

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on
intentionally-added microplastics

ECHA/RAC/RES-O-0000006790-71-01/F

ECHA/SEAC/(opinion number will be added after adoption)

11 June 2020

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11 June 2020

[SEAC opinion number will be added after adoption of the final
opinion]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	intentionally-added microplastics
EC No.:	-
CAS No.:	-

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at <https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22921/term> on **20 March 2019**. Interested parties were invited to submit comments and contributions by **20 September 2019**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: **Laure GEOFFROY**

Co-rapporteur, appointed by RAC: **Pietro PARIS**

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **11 June 2020**.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: **Karen THIELE**

Co-rapporteur, appointed by SEAC: **Simon COGEN**

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on **11 June 2020**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at <https://echa.europa.eu/fi/restrictions-under-consideration/-/substance-rev/22921/term> on **1 July 2020**. Interested parties were invited to submit comments on the draft opinion by **1 September 2020**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **[date of adoption of the opinion]**. [The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]**]¹.

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and]⁵ 71(1) of the REACH Regulation.] [No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and]³ 71(1)]⁶.

The opinion of SEAC was adopted **by [consensus.] [a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion.]⁶.

¹ Delete the unnecessary part(s)

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A. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Table 1 Proposed restriction by the Dossier Submitter

Substance (or group) identity	Conditions of the restriction
Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	<ol style="list-style-type: none"> 1. 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. 2. For the purposes of this entry: <ol style="list-style-type: none"> 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). 3. Paragraph 2a and 2b shall not apply to:

	<ul style="list-style-type: none"> 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 (bio)degradable, according to the criteria in Appendix X. c. Polymers with a solubility > 2 g/L, according to the criteria in Appendix Y. <p>4. Paragraph 1 shall not apply to the placing on the market of:</p> <ul style="list-style-type: none"> 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/EC. 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. <i>In vitro</i> diagnostic devices. f. Sewage sludge (as defined in Directive XXX/XXX) and compost. g. Food and feed. h. <i>[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]</i> <p>5. Paragraph 1 shall not apply to the placing on the market of:</p> <ul style="list-style-type: none"> 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. <p>6. Paragraph 1 shall apply from:</p> <ul style="list-style-type: none"> 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.
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	<ul style="list-style-type: none"> b. EiT + 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. EiT + 4 years for 'rinse-off' cosmetic products (as defined in Regulation (EC) No 1223/2009) not already included in paragraph 6(a). d. EiT + [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. EiT + 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. EiT + 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. EiT + 8 years for plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012. h. EiT + 5 years for other agricultural and horticultural uses including seed treatments. i. EiT + 6 years for 'leave-on' cosmetic products (as defined in Regulation (EC) No 1223/2009). j. [Either <ul style="list-style-type: none"> i. EiT + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – <u>OPTION A</u>) or, ii. EiT + 6 years for granular infill used on synthetic sports surfaces (if 4(h) not retained– <u>OPTION B</u>)] <p>7. From [EiT + 24 months] any supplier² 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' (IFU) 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.</p>
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² According to REACH definition in article 3(32), a supplier means "manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".

	<p>The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms.</p> <p>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.</p> <p>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' (IFU) 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.</p> <p>8. 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:</p> <ul style="list-style-type: none"> 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. <p>Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for consumer or professional end uses 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:</p> <ul style="list-style-type: none"> 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. <p>ECHA shall publish a report summarising the information received by 30 June every year.</p>
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Note: In the event that the proposed restriction is added to Annex XVII of REACH Appendix X and

Appendix Y will be an appendix to Annex XVII. The details of Appendix X and Appendix Y can currently be found in Table 22 and Table 23, respectively, in Section 2.2.1.6 of the Background Document

A.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on polymers as **microplastics** is the most appropriate Union-wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the scope and conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

Substance (or group) identity	Conditions of the restriction
<p>Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006</p>	<p>Entry as proposed by the Dossier Submitter above, with the following modifications:</p> <p>2. For the purposes of this entry:</p> <p style="padding-left: 40px;">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 $\leq 5\text{mm}$, or (ii) a length of $\leq 15\text{mm}$ and length to diameter ratio of >3.</p> <p>3. Paragraph 2a and 2b shall not apply to:</p> <p style="padding-left: 40px;">b. Polymers that are (bio)degradable, according to the criteria in Appendix X.</p> <p><i>RAC proposes modifications to the criteria in Appendix X (as described in section B.1.1.3.6 of the opinion justification)</i></p> <p><i>In terms of infill materials on synthetic sports pitches, RAC has a clear preference for OPTION B (ban on placing on the market) over OPTION A (derogation from ban on the basis of use of RMMs). RAC recommends that OPTION A is removed from the proposal.</i></p> <p>4. Paragraph 1 shall not apply to the placing on the market of:</p> <p style="padding-left: 40px;">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 $7\text{g}/\text{m}^2$]</p> <p>6. Paragraph 1 shall apply from:</p> <p style="padding-left: 40px;">j. [Either</p>

	<p>a. EIF + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – <u>OPTION A</u>) or,</p> <p>b. EIF + 6 years for granular infill used on synthetic sports surfaces (if 4(h) not retained– <u>OPTION B</u>)]</p>
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A.2. THE OPINION OF SEAC

See SEAC opinion

B. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

B.1. RISK ASSESSMENT

Justification for the opinion of RAC

B.1.1. Grouping and targeting

B.1.1.1. Summary of Dossier Submitter's proposal

The 'microplastics concern' arises due to the presence of solid particles of polymer-based materials in the environment that:

- Are small (typically microscopic) making them readily available for ingestion and potentially liable to transfer within food chains;
- Are very resistant to environmental (bio)degradation, which will lead to them remaining in the environment for a long time after their initial release;
- progressively fragment into smaller and smaller particles, theoretically to 'nanoplastic' particles in the environment.
- Impossible to remove from the environment after release; and
- Are associated with various adverse biological effects.

For the purposes of this restriction proposal, the Dossier Submitter proposes that any synthetic polymer (with or without additives) that has the potential to exist as a small (typically microscopic) solid particle in the environment, and which is resistant to (bio)degradation, should be considered to be consistent with the concerns associated with the term 'microplastic'.

To ensure sufficient risk reduction (and to minimise the potential for regrettable substitution), the substance identification proposed for the restriction is a group entry, underpinned by the term 'polymer', as defined in REACH Article 3(5), supplemented with further criteria that target (i) the physical state and dimensions of particles associated with the concern and (ii) the long-term persistence of those particles in the environment.

After considering the comments submitted in the consultation on the Annex XV report, the Dossier Submitter revised several elements of the microplastics definition. Details of these revisions are provided in the Background Document. The Dossier Submitter's revised proposal is as follows:

- **'microplastic'** means particles containing solid³ polymer, to which additives or other substances may have been added, and where $\geq 1\%$ w/w of particles have (i) all

³ For the purpose of this entry, the following additional definitions are also proposed from the CLP regulation:

- **'solid'** means a substance or a mixture which does not meet the definitions of liquid or gas.
- **'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.
- **'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

dimensions $100\text{nm} \leq x \leq 5\text{mm}$, or (ii) a length of $300\text{nm} \leq x \leq 15\text{mm}$ and length to diameter ratio of >3 . Natural polymers that have not been chemically modified are excluded, as are polymers that are (bio)degradable (according to the criteria set out in Appendix X of the proposal) or soluble (according to the criteria set out in Appendix Y on the proposal).

- **'microbead'** means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.
- **'polymer'** means a substance within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 (REACH).
- **'particle'** is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface. Single molecules are not particles
- **'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.

The justification for grouping is underpinned by the similarity in physical and persistence properties. All substances with these properties are therefore identified as 'microplastics', irrespective of the identity of the particular polymer, or the identity of any additives or other substances that could also be present. Polymers that are not present as solid particles are not 'microplastics'. By analogy to the EU definition of nanomaterials, individual molecules are not particles.

The Dossier Submitter notes that the upper size limit of 5mm has been established largely on the basis of operational considerations (e.g. marine litter monitoring programmes) rather than specific ecotoxicological considerations. However, this size range is associated with particles that would be readily ingested by organisms in the environment.

The targeting of the restriction is a combination of (i) the definition of a microplastic (as set out in paragraphs 2 and 3) (ii) the generic restriction on placing microplastics on the market above a concentration of 0.01% w/w (paragraph 1), and (iii) the various derogations proposed that ensure that the placing on the market of microplastics for uses that do not inevitably result in releases of microplastics to the environment are not prohibited (as set out paragraph 5). The scope of the proposed restriction is also targeted by the derogations set out in paragraph 4, that exclude microplastics regulated under other EU legislation from the scope of paragraph 1, and the proposed transitional arrangements for different sectors/uses that are set out in paragraph 6. The requirements for minimum supply chain communication set out in paragraph 7 ensure that downstream uses have the necessary information to comply with the conditions of paragraph 1 and 5 and the reporting elements set out in paragraph 8 ensure that the effectiveness of the paragraph 4 and 5 derogations can be monitored over time.

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).

B.1.1.2. RAC conclusion(s)

Taking into account the large variability in composition, properties and dimensions, RAC agrees with the Dossier Submitter that intentionally-added microplastics should be addressed as a group of polymer-based materials sharing intrinsic, mainly but not exclusively physical properties such as solid state with defined physical boundaries, resulting in a common concern for the environment, especially due to their long-term persistence. In addition, RAC agrees with the Dossier Submitter that all substances with these properties should be identified as 'microplastics', irrespective of the identity of the particular polymer, or the identity of any additives or other substances that they may contain. Conversely, such an approach means that polymers without these intrinsic properties are outside of the scope of the restriction.

In relation to the term polymer, the proposal refers to the definition of a polymer according to the REACH regulation (Article 3(5)). RAC acknowledges that a broad and generic definition of microplastics is needed and agrees with the use of the REACH definition of polymer as the starting point for the scope of the proposed restriction.

RAC notes that various aspects of the Dossier Submitter's proposal for the microplastic definition were revised during opinion making in response to comments received in the consultation. RAC agrees that this revised definition of a 'microplastic' is appropriate, with the exception of the revised lower size limits of 100 and 300nm for particles and fibre-like particles, respectively. RAC concluded that these size limits could exclude relevant nanoscale (nanoplastic) particles from the scope of the proposed restriction. Therefore, RAC agreed that a definition of microplastics without a lower limit was more appropriate, as follows:

'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 $\leq 5\text{mm}$, or
- (ii) a length $\leq 15\text{mm}$ and length to diameter ratio of > 3 .

RAC agreed with the Dossier Submitter's revised definitions of 'particle', 'particle containing solid polymer' and 'solid'.

RAC agreed that polymers in physical forms consistent with a microplastic should be derogated completely from the restriction if they are either:

- (i) natural polymers that have not been chemically modified [paragraph 3a];
- (ii) biodegradable (demonstrated according to specific criteria in Appendix X) [paragraph 3b], or;
- (iii) water soluble $> 2\text{ g/L}$ (demonstrated according to specific criteria in Appendix Y) [paragraph 3c].

This is on the basis that these polymer-based materials do not have all of the necessary intrinsic properties associated with the microplastic concern i.e. they would not remain in the environment as particles for a long time after they are released. RAC agrees that these should not be considered as microplastics. However, RAC notes that if a polymer has been derogated from the proposed restriction on microplastics, this does not mean that it has been demonstrated to be safe as it may have other hazards in addition to those associated with the microplastic concern.

In terms of the biodegradation criteria, RAC identified several uncertainties in its evaluation and considered at length whether materials so derogated from the restriction could still contribute to the microplastic concern. RAC has proposed modified criteria for assessing the biodegradation of polymers in Appendix X in an attempt to limit these uncertainties whilst ensuring that the conditions of the derogation remained practical (further details are presented in the key elements section below). However, the proposed modifications do not address all of the identified uncertainties and, therefore, RAC recommends that additional research is undertaken to further explore and understand:

- the environmental relevance of the 'relative to reference material' based test methods included in group 4;
- the practicality and applicability of group 5 test methods to microplastic test materials and, more generally;
- the applicability of REACH Annex XIII half-life criteria to particulate materials.

In terms of appropriate test material, RAC supports the Dossier Submitter's proposed approach and emphasises the importance of ensuring an adequate characterisation of biodegradability when test materials are comprised of blends of different polymers.

As a general observation, RAC notes that the scope of the restriction is set by numerous criteria which may require careful interpretation in some cases to decide if a particular polymer is in or outside of the scope of the proposed restriction (e.g. biopolymers, swellable polymers, soluble polymers...). It is generally difficult to anticipate all the possible issues related to broad definitions.

For this restriction proposal the Dossier Submitter adopted a three component approach to risk management: (i) a ban on placing on the market, (ii) instructions for use and disposal (minimum standards for supply chain communication) for derogated uses and (iii) reporting requirements for derogated uses. RAC supports the revised proposal of the Dossier Submitter and considers that the implementation of the instructions for use and disposal requirement is fundamental for including derogations for the uses that could result in releases of microplastics to the environment.

The proposed reporting requirement (Paragraph 8 of the conditions of the proposed restriction) for derogated uses of microplastics is intended to be complementary to the requirement for suppliers⁴ to provide instructions for use and disposal. The specific information to be reported has been re-evaluated in response to the comments submitted in the consultation. The information requested has been revised by the Dossier Submitter to maximise the availability of useful data to both companies and the Agency, whilst minimising administrative burden. RAC considers the rationale for the revised reporting requirement proposed by the Dossier Submitter to be reasoned and well-founded.

