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ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) …/…
of XXX

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards synthetic polymer microparticles

ANNEX

Annex XVII is amended as follows:

(1) the following entry is added:

'[*Publications Office, please insert the next consecutive number*] Synthetic polymer microparticles: polymers that are solid and which fulfil both of the following conditions: (a) are contained in particles and constitute at least 1 % by weight of those particles; or build a continuous surface coating on particles; (b) at least 1 % by weight of the particles referred to in point (a) fulfil either of the following conditions: (i) all dimensions of the particles are equal to or less than 5 mm; (ii) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3. The following polymers are excluded from this designation: (a) polymers that are	1. Shall not be placed on the market as substances on their own or, where the synthetic polymer microparticles are present to confer a sought-after characteristic, in mixtures in a concentration equal to or greater than 0,01 % by weight. 2. For the purposes of this entry, the following definitions apply: (a) 'particle' means a minute piece of matter, other than single molecules, with defined physical boundaries; (b) 'solid' means a substance or mixture other than a liquid or gas; (c) 'gas' means a substance or mixture which at 50 °C has a vapour pressure greater than 300 kPa (absolute), or is completely gaseous at 20 °C at a standard pressure of 101,3 kPa; (d) 'liquid' means a substance or mixture that meets any of the following conditions: (i) the substance or mixture at 50 °C has a vapour pressure of not more than 300 kPa, is not completely gaseous at 20 °C and at a standard pressure of 101,3 kPa, and has a melting point or initial melting point of 20 °C or less at a standard pressure of 101,3 kPa; (ii) the substance or mixture fulfils the criteria in the American Society for Testing and Materials (ASTM) D 4359-90 Standard Test Method for Determining Whether a Material Is a Liquid or a Solid; (iii) the substance or mixture passes the fluidity test (penetrometer test) described in chapter 2.3.4 of Part 2 of Annex A to the European Agreement

the result of a polymerisation process that has taken place in nature, independently of the process through which they have been extracted, which are not chemically modified substances; (b) polymers that are degradable as proved in accordance with Appendix [X]; (c) polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix [Y]; (d) polymers that do not contain carbon atoms in their chemical structure.	concerning the International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957; (e) 'make-up product' means any substance or mixture intended to be placed in contact with specific external parts of the human body, namely the epidermis, eye brows and eye lashes, with a view to, exclusively or mainly, changing their appearance; 3. Where the concentration of synthetic polymer microparticles covered by this entry cannot be determined by available analytical methods or accompanying documentation, in order to verify the compliance with the concentration limit referred to in paragraph 1, only the particles of at least the following size shall be taken into account: (a) 0,1 µm for any dimension, for particles where all dimensions are equal to or smaller than 5 mm; (b) 0,3 µm in length, for particles that have a length that is equal to or smaller than 15 mm and a length to diameter ratio greater than 3. 4. Paragraph 1 shall not apply to the placing on the market of: (a) synthetic polymer microparticles, as substances on their own or in mixtures, for use at industrial sites; (b) medicinal products within the scope of Directive 2001/83/EC and veterinary medicinal products within the scope of Regulation (EU) 2019/6 of the European Parliament and of the Council*; (c) EU fertilising products within the scope of Regulation (EU) 2019/1009 of the European Parliament and of the Council**; (d) food additives within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council***; (e) in vitro diagnostic devices, including devices

	within the scope of Regulation (EU) 2017/746[****]; (f) food within the meaning of Article 2 of Regulation (EC) No 178/2002, not covered by point (d) of this paragraph, and feed as defined in Article 3(4) of that Regulation. 5. Paragraph 1 shall not apply to the placing on the market of the following synthetic polymer microparticles, as substances on their own or in mixtures: (a) synthetic polymer microparticles which are contained by technical means so that releases to the environment are prevented when used in accordance with the instructions for use during the intended end use; (b) synthetic polymer microparticles the physical properties of which are permanently modified during intended end use in such a way that the polymer no longer falls within the scope of this entry; (c) synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use. 6. Paragraph 1 shall apply as follows regarding the following uses: (a) from… [*Publications Office, please insert the date = 6 years after the entry into force of this amending Regulation*] to synthetic polymer microparticles for use in the encapsulation of fragrances; (b) from …[*Publications Office, please insert the date = 4 years after the entry into force of this amending Regulation*] for 'rinse-off products' as defined in point (1)(a) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009 unless such products are covered by point (a) of this paragraph or contain synthetic polymer microparticles for use as an abrasive, i.e. namely to exfoliate, polish or clean ('microbeads');

