the polymer or polymers contained in the tested material and subject to the test are degradable and are therefore excluded from the scope of entry 78. Where group 4 or group 5 tests are used to demonstrate degradability of polymers for uses other than agricultural and horticultural uses, the pass criteria shall be met in three environmental compartments chosen as follows:

Compartment 1: fresh, estuarine or marine water;

Compartment 2:

(a) fresh, estuarine or marine sediment; or

(b) fresh, estuarine or marine water/sediment interface

Compartment 3: soil.

1.1. Group 1. Screening test methods and pass criteria to demonstrate ready biodegradation

1.1.1. Permitted test methods in group 1:

T1. "Ready Biodegradability" (OECD TG 301 B, C, D, F)

T2. "Ready Biodegradability – CO₂ in sealed vessels (Headspace Test)" (OECD TG 310).

1.1.2. Pass criteria: 60 % mineralisation measured, over 28 days, as evolved CO₂ or consumed O₂. The 10-day window requirement mentioned in the T1 and T2 test guidelines does not need to be fulfilled.

1.2. Group 2. Modified and enhanced screening test methods and pass criteria to demonstrate ready biodegradation

1.2.1. Permitted test methods in group 2:

T1. "Ready Biodegradability" (OECD TG 301 B, C, D, F);

T2. "Ready Biodegradability – CO₂ in sealed vessels (Headspace Test)" (OECD TG 310);

T3. "Biodegradability in Seawater" (OECD TG 306).

1.2.2. For group 2 test methods, the test duration can be extended to up to 60 days and larger test vessels used.

1.2.3. Pass criteria: 60 % mineralisation measured, over 60 days, as consumed O₂ (allowed for T1 and T2 tests only) or evolved CO₂. The 10-day window requirement mentioned in the T1 and T2 test guidelines does not need to be fulfilled.

1.3. Group 3. Screening test method and pass criteria to demonstrate inherent degradation

1.3.1. Permitted test method in group 3:

T4. "Inherent Biodegradability: modified MITI Test (II)" (OECD 302C).

- 1.3.2. The pre-adaptation of the inoculum mentioned in the T4 test guideline shall not be allowed.
- 1.3.3. Pass criteria: $\geq 70\%$ mineralisation measured as consumed O_2 or evolved CO_2 within 14 days.
- 1.4. *Group 4. Screening test methods and pass criteria to demonstrate degradation relative to a reference material*
- 1.4.1. Permitted test methods in group 4:
- T5. "Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium – Method by analysis of evolved carbon dioxide." (EN ISO 14852:2021);
 - T6. "Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium – Method by measuring the oxygen demand in a closed respirometer." (EN ISO 14851:2019);
 - T7. "Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sediment interface – Method by analysis of evolved carbon dioxide" (EN ISO 19679:2020);
 - T8. "Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sandy sediment interface – Method by measuring the oxygen demand in closed respirometer" (EN ISO 18830:2016);
 - T9. "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" (EN ISO 17556:2019);
 - T10. "Plastics – Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment – Method by analysis of evolved carbon dioxide" (ISO 22404:2019).
- 1.4.2. The specifications laid down in ISO 22403:2020 "Plastics – Assessment of the intrinsic biodegradability of materials exposed to marine inocula under mesophilic aerobic laboratory conditions – Test methods and requirements" shall be taken into account when applying T7 and T8.
- 1.4.3. For group 4 test methods, the pre-adaptation of the inoculum shall not be allowed. The result shall be reported as the maximum level of degradation determined from the plateau phase of the degradation curve, or as the highest value if the plateau has not been reached. The form, size and surface area of the reference material shall be comparable to that of the test material. The following materials may be used as reference materials:
- positive controls: biodegradable materials such as micro-crystalline cellulose powder, ashless cellulose filters or poly- β -hydroxybutyrate.
 - negative controls: non-biodegradable polymers such as polyethylene or polystyrene.
- 1.4.4. Pass criteria: ultimate degradation of $\geq 90\%$ relative to the degradation of the reference material within:
- 6 months in aquatic tests, or,
 - 24 months in soil, sediment or water/sediment interface tests.
- 1.5. *Group 5. Simulation test methods and pass criteria to demonstrate degradation under relevant environmental conditions*
- 1.5.1. Permitted test methods in group 5:
- T11. "Aerobic and Anaerobic Transformation in Soil" (OECD TG 307);
 - T12. "Aerobic and Anaerobic Transformation in Aquatic Sediment Systems" (OECD TG 308);
 - T13. "Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test" (OECD TG 309)

