

How to document to the ECHA's Proposal for an EU-wide Restriction on Intentionally Added Microplastics

Implications for pharmaceutical excipients,
medicinal products and food additives

March 2022



IPEC Europe and IPEC-Americas “How to” document to the ECHA’s Proposal for an EU-wide Restriction on Intentionally Added Microplastics

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INTRODUCTION

ECHA’s proposal for a restriction on intentionally added microplastics affects nearly all industrial sectors, which results in a very complex proposal with very diverse implications and derogations specific for individual markets.

This document reflects IPEC Europe and IPEC-Americas’ current understanding of the ECHA’s “Proposal for an EU-wide Restriction on Intentionally Added Microplastics” and may be subject to change until the proposal is formally adopted and more is learnt about the practical consequences of its implementation. It summarizes the core elements of the restriction proposal and intends to provide guidance for excipient manufacturers and users on how to prepare for compliance with the current proposed restriction. While IPEC Europe and IPEC-Americas have verified the information in this document to the best of our abilities, IPEC Europe and IPEC-Americas cannot guarantee that there are no mistakes or errors.

This document represents voluntary guidance for the excipient industry and is for information purposes. Alternatives to the approaches in this Guide may be used.

This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

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ELEMENTS OF THE RESTRICTION

- **Paragraph 1** = Restriction to the placing of microplastics on the market (=Ban)
- **Paragraph 2** = Definitions of microplastics based on physical criteria.
- **Paragraph 3** = Derogation from all restriction measures (ban, labelling and reporting requirements). Applicable to all industry branches.
- **Paragraph 4** = Derogations from Paragraph 1 only - labelling and reporting requirements apply. Paragraph 4 derogations apply to specific industry branches.
- **Paragraph 5** = Derogations focusing on the **physical state of the polymer as marketed**. Paragraph 5 is a derogation only from Paragraph 1 (the ban) – labelling and reporting requirements apply.
- **Paragraph 6** = Defines Industry specific **transition periods** for implementation of restriction measures. Implementation of the labelling and reporting requirements by the relevant stakeholders.
- **Paragraph 7** = Defines the **requirements and responsibilities for the provisions of appropriate instructions for use and disposal**. Paragraph 7 applies if a product containing microplastics is placed on the market based on Paragraph 4 and/or Paragraph 5.
- **Paragraph 8** = Defines which **data are to be reported to ECHA and who is responsible for the reporting**. Paragraph 8 applies if a product containing microplastics is placed on the market based on Paragraph 4 and/or Paragraph 5.

IMPLICATIONS FOR THE EXCIPIENT MANUFACTURERS AND THE PHARMACEUTICAL INDUSTRY



Texts in shaded boxes are original citations from the restriction document.
Text in bold is the most relevant for pharmaceutical excipients.

Paragraph 1 - Restriction

Polymers within the meaning of Article 3(5) of Regulation (EC) No. 1907/2006 shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.

The entire **pharmaceutical supply chain is exempted from the microplastics ban**, based on the derogation in Paragraph 4 and Paragraph 5. Nevertheless, the restriction significantly impacts all stakeholders as the derogations based on Paragraph 4 and Paragraph 5 come with an obligation for providing appropriate instructions for use and disposal (Paragraph 7) and a reporting requirement (Paragraph 8).

Paragraph 2 – Definition of microplastic

For the purposes of this entry:

- a. **‘microplastic’** means particles containing solid polymer, to which additives or other substances may have been added, and where $\geq 1\%$ w/w of particles have (i) all dimensions $0.1\mu\text{m} \leq x \leq 5\text{mm}$, or (ii) a length of $0.3\mu\text{m} \leq x \leq 15\text{mm}$ and length to diameter ratio of >3 .
- b. **‘microbead’** means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.
- c. **‘particle’** is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface. Single molecules are not particles.
- d. **‘particles containing solid polymer’** means either (i) particles of any composition with a continuous solid polymer surface coating of any thickness or (ii) particles of any composition with a solid polymer content of $\geq 1\%$ w/w.
- e. **‘solid’** means a substance or a mixture which does not meet the definitions of liquid or gas.
- f. **‘gas’** means a substance which (i) at 50°C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20°C at a standard pressure of 101.3 kPa.
- g. **‘liquid’** means a substance or mixture which (i) at 50°C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20°C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20°C or less at a standard pressure of 101.3 kPa; or (b) fulfilling the criteria in ASTM D 4359-90; or (c) the fluidity test (penetrometer test) in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).

Even if a material meets the definition criteria of a “microplastic” as per Paragraph 2, it can be placed on the market, based on derogations defined in Paragraph 3, 4, and 5.