	(c) from… [*Publications Office, please insert the date = 12 years after the entry into force of this amending Regulation*] for lip products as defined in point (1)(e) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009, nail products as defined in point (1)(g) of the Preamble to Annexes II to VI to that Regulation, and make-up products within the scope of that Regulation, unless such products are covered by points (a) or (b) of this paragraph or contain microbeads; (d) from… [*Publications Office, please insert the date = 6 years after the entry into force of this amending Regulation*] for leave-on products, as defined in point (1)(b) of the Preamble to Annexes II to VI to Regulation (EC) No 1223/2009, unless such products are covered by points (a) or (c) of this paragraph; (e) from… [*Publications Office, please insert the date = 5 years after the date of entry into force of this amending Regulation*] for detergents, as defined in Article 2(1) of Regulation (EC) No 648/2004, waxes, polishes and air care products, unless those products are covered by point (a) of this paragraph or contain microbeads; (f) from… [*Publications Office, please insert the date = 6 years after the date of entry into force of this amending Regulation*] for 'devices', within the scope of Regulation (EU) 2017/745[*****], unless those devices contain microbeads; (g) from… [*Publications Office, please insert the date = 5 years after the date of entry into force of this amending Regulation*] for 'fertilising products', as defined in Article 2, point (1), of Regulation (EU) 2019/1009, which do not fall within the scope of that Regulation; (h) from… [*Publications Office, please insert the date = 8 years after the date of entry into force of this amending Regulation*] for plant protection products within the meaning of Article 2(1) of Regulation (EC) No 1107/2009[******] and seeds

	treated with those products, and biocidal products as defined in Article 3(1), point (a), of Regulation (EU) No 528/2012 of the European Parliament and of the Council[*******]; (i) from… [*Publications Office, please insert the date = 5 years after the date of entry into force of this amending Regulation*] for products for agricultural and horticultural uses not covered by points (g) or (h); (j) from… [*Publications Office, please insert the date = 8 years after the date of entry into force of this amending Regulation*] for granular infill for use on synthetic sports surfaces. 7. From… [*Publications Office, please insert the date = 24 months after the date of entry into force of this amending Regulation*] suppliers of synthetic polymer microparticles referred to in paragraph 4, point (a), shall provide the following information: (a) instructions for use and disposal explaining to industrial downstream users how to prevent releases of synthetic polymer microparticles to the environment; (b) the following statement: 'The synthetic polymer microparticles supplied is subject to conditions laid down by entry [*Publications Office, please insert the number of the entry in point (1) of the Annex*] of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council'; (c) the information on quantity or, as applicable, concentration of synthetic polymer microparticles in the substance or mixture; (d) generic information on the identity of the polymers contained in the substance or mixture that enables manufacturers, industrial downstream users and other suppliers to comply with their obligations laid down in paragraphs 11 and 12. 8. From… [*Publications Office, please insert the date = 36 months after the date of entry into force of this amending Regulation*] suppliers of products containing synthetic polymer microparticles referred