The restriction aims at avoiding the placing on the market and intentional use microplastics as a substance on its own or in a mixture in a concentration equal to or greater than 0.01 % w/w. In order to establish if a substance/mixture meets the definition of microplastic (paragraph 2 of the conditions of the restriction), all the relevant criteria should be met. The

⁴ Suppliers as defined in REACH Article 3(32) i.e. "manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".

concentration limit of 0.01 %, based on information collected through literature searches, the Dossier Submitter's call for evidence and the consultation on the Annex XV report, corresponds to the lowest concentration at which it is generally reported that microplastics have an influence on the function of the product. RAC agrees that the proposed concentration limit is appropriate.

B.1.1.3. Key elements underpinning the RAC conclusion

B.1.1.3.1. Justification for a grouping approach

The justification for grouping is underpinned by similar

- i. substance identity (i.e. polymers),
- ii. physical properties (i.e. solid particle with relevant dimensions) and
- iii. intrinsic properties (i.e. insoluble and non-degradable in the environment).

All substances with these properties are therefore identified as 'microplastics', irrespective of the identity of the particular polymer, or the identity of any additive or other substance that could also be present. Polymers that are not solid particles are not 'microplastics'.

Since no established definition of microplastic existed in the EU, and the term 'plastic' is not defined in the REACH regulation, the Dossier Submitter proposed a deliberately inclusive definition of microplastic that recognised the fact that the microplastic concern is not limited to discrete substances but to a generic 'group' of synthetic polymeric substances with shared physical and persistence properties (i.e. persistent solid particles). Nevertheless, it is noted that this could leave some uncertainty as to whether a particular substance is within the scope of the restriction as, in addition to substance identity, the physical form of the polymer needs to be known. Indeed, it is quite possible for some forms of a substance to be within the scope of the restriction, whilst others are outside e.g. based on differences in polymer chain length, degree of branching, cross-linking or particle size, etc.

The proposed microplastic definition consists of five elements set out in paragraph 2 of the conditions of the restriction. All five elements need to be fulfilled for a substance or mixture to fall within the scope of the restriction.

B.1.1.3.2. Microplastic definition

Polymer definition

The first part of the definition is the identity of the substance. The Dossier Submitter proposed that relevant substances are polymers referring to Article 3 (5) of REACH. In this article, polymers are defined as:

"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”.

The REACH polymer definition is considered by the Dossier Submitter to be adequately wide to cover all substances that could potentially contribute to the microplastic concern. This approach is also consistent with the definition of plastic used in the Single Use Plastic (SUP) Directive (EU) 2019/904.

The breadth of the definition was the subject of many of the comments submitted in the consultation on the Annex XV report. Industry considered that the REACH polymer definition was not an appropriate (sufficiently specific) description of substance identity for use in a restriction, primarily because not all polymers are microplastics. Industry requested that substances should be identified individually and that the proposal should include a list of polymers that are specifically within the scope of the restriction.

RAC considers that all microplastics contain polymers and since restriction is a REACH process, using an existing definition from within that regulatory context would appear necessary for consistency. Industry stakeholders' concern that polymers which do not contribute to the microplastic concern would also be targeted seems to be unfounded as the other four elements of the conditions of the restriction are intended to constrain the scope to only the polymers contributing to the microplastic concern (as discussed below). Furthermore, RAC agrees that the microplastic definition should be inclusive enough to avoid regrettable substitution and that because of the diversity of different polymers, and the fact that they do not have to be registered under REACH, a sufficiently comprehensive list of polymers to achieve such an aim could not be made.

During the consultation on the Annex XV report, the ISO 472:2013 definition of plastic was suggested as an alternative basis for substance identity. ISO define plastic as '*material which contains as an essential ingredient a high polymer and which at some stage in its processing into finished products can be shaped by flow*'. RAC considers that this definition is unsuitable for the current proposal as products like polymer capsules (manufactured, for example, using emulsion polymerisation rather than flow) would not be captured by this definition whilst they represent an important source of synthetic polymer particles released into the environment. RAC also notes that the ISO definition of plastic specifically excludes elastomeric materials, which are frequently associated with the microplastic concern i.e. from tyre wear or as infill on synthetic sports pitches. As such it is not a sufficiently inclusive starting point for a regulatory definition of a microplastic.

Particle

The second element of the microplastics definition, as defined in paragraph (c) of the proposal, is the requirement for polymer to be present as a particle⁵. The proposed definition, which is supported by RAC is consistent with that previously established as part of the European Commission Recommendation on the definition of nanomaterial (2011/696/EU), which, in turn, follows the definition of particle in a relevant ISO standard (6824:2013)⁶.

⁵ A 'particle' is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface. Single molecules are not particles.

⁶ In 2019 the EU's Joint Research Centre (JRC) published guidance on the concepts and terms used in the European Commission definition of nanomaterial in which it is specified that a 'minute piece of matter' is only a particle if this

Solid

A third element of the definition concerns the physical properties of the polymer, specifying that the polymer shall be present as a **solid**. The Dossier Submitter proposed to use the existing CLP definition of solid (Annex I part 1). RAC notes that this creates a harmonised understanding of the term. As stated by the Dossier Submitter, solid particles contribute to the concern addressed by the proposed restriction and liquid particles, such as emulsions and aerosols, would not be subject to the restriction. RAC agrees that the microplastic concern is related to solid particles and that, therefore, the state of the polymer is fundamental to the microplastic definition.

Since 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas, the CLP definitions of liquid and gas are also necessary and are included in the conditions of the restriction in paragraphs 2(f) and 2(g), respectively. These definitions are based on a threshold for vapour pressure and the state of the compound under standard conditions. A liquid is also characterised with an additional parameter, the melting point.

During the consultation on the Annex XV report, several respondents noted that fully amorphous polymers do not have a melting point. RAC agrees with the Dossier Submitter's proposal to address this issue by including supplementary criteria to the microplastic definition from the GHS definition for a liquid, as follows: *A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to two possible additional tests (ASTM D 4359-90 or the fluidity test described in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)*. RAC notes that, based on these criteria, substances with 'semi-solid' properties (such as waxes) are either solids or liquids and can be determined to be either within or outside of the scope of the proposed restriction by comparison with these thresholds.

Particle dimensions

The fourth element of the definition are the relevant particle dimensions comprising upper and lower size limits and a minimum weight threshold of relevant particles in a substance or a mixture.

The 5 mm upper limit for microplastics is partly biologically selected as particles of this size were considered more likely to be ingested by biota when compared to larger items. It is stated in the Background Document that there is consensus on the upper size limit (5 mm) for what is considered to be a microplastic (GESAMP, 2015; UNEP, 2015). This upper size limit is already used in existing microplastic regulation in EU Member States and elsewhere (Annex A to the Background Document) and would be consistent with the EU Marine Strategy Framework Directive definition. RAC considers that this part of the definition to be sufficiently justified since this was based on the premise that it would include a wide range of small particles that could readily be ingested by biota, and that these particles that might be expected to present different kinds of risks than larger plastic items (such as entanglement)

piece of matter has defined physical boundaries. The Dossier Submitter's proposed definition has included this clarification. RAC notes that this proposal harmonises the definition of the term 'particle' with the implementation of the nanomaterial definition. During the consultation on the Annex XV report, commentators pointed out the fact that JRC, in the same publication, had concluded that single molecules should not be considered as particles and that this should also be specified in the legal text of the restriction. RAC notes that the Dossier Submitter agrees that this clarification should be included in the particle definition and that this was added to paragraph 2c during opinion development.

(GESAMP, 2015). Nevertheless, RAC notes that the upper size limit of 5 mm has been established largely on the basis of operational considerations (e.g. marine litter monitoring programmes) rather than specific (eco)toxicological considerations.

RAC notes that some intentionally-added particles containing solid polymer (e.g. coated seeds) could marginally exceed the upper size limit of 5 mm. In this case, these particles would be out of the scope of the proposed restriction whilst posing a similar risk to particles < 5mm in all dimensions (unless $\geq 1\%$ by weight of the seeds are smaller than 5 mm).

Fibre-like particles are included in the conditions of the restriction because certain intentionally-added polymer particles are reported to have a fibre-like morphology with a length exceeding 5 mm (but <15mm), for example the fibre-like particles used for the reinforcement of adhesives and concrete. The Dossier Submitter considered that these particles were relevant to the microplastic concern and should be captured by the definition. The aspect ratio for a fibre (length/diameter >3), established in the 1960s by the WHO for the measurement of asbestos fibres, was proposed by the Dossier Submitter as an appropriate length/diameter relationship upon which to differentiate fibre-like from other particles. Consequently, to maintain a maximum diameter of 5 mm and an aspect ratio > 3, the Dossier Submitter proposed an upper limit of 15 mm. RAC supports the choice of this definition as a pragmatic way to include fibre-like particles within the scope of the restriction.

The lower size limit of 1 nm for particles (3 nm for fibre-like particles) initially proposed by the Dossier Submitter (after taking into account both risk and practicality considerations) was selected to be consistent with the lower size limit already established by the EU nanomaterial definition. During the consultation on the Annex XV report, several stakeholders stated that this lower limit was not enforceable and proposed an alternative, larger, limit of 1 μm . Certain stakeholders considered a lower limit of 1 nm as not appropriate in relation to a definition for microplastics, being more appropriate to define nanoplastics.

Theoretical considerations suggest that nanoplastics (<100nm) would be more readily taken up into cells than microplastics, which would lead to greater potential for adverse effects and bioaccumulation. In general, although considered likely to occur in the environment, there is an absence of information on nanoplastics, which is a significant knowledge gap.

As detailed in the Background Document, solid polymer particles with a size below 1 μm are widely used as opacifiers and other ingredients in cosmetics, for fragrance encapsulation in detergents for laundry and cosmetic products and binder particles in latex paints which would limit the risk reduction potential of a restriction if a limit of 1 μm was used as the lower boundary of the microplastics definition.

The nanometre measurement scale is applicable to the molecular scale. For example, a length of 1 nm is equivalent to the length of three water molecules or a single molecule of octane. On this basis, stakeholders responding to the consultation considered that a particle of 1 nm would be unlikely to be a solid polymer and that the presence of particles comprising either single molecules or several molecules with a dynamic surface structure (such as a detergent micelle) would be likely to confound the interpretation of polymer particle characterisation at the nanoscale (e.g. by Dynamic Length System, DLS). Taking into account the 3+1 rule the Dossier Submitter also considered that a particle would be unlikely to be a REACH polymer if it was <50nm in size.

Taking into account these comments, and based primarily on enforceability/practicality

considerations, the Dossier Submitter proposed to increase the lower size limit from 1 nm to 100 nm for particles and from 3 nm to 300 nm for fibre-like particles recognising the significant practical concerns linked to the originally proposed limits (e.g. particle characterisation at the nanoscale). Not least that polymers below 100 nm, based on the properties of “no longer polymer” (NLP) substances, could exist as liquid particles (which are challenging to distinguish from solid particles at the nanoscale).

RAC notes that polymer particles below 100 nm are reported in the literature. For example, in three commercial facial scrubs containing polyethylene microbeads, nanoparticles consisted of polyethylene ranging in size from 24 to 54 nm were identified by X-ray photoelectron spectroscopy and Fourier transform infrared spectroscopy (Hernandez et al. 2017). 3D printing has been reported to emit⁷ nanometre-sized polymer particles, in the range of ~11–116 nm (Pinto da Costa et al., 2016). Furthermore, several polymers that may fall in the scope of the proposed restriction are quoted in cosmetics list of ingredients in nano form.⁸ In this list, some colourants and UV filters in nano form, like TiO₂, could be coated with polymers and fall in the scope of the restriction. These ingredients are mainly used as leave-on product ingredients (although RAC does not have information on the quantities of these substances placed on the market in the EU/EEA). The omission of polymer nanoparticles <100 nm from the scope of the restriction could potentially allow the continued use of nano-scale polymer particles consistent with the microplastic concern, or promote innovation to smaller particle sizes to circumvent the restriction.

Nanoscale polymer particles are likely to have different properties to micro-scale polymer particles. Smaller particles are more easily taken up by cells and distributed within organisms (Velzeboer, et al., 2014; Rios Mendoza, et al., 2018). Indeed, the Scientific Opinion on Environmental and Health Risks of Microplastic Pollution (European Commission, 2019), states that it is expected that the ease with which plastic particles can be absorbed by biota increases with decreasing size. Moreover, toxicity is expected to increase with decreasing plastic particle size (Jeong et al., 2016, Jeong et al., 2018) because of the increase in surface-to-volume ratio.

RAC considers that increasing the lower size limit to 100nm may lead to regrettable substitution to particles with smaller size, potentially compromising the effectiveness of the proposed restriction. The toxicity of particles is expected to increase with the reduction of its size linked to an increase in the surface/volume ratio. Smaller particles are easily absorbed by biota, penetrate deeply into organs, cells and even organelles, translocate across biological barriers and may cause more severe effects. Zhang et al. (2019) noticed that nanoplastics (50 nm) can penetrate the cell wall of bacteria and fungi causing growth inhibition and interrupt their ecological function, can cross the highly selective membranes of the fish brain causing behavioural disorders and brain damage.

Practical and technical difficulties for analysis of microplastics have been noted, such as the difficulty to demonstrate the solid state of a particle smaller than 100 nm and the need for

⁷ Emission during service life may be different from “intentionally added”

⁸ Catalogue of cosmetic ingredients from the European Union Observatory for Nanomaterials: <https://euon.echa.europa.eu/catalogue-of-cosmetic-ingredients> and Catalogue of nanomaterials in cosmetic products placed on the market - Version 2, DG Grow: <https://ec.europa.eu/docsroom/documents/38284>

several different analytical methods to cover the applicable size range from 5 mm to 1 nm⁹.