Examples for Polymer containing particles (dark colour represents the polymer):



a) polymer on the particle surface
(e.g. film coated particle/ tablet)



b) polymer within the particle
(e.g. matrix component of the core of a tablet)



c) combination of a) and b)

Paragraph 3 – Derogations (physic-chemical aspects)

Paragraph 2a and 2b shall not apply to:

- a. Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)).
- b. Polymers that are biodegradable, according to the criteria in Appendix X.
- c. Polymers with a solubility > 2 g/L, according to the criteria in Appendix Y.
- d. *Polymers without any carbon C in their chemical structure (i.e. polymer backbone or side-groups)**

If at least one of the derogations (a, b, c) according to Paragraph 3 applies, the material is **not considered a microplastic and therefore out of the scope of the restriction**, even if it meets the physical properties described in paragraph 2. Accordingly, the labelling and reporting requirements as per Paragraphs 7 and 8 do not apply.

The Risk Assessment Committee (RAC) and the Socioeconomic Assessment Committee (SEAC)* suggested adding derogation 3d however, it has not yet been adopted in ECHA’s most current background document. It is nevertheless possible that 3d will be adopted in the final restriction.

*RAC/SEAC Opinion on an Annex XV dossier proposing restrictions on intentionally added microplastics, 10 Dec. 2020

Paragraph 4 – Derogations (industry specific)

Paragraph 1 shall not apply to the placing on the market of:

- a. Substances or mixtures containing microplastics for use at industrial sites.
- b. Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC6.

- c. Substances or mixtures that are regulated in the EU under Regulation (EC) No. 2019/1009 on Fertilising Products.
- d. Substances or mixtures containing food additives as defined in EU Regulation (EC) No. 1333/2008.
- e. In vitro diagnostic devices.
- f. Sewage sludge (as defined in Directive 86/278/EEC) and compost.
- g. Food and feed.
- h. [OPTION A: granular infill used on synthetic sports surfaces where risk management measures are used to ensure that annual releases of microplastic do not exceed 7g/m²]

Paragraph 4 is a derogation from the ban only and is combined with an obligation for providing appropriate instructions for use and disposal (Paragraph 7) and reporting requirements as defined in Paragraph 8. However, if a derogation based on Paragraph 3 applies at the same time, then Paragraphs 7 and 8 do not apply.

Paragraph 5 – Derogations (technical aspects)

Paragraph 1 shall not apply to the placing on the market of:

- a. Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use.
- b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use, such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a).
- c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use.

Paragraph 5 is not applicable to pharma as pharmaceutical excipients and medicinal products are derogated under paragraphs 4(a) & 4(b).

Paragraph 6 – Transition periods (market and product specific)

Paragraph 1 shall apply from:

- a. EiF for cosmetic products (as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009) and other substances or mixtures containing microbeads.
- b. EiF + 6 years for medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to Regulation (EU) 2017/745.
- c. EiF + 4 years for ‘rinse-off’ cosmetic products (as defined in Regulation (EC) No 1223/2009) not already included in paragraph 6(a).

- d. EiF + [5/8] years for the encapsulation of fragrances in detergents (as defined in Regulation (EC) No 648/2004), cosmetic products (as defined in Regulation (EC) No 1223/2009) or other mixtures.
- e. EiF + 5 years for detergents (as defined in Regulation (EC) No 648/2004), waxes, polishes and air care products not already included in paragraphs 6(a) or 6(d).
- f. EiF + 5 years for fertilising products not regulated in the EU as fertilising products under Regulation (EC) No 2019/1009 that do not meet the requirements for biodegradability contained in that Regulation.
- g. EiF + 8 years for plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012.
- h. EiF + 5 years for other agricultural and horticultural uses including seed treatments.
- i. EiF + 6 years for ‘leave-on’ cosmetic products (as defined in Regulation (EC) No 1223/2009).
- j. [Either
- i. EiF + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – OPTION A) or,
 - ii. EiF + 6 years for granular infill used on synthetic sports surfaces (if 4(h) not retained – OPTION B)]

Paragraph 6 does not apply to stakeholders of the pharmaceutical and food additive supply chains. For medical devices, a transition period of 6 years is envisaged.