	to in paragraph 4, point (e), and from [*Publications Office, please insert the date = 24 months after the date of entry into force of this amending Regulation*] suppliers of products containing synthetic polymer microparticles referred to in paragraph 4, point (d), and paragraph 5, shall provide instructions for use and disposal explaining to professional users and the general public how to prevent releases of synthetic polymer microparticles to the environment. 9. From … [*Publications Office, please insert the date = 8 years after the date of entry into force of this amending Regulation*] until… [*Publications Office, please insert the date = 12 years – 1 day after the date of entry into force of this amending Regulation*] suppliers of products referred to in paragraph 6, point (c), containing synthetic polymer microparticles shall provide the following statement: 'This product contains microplastics.' However, products placed on the market before [*Publications Office, please insert the date = 8 years after the date of entry into force of this amending Regulation*] are not required to bear that statement until [*Publications Office, please insert the date = 8 years + 2 months after the date of entry into force of this amending Regulation*]. 10. The information referred to in paragraphs 7, 8 and 9 shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in paragraphs 7 and 8, in the form of pictograms. The text or pictograms shall be placed on the label, the packaging, or the package leaflet of the products containing synthetic polymer microparticles or, regarding the information in paragraph 7, on the safety data sheet. In addition to the text or pictograms, suppliers may provide a digital tool that gives access to an electronic version of that information. Where instructions for use and disposal are provided in accordance with paragraphs 7, 8 and 9 in the form

	of a text, they shall be in the official languages of the Member States where the substance or mixture is placed on the market, unless the Member States concerned provide otherwise. 11. Starting from… [*Publications Office, please insert the calendar year in which the date 24 months after the date of entry into force of this amending Regulation falls. However, if this calculated date is later in the year than 31 May, please insert the following calendar year.*] manufacturers and industrial downstream users of synthetic polymer microparticles in the form of pellets, flakes, and powders used as feedstock in plastic manufacturing at industrial sites, and, starting from … [*Publications Office, please insert the calendar year in which the date 36 months after the date of entry into force of this amending Regulation falls. However, if this calculated date is later in the year than 31 May, please insert the following calendar year.*], other manufacturers of synthetic polymer microparticles and other industrial downstream users using synthetic polymer microparticles at industrial sites shall submit the following information to the Agency by 31 May of each year: (a) a description of the uses of synthetic polymer microparticles in the previous calendar year; (b) for each use of synthetic polymer microparticles, generic information on the identity of the polymers used; (c) for each use of synthetic polymer microparticles, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation. (d) for each use of synthetic polymer microparticles, a reference to the derogation laid down in paragraph 4, point (a). 12. From … [*Publications Office, please insert the*

	calendar year in which the date 36 months after the date of entry into force of this amending Regulation falls. However, if this calculated date is later in the year than 31 May, please insert the following calendar year], suppliers of products containing synthetic polymer microparticles referred to in paragraphs 4, points (b), (d) and (e), and paragraph 5, placed on the market for the first time to professional users and the general public, shall submit the following information to the Agency by 31 May of each year: (a) a description of the end uses for which the synthetic polymer microparticles were placed on the market in the previous calendar year; (b) for each end use for which the synthetic polymer microparticles were placed on the market, generic information on the identity of the polymers placed on the market in the previous calendar year; (c) for each end use for which the synthetic polymer microparticles were placed on the market, an estimate of the quantity of synthetic polymer microparticles released to the environment in the previous calendar year, which shall include also the quantity of synthetic polymer microparticles released to the environment during transportation. (d) for each use of synthetic polymer microparticles, a reference to the applicable derogation or derogations laid down in paragraph 4, point (b), (d) or (e), or 5 point (a), (b) or (c). 13. The Agency shall make the information submitted under paragraphs 11 and 12 available to the Member States. 14. Manufacturers, importers and industrial downstream users of products containing synthetic polymer microparticles shall provide specific information on the identity of polymers covered by this entry contained in those products and the function of those polymers in the products to competent authorities upon their request. The

	specific information on the polymer identity shall be sufficient to unequivocally identify polymers and shall at least include the information laid down in points 2.1 to 2.2.3 and points 2.3.5, 2.3.6 and 2.3.7 of Annex VI, where applicable. If the information is not available to industrial downstream users, they shall request it from their supplier within 7 days from the receipt of the request from the competent authorities and shall inform the authorities of the request made without delay. Having received the request referred to in the second subparagraph, the suppliers shall provide the requested information within 30 days to the industrial downstream user or directly to the competent authority requesting it. Where the supplier provides the information to the industrial downstream user, the industrial downstream user shall forward that information to the competent authorities without delay. Where the supplier provides the information directly to the authority, it shall without delay inform the industrial downstream user concerned to that effect. 15. Manufacturers, importers and industrial downstream users of products containing polymers claimed to be excluded from the designation of synthetic polymer microparticles on grounds of degradability or solubility shall provide, without delay, information proving that those polymers are degradable in accordance with Appendix X or soluble in accordance with Appendix Y, as applicable, to competent authorities upon their request. 16. Paragraph 1 shall not apply to placing on the market of synthetic polymers microparticles, on their own or in mixtures, placed on the market before … [*Publications Office, please insert the date of entry into force of this Regulation*]. However, the first subparagraph shall not apply to