During opinion-development, and after finalising their opinion, the Forum was requested by the Rapporteurs to consider, from an enforcement perspective, the advantages and disadvantages of (i) the Dossier Submitter's original lower limit of 1nm (ii) the Dossier Submitter's revised lower limit of 100nm and (iii) the RAC proposal for no lower limit. The Forum considers that the "no lower size limit" approach favoured by RAC, has technical issues due to the difficulties in demonstrating solid state for polymeric particles at the size range below 100 nm and noted that the lowest technically achievable limit seems to be around 100nm.

In the event that no lower limit is recommended in the definition of a microplastic, the Forum's working group on the enforceability of restrictions suggests to consider a compromise for the conditions of the restriction based on what is practicable, according to the currently available analytical techniques. In addition, Forum considers that it is advisable to include in the legal text that the definition in the legal text will be reviewed in the light of experience and with scientific and technological developments. The Forum recommends that a limit value is included in the legal text. However, it should be noted that some experts of the working group on the enforceability of restrictions were in favour of no lower size limit.

RAC considers that the lower size limit for defining micro/nanoplastics, irrespective of issues of enforceability, should be less than 100 nm. However, as there is no clear scientific basis for determining a specific lower size limit in terms of hazard, RAC considers that it is appropriate to define microplastics without the use of a lower size limit i.e. <5 mm for particles and <15 mm for the longest dimension of a fibre-like particle. This is further considered in relation to the enforceability/practicality of the proposed restriction.

As a substance or a mixture could contain a range of different particle sizes, some of them could fall within the relevant dimensions and some of them could be larger or smaller, a threshold for the quantity of relevant particles within a group of non-relevant particles needs to be set. The Dossier Submitter proposed 1 w/w % as the limit value for the quantity of relevant particles that would need to be present in a substance or a mixture for it to be considered a microplastic. This value takes into account the inherent skew to larger particles in weight-based distributions. RAC is of the opinion that this approach is feasible, pragmatic and compatible with existing methods for characterising particle-based substances or mixture (e.g. *via sieving*).

Particle containing solid polymer

For the fifth element of the revised microplastics definition, the Dossier Submitter proposes a definition for a so-called '**particle containing solid polymer**¹⁰'. The Dossier Submitter

⁹ Currently, two analytical routes are applied to identify microplastics: vibrational spectroscopy and thermal degradative methods, such as thermogravimetry or pyrolysis, in tandem with GC-MS. The choice of one or the other method depends on the objective of the analysis. Spectroscopic methods (e.g. (μ)FTIR microscopy or (μ)Raman) can lead to a precise description of single particles regarding size, shape and main polymer type, but are not appropriate for measuring quantities or concentrations. In contrast, thermal degradation methods (e.g., TED-GC-MS or pyrolysis GC-MS) can quantify the exact mass of certain polymers in samples, but, as they are degradative methods, they do not allow any further characterisation such as, shape or number of particles (Elert et al., 2017). Depending on the setup of the application small particles can be measured down to the range of 20 μm or if needed even lower to the range of 1 μm using μ-FTIR or μ-Raman.

¹⁰ The Dossier Submitter had proposed a definition for a 'particle containing polymer' in the Annex XV report.

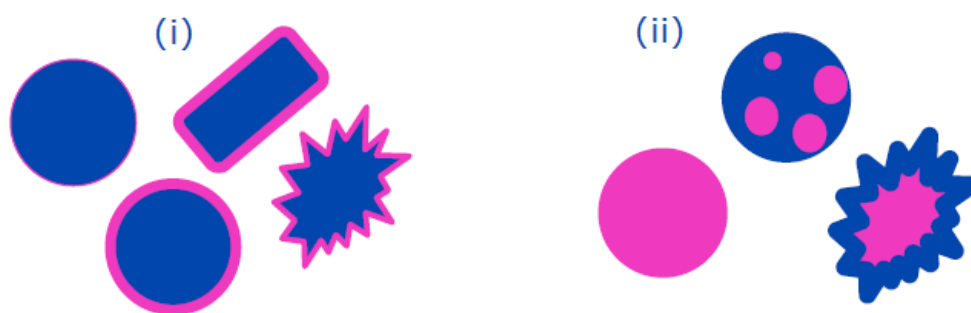
identifies two types of particles that could fit the term:

- (i) *A particle of any composition with a continuous solid polymer surface coating of any thickness (polymer encapsulated materials).*

It was decided not to introduce a polymer threshold value reflecting the weight of the polymeric coating versus the weight of the whole particle in this first scenario. RAC finds this justified since this introduces a bias in the determination of the weight percentage value. A larger and smaller particle may be coated with the same amount of polymer material, but due to their different size the relative weight percentage would be different.

- (ii) *A particle of any composition with a solid polymer content of $\geq 1\%$ w/w.*

RAC finds it justified to propose this specific value, since it is consistent with the impurity level threshold under REACH.



Stakeholders had pointed out during the consultation that liquid polymers associated with solid inorganic particles would be captured by the wording 'solid polymer-containing-particle' that was initially proposed by the Dossier Submitter in the Annex XV report. The microplastic concern is primarily associated with particles of solid polymers. As such, the originally proposed wording could inadvertently capture particles that do not include solid polymer. The Dossier Submitter subsequently proposed to rephrase the term 'polymer-containing particles' with '**particles containing solid polymer**'. RAC supports the revised wording.

Microbead

The Dossier Submitter also considered some additional terminology and characteristics. While the term '**microbead**' is sometimes interchangeably used with the term 'microplastic', in within the context of the proposed restriction it is used to describe a microplastic with exfoliating or cleansing functions typically added to cosmetic or detergent products. RAC notes that the need for a definition for this subset of microplastics is necessary to set different transitional periods (see further in this opinion). No transitional period is necessary as alternatives are widely available and European industry has voluntarily agreed to phase out the use of microbeads by 2020. Several national bans already exists on this use in the EEA. The Dossier Submitter has clarified that if a microplastic does not have an abrasive function (e.g. it is intentionally added for an opacifying function or to encapsulate another substance) then it is not a microbead for the purposes of this restriction, even if it is described as such by e.g. a manufacturer.

B.1.1.3.3. Concentration limit of 0.01%

RAC notes that this concentration limit is based on information collected through literature searches, the Dossier Submitter's call for evidence and the consultation on the Annex XV report and this specific threshold was chosen since it seems to correspond to the lowest concentration at which it has been reported that addition of microplastics has an effect on the function of the product.

The Dossier Submitter considers a concentration limit of 0.01% as appropriate as microplastics are frequently reported to be intentionally added to products at this concentration to achieve a function i.e. in detergents (from 0.01 to 43.25%), waxes and polishes (< 0.01% to 40%) as well as anti-caking agents in fertilisers (0.01% - 0.5%) where they are added in a concentration of around 0.01% w/w.

Although the concentration of microplastics in cosmetics products has been reported to be as low as 0.00003 % w/w; the Dossier Submitter is not aware of cosmetic products put on the market with intentionally added concentration lower than 0.01% or between 0.01 and 0.1%. Lower concentrations are reported for the calibration of *in vitro* diagnostic medical devices (0.0001-10%).

Stakeholders criticised this concentration limit during the consultation. A few of them considered that a concentration limit of 0.01% w/w was too high and requested a total ban. Some comments considered that a concentration limit of 0.1% w/w or 1% w/w in end products would be more consistent with previous restrictions for PBT/vPvB substances (e.g. #2124, #2352).

As the aim of the restriction is a complete ban on the placing on the market for sectors, product groups and applications where the releases of microplastics due to their use are unavoidable, RAC considers that it is appropriate to set the limit concentration as the lowest concentration added in products put on the market.

Regarding the large range of used concentrations of microplastics, a proposal to set different concentration limits according to the uses, although explored in the specific questions included in the consultation on the Annex XV report, does not seem to be justified based on the information available. Indeed, the restriction aspires to minimise releases of microplastics to the environment. Nevertheless, it should be borne in mind that the content of synthetic polymers in a mixture can be assessed by pyrolysis/GC-MS after sample preparation, as is already done for food products. However, these techniques are neither widespread nor inexpensive. Nevertheless, they are likely to be applicable to matrices other than food or water after appropriate method development and validation.

B.1.1.3.4. Three element risk management approach

For this restriction proposal the Dossier Submitter adopted a three-element approach to address the risks from microplastics that are not adequately controlled.

As the aim of this restriction is to avoid the release of extremely persistent microplastics, a complete **ban** on the placing on the market is proposed for sectors and applications where the Dossier Submitter considered the releases of microplastics as unavoidable. When releases

are not considered to be inevitable and could be minimised by appropriate conditions of use and disposal, '**instructions for use and disposal requirements**' were proposed.

This is the case for the placing on the market of the substances and/or mixtures containing microplastics :

- For use at industrial sites;
- Medicinal products for human and veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC, and in EU Regulation (EC) No 726/2004;
- Food additives as defined in EU Regulation (EC) 1333/2008
- *In vitro* diagnostic devices
- Where the microplastic is contained through technical means to prevent releases to the environment during end use;
- Where the physical properties of the microplastic are permanently modified during end use;
- Where the microplastic is permanently incorporated into a solid matrix during end use.

To obtain information on releases from these derogated uses, the Dossier Submitter proposed a **reporting requirement**:

The aims of the instructions for use and disposal requirement are:

- To avoid inappropriate or inadequate conditions of use or disposal by downstream users or consumers and therefore to facilitate the minimisation of microplastic releases to the environment
- To enhance the availability of information on microplastics in industrial supply chains and therefore to facilitate the compliance with the conditions of the restriction (specifically paragraph 1)
- Derogations 4a, 4b, 4d and 5 are conditional to the instructions for use and disposal requirement.

This requirement introduces obligations for suppliers¹¹, according to REACH Article 3(32), and is in line with the REACH requirements (Articles 31 and 32) and the specific requirements of existing sectors (Cosmetic Products, Medicinal Products, Medical Devices and Food Additives)

During the consultation on the Annex XV report several stakeholders stated that the reporting requirement should be clarified and that the reporting requirement entails a significant administrative burden, will lead to double counting and requires the disclosure of confidential business information. Taking these comments into consideration, the Dossier Submitter has made significant revisions to the proposal to address the concerns of stakeholders. For example, the exact polymer identify is no longer mandatory information and only release

¹¹ Suppliers as defined in REACH Article 3(32) i.e. "manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".

quantities are requested rather than use quantities (to avoid confidentiality and double counting issues). the Dossier Submitter has also proposed to extend the paragraph 7 ('instructions for use and disposal') requirement to oblige actors placing substances or mixtures on the market for downstream use at industrial sites (paragraph 4(a)) to clearly identify that the substance/mixture is subject to the conditions of the proposed restriction and provide information on the quantity (or concentration) of microplastics present and sufficient information on polymer identify for downstream users or suppliers to comply with the paragraph 8 reporting requirements. In this respect paragraph 7 introduces minimum standards for supply chain communication for microplastics and allows downstream users to better comply with paragraph 1 and 5 of the proposed restriction.

Longer implementation periods of 24 and 36 months for the paragraph 7 and 8 requirement, respectively, are also proposed by the Dossier Submitter, who considers that it does not compromise the risk reduction capacity of the proposed restriction, and it allows affected industrial supply chains to identify affected products and develop appropriate instructions for use and disposal.

RAC supports the revised proposal of the Dossier Submitter and considers that the implementation of the instructions for use and disposal requirement is fundamental for including the derogations for the uses that could feasibly, but not inevitably, result in releases of microplastics to the environment. RAC considers that providing instructions for use and disposal will increase the knowledge of downstream users and consumers and reduce the likelihood that microplastics will be inadvertently released to the environment. The Dossier Submitter outlines several studies in the Background Document reporting the effectiveness of labelling as a means to communicate information on chemicals. Indeed, RAC notes that the key requirement under REACH to provide extended safety data sheets throughout supply chains, and the labelling of the hazardous properties of substances and mixtures under CLP, has a similar intention. As such, it can be readily assumed that providing information along supply chains is an appropriate and effective means to achieve risk reduction. Nevertheless, RAC notes that the effectiveness of the proposed instructions (to prevent releases) will depend, in part, on how these are developed and communicated by those placing microplastics on the market. The proposed reporting obligation is complimentary to the instructions for use and should allow the effectiveness of the labelling to be monitored. This is further discussed in the uncertainties part of the opinion.

The proposed reporting requirement (Paragraph 8 of the conditions of the proposed restriction) for derogated uses of microplastics is intended to be complementary to the requirement for suppliers to provide instructions for use and disposal. The specific information to be reported has been re-evaluated in response to the comments submitted in the consultation. The information requested has been revised by the Dossier Submitter to maximise the availability of useful data to both companies and the Agency, whilst minimising administrative burden. RAC considers the rationale for the revised reporting requirement proposed by the Dossier Submitter to be reasoned and well-founded. RAC notes that reporting only gives information on the evolution of emissions to the environment from uses not covered by the ban, not overall emissions of microplastics (e.g. those that could occur from uses during the transitional period prior to the ban taking effect). The risk management strategy proposed by the Dossier Submitter (ban, instructions and/or reporting requirement) can be considered appropriate since they seem to strike a balance between data availability and the

identified risk.