Paragraph 7 – Labelling (instructions for use and disposal)

From [EiF + 24 months] **any supplier** of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of **paragraphs 4(a), 4(b), 4(d), 4(e) or 5** shall ensure that, where applicable, either the label and/or SDS and/or ‘instructions for use’ and/or ‘package leaflet’ provides, in addition to that required by other relevant legislation, any **relevant instructions for use to avoid releases of microplastic to the environment, including at the waste life-cycle stage.**

The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms. Where written instructions are given, these shall be in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

In addition, any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of **paragraph 4(a)** shall identify, where applicable, either on the label and/or SDS and/or ‘instructions for use’ and/or ‘package leaflet’ that **(i) the substance or mixture is subject to the conditions of this restriction (ii) the quantity (or concentration) of microplastic in the substance or mixture and (iii) sufficient information on the polymer(s) contained in the substance or mixture for downstream users or suppliers to comply with paragraph 8.**

Labelling / instructions for use apply to both excipient manufacturers and users. More details can be found in Table 1.

Paragraph 8 - Reporting

From [EiF + 36 months], any [industrial] downstream user using microplastic(s) derogated from paragraph 1 on the basis of paragraph 4(a) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year:

- a) a description of the use(s) of microplastic in the previous calendar year,
- b) for each use, generic information on the identity of the polymer(s) used,
- c) for each use, an estimate of the quantity of microplastic *released* to the environment in the previous calendar year.

Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for a professional or consumer end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year:

- d) a description of the intended end use(s) of microplastic placed on the market in the previous calendar year,
- e) for each intended end use, generic information on the identity of the polymer(s) placed on the market,
- f) for each intended end use, an estimate of the quantity of microplastic *released* to the environment in the previous calendar year.

ECHA shall publish a report summarising the information received by 30 June every year.

Generally, the reporting requirement applies to all industries, including the pharma industry. In order to collect more information on the quantity of microplastics released via derogated uses by the different industries, generic information on the (end) use, the identity of the polymer, as well as the amount of microplastics released to the environment shall be reported to ECHA.

Table 1 provides specific reporting information required for excipient manufacturers and users.

Paragraph 8 a,b,c applies to any downstream user of substances or mixtures containing microplastics at industrial sites.

Paragraph 8 d,e,f applies to any supplier (drug manufacturer or distributor) placing a medicinal product containing the excipient.

TABLE 1

	Labelling	Reporting
<p>Downstream users; for example:</p> <ul style="list-style-type: none"> Excipient formulator/manufacturers who receive and further process microplastic (e.g. toll manufacturer for excipient mixtures or co-processed excipients) Drug intermediate formulator Distributor (only if repackaging takes place) 	<ul style="list-style-type: none"> Sufficient information on the polymer(s) contained in the substance or mixture for downstream users or suppliers to comply with paragraph 8 : Instructions for use and disposal (e.g. “avoid release to the environment”) May already be covered by the EMA QRD wording. The substance (or mixture) is subject to the conditions of the restriction <p>The quantity (concentration) of microplastic in the substance or mixture</p>	<p>Only if the use at industrial sites takes place in Europe</p> <ul style="list-style-type: none"> 8 a. Description of use e.g. “Industrial use as pharmaceutical excipient/food additive”, (as applicable) 8 b. Generic information on the identity of the polymer(s) Ph.Eur. monograph title (if applicable), alternatively monograph titles of other pharmacopoeias or any other official titles, E numbers, the International Nomenclature Cosmetic Ingredients (INCI) or the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC). The Chemical Abstract Service number (CAS number) is not recommended for this purpose as it may not sufficiently differentiate polymers of different molecular weight within the same polymer family (of which some may be microplastic, others not).
Medicinal product manufacturer	<ul style="list-style-type: none"> Instructions for use and disposal (e.g., “Do not discard unused product down the drain”) It is not required to state that “the product contains microplastics”. 	<ul style="list-style-type: none"> 8 c. estimate of the quantity of microplastics released to the environment <p>The downstream user may report that there is no release to the environment as the product is not placed on the end user market and the release during the use at industrial sites is avoided by appropriate waste management.</p>
Food supplement manufacturer	<ul style="list-style-type: none"> Instructions for use and disposal (e.g. “Do not discard unused product down the drain”) It is not required to state that “the product contains microplastics”. 	<ul style="list-style-type: none"> In case of unavoidable release, report the estimated quantity released.