1.5.2. The required test temperatures shall be 12 °C for fresh/estuarine water, fresh/estuarine water sediment and soil, and 9 °C for marine water and marine sediment because these are the average temperatures for those compartments in the Union.

1.5.3. Pass criteria:

- the degradation half-life in marine, fresh or estuarine water is less than 60 days;
- the degradation half-life in marine, fresh or estuarine sediment is less than 180 days;
- the degradation half-life in soil is less than 180 days.

2. Specific requirements for demonstrating the degradability of polymers in products for agricultural and horticultural applications

2.1. *Fertilising products containing polymers which are coating agents or increase the water retention capacity or the wettability of the product*

The degradability of polymers which are coating agents or increase the water retention capacity or the wettability in fertilising products, as defined in Article 2, point (1), of Regulation (EU) 2019/1009, which do not fall within the scope of that Regulation shall be demonstrated in accordance with the delegated acts referred to in Article 42(6) of that Regulation. In the case of absence of such delegated acts, such polymers shall not be placed on the market in fertilising products which do not fall within the scope of Regulation (EU) 2019/1009 after 17 October 2028.

2.2. *Agricultural and horticultural products other than fertilising products referred to in paragraph 2.1*

Where group 4 or group 5 test methods are used, the degradability of polymers in products for agricultural or horticultural applications other than fertilising products referred to in point 2.1 shall be demonstrated in at least two environmental compartments chosen as follows:

Compartment 1: fresh, estuarine or marine water;

Compartment 2: soil.

To be considered degradable for the scope of entry 78, a polymer in a product for agricultural or horticultural applications other than a fertilising product referred to in point 2.1 shall achieve 90 % degradation in:

- (a) soil within 48 months after the end of that product functionality period; the functionality period is the time following the product application during which the product exerts its function.
- (b) water within:
 - (i) 12 months plus the product functionality period, where group 4 test methods are used; or
 - (ii) 16 months plus the product functionality period, where group 5 test methods are used.

To this end, the pass criteria for group 4 and 5 test methods shall be modified to indicate the percentage of degradation (for group 4) or the half-life (for group 5) that needs to be observed at the end of the standard test duration in order to achieve the conditions laid down in the previous paragraph.

The modified pass criteria of group 4 and 5 test methods are set in Tables A and B, respectively.

Table A

Group 4 pass criteria for polymers in products for agricultural or horticultural applications, listed by duration of the functionality period (FP) and type of test

Test method	Criterion assessed	Pass criterion (FP = 0)	Pass criterion (1 month FP)	Pass criterion (2 month FP)	Pass criterion (3 month FP)	Pass criterion (6 month FP)	Pass criterion (9 month FP)
T9 (soil)	Target degradation after 24 months	≥ 68,4 %	≥ 67,6 %	≥ 66,9 %	≥ 66,2 %	≥ 64,1 %	≥ 62,1 %

T5 and T6 (surface water)	Target degradation after 6 months	≥ 68,4 %	≥ 65,4 %	≥ 62,7 %	≥ 60,2 %	≥ 53,6 %	≥ 48,2 %
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Table B

Group 5 pass criteria for polymers in products for agricultural or horticultural applications, listed by duration of the functionality period (FP) and type of test