B.1.1.3.5. Paragraph 3(a): Derogation for natural polymers that have not been chemically modified

The Dossier Submitter proposed a derogation in the Annex XV report for polymers that occur in nature that have not been chemically modified. This was on the basis that the concerns regarding microplastics are related to synthetic polymers.

The Dossier Submitter subsequently stated during opinion development that the wording “occur in nature” implies that only certain processes, as listed in Article 3 (39) of REACH (i.e. manual, mechanical, gravitational, dissolution in water, by floatation, by extraction by water, by steam distillation, or by heating (solely to remove water)), can be used to obtain these polymers and benefit from the derogation. The Dossier Submitter considered this condition as too stringent for the purposes of the proposed restriction. The Dossier Submitter therefore revised the wording of the derogation during opinion development to “natural polymers”, as defined in the guidance on monomers and polymers, *“polymers which are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted”*, that have not been chemically modified (as defined in REACH Article 3(40)).

The Dossier Submitter notes that natural polymers must not have been chemically modified (as defined in REACH Article 3(40) to benefit from the derogation. This is on the basis that the process by which a polymer is extracted from a natural material should be irrelevant in terms of its biodegradability unless it is chemically modified during the extraction, as this could adversely affect its biodegradability. The Dossier Submitter notes that the term ‘natural polymer’ has been used in the Single Use Plastic (SUP) Directive (EU) 2019/904.

RAC finds it justified to include a derogation for “natural polymers”, and notes that in order to benefit from this derogation the polymer should exist in nature (e.g. vegetable origin as cellulose, hemicellulose, glucomannan, agar, starch, pectin, inulin, rosin, guar gum, locust bean gum, gum cacia, karaya gum, gum tragacanth, *Aloe vera* gel, or animal origin as chitin, alginates, carageenans, psyllium, xanthum gum) and the synthesis process resulting in this polymer must have occurred in nature. RAC notes that some manufactured fibres made by the transformation of natural polymers (macromolecular material existing in nature) would **not** be excluded from the proposed restriction on the basis of this derogation.

The wording “other than by hydrolysis” was initially proposed in the Annex XV report by the Dossier Submitter because when functional groups react with water the polymer chain is broken down but no chemical modification occurs on the polymer chain itself. Hydrolysis might also occur in nature when the polymer takes up moisture or comes into contact with water.. However, neither the SUP Directive (2019/904) nor the REACH guidance on monomers and polymers refers to chemical modification ‘other than hydrolysis’. In the interests of consistency between other Guidance and legislation, and without prejudice to the observations above, The Dossier Submitter removed the reference to ‘other than hydrolysis’ during opinion-making. RAC notes that the precise conditions for hydrolysis (pH, enzyme...) should be clarified and defined in the event that the derogation is retained in the conditions of the restriction.

B.1.1.3.6. Paragraph 3(b): Derogation for biodegradable polymers

RAC agrees with the Dossier Submitter that it is justified to include an exemption for polymers that biodegrade¹² in the environment since these polymers would in principle not be consistent with the microplastic concern. Under the REACH regulation, the identification of PBT and vPvB substances is based on the criteria included in Annex XIII of REACH. In relation to persistence, criteria have been developed based on biodegradation rates in various environmental compartments. It should be borne in mind that in the event that a polymer has the inherent capability to biodegrade the biodegradation rate of a particle made of the polymer, as opposed to the polymer itself, is limited by the surface area available to bacteria and the criteria for biodegradability applied to the former may need to be adapted when considering the biodegradation of particles.

Biodegradation of solid substances is a heterogeneous reaction because it happens at the solid/liquid interface, where the microbial enzymes present in the liquid phase interact with the macromolecules available at the surface of the solid plastic sample. The macromolecules in the inner parts of the plastic sample are not yet involved in the reaction, as they are not available. This complicates the assessment of the biodegradation rate, because the amount of polymer carbon effectively available to biodegradation is much lower than the nominal amount (ThCO₂) and is not generally known (Chinaglia et al 2018). In this respect it can be useful to distinguish between intrinsic chemical persistence of a polymer and extrinsic physical persistence of a particle or article made of the same polymer.

The Dossier Submitter proposed specific test methods, pass criteria and guidance on appropriate test materials¹³ for assessing the biodegradability of polymers as an Appendix to the proposed restriction (termed Appendix X in the Background Document, Table 22). Appendix X includes standard methods that are used to assess the biodegradability of chemicals (e.g. OECD and ISO methods). Some of the proposed test methods can be used to derive the half-life of substances in simulated environmental compartments that can be directly compared against the P or vP criteria in Annex XIII of REACH. Other methods measure biodegradation in comparison to that of a known biodegradable reference material.

The comments received in the consultation on the on the Annex XV report reflected diverse views and ranged from requests for no biodegradation derogation to proposals for less stringent biodegradation criteria (e.g. # 2236, # 2160, # 2167, # 2241, # 2080, # 2215, #

¹² Biodegradation of organic substances (including organic polymers) may occur under aerobic or anaerobic conditions. The carbon of the polymer is assimilated by microorganisms into biomass carbon and then is either rapidly mineralised into CO₂ and H₂O (or CH₄ in anoxic conditions) or used for growth and reproduction (increase of biomass carbon). This biomass is also mineralised in the long term as a result of the subsequent turnover of the microbial community or storage polymers leading to the production of CO₂. As a consequence, a bi-phasic pattern with a rapid phase of CO₂ production followed by a slower secondary phase of CO₂ evolution is recognisable in the mineralisation of organic matter. Hence, during the degradation process, polymers are converted into smaller molecular units (e.g., oligomers, monomers, or chemically modified versions) and possibly are completely mineralised. Similarly to any chemical reaction, it is possible to monitor biodegradation either by following the consumption of reagents, the appearance of products or the disappearance of the polymer itself. From a technical viewpoint the easiest way to monitor and quantify biodegradation is to measure either the reagent (O₂) or the end product (CO₂) of energy metabolism. The biodegradation percentage is the ratio between the evolved CO₂ and the theoretical CO₂ (ThCO₂) i.e. the amount of CO₂ expected in case of total oxidation of the carbon present in the sample introduced in the test vessels. These measurements are the foundation of OECD screening tests for biodegradation, for example.

¹³ The guidance explains that polymers shall be tested in the physical form placed on the market consistent with paragraph 2(a) of the proposal including, where relevant, any additives or other substances present.

2399, # 2430, # 2437, # 2442, # 2609, # 2600, # 2624).

In addition to conventional screening and simulation studies used to assess the biodegradation of water soluble substances, Appendix X also includes a group of standard ISO test methods (group 4 in Appendix X) that have been specifically developed for assessing the biodegradability of plastic materials by ISO technical committee ISO/TC61.

Thus, the standard test methods listed in Appendix X include methods used to measure ready biodegradation (groups 1 and 2), inherent biodegradation (groups 3), as well as biodegradation in various simulated environmental compartments (groups 4 and 5). In general terms, the tests become more complicated and time-consuming to perform from group 1 to group 5. Test methods for process environments (e.g. sewage treatment plants, anaerobic digester and composting) are not included. RAC notes that polymer degradation in managed and unmanaged environments is not universally well understood (Harrison et al 2018, Narancic et al 2018, Bagheri et al 2017, Kjeldsen et al 2019) and the diversity of biodegradable materials and environments makes it difficult to assess their end-of-life fate in a generic manner (Narancic et al 2018).

Whether a polymer-based material will biodegrade in a certain environment depends on many factors such as its crystallinity, its density, the presence of additives, the presence and diversity of competent micro-organisms, temperature, moisture and the pH of the environment. This point was raised during the consultation on the Annex XV report (#2707, #2613, #2139, #2161). During the consultation, a need to clarify how the criteria were derived and whether there is a need to conduct testing in all testing tiers, arose.

The Dossier Submitter subsequently clarified in a revision to the Background Document that it was not intended that testing would proceed in a tiered fashion (i.e. from group 1 to group 5 tests). Although the tests are arranged such that the most stringent (i.e. difficult to pass tests particularly for surface limited test materials such as microplastics) are presented in groups 1 to 3, whilst more technically demanding, but more environmentally relevant, tests to perform for plastics are presented in groups 4 and 5, it was only necessary to demonstrate a positive test result in one of them. In practice, group 4 or 5 tests would only be required to be performed if a polymer would have failed the more stringent tests, but rapidly performed, groups 1 to 3 tests.

Screening biodegradation testing (Groups 1, 2 and 3)

This group consists of ready biodegradation tests, permitted test methods are OECD TG 301 B,C,D,F and OECD TG 310 with a test duration extension up to 60 days. During the consultation a further extension of this test duration from 60 days to 90 days (#2600) and a modification of the criteria for 20 % after 28 days and 40% degradation after 3 months were requested (#2492). The pass level is considered to indicate the ultimate degradation of the test substance, as the remaining fraction of 40% of the test substance is assumed to be assimilated by the biomass or to be present as products of biosynthesis. Nevertheless, no scientific data on polymer particles are available to assess the consequences of an additional extension of test duration beyond 60 days or any further modification of the test methods or pass criteria, in term of environmental perspectives and biodegradation in the environment.

These ready biodegradation tests¹⁴ are widely used in European regulations (Table 3 Annex C of the Background Document) and they are part of the data requirement for REACH registration. The results can be used to draw conclusions that the substance does not meet the P and vP criteria as set out in REACH Annex XIII¹⁵.

Using these tests in the context of the microplastics restriction is consistent in the context of REACH regulation. However, RAC notes that the OECD Guidelines were originally developed for water soluble mono-constituent substances and not for polymer particles. The ISO 10634 standard was developed to outline how to carry out these tests with poorly water soluble or insoluble substances. Plastics are based on macromolecules that are solid at room temperature and generally not soluble in water. Nevertheless, literature reported that these tests are applicable for microplastics and polymers microparticles like PHBV (Poly(β -hydroxybutyrate- β -hydroxyvalerate)), considered as alternatives to microplastics in cosmetic product applications. PHBV with a diameter of 125-500 μm passed the OECD 301B test and were mineralised with more than 66% biodegradation (measured by CO_2 evolution) in 28d (Mc Donough et al., 2017). Furthermore, Pandard et al (2020 personal communication) observed that the polymer polyhydroxybutyrate/polyhydroxyvalerate 2% is readily biodegradable in an OECD 301F test as it fulfilled the pass level (i.e. 60.9% theoretical oxygen demand in a 10-day window). Biodegradation reached 79.2% at day 28.

Tests on inherent biodegradability are useful to give an indication of biological degradability on a screening level and are performed using more favourable conditions than ready biodegradability tests. Thus, they are optimised to show whether a potential for degradability exists.

Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series would provide sufficient information to confirm persistence without the need for further simulation testing (REACH Guidance for PBT-assessment, chapter R.11.4.1.1.3; ECHA, 2017). The inherent degradation tests provide optimum conditions to stimulate adaptation of the micro-organisms thus increasing the biodegradation potential, compared to natural environments. A lack of degradation therefore provides convincing evidence that degradation in the environment would be slow. Care should be taken in the interpretation of such tests, however, since for example a very low solubility of a test substance may reduce the availability of the substance for the inoculum. Stakeholders considered that only modified OECD TG 302B would be applicable (#2582) with a combination of TOC and CO_2 production being measured. OECD TG 302B is unsuitable for testing polymer particles as it requires test materials with water solubility of at least 50 mg DOC/L.

¹⁴ A “ready biodegradable” chemical is assumed to undergo rapid and ultimate biodegradation (“mineralisation”) in the environment and no further investigation of the chemical itself, or of the possible environmental effects of transformation products, is required. Ready biodegradability tests are not simulation tests, but tests for potential to biodegrade (meaning the compatibility between the substance and microorganisms metabolic pathways). The data from screening tests indicate that chemicals passing the test do not offer a serious challenge to the metabolic capability of aerobic aquatic environments (given the presence of bacteria, nutrients, etc.) and that they would be readily degraded in the real environment.

¹⁵ Taking into account the stringent test conditions, ECHA Guidance Chapter R.11 – PBT/vPvB assessment implies that there is high confidence that a monoconstituent “readily (bio)degradable substance” will not be persistent under environmental conditions.

ISO Methods: Group 4

Table 2 (see below) summarises the ISO tests in Appendix X specifically developed to determine the biodegradability of plastics¹⁶. The test methods are characterised by assessing the degradation of plastic relative to a reference material, typically but not exclusively cellulose.

ISO tests are terminated when the biodegradation of the reference and test material reaches a plateau within a maximum of 6 months in aqueous tests and 48 months in soil/sediment. Pass criteria are not defined in the ISO test methods, only test validity criteria, including a criterion that the reference material must reach at least 60% biodegradation based on ThOD/ThCO₂. The pass level for group 4 tests specified in Appendix X was derived by the Dossier Submitter based on the pass criteria used in similar contexts. Specifically, the pass criterion for group 4 tests is derived from ISO 13432:2000 on the requirements for 'packaging recoverable through composting and biodegradation', where, it is stated that *"for the test material the percentage of biodegradation shall be at least 90 % in total or 90 % of the maximum degradation of a suitable reference substance after a plateau has been reached for both test material and reference substance"*. RAC notes that a similar pass criterion has recently been included in an ISO specification for biodegradable plastics in the marine environment (ISO 22403:2020)¹⁷. Significantly, ISO tests are not used to derive a half-life, but to identify materials that have comparable biodegradation behaviour to biodegradable reference substances.