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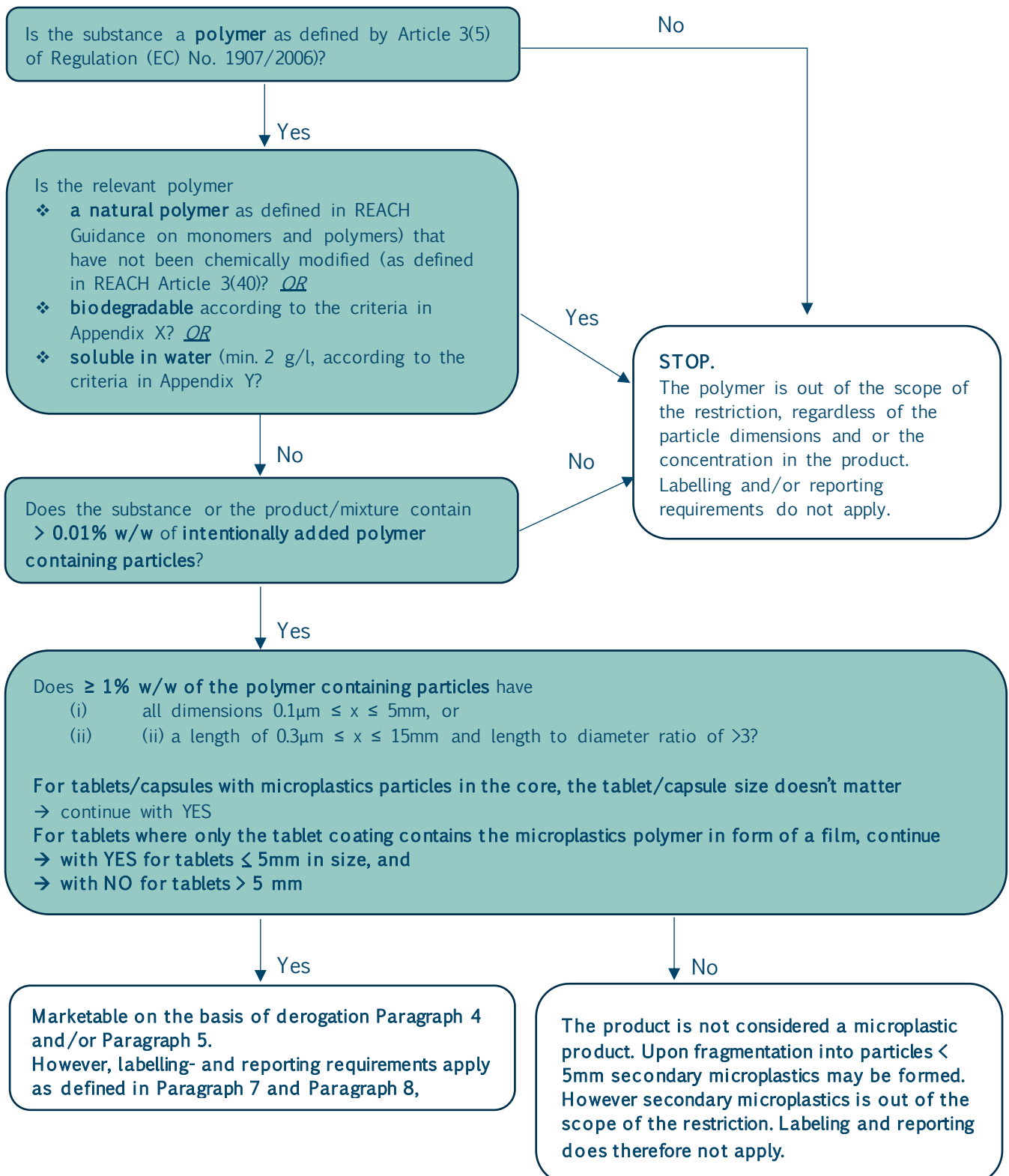
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	Labelling	Reporting
		<ul style="list-style-type: none"> • 8 d. Description of the intended end use(s) e.g. “Pharmaceutical excipient” • 8 e. generic information on the identity of the polymer(s). Use the identity information provided by the supplier. • 8 f. estimate of the quantity of microplastics <i>released</i> to the environment The quantity of microplastics released to the environment is difficult to estimate. The quantity placed on the market is significantly higher and would, as a conservative proximation, significantly overrate the amount released to the environment. The supplier cannot control whether the end user (patient) takes the entire medication or if the medication plan is changed or the medication stopped for any other reason.

DECISION TREE - Applicability of the restriction and the need for labelling or reporting

To be considered for **each substance or ingredient of the product** placed on the market.



GLOSSARY OF OFFICIAL TERMS USED IN THE RESTRICTION

Downstream user / use at industrial sites

Downstream users are users of chemicals under REACH and CLP. They are companies or individuals:

- within the European Union/European Economic Area,
- who use a substance, either on its own or in a mixture,
- in their industrial or professional activities.

When the use takes place in a factory or other industrial site, this is termed as "use at industrial sites".

<https://echa.europa.eu/regulations/reach/downstream-users/about-downstream-users/who-is-a-downstream-user>

REFERENCES AND CITATIONS

Article 3(5) of Regulation (EC) No. 1907/2006)

Definitions:

5. Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a ‘monomer unit’ means the reacted form of a monomer substance in a polymer;

6. monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

REACH Article 3(40)

40. not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities.