Test method	Criterion assessed	Pass criterion (FP = 0)	Pass criterion (1 month FP)	Pass criterion (2 month FP)	Pass criterion (3 month FP)	Pass criterion (6 month FP)	Pass criterion (9 month FP)
T11 (soil, 48 months + F-P)	Degradation half-life (DegT50)	DegT50 ≤ 440 days	DegT50 ≤ 449 days	DegT50 ≤ 458 days	DegT50 ≤ 467 days	DegT50 ≤ 495 days	DegT50 ≤ 522 days
T13 (surface water, 16 months + F-P)	Degradation half-life (DegT50)	DegT50 ≤ 147 days	DegT50 ≤ 156 days	DegT50 ≤ 165 days	DegT50 ≤ 174 days	DegT50 ≤ 202 days	DegT50 ≤ 229 days

For functionality periods not covered in Tables A or B, the pass criteria shall be calculated using the exponential decay formulas indicated below.

Group 4, T9 (soil):

The target degradation over 24 months (TD_{24m}) shall be calculated as follows:

$$TD_{24m} = 1 - \exp(-\lambda \times c \times 24)$$

Group 4, T5 and T6 (surface water)

The target degradation over 6 months (TD_{6m}) shall be calculated as follows:

$$TD_{6m} = 1 - \exp(-\lambda \times c \times 6)$$

Group 5, T11 (soil) and T13 (surface water):

The degradation half-life (DegT50) observed at the end of the group 5 test duration shall be calculated as follows:

$$\text{DegT50} = \ln(2)/\lambda$$

where:

c is the average number of days per month, calculated as:

$$c = 365,25/12$$

λ is the degradation rate, calculated as:

$$\text{for T9 and T11: } \lambda_{T9/T11} = \ln(0,1)/-t_{90,T9/T11}$$

$$\text{for T5 and T6: } \lambda_{T5/T6} = \ln(0,1)/-t_{90,T5/T6}$$

$$\text{for T13: } \lambda_{T13} = \ln(0,1)/-t_{90,T13}$$

t_{90} is the time- to- 90 %-degradation, calculated as:

for T9 and T11: $t_{90,T9/T11} = c \times (48 + FP)$

for T5 and T6: $t_{90,T5/T6} = c \times (12 + FP)$

for T13: $t_{90,T13} = c \times (16 + FP)$

FP is the functionality period, expressed in months.

3. Specific requirements for the test material to be used in degradation tests

The test shall be performed on a test material consisting of a 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 polymer particles present in the product or, if not technically feasible, to the polymer particles that are disposed of or released to the environment.

By way of derogation from the first paragraph, polymers used for encapsulation may be tested in any of the following forms:

- in the form placed on the market;
- in the form of isolated coating;
- in the form placed on the market where the organic core of the material is replaced by an inert material such as glass.

The test material shall be of comparable thickness to the solid polymer coating of the particle placed on the market. When the degradation is assessed in relation to a reference material, as referred to in point 1.4.3, the form, size and surface area of the reference material shall be comparable to that of the test material.

Where the test material contains more than one polymer and test methods from groups 1, 2 or 3 are used to prove degradation, the degradation of each of the polymers shall be demonstrated in either of the following ways:

- separately testing the degradation of the test material and of each polymer in the test material using the permitted test methods and pass criteria set out in this Appendix,
- testing the degradation of the test material using the permitted test methods and pass criteria set out in this Appendix and, during testing, demonstrating, by any appropriate means, that all polymers in the test material contribute to the degradation observed during testing and that each polymer meets the pass criteria in the relevant permitted test method set out in this Appendix.

Where the test material is composed of a single polymer but contains other non-polymeric organic substances in concentration higher than 10 % by weight of the test material, and test methods from groups 1, 2 or 3 are used to prove degradation, either of the following conditions shall apply:

- the degradation of the test material and of the polymer in the test material shall be tested separately using the permitted test methods and pass criteria set out in this Appendix;
- the degradation of the test material shall be tested using the permitted test methods and pass criteria set out in this Appendix and, during testing, it shall be demonstrated, by any appropriate means, that the polymer contributes to the degradation of the test material observed during testing and meets the pass criteria in the relevant permitted test method set out in this Appendix.