¹⁶ The ISO test methods included in Appendix X (14851:2019, 1482:2018, 17556:2019, 19679:2017, 22404:2019), are specially designed to determine the biodegradability of plastic materials (natural and/or synthetic polymers or copolymers, including those containing formulation additives such as plasticisers, colourants or other compounds). The test material may be used in powder form, but it may also be introduced as films, pieces, fragments or shaped articles. When in powder form, a particle-size distribution with the maximum at 250 µm diameter is recommended.

¹⁷ <https://www.iso.org/standard/73121.html>

Table 2 Summary of ISO biodegradation test methods included in Appendix X

Method	Reference	Analytical Method	Concentration of Test Material	Duration	Concentration of Inoculum	Inoculum	Pass level restriction
Ultimate aerobic biodegradability of plastic materials in aqueous medium	EN ISO 14851	Respirometry: oxygen consumption	100 – 2000 mg OC /l	2 months (up to 6 months)	30 – 1000 mg/l SS	Activated sludge	≥ 90% relative to the degradation of the reference chemical in 6 months
Ultimate aerobic biodegradability of plastic materials in aqueous medium	EN ISO 14852	CO ₂ evolution	100 – 2000 mg OC /l	≤ 6 months	30 – 1000 mg/l SS	Activated sludge; soil; compost	≥ 90% relative to the degradation of the reference chemical in 6 months
Ultimate aerobic biodegradability of plastic materials in soil	EN ISO 17556	Respirometry: oxygen consumption; CO ₂ evolution	(Suitable concentrations) 1000 mg/kg 12500 mg/kg	6 months (up to 24 months)	-	No inoculum added	≥ 90% relative to the degradation of the reference chemical in 24 months
Aerobic biodegradation of non-floating plastic materials in a seawater/sediment interface	EN ISO 19679 / 18830	CO ₂ evolution / oxygen consumption	150 – 300 mg/l (water + sediment)	≤ 24 months	-	No inoculum added	≥ 90% relative to the degradation of the reference chemical in 24 months
Determination of the aerobic biodegradation of non-floating materials exposed to marine sediment - Method by analysis of evolved carbon dioxide	EN ISO 22404	CO ₂ evolution	solid, milled, 100 mg in 400 g sediment	≤ 24 months		No inoculum added	mineralisation relative to reference material is at least 90% or 90% absolute

This means that, in a worst case scenario (assuming only just acceptable control performance), a substance/mixture can achieve the pass criterion after reaching a biodegradation of 54% (= 90% of 60%) after 6 months in water and 2 years in soil. It should also be kept in mind that the reference and the testing material (e.g. cellulose) can present different types of kinetic curves and the reference compound can reach the biodegradation plateau earlier than the test material. Similarly, considering the test duration, a polymer could theoretically achieve the pass criterion in an ISO test despite a DT50 in simulation studies longer than the P or vP criteria in Annex XIII.

During the consultation, it was stated by some respondents that passing one test should be sufficient to conclude on biodegradability as it is an intrinsic property (e.g. #2582) and the wording of Appendix X should be modified in relation to ISO tests from 'and' (requiring multiple ISO test method passes) to 'or' (requiring only a single test method pass). Some stakeholders consider that the ISO 17556:2012 test method (biodegradation in soil) is not appropriate (too stringent) as some natural polymers would not meet the pass criteria, even after a 48 month test duration (#2047, #2164).

Due to a lack of knowledge of detailed kinetics and actual duration of degradation, there are some difficulties to link the results of the ISO tests with what would be likely to occur in the environment. Furthermore, certain studies in the scientific literature discuss uncertainties in predicting the biodegradation in the environment using laboratory scale (standard and non-standard) methods (Harrison et al 2018, Klein et al 2018; Chinaglia et al 2018; Bagheri et al 2017).

Another uncertainty relates to the extrapolation of a result in one compartment to another environmental compartment. For OECD screening tests, it is widely accepted that a positive result in these tests is predictive of degradability in all environmental compartments. For the ISO tests, no data considering this point would appear to be available. In this case, despite the proposal of the Dossier Submitter that only a single ISO method pass would be required to demonstrate that a polymer was biodegradable, the requirement to pass tests indicative of multiple environmental compartments (e.g. soil, surface water and sediment) would seem to be reasonable to justify this derogation with sufficient certainty.

Simulation testing –Group 5

The simulation tests in group 5 consist of the standard OECD simulation tests (OECD 307, OECD 308, OECD 309) that may be used to simulate degradation half-lives and distribution under semi-realistic environmental conditions and also more recently, to assess the persistence of substances under REACH. Some respondents to the Annex XV report consultation considered that they were not appropriate (#2389, #2422) for testing polymer particles due to the difficulty to appropriately radiolabel test materials. Nevertheless, biodegradation simulation studies performed in appropriate environmental media and at environmentally relevant conditions are the only tests that can provide a definitive degradation half-life (that could be used to compare with REACH Annex XIII criteria). Radiolabelling of polymer particles would appear to be feasible as it is used in a medical context (Wolf, 2018; Zumstein et al., 2018). This would require synthesizing a monomer suitably radiolabelled in the right position, the polymerisation of the required monomers and plasticizers, extruding or otherwise forming of the polymeric material, followed by e.g. grinding or milling to the appropriate test size, all in a suitably equipped and certified radio-isotope laboratory. The test scale would also need to be similar to that for soluble mono-

constituent chemicals in order to fit in existing test climate rooms. There seems to be little experience or knowledge of these simulation tests being applied to polymer particles. As noted by the Dossier Submitter, if simulation tests are applied for microplastics, poorly soluble particles, the test results should be interpreted with caution and 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 first order kinetics.

Microplastics are ubiquitous and even if the main releases are to soil and down the drain, it is difficult to determine in which compartment the microplastics will finally end up. Furthermore, Narancic et al (2018) and Karamanlioglu et al (2017), for example, have reported that polymers degrade and behave differently in different environmental compartments. Due to the different (bio)degradation behaviour in different environmental compartments it is uncertain if testing in one compartment would reflect the (bio)degradation behaviour in another. Therefore, in contrast to the Dossier Submitter's proposal, testing each compartment (soil, freshwater/sediment, marine water/sediment) seems to be justified, even if the compartment of initial release is known.

Non-testing methods

Proposals to introduce weight of evidence, read-across or quantitative structure-activity relationships (QSAR) methodologies into the approach were also submitted during the consultation. Since, to our knowledge, no QSARs for biodegradation have been developed for polymers and read-across with monomers is not relevant (because the size and the shape of the polymer is not taken into account and these properties are known to influence biodegradation). Furthermore, the enforceability of these approaches without clear pass/fail criterion would be challenging. Consequently, RAC agrees with the Dossier Submitter that such non-testing approaches would not be appropriate to include in Appendix X.

Detailed evaluation of Appendix X

The RAC evaluation of the Dossier Submitter's proposal identified two main uncertainties. The first one is linked with the environmental fate of microplastics, which may vary from one compartment to another. The second uncertainty is based on the relevance and the transferability of the test results to the fate of the material in the environment.

Regarding the general scheme proposed by the Dossier Submitter, this could be considered to comprise a 'picklist' as no hierarchy exists between the different groups of tests. Theoretically, tests having the most likelihood of passing could be performed preferentially. However, uncertainties remain regarding the suitability of the specified test guidelines to the characteristics of the test material. Extrapolation between compartments and to realistic environmental conditions appears to be hampered by a lack of comparative datasets, mainly for ISO and OECD tests, the latter where particulate materials are concerned. In addition, ISO tests are used to determine the relative biodegradation performance of a test material compared to reference materials that are generally regarded as biodegradable (e.g. cellulose) while the environmental relevance of the OECD tests is in relation to the half-lives specified for P and vP substances in Annex XIII. In this respect the ISO and OECD test have fundamentally different underlying rationales.

Recognising this, RAC considers that it could perhaps be confusing to accommodate tests with different underlying rationale within the same framework. The basis of the derogation could potentially be clarified if the rationale were based only on the OECD tests or only on the ISO

tests.

RAC discussed modifications to the Dossier Submitter's scheme that could explicitly address the uncertainties identified above (RAC-52 proposal – see Figure 1). The modified scheme incorporated ISO tests but required additional testing to be conducted where they were used, as follows:

- In order to achieve the derogation criteria when group 4 (ISO) tests are used, positive (pass) test results should be obtained from ISO tests indicative of multiple (three) environmental compartments (i.e. soil, surface water and sediment – See G4 box in Figure 1), rather than in a single test as proposed by the Dossier Submitter. This is to address the uncertainties arising from extrapolating from one compartment to others (where it could be reasonably expected that biodegradation behaviour could be different in different compartments).
- If the results of one of the three ISO tests do not achieve the pass criteria, RAC considers that to pass the derogation as whole the OECD simulation studies in group 5 should be performed in the failed environmental compartments before a test material can be placed on the market on the basis of the paragraph 2b derogation.
- Whilst acknowledging that the ISO tests in group 4 are not intended to provide information on the half-life of polymers, if the results of the three ISO tests (ISO 17556; ISO 14851 or 14852; ISO 19679 or 22404) meet the pass criteria, RAC considers this as sufficient justification for conditionally meeting the conditions of the derogation pending validation in one or more relevant OECD simulation studies (e.g. within 10 years of first placing the polymer on the market) to demonstrate that the half-life of the substance in simulation studies was less than the P or vP criteria (see figure below).
- The requirement for validation should be considered as temporary and should be necessary only until sufficient information on the relationship between the results of ISO and OECD simulation studies is available to allow a more comprehensive review (e.g. for 10 years after EiF).

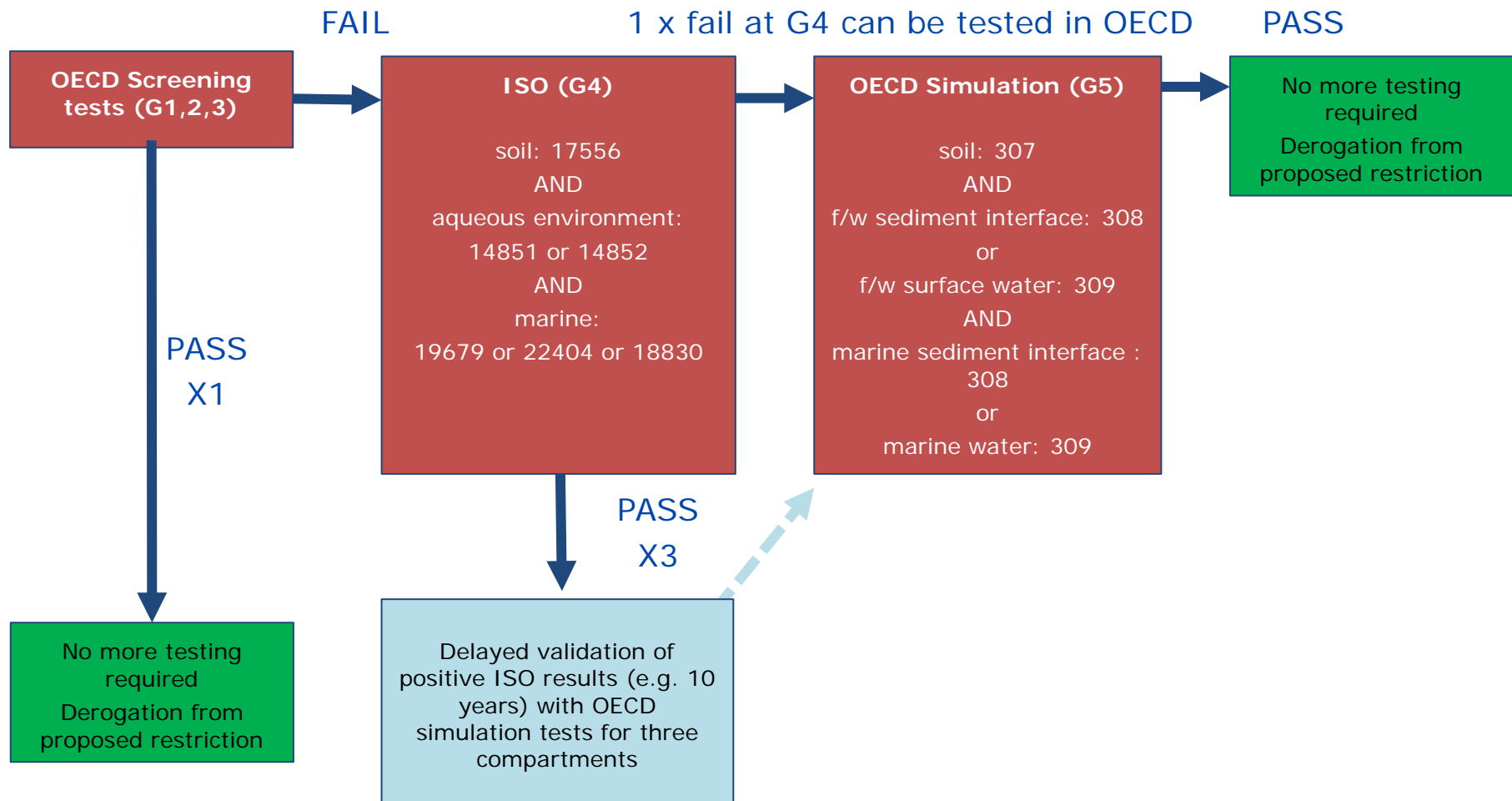


Figure 1 RAC-52 scheme for biodegradability assessment

Whilst addressing many of the identified uncertainties, the RAC-52 scheme was not considered to be particularly practical and could act as a barrier to biodegradable alternatives being developed. To assist with the further evaluation of the Dossier Submitter's proposal, the Rapporteurs together with the ad-hoc RAC working group developed a series of eight scenarios comprising different approaches to the testing needed to justify a derogation from the proposed restriction (including the Dossier Submitter's proposal and the RAC scheme discussed at RAC-52) and systematically evaluated each of them in detail. The eight schemes were developed based on either comments received in the consultation or in response to uncertainties identified in the Dossier Submitter's proposal.