	the placing on the market of synthetic polymers microparticles for uses listed in paragraph 6. * Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43). ** 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 (OJ L 170, 25.6.2019, p. 1). *** Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16). **** Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176). ***** Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117 5.5.2017, p. 1). ****** Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1). ******* Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).’

(2) the following Appendices [X] and [Y] [*Publications Office, please insert the numbers of the Appendices*]are added:

'*Appendix [X]* [*Publications Office, please insert the number of the Appendix*]

Entry [*Publications Office, please insert the number of the entry in point (1) of the Annex*] **– Rules on proving degradability**

This appendix lays down the rules for proving degradability of polymers for the purposes of entry [*Publications Office, please insert the number of the entry in point (1) of the Annex*], 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 [*Publications Office, please insert the number of the entry in point (1) of the Annex*]. 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 – CO_2 in sealed vessels (Headspace Test)' (OECD TG 310).

1.1.2. Pass criteria: 60% mineralisation measured, over 28 days, as evolved CO_2 or consumed O_2. 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 – CO_2 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 O_2 (allowed for T1 and T2 tests only) or evolved CO_2. 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: ≥ 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 ≥ 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 [*Publications Office, please insert the date = 5 years after the date of entry into force of this amending Regulation]*.

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 [*Publications Office, please insert the number of the entry in point (1) of the Annex*], 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%

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 + FP)	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	Degradation half-life	DegT50 ≤ 147 days	DegT50 ≤ 156 days	DegT50 ≤ 165 days	DegT50 ≤ 174 days	DegT50 ≤ 202 days	DegT50 ≤ 229 days

months + FP)	(DegT50)						

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:

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

Group 4, T5 and T6 (surface water)

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

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

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:

$$DegT50 = \ln(2)/\lambda$$

where:

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

$$c = 365.25/12$$

λ is the degradation rate, calculated as:

for T9 and T11: $\lambda_{T9/T11} = \ln(0.1)/-t_{90,T9/T11}$

for T5 and T6: $\lambda_{T5/T6} = \ln(0.1)/-t_{90,T5/T6}$

for T13: $\lambda_{T13} = \ln(0.1)/-t_{90,T13}$

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

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

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

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

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.

Appendix [Y] [*Publications Office, please insert the number of the Appendix*]

Entry [*Publications Office, please insert the number of the entry in point (1) of the Annex*] - **Rules on proving solubility:**

This appendix lays down the permitted test methods and the test conditions to prove that a polymer is soluble for the purposes of entry [*Publications Office, please insert the number of the entry in point (1) of the Annex*]. 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.

Permitted test methods:

1. OECD Guideline 120
2. OECD Guideline 105

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 third paragraph, for polymer particles that have all dimensions greater than 0,25 mm or have a length to diameter ratio greater than 3 and are longer than 0,25 mm, the size of the polymer particles to be tested shall be reduced in accordance with OECD guideline 120, so that at least one dimension of the polymer particle or, for polymer particles that have a length to diameter ratio greater than 3 the length of the polymer particle, is between 0,125 mm and 0,25 mm. For polymer particles containing inorganic substances in addition to a polymer or polymers, such as polymer particles encapsulated with inorganic substances or polymer particles where a polymer is grafted onto an inorganic carrier, it shall be sufficient to demonstrate that the polymer meets the pass criterion. To this end, it is allowed to test the solubility of the polymer or the polymers prior to the formation of the polymer particles.

The conditions for the solubility test shall be the following:

- Temperature 20 ºC
- pH 7
- Loading: 10 g/1000 mL

- Test time: 24 h

Pass criterion: solubility >2 g/L.’