Appendix X (Biodegradability) (Table 22 RAC/SEAC Background Document 11 June 2020)

Group 1. Ready biodegradation

- Pass criteria: 60% mineralisation measured as evolved CO₂ or consumed O₂ in 28 days (10-day window does not apply). Y
- Permitted test methods:

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- i. Ready Biodegradability (OECD TG 301 B, C, D, F)
- ii. Ready Biodegradability – CO₂ in sealed vessels (Headspace Test) (OECD TG 310).

or

Group 2. Enhanced/modified ready biodegradation

- Test duration may be extended to up to 60 days and larger test vessels used
- Pass criteria: 60% mineralisation measured as evolved CO₂ or consumed O₂ in 60 days (10-day window does not apply)
- Permitted test methods:
 - Ready Biodegradability (OECD TG 301 B,C,D,F)
 - Ready Biodegradability – CO₂ in sealed vessels (Headspace Test) (OECD TG 310)
 - Modified Biodegradability in Seawater (OECD TG 306, mineralisation measured as evolved CO₂)

or

Group 3. Inherent biodegradation

- Pass criteria: ≥ 70% mineralisation (measured as O₂ uptake or evolved CO₂) fulfilling the TG specific criteria as indicated below.
- Permitted test method 68:
 - i. %Inherent Biodegradability: Modified MITI Test (II) (OECD 302C), ≥ 70% mineralisation within 14 days, pre-adaptation of the inoculum is not allowed.

or

Group 4. (Bio)degradation relative to a reference

- Pass criteria: The degradation half-life in marine, fresh or estuarine sediment is less than 180 days or
- Pass criteria: The degradation half-life in soil is less than 180 days.
- Permitted test methods:
 - i. Aerobic and Anaerobic Transformation in Soil (OECD TG 307: 2002)
 - ii. Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308: 2002)
 - iii. Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (OECD TG 309: 2004) Results should be interpreted with caution and the half-life should be estimated with care when the particle size (surface area) is a degradation rate-limiting factor and the degradation is not following the first order kinetics. Demonstrating (bio)degradability if microplastics are deliberately applied to soil or foliage Where microplastics are deliberately applied to soil or foliage (e.g., controlled-release fertilising products) test methods and pass criteria applicable to this compartment (any test method in groups 1 to 3, test method 4(iii) or test method 5(i)) shall be used.

The application period in soil may be taken into account when demonstrating the biodegradability of microplastics with direct soil application. The allowed time for reaching the screening criteria as specified in the group 4 test method for soil, ultimate degradation of 90% relative to the degradation of the reference material within 24 months, may be extended by the application period in soil, but shall not exceed 48 months in total. Test material in (bio)degradation tests The test material should be comparable (in terms of composition, form, size and surface area) to the particles that are produced 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 (bio)degradation behaviour.

Polymers used for encapsulation may be tested

(i) in the form placed on the market,

(ii) in form of isolated coating or

(iii) the organic core of the material may be 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, the form, size and surface area of the reference material should be comparable to that of the test material. Where the test material consists of more than one polymeric component (i.e., it is a blend), in addition to demonstrating the (bio)degradation of the microplastic as described above, the biodegradation potential of each of the polymeric components in the blend must also be demonstrated.

This can be done by:

a) in addition to testing the (bio)degradation of the particle, polymeric components of the blend must be separately assessed using the permitted test methods and pass criteria set out above.

or

b) performing chemical analysis to demonstrate that all polymeric components in the blend contribute to the (bio)degradation observed during testing using permitted methods, each polymeric component shall meet the pass criteria in the relevant permitted test method.

Tests shall be conducted by laboratories accredited to ISO 17025 or certified to GLP.

Appendix Y (Solubility in water) (Table 23 RAC/SEAC Background Document 11 June 2020)

The conditions for the test are the following:

- Temperature 20°C
- pH 7
- Loading: 10g/1000mL
- Test time: 24h Quantification can be done either via the procedure described in OECD Guideline 120 or in OECD Guideline 105.

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Test is to be carried out with the particles as they are placed on market. As “particle containing solid polymer” may refer to particles which are comprised of polymers and inorganic elements (e.g. capsulation or for example particles where polymer is grafted onto inorganic carrier). In such cases it will be sufficient to demonstrate that the polymer part meets the suggested criteria. In practice this may mean testing the polymer(s) prior to the formation of the particle.

Test should be conducted by laboratories certified to GLP or accredited to ISO 17025.

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