1. **'Dossier Submitter's proposal'** – As described in the Background Document
2. **'RAC-52 proposal'** – As described above
3. **'All compartments requirement at G4/G5'** – A modified Dossier Submitter approach incorporating a requirement to test a greater number of compartments (three) if derogation is justified on the basis of either group 4 (ISO) or group 5 (OECD simulation) testing
4. **'OECD test methods only'** – A modified Dossier Submitter approach based on the OECD standardised tests included groups 1, 2, 3 and/or multiple (three) compartments at group 5.
5. **'ISO test methods only'** – A modified Dossier Submitter approach based on performing tests on multiple compartments (three) in group 4 (ISO) only. No screening level tests would be included.
6. **'Polymer testing only'** – An approach based on a requirement to test the generic polymer only, not the microplastic placed on the market
7. **'Confirmatory polymer data requirement at G1/G2/G3'** – An supplementary requirement to also test polymers where derogation is based on the results of screening level testing only
8. **'Weight of evidence approaches'** – An approach where non-testing data or read-across could be used to justify derogation

The evaluation considered the advantages, disadvantages and uncertainties of each of the scenarios as well as their relevance to the environment, practicality (including enforceability) and overall stringency.

The results of the evaluation of the scenarios are summarised in the table below and elaborated in Annex 1 of the opinion.

Table 3 Summary of the systematic evaluation of biodegradation scenarios

Scenario	Conclusion, including key uncertainties
<p>1. Dossier Submitter's proposal</p>	<p>The Dossier Submitter's proposal provides the necessary clarity to both industry and enforcement authorities, but it is not possible to rule out that some derogated materials could persist for extended periods in the environment after release, therefore continuing to contributing to the microplastic concern.</p> <p>This is because, unless a compartment-independent screening test was used to demonstrate biodegradability, biodegradation is only required to be demonstrated in a test representative of a single environment compartment. As microplastics may move between environmental compartments after they are released (e.g. from soil to water to sediment) it is not possible to conclude with sufficient confidence that a microplastic is sufficiently biodegradable in all relevant environmental compartments from a single test.</p> <p>Equally, whilst all of the test methods included in the proposal allow a conclusion to be drawn on the inherent capacity of a material to biodegrade under the conditions of the test, only some of the test methods (those in group 5 – OECD simulation studies) are theoretically capable of estimating the time needed for a material to biodegrade under environmentally relevant conditions, typically expressed as a DT50 (half-life), which could then be compared to the half-life criteria used to identify persistent (P) or very persistent (vP) substances under REACH (Annex XIII criteria). However, there is currently very limited practical experience in running these types of tests with particulate test materials and there could be significant technical challenges associated with synthesising the radiolabelled test materials needed to undertake these tests. Similarly, Annex XIII criteria are applicable to organic substances, but their applicability to particulate materials, and to the microplastic concern specifically, is less certain.</p> <p>The test methods included in group 4 (ISO test methods) that are specifically designed for plastic test materials and which measure biodegradation relative to a GRAB¹⁸ reference material (but not under environmentally representative test conditions) may potentially derogate materials that would biodegrade in the environment, but not sufficiently quickly to avoid them contributing to the microplastic concern.</p> <p>As such, the effectiveness of the Dossier Submitter's proposal is associated with various types of uncertainties. The screening tests and pass/fail criteria included in groups 1,2 and 3 are deliberately stringent and achieving the pass criteria for these tests is considered to indicate that a test material is biodegradable in the environment within an acceptable timeframe. However, as a result of their stringency they are associated with a high likelihood to return a negative test result for test materials that would degrade sufficiently in the environment to avoid contributing to the microplastic concern.</p> <p>To address these uncertainties less conservative tests are also proposed by the Dossier Submitter (group 4 and 5 tests). However, as described above, both of these groups of tests are associated with not insignificant</p>

¹⁸ Generally regarded as biodegradable, e.g. cellulose

Scenario	Conclusion, including key uncertainties
	<p>uncertainties, and it is not possible to definitively prefer one group of tests to the other based on current knowledge.</p> <p>It may be possible to address the uncertainties associated with the group 4 and 5 tests by undertaking further empirical research to compare the performance of test materials, including reference materials, in these different types of tests. This would help to establish their equivalence or whether one group of tests should indeed be preferred over the other.</p> <p>RAC considers that a more critical weakness of the Dossier Submitter's proposal is associated with the lack of a requirement to test biodegradation behaviour in tests representative of, or at least characteristic of, different environmental compartments. RAC acknowledges the Dossier Submitter's intention to limit the quantity of testing that is required to fulfil the derogation, but considers that the risk of derogating a persistent material on the basis of limited compartment testing to be significant. The risk of derogating a persistent material would appear to be relatively greater from failing to test relevant environmental compartments than from the uncertainties inherent to the group 4 and 5 test methods.</p> <p>Another element to consider in the Dossier Submitter's proposal is the requirement to test the polymer in the form that it is placed on the market (i.e. particle size, shape, surface area and the presence of any additives or other substances). RAC acknowledges that these parameters will affect the biodegradation of the particle, but notes that this will require many biodegradation tests to be conducted, potentially on relatively similar materials. RAC recommends that approaches to minimise the required testing should be considered, but this should not be at the expense of the effectiveness of the restriction.</p>
2. RAC-52 proposal	<p>In an attempt to address the uncertainties inherent in the Dossier Submitter's proposal, RAC-52 discussed a modified approach to the biodegradation derogation that would explicitly address the key uncertainties that had been identified in the Dossier Submitter's proposal (Figure 1).</p> <p>The modified proposal was similar to the Dossier Submitter's with the exception that where tests in groups 4 and 5 were necessary (i.e. because test material did not achieve the pass criteria in the group 1,2 and 3 screening tests) then tests should be conducted (and pass criteria achieved) in three relevant environmental compartments (soil, aqueous environment, marine – see Figure 1) rather than one. This was designed to address RAC's key concern with the Dossier Submitter's proposal that derogated materials could be persistent in certain environmental compartments even if biodegradable in one.</p> <p>To address the uncertainties identified in the group 4 (ISO) tests that rely on the performance of the test material relative to a GRAB reference material, the modified proposal also contained a provision that where group 4 tests were used to satisfy the conditions of the derogation these data would need to be accompanied, in due course, with group 5 test data. This was to allow the generation of sufficient high quality data to allow the comparison of these two different test regimes at an appropriate time in the future (possibly as part of a review of the restriction).</p> <p>Acknowledging the current lack of experience with conducting group 5 tests</p>

Scenario	Conclusion, including key uncertainties
	<p>with polymeric particulate test materials, and the uncertainties associated with this, the RAC-52 proposal recommended that the group 5 data would not be needed immediately, but could be postponed for a period of 10 years (after placing the derogated material on the market for the first time), which was considered to be a reasonably sufficient time for laboratories to gain experience and competence with undertaking group 5 tests with polymeric particulate test materials and to further consider the appropriate pass/fail criteria that should be applied to group 5 tests (e.g. P, vP or some other half-life).</p> <p>These three elements were, together, considered by RAC to explicitly address key uncertainties identified in the Dossier Submitter's proposal. The exercise was useful to identify the extent of uncertainties and the scope for the conditions of the derogation to be modified to explicitly address them. The recommendation minimised the requirement for data to be generated outside of the restriction process and was considered to be compatible with the concept of the reversal of the burden of proof that underpins REACH. Nevertheless, not all uncertainties could be addressed by the recommendation. Specifically, the requirement to overcome any technical barriers to performing group 5 tests was not addressed by the proposal. As such, the technical feasibility of performing group 5 tests, which are mandatory under the proposed scheme if group 1,2,3 tests are not passed, is unknown.</p> <p>Recognising this, it is not feasible for RAC to include the RAC-52 recommendation as the only option in its opinion. RAC also recognised that the proposal would lead to significant challenges to industry in relation to predictability and certainty in the period between completing the group 4 and group 5 tests.</p>
<p>3. 'All compartments requirement at G4/G5'</p>	<p>This scenario is similar to the Dossier Submitter's proposal but requires, where the pass criteria are not achieved with the screening tests included in groups 1, 2 and 3, multiple (three) compartments to be tested (and the pass criteria achieved) in either group 4 or group 5 tests (See Group 4/5 boxes in Figure 1 for the specific test methods and compartments required).</p> <p>Under this scenario there is no requirement for mandatory testing in group 5, but group 5 tests can be used to achieve the requirements for the derogation when the corresponding group 4 test did not achieve the necessary pass criteria (i.e. G5 soil test pass can be used if the G4 soil test pass criteria is not achieved, and <i>vice versa</i>). The scenario recognises that the uncertainties associated with the group 4 and 5 tests are such that one group cannot be preferred over the other (i.e. in terms of a hierarchy).</p> <p>RAC considers that such an approach would address the key uncertainty identified in the Dossier Submitter's proposal related to insufficient testing of different compartments. The approach is implementable, practical and flexible and would minimise the likelihood that materials that would contribute to the microplastic concern would be derogated, but not eliminate this possibility entirely.</p> <p>However, this scenario would not explicitly address the uncertainties related to the environmental relevance and practical implementation of the group 4 and group 5 tests, respectively (outlined above), which RAC recommends ought to be investigated as a matter of urgency and the</p>

Scenario	Conclusion, including key uncertainties
	outcome used, if necessary, as part of a review of the conditions of the derogation in the future.
4. OECD test methods only	<p>This scenario is based on the OECD standardised tests included groups 1, 2, 3 and/or multiple (three) compartments at group 5.</p> <p>The scenario would effectively derogate materials that would meet the pass criteria associated with the conservative screening tests in groups 1, 2 and 3. Acknowledging that only a minority of particulate materials that would not contribute to the microplastic concern would achieve the groups 1, 2 and 3 screening criteria many test materials would need to be tested in group 5 tests.</p> <p>Although multiple compartments would need to be tested, addressing RACs key concern with the Dossier Submitter's proposal, given the uncertainties surrounding the feasibility of currently performing group 5 tests, which could preclude their use entirely (at least in the short to medium term) this proposal could prove to be a very stringent derogation, with only readily biodegradable materials having potential to pass.</p>
5. ISO test methods only	<p>This scenario is based on performing multiple tests in group 4 (ISO) only. No screening level tests would be included.</p> <p>The proposal would address the key concern that multiple compartments should be tested, but would require long term tests to be conducted for all test materials, including those that would achieve the conservative OECD screening criteria.</p>
6. Polymer testing only	<p>A polymer only approach would address the concerns associated with the need to test many different, but relatively similar, microplastic formulations based on the same polymer (large testing burden).</p> <p>Although attractive from an efficiency perspective there is currently insufficient information to conclude on the effectiveness of such an approach (i.e. in terms of only derogating materials that would not contribute to the microplastic concern). This is because there are several studies that indicate that the presence of additives in the polymer matrix can affect the biodegradability of the resulting mixture.</p> <p>As such, it is not possible to currently recommend such an approach as an alternative to the Dossier Submitter's proposal, but it should be reviewed in the future once there is further data available to do so.</p>
7. Confirmatory polymer data requirement at G1/G2/G3	<p>In response to a concern that under very specific conditions the results of OECD screening tests (G1/2/3) could be disproportionately influenced by the presence of readily biodegradable non-polymeric organic additives (or other constituents) present in the test material, this scenario explored the potential to require confirmatory polymer degradation data (similar to the approach for blends of polymers outlined in the Dossier Submitter's proposal) where materials are derogated from the restriction on the basis of screening level data only. Confirmatory data would not be required for tests included in group 4 as, unlike the G1/2/3 tests, these are specifically designed for mixtures of polymers and additives.</p>

Scenario	Conclusion, including key uncertainties
	<p>The likelihood of such an event occurring is unclear to RAC, but could consider an approach to be appropriate to minimise the possibly of a false pass test result in screening tests.</p> <p>As screening tests are relatively straightforward (and the requirement to assess the biodegradation of individual polymers in test materials comprising 'blends' already applies) RAC can see the advantages of including such an approach, but this should be reviewed in the future to ensure that the testing burden is not disproportionate.</p> <p>In terms of the relative concentration of non-polymeric organic constituents to polymeric constituents of a test material, RAC acknowledges that if the total of non-polymeric organic constituents in a test material are present at a relatively low concentration (e.g. <10% total weight of the test material) they would be unlikely to confound the results of a group 1,2,3 test. Therefore, where total non-polymeric organic constituents make up <10% w/w of the test material it would not be useful to request confirmatory polymer data and the results of a group 1, 2 or 3 test on the test material including non-polymeric constituents can be reliably compared to the relevant pass criteria in Appendix X.</p>
8. Weight of evidence	<p>A weight of evidence (WoE) approach including the use of (i) non-testing or (ii) 'non-standard' test method data to waive Appendix X testing requirements e.g. based on QSAR, read-across (including between different sizes of the same MP), use pattern or environmental fate information (to justify lack of exposure in a particular compartment) would not be protective for the environment and would be extremely difficult to enforce. While reducing the burden of standard testing it would significantly increase the uncertainty of the derogation.</p>

In conclusion, although each of the scenarios evaluated present their own advantages, there is no scenario that addresses all of the identified uncertainties. Nevertheless, it appears that scenario three ('all compartments requirement at G4/G5') would satisfy the key concern raised during RAC's evaluation of the Dossier Submitter's proposal whilst remaining practical. A revised requirement to achieve the pass criteria in tests specific to three environmental compartments before a material is derogated addresses RAC's key concern that a material could be demonstrated as biodegradable in one compartment whilst remaining persistent for long periods in another (and thus contributing to the microplastic concern).

