



Brussels, XXX
[...] (2022) XXX draft

ANNEX

ANNEXES

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:

<p><i>‘[OP please insert the next consecutive number] Synthetic polymer microparticles: polymers that are solid and which either are contained in particles and constitute at least 1 % by weight of those particles, or build a continuous surface coating on particles, where at least 1 % by weight of those particles fulfil either of the following conditions:</i></p> <p>(a) all dimensions of the particles are equal to or less than 5 mm;</p> <p>(b) the length of the particles is equal to or less than 15 mm and their length to diameter ratio is greater than 3.</p> <p>The following polymers are excluded from this designation:</p> <p>(a) polymers that are the result of a polymerisation process that has</p>	<p>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.</p> <p>2. For the purposes of this entry, the following definitions apply:</p> <p>(a) ‘particle’ means a minute piece of matter, other than single molecules, with defined physical boundaries;</p> <p>(b) ‘solid’ means a substance or a mixture other than liquid or gas;</p> <p>(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;</p> <p>(d) ‘liquid’ means a substance or mixture that meets any of the following conditions:</p> <p>(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;</p> <p>(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;</p> <p>(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</p>
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<p>taken place in nature, which are not chemically modified substances;</p> <p>(b) polymers that are degradable as proved in accordance with Appendix [X];</p> <p>(c) polymers that have a solubility greater than 2 g/L as proved in accordance with Appendix [Y];</p> <p>(d) polymers that do not contain carbon atoms in their chemical structure.</p>	<p>concerning the International Carriage of Dangerous Goods by Road (ADR) concluded at Geneva on 30 September 1957.</p> <p>3. Where the concentration of synthetic polymer microparticles covered by this entry cannot be determined by existing 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:</p> <p>(a) 0,1 µm for any dimension, for particles where all dimensions are equal to or smaller than 5 mm;</p> <p>(b) 0,3 µm for any dimension, for particles that have a length that is equal to or smaller than 15 mm and a length to diameter ratio greater than 3.</p> <p>4. Paragraph 1 shall not apply to the placing on the market of:</p> <p>(a) synthetic polymer microparticles for use at industrial sites;</p> <p>(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*;</p> <p>(c) EU fertilising products within the scope of Regulation (EU) No 2019/1009 of the European Parliament and of the Council**;</p> <p>(d) food additives within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council***;</p> <p>(e) in vitro diagnostic devices, including devices within the scope of Regulation (EU) 2017/746.</p> <p>5. Paragraph 1 shall not apply to the placing on the market of the following synthetic polymer microparticles:</p> <p>(a) synthetic polymer microparticles which are contained by technical means so that releases to the</p>
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	<p>environment are prevented when used in accordance with the instructions for use during the intended end use;</p> <p>(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;</p> <p>(c) synthetic polymer microparticles which are permanently incorporated into a solid matrix during intended end use.</p> <p>6. Paragraph 1 shall apply as follows regarding the following uses:</p> <p>(a) from... [<i>OP please insert the date: 6 years after the entry into force of this amending Regulation</i>] to synthetic polymer microparticles for use in the encapsulation of fragrances;</p> <p>(b) from ... [<i>OP please insert the date: 4 years after the entry into force of this amending Regulation</i>] 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’);</p> <p>(c) from... [<i>OP please insert the date: 12 years after the entry into force of this amending Regulation</i>] 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 within the scope of that Regulation, unless such products are covered by points (a) or (b) of this paragraph or contain microbeads;</p> <p>(d) from... [<i>OP please insert the date: 6 years after the entry into force of this amending Regulation</i>] for leave-on products, as defined in point (1)(b) of the Preamble to Annexes II to VI to Regulation (EC) No</p>
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	<p>1223/2009, unless such products are covered by points (a) or (c) of this paragraph;</p> <p>(e) from... [<i>OP please insert the date: 5 years after the date of entry into force of this amending Regulation</i>] 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;</p> <p>(f) from... [<i>OP please insert the date = 6 years after the date of entry into force of this amending Regulation</i>] for ‘devices’, within the scope of Regulation (EU) 2017/745, unless those devices contain microbeads;</p> <p>(g) from... [<i>OP please insert the date = 5 years after the date of entry into force of this amending Regulation</i>] 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;</p> <p>(h) from... [<i>OP please insert the date = 8 years after the date of entry into force of this amending Regulation</i>] for plant protection products within the meaning of Article 2(1) of Regulation (EC) No 1107/2009****, and biocidal products as defined in Article 3(1), point (a), of Regulation (EU) 528/2012 of the European Parliament and of the Council*****;</p> <p>(i) from... [<i>OP please insert the date = 5 years after the date of entry into force of this amending Regulation</i>] for products for agricultural and horticultural uses not covered by points (g) or (h);</p> <p>(j) from... [<i>OP please insert the date = 6 years after the date of entry into force of this amending Regulation</i>] for granular infill for use on synthetic sports surfaces.</p> <p>7. From... [<i>OP please insert the date = 24 months after the date of entry into force of this amending Regulation</i>] suppliers of products containing synthetic polymer microparticles referred to in</p>
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paragraph 4, points (d) and (e), and suppliers of synthetic polymer microparticles referred to in paragraph 5 shall provide instructions for use and disposal to avoid releases of synthetic polymer microparticles to the environment.

From... [*OP 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 to avoid 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 [*OP please insert the number of the entry in point (1) of the Annex*] of Annex XVII to Regulation (EC) 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) information on the polymers contained in the substance or mixture that enables downstream users and other suppliers to comply with their obligations laid down in paragraph 8.