The long-term persistence of microplastics in the environment will lead, inevitably, to transport from one environmental compartment to another after release (e.g. from soil to freshwater to marine). To adequately reflect the reality of this transport, any derogation for biodegradable polymers must be sufficiently rigorous that biodegradability across different compartments, irrespective of the compartment where they are initially released to the environment, should be addressed.

Irrespective of the potential for transport between environmental compartments after release, it is also worth considering that the same microplastic-containing product could, according to the Dossier Submitter's exposure assessment lead to releases to several different environmental compartments. For example, consider a moisturiser or sun-protection product containing a microplastic, if this product is washed-off after use (e.g. in a shower) the down-

the-drain release pathway determines that releases of microplastics could occur to either the aqueous or terrestrial compartments depending on the local wastewater treatment and sludge disposal practices. Equally, use of the same product if worn during swimming or sunbathing could result in direct releases to the marine environment. Demonstrating biodegradability across multiple environmental compartments is considered by RAC as an absolute minimum requirement for justifying a derogation.

The benefit of using either group 4 or group 5 tests to achieve the derogation requirements is that it retains flexibility, recognising that group 5 tests may not be practical for testing microplastics. However, it is important to note that scenario three does not address all of the uncertainties identified by RAC. Therefore, RAC concludes that should a derogation based on scenario three be adopted by decision makers, then additional research would be required to further explore and understand the environmental relevance of the 'relative to reference material' test methods included in group 4 as well as the applicability of group 5 test methods to microplastic test materials as well as, more generally, the applicability of REACH Annex XIII half-life criteria to particulate materials. This research should be conducted as soon as practically possible. RAC notes that this research should generally be conducted by industry (in line with the principle of the reversal of the burden of proof established under REACH). RAC considers that a better understanding of the relevance and applicability of the diverse range of standardised biodegradability tests is required to facilitate the development of appropriate and sustainable biodegradable polymers in general.

Noting the need for rapid development of understanding and standardisation in this discipline, RAC agrees with the Dossier Submitter that the conditions of the derogation should be reviewed in light of technical progress in the future. The Dossier Submitter proposed a review of the restriction 5 years after its entry into force and RAC can support this, at the same time recommending that the above research needs and possible advances in methodology are considered.

Scenario seven (confirmatory polymer data at G1/2/3) would also seem to be a reasonable element to incorporate, for now, into Appendix X to ensure that screening tests do not generate false pass results.

Pass criteria for group 5 tests

The Dossier Submitter proposed to derogate microplastics that do not fulfil the vP criteria defined in REACH Annex XIII meaning that microplastics which fulfilled the P criteria (but not the vP criteria) would be derogated.

The release of persistent substances, and the creation of a persistent (P) microplastic stock, could induce undesirable impacts on ecosystem functioning. These effects are not taken into account in standard ecotoxicity tests and quantitative risk assessment. On the other hand, regarding REACH regulation, the substances of very high concern (SVHC) are those that fulfil the persistence (P), bioaccumulation (B) and toxicity (T) criteria altogether. This is not the case for microplastics¹⁹. Nevertheless, RAC is of the opinion that the P criteria should be preferred instead of vP.

¹⁹ Principally as the criteria in Annex XIII for bioaccumulation cannot be reliably applied to particulate substances.

Test material

Microplastics will frequently be mixtures comprising one or more polymers together with other substances (e.g. additives). Therefore, another important issue to consider when assessing their biodegradability is the test material itself.

However, some of the tests included in Appendix X are not recommended for mixtures and some microplastics could be comprised of a blend of polymers. Indeed, the pass levels specified in Appendix X do not allow to distinguish the biodegradability or the lack of biodegradability of any polymeric constituents present at low concentrations in a test material. The Dossier Submitter acknowledged this limitation and addressed this by revising the proposal to require, when the test material comprised a blend of polymers, either the testing of each of the polymeric components of the blend separately or performing chemical analysis to demonstrate that each polymeric component achieves the threshold of biodegradation is proposed. RAC agrees that adequate assessment of blends of polymers is important to ensure that the derogation functions as envisaged and supports the modification proposed to the conditions of Appendix X by the Dossier Submitter.

Roughness, size, surface, etc are very important for the degradation outcome and should be taken into account when performing the test, particularly the physical characteristics of the reference material (relevant for the ISO test methods) should emulate the physical characteristics of the test material. The literature shows that biodegradation is clearly linked to the particle size, and more precisely, the surface area of the particles available to microorganisms. The smaller the particle, the greater the surface area that is available for microorganisms and the more degradation is facilitated. Testing the largest feasible particle size (5 mm diameter) represents a worst-case scenario with the lowest surface area to volume ratio. Nevertheless, requiring a test material to have these dimensions could be considered as too stringent if this particle size is not placed on the market.

Similarly, RAC considered that where a test material with a particular particle size has achieved the biodegradation pass criteria, it can be assumed that smaller particles of the same chemical composition (with higher surface to volume ratios and thus less surface limitation to biodegradation) would also achieve the pass criteria and would not need to be tested separately.

Some respondents to the consultation considered that only the polymer itself should be tested (#2215). Due to the potential variety of different microplastics placed on the market they considered that it would disproportionate to test all the different microplastics based on the same polymer(s). Many of the comments received considered that each polymer and substance should be assessed separately (# 2707, #2080, #2437, #2690). RAC notes that the polymer-only approach was considered as part of its evaluation of the Dossier Submitter's proposal. The polymer-only approach has some merit, but also uncertainties. Therefore, RAC supports the Dossier Submitter's proposal to test the material as placed on the market or released to the environment (which could be considered as the primary test material) and, where appropriate, demonstrate the biodegradation potential of the polymeric components in a blend with separate additional tests of the polymeric components (which could be considered as a secondary test material) or by performing chemical analysis demonstrating that all polymeric components in the blend contribute to the observed degradation during the testing, each component meeting the threshold of degradation in the corresponding method.

B.1.1.3.7. Paragraph 3c: Derogation for polymers with water solubility > 2 g/L

The Dossier Submitter indicated that many definitions of microplastics include an element of water (in)solubility and that stakeholders are also in favour of including an (in)solubility criterion in the microplastic definition. RAC acknowledges that in many other definitions of microplastics, water solubility criteria are included. For example, Hartman et al. (2019) consider a solubility threshold of 1 mg L⁻¹ at 20°C. Below this threshold, the polymer could be considered as poorly soluble and should be identified as plastic.

However, RAC agrees with the Dossier Submitter that solubility is not a straightforward concept for polymers and that no internationally standardised test methods used to determine polymer solubility include threshold criteria for differentiating water insoluble polymers from water soluble ones. As noted by the Dossier Submitter, on a conceptual level “water insoluble” seems to be clear but, on a practical and empirical level it is open to interpretation. For example, the OECD 120 test method used to determine the solution/extraction behaviour of polymers in water (OECD, 2000), describes the required experimental conditions for testing (sample preparation, temperature, time) but not the methods to quantify polymer solubility. In addition, no distinction is usually made between “true” solubility and colloidal dispersion or “colloidal” solubility of polymers.

Since different solubility scales are reported for polymers and the definition of a water soluble polymer is context specific, the Dossier Submitter initially considered that solubility was not a useful element of the microplastic definition and that the “solid” and “particle” elements of the definition are sufficient. Solubility was therefore not initially proposed by the Dossier Submitter as an element in the regulatory definition.

The Dossier Submitter had considered that the ‘loss of particulate form at the point of end use’ (as described in the para 5(b) derogation) is the main parameter to decide on whether or not a microplastic was subject to paragraph 1 of the restriction (ban on placing on the market).

However, stakeholders noted in the consultation that the consequences of a release of ‘soluble microplastics’, that would inevitably and immediately lose their particle form in the environment, are different from insoluble microplastics that would retain their particle form once released to the environment (e.g. pre-production pellets [nurdles] or binder particles in paints). As soluble and insoluble microplastics were treated similarly in derogation 5(b) stakeholders argued that the associated paragraph 7 and 8 requirements for ‘instructions for use and disposal’ and ‘reporting’, respectively, were disproportionate. Stakeholders have suggested that either the OECD 120 test guideline (solution/extraction behaviour of polymers in water) or the OECD 105 test guideline (water solubility) could be used as the basis for establishing the solubility of polymers and establishing pass/fail criteria for the purposes of the restriction.

In response to the comments submitted in the consultation, the Dossier Submitter reassessed whether the concept of water solubility could be usefully incorporated into the conditions of the restriction. On the basis of this reassessment, the Dossier Submitter concluded that solubility could be usefully included in the definition as long as (i) a standardised methodology was used for the measurement of solubility and that (ii) a suitable threshold could be established corresponding with the microplastic concern.

In terms of a standard methodology, and by analogy to the approach for assessing biodegradation of polymers, the Dossier Submitter has established standard test methods and conditions for measuring the water solubility of polymers for the purposes of the restriction. These standard conditions are based on existing OECD standard methods and are detailed in Appendix Y of the conditions of the restriction.

In terms of a suitable threshold, the Dossier Submitter explored the relevance and suitability of various existing criteria for identifying 'soluble'/'insoluble' substances²⁰ in relation to the microplastics concern. The Dossier Submitter considered that none of the existing criteria were fit-for-purpose in the context of proposed restriction, primarily as they were arbitrary criteria used to describe the relative properties of substances, and decided instead to apply a threshold of >2 g/L for water solubility.

Rather than corresponding with an existing criteria for solubility/insolubility, the >2 g/L threshold proposed by the Dossier Submitter corresponds with the maximum test material concentration (as TOC) under optimal conditions specified in the test methods specified in Appendix X for assessing the biodegradation of polymers in aqueous environments (ISO 14851 and 14852). The approach of the Dossier Submitter recognises that where a polymer would be soluble under the typical conditions of the proposed biodegradation testing then it would not make sense to undertake such testing (as no microplastic would be present in the test system) and therefore it would be unlikely to contribute to the microplastic concern.

RAC notes that in the relevant ISO standards, this concentration relates to the optimisation of the test medium rather than to the solubility of the test material. Nevertheless, RAC can follow the rationale of the Dossier Submitter that where microplastics would not be present in a test system it makes little sense to undertake biodegradation testing and agrees with the use of a threshold of 2 g/L as the basis for the new derogation proposed for paragraph 3b.

The Dossier Submitter also notes that "particle containing solid polymer" may refer to particles which are only partly comprised of polymers (e.g. are for example partly inorganic). In such cases the Dossier Submitter proposes that it will be sufficient to demonstrate that the polymer parts meets the suggested criteria. In practice this would mean testing the polymer prior to the formation of the particle. RAC agrees that hybrid particles will need to be given special consideration, as set described by the Dossier Submitter in Appendix Y.

B.1.2. Information on hazard(s)

B.1.2.1. Summary of Dossier Submitter's proposal

The Dossier summarises the available information on the hazard and risk of microplastics; principally from an environmental perspective, although relevant information for human health risks is briefly discussed (indirect exposure via food). Hazard and risks are explored from three complementary perspectives and overall conclusions are presented in a 'weight of evidence', as follows:

²⁰ ≥33 g/L: soluble substances according to the European Pharmacopeia; <1mg/L: poorly soluble substances under REACH; <100 mg/L: the OECD Guidance document on aqueous-phase toxicity testing of difficult test chemicals notes that substance solubility of <100 mg/L can result in difficulties in aquatic ecotoxicity testing.

1. 'Conventional' (eco)toxicological risk assessment based on the derivation of an effects threshold (PNEC) and quantitative risk characterisation (PEC/PNEC or RCR approach),
2. PBT/vPvB assessment,
3. A case-by-case assessment according to paragraph 0.10 of Annex I of REACH.

B.1.2.1.1. Conventional risk assessment (PEC/PNEC approach)

Approximately 900 articles were prioritised in the literature screening (see Background Document). Microplastics have been documented to occur in almost all environments investigated, including seawater, sea ice and sediments in polar regions (Obbard, 2018) and the deepest ocean trenches (Peng et al., 2018); they are globally pervasive pollutants. Based on the increasing use of plastics, concentrations of microplastics in the environment are forecast to progressively increase as they are almost impossible to remove once dispersed within the environment and persist almost indefinitely (Jambeck et al., 2015, Geyer et al., 2017a).

Many of the reviews conclude with the observation that contamination will continue to increase into the foreseeable future with the result that exposure of organisms is therefore largely unavoidable and likely to increase in magnitude in the future.

The Dossier Submitter summarises relevant information on:

- Exposure and ingestion;
- Translocation between tissues after ingestion;
- Trophic transfer; and
- Observed effects.

Various hazards have been associated with microplastic particles, including physical/mechanical hazards e.g. obstructing or interfering with the normal functioning of feeding apparatus (potentially after being mistaken for food) or gills. (Eco)toxicological hazards may also occur from the polymers themselves, or possibly via the presence of unreacted monomers, impurities (e.g. residual catalyst/initiators or derivative) additives (e.g. stabilisers) or other substances within the polymer matrix (e.g. pigments, lubricants, thickeners, anti-static agents, anti-fogging/clarifying agents, nucleating agents, plasticisers, flame-retardants, etc.).