From... [*OP please insert the date = 8 years after the date of entry into force of this amending Regulation*] until... [*OP please insert the date = 12 years – 1 day after the date of entry into force of this amending Regulation*] suppliers of products containing synthetic polymer microparticles referred to in paragraph 6, point (c), shall provide the following statement: ‘This product contains microplastics.’

The information referred to in the first, second and third subparagraphs of this paragraph shall be provided in the form of clearly visible, legible and indelible text or, where appropriate regarding the information in the first and second subparagraphs, in

	<p>the form of pictograms. The text or, where appropriate, pictograms, shall be placed on the label, the packaging, the safety data sheet, or the package leaflet of the products containing synthetic polymer microparticles. In addition to the text or, where appropriate, pictograms, suppliers may provide a digital tool that gives access to an electronic version of that information.</p> <p>Where instructions for use and disposal are provided in accordance with this paragraph 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.</p> <p>8. Starting from... [<i>OP 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.</i>] 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 ... [<i>OP 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.</i>], 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:</p> <ul style="list-style-type: none">(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
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	<p>environment in the previous calendar year.</p> <p>From ... [<i>OP 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</i>], suppliers of products containing synthetic polymer microparticles referred to in paragraphs 4, points (b), (d) and (e), placed on the market for the first time, and suppliers of synthetic polymer microparticles referred to in paragraph 5 placed on the market for the first time shall submit the following information to the Agency by 31 May of each year:</p> <ul style="list-style-type: none">(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. <p>* 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).</p> <p>** 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).</p>
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	<p>*** 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).</p> <p>**** 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).</p> <p>***** 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).'</p>
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(2) the following Appendices ... and ... [*OP: please insert the numbers of the Appendices*] are added:

‘Appendix ...

Entry [*OP 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 [*OP, 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 [*OP, 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 at least three of the following environmental compartments:

- fresh or estuarine water,
- fresh or estuarine water sediment,
- marine water,
- marine sediment,
- marine water/sediment interface,
- soil.

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

2.1. 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).

2.2. 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.

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

3.1. 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).

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

3.3. 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.

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

4.1. Permitted test method in group 3:

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

4.2. The pre-adaptation of the inoculum mentioned in the T4 test guideline shall not be allowed.

4.3. Pass criteria: $\geq 70\%$ mineralisation measured as consumed O₂ or evolved CO₂ within 14 days.

5. Group 4. Screening test methods and pass criteria to demonstrate degradation relative to a reference material

5.1. 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 14852:2018);

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 14851:2004);

T7. 'Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sediment interface – Method by analysis of evolved carbon dioxide' (EN ISO 19679:2016);

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).

5.2. 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.

5.3. 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.

5.4. 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.

6. Group 5. Simulation test methods and pass criteria to demonstrate degradation under relevant environmental conditions

6.1. 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)

6.2. 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 that compartment in the Union.

6.3. 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.

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

Where group 4 or group 5 test methods are used, the degradability of polymers in products for agricultural or horticultural applications 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 [*OP please insert the number of the entry in point (1) of the Annex*], a polymer in a product for agricultural or horticultural applications 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 1/4 of the product functionality period, where group 4 test methods are used; or
 - (ii) 16 months plus 1/3 of 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)	Pass criterion (12 month FP)	Pass criterion (18 month FP)	Pass criterion (24 month FP)
T9 (soil)	% of ultimate degradation relative to the degradation of the reference material after 24 months	≥ 68%	≥ 67,5%	≥ 67%	≥ 66%	≥ 64%	≥ 62%	≥ 60%	≥ 57%	≥ 54%
T5 and T6 (water)	% of ultimate degradation relative to the degradation of the reference material after 6 months									

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)	Pass criterion (12 month FP)	Pass criterion (18 month FP)	Pass criterion (24 month FP)
T11	Half-life (DT50) observed at the end of the	Half-life ≤ 440 days	Half-life ≤ 449 days	Half-life ≤ 458 days	Half-life ≤ 467 days	Half-life ≤ 495 days	Half-life ≤ 522 days	Half-life ≤ 550 days	Half-life ≤ 605 days	Half-life ≤ 660 days

	standard test duration									
T13	Half-life (DT50) observed at the end of the standard test duration	Half-life ≤ 147 days	Half-life ≤ 150 days	Half-life ≤ 153 days	Half-life ≤ 156 days	Half-life ≤ 165 days	Half-life ≤ 174 days	Half-life ≤ 183 days	Half-life ≤ 202 days	Half-life ≤ 220 days

In case the duration of the functionality period falls in between two values of Tables A or B, the applicable pass criterion shall be the more stringent of the two.

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

The test material shall be 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 particles that are disposed or released to the environment. Comparability is important as the composition, form, size and surface area of particles affect the degradation behaviour.

Polymers used for encapsulation may be tested:

- in the form placed on the market, or,
- in the form of isolated coating, or,
- 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 5.3., the form, size and surface area of the reference material shall be comparable to that of the test material. Where the test material is a blend of more than one polymer, the degradation of the blend as well as that of each of the polymers in the blend shall be demonstrated. This shall be done by:

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

Appendix [OP: please insert the number of the Appendix]

Entry [OP, 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 [OP, 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 material shall be comparable in terms of composition, form, size and surface area to the polymer particles present in the product. For polymeric particles containing inorganic elements, such as particles encapsulated with inorganic substances or particles where the polymer is grafted onto an inorganic carrier, it shall be sufficient to demonstrate that the polymeric part of the particle meets the pass criteria. This may require the testing of the polymer(s) prior to the formation of the particle.

The conditions for the solubility test shall be the following:

- Temperature 20 °C
- pH 7
- Loading: 10 g/1000 mL
- Test time: 24 h'