Hazards have also been associated with environmental pollutants, such as Persistent Organic Pollutants (POPs) or metals that adsorb/absorb to microplastic particles in the environment and which may subsequently be released if microplastics are ingested, leading to enhanced bioaccumulation and/or adverse effects from the 'transferred' substances. However, the current scientific consensus on this issue would suggest that ingestion of microplastics does not significantly enhance bioaccumulation of POPs or other contaminant present in the environment.

The Dossier Submitter's assessment was informed by a comprehensive literature screening and mapping. The Dossier Submitter noted that several comprehensive assessments of the (eco)toxicity of microplastics have been published in recent years, such as those reported by Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP, 2010, GESAMP, 2015, GESAMP, 2016) and the Food and Agriculture organisation of the United Nations, FAO (Lusher et al., 2017). The European Food Safety Authority has also published a

note on the risks of microplastics in food (EFSA, 2016). The Dossier Submitter also notes the *evidence review report* on microplastics in nature and society published by SAPEA²¹ in January 2019 as part of the European Commission Group of Chief Scientific Advisors work on microplastics²².

Some authors have investigated the potential for quantitative risk characterisation for microplastics, by deriving no effect thresholds and comparing these to environmental exposure concentrations (Everaert et al., 2018, Burns and Boxall, 2018, Besseling et al., 2018). However, the Dossier Submitter concluded that the PNEC or no-effect thresholds currently reported in the literature should be considered as tentative as they have not been derived strictly in accordance with the appropriate standards required for a conventional chemical safety assessment (such as according to REACH Guidance).

For example, Besseling et al. (2018) constructed separate provisional SSDs for microplastics and nanoplastics for exposure via water using the available literature data for apical endpoints (survival, reproduction and growth). As effects thresholds were expressed in terms of either LC50, EC50, or LOEC values, and exposures varied from 'minutes to months', all effects data were converted to chronic LOEC values using extrapolation factors (acute to chronic ratios), after Diepens et al. (2017). Effects thresholds for marine, estuarine and freshwater species were combined in the same SSD (Figure 2). Based on these HC5 values and an assessment factor of five Besseling et al. (2018) derived PNEC values, termed preliminary safe standards (PSS) of 0.33 ng/L and 1.1 µg/L for microplastics and nanoplastics, respectively.

Besseling et al. (2018) clearly state that the HC5 estimates reported should be considered as preliminary. Nevertheless, with reference to applicable ECHA Guidance on the use of SSDs for hazard assessment, the Dossier Submitter noted that the datasets used in this study would not be considered appropriate for PNEC derivation for chemical safety assessment under REACH. Primarily as the minimum standards of taxonomic diversity required for SSD derivation are not achieved (fish and insects are notable omissions from the available dataset), but also as effects thresholds are normalised to LOECs, whilst ECHA Guidance requires the use of NOECs or EC10s to derive SSDs. The normalisation (acute to chronic ratio) approach applied, although used in good faith to facilitate the derivation of HC5 in the absence of representative long-term exposure data, is also unconventional and is unlikely to be acceptable for regulatory purposes for PNEC derivation, without further validation.

Nevertheless, the review by Besseling et al (2018) indicates that microplastics may be relatively toxic in the aquatic environment, and application of the tentative threshold values they calculated suggests that the observed concentrations of microplastics in certain locations in the marine environment (from both primary and secondary sources) may currently be sufficiently high to cause adverse effects (Everaert et al., 2018, Besseling et al., 2018).

Given the persistent nature of microplastics (without potential for remediation) it is clear that the scale of these risks, are likely to increase in the future as long as releases of microplastics, or the formation of microplastics from the fragmentation of larger plastic articles, continues. As there is uncertainty about the precise values of effects thresholds for different compartments as well as if, when and where these values would be exceeded in the future it

²¹ Science Advice for Policy by European Academies. www.sapea.info/topic/microplastics

²² <https://ec.europa.eu/research/sam/index.cfm?pg=pollution>

is not possible to adequately assess risks using quantitative risk characterisation. In the event that effects thresholds were well understood (or modified using assessment factors) this would still not enable a meaningful risk characterisation conclusion (i.e. that releases do not pose an unacceptable risk; are 'safe') as, because of their long-term persistence, effects thresholds that were not currently exceeded based on current uses, releases and exposures would be exceeded at some point further into the future (assuming releases continue).

The lack of sufficient information for a threshold-based risk assessment is particularly apparent for the terrestrial compartment, which is a key receptor for intentionally added microplastics either via direct application (e.g. fertilisers or plant protection products) or the spreading of biosolids. The absence of information to assess risks posed via secondary poisoning (in all compartments) is also notable.

Equally, the bioaccumulation and hazard of nanoplastics, that are likely to be formed as microplastics progressively fragment after release to the environment, are only currently poorly understood, which prevents an assessment of the risks posed by relevant breakdown/transformation products of microplastics in the environment. Theoretical considerations on cellular uptake mechanisms would suggest that nanoplastics would be more readily taken up into cells than microplastics.

Coupled with the uncertainty associated with measured and/or modelled exposure concentrations of microplastics, the Dossier Submitter has concluded that, similar to PBT/vPvB substances, conventional threshold-based risk assessment cannot currently be carried out for microplastics with sufficient reliability, even with PNEC values derived using large assessment factors e.g. 1 000 to 10 000.

An important property of microplastics to also bear in mind when considering appropriate risk assessment is their long-term persistence in the environment. This property will mean that continuing releases will increase the environmental stock over time, which could eventually

exceed even tentative PNECs in the future.

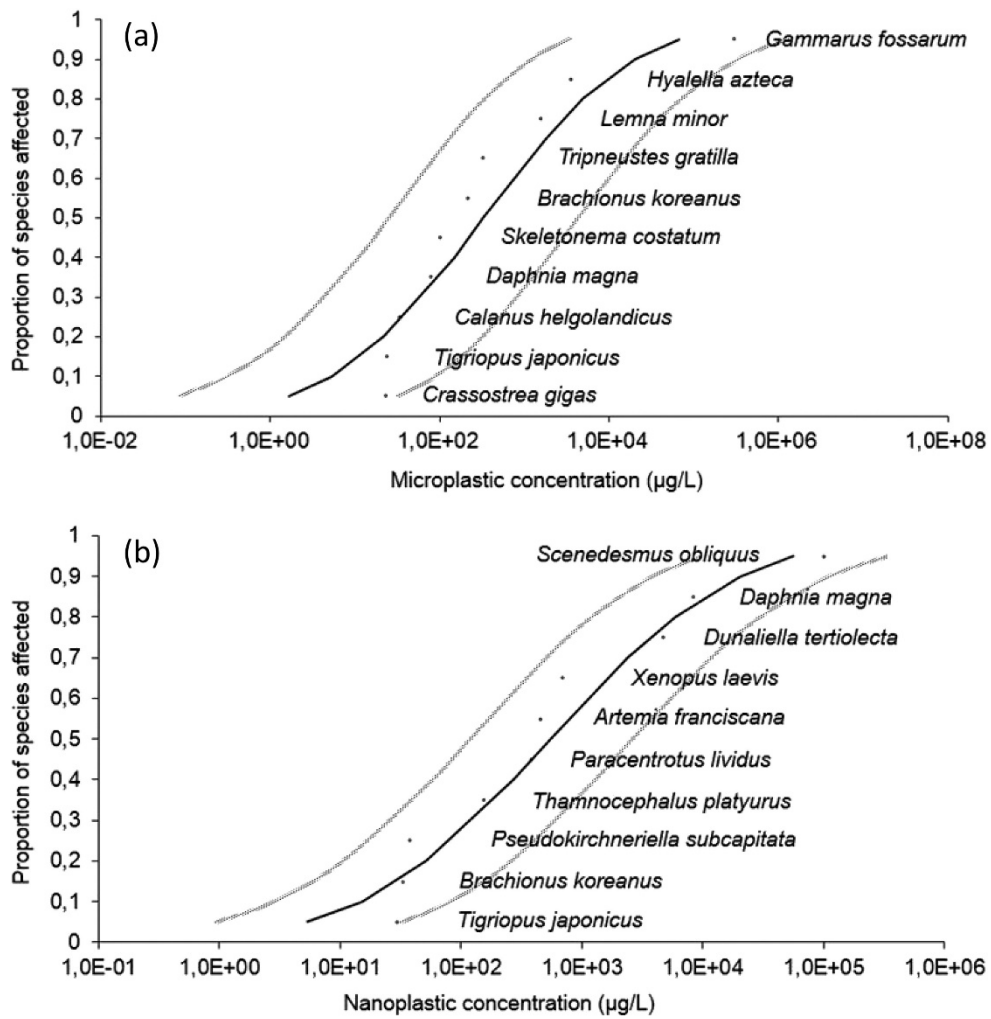


Figure 2 SSDs for microplastics (a) and nanoplastics (b), after Besseling et al. (2018)

Table 4 Summary of effects concentrations for micro and nanoplastics in aquatic species after Besseling et al. (2018).

Exposure medium	Size category	Compartment	LC ₅₀	EC ₅₀	LOEC	NOEC
Water (mg/L)	Micro	Fresh	0.4 - 57	5 - 172	$6.9 \times 10^{-9} - 2 \times 10^5$	0.02 - 400
		Brackish	23.5	0.04 - 0.1	$6.9 \times 10^{-9} - 1.8 \times 10^4$	0.4 - 313
		Marine	-	-	$9.1 \times 10^{-3} - 2.5 \times 10^3$	$2 \times 10^{-3} - 510$
	Nano	Fresh	4 - 36	0.5 - 1.6	$4.5 - 1 \times 10^3$	0.5 - 1
		Brackish	0.2 - 2.2	-	-	1 - 313
		Marine	0.8 - 3.9	13	0.1 - 250	10 - 100
Sediment/food (g.kg DW)	Micro	Fresh	-	-	-	700
		Brackish	-	-	-	-
		Marine	-	-	0.1 - 100	0.3 - 100
	Nano	Fresh	-	-	1	-
		Brackish	-	-	-	-
		Marine	-	-	-	-

Note: Effect concentrations converted to mg/L; plastic ingestion not considered as an endpoint

B.1.2.1.2. PBT/vPvB assessment

The Dossier Submitter does not propose a PBT/vPvB assessment as, based on the currently available information, the criteria in REACH Annex XIII for biodegradation are not practicable for assessing particulate materials such as microplastics. The classical concept of bioaccumulation and biomagnification, established on a molecular level, is not satisfied by polymer particles despite evidence that microplastics can be accumulated by organisms and are present in top predators via trophic transfer. As such, the Dossier Submitter concludes that the approach, as a whole, is not practicable for microplastics. Nevertheless, microplastics

would be considered to readily meet the criteria for very persistent (vP) substances for different environmental compartments in Annex XIII of REACH.

B.1.2.1.3. Case-by-case assessment

In cases where quantitative risk characterisation or PBT/vPvB assessment are not practicable, under REACH, risks can be assessed by means of a 'case-by-case' approach. The Dossier Submitter describes this approach to the risk assessment of microplastics based on (i) their long-term persistence in the environment and (ii) the potential for this to give rise to a non-reversible pollution stock that is associated with environmental and/or human health risks (effects threshold exceeded, see section above). On this basis, risk characterisation may be considered in terms of when, rather than if.

Therefore the Dossier Submitter concluded that the risks arising from intentional uses of microplastics that lead to releases to the environment are not adequately controlled.

As all releases contribute to the potential for effects thresholds to be exceeded in the future, the Dossier Submitter considers that microplastics should be treated as non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment assumed to result in a risk.

To minimise the likelihood of adverse effects arising as a consequence of the exposure concentrations arising today, or that would arise in the future, the Dossier Submitter considers that a restriction under REACH should minimise releases of intentionally added microplastics to the environment, similar to the existing obligations for registrants of PBT/vPvB substances under REACH. Minimisation of release would also minimise the potential for cumulative effects arising from the presence of both primary (intentionally added) and secondary microplastics in the environment.

B.1.2.2. RAC conclusion(s)

RAC agrees that although there are uncertainties in the understanding of the hazard and risk of microplastics, there is sufficient evidence to conclude that they constitute an intrinsic hazard because of their long-term persistence in the environment in combination with their particulate form and potential to cause adverse effects. As it is practically impossible to remove microplastics from the environment, releases contribute to a long term irreversible environmental stock.

Hazard and risk was explored from three complementary perspectives and overall conclusions presented in a 'weight of evidence', as follows:

B.1.2.2.1. Conventional risk assessment (PEC/PNEC approach)

The Dossier Submitter addressed conventional (eco)toxicological risk assessment based on the derivation of an effects threshold (PNEC) and quantitative risk characterisation (PEC/PNEC).

PNEC values are currently only available for the marine compartment, whereas the most significant compartments for intentionally added microplastics are the terrestrial and freshwater compartments. PNEC values reported by the Dossier Submitter for the marine compartment are acknowledged as tentative, because they are not derived in accordance with the minimum standards required for a PNEC used for chemical safety assessment under REACH Guidance. They indicate exposure concentrations in the environment, where effects

are likely to occur. However, the uncertainties are such that it is not possible to conclude that exposures below these tentative PNEC values are 'safe' (effects unlikely to occur). Currently, it is not possible to reliably quantify the hazard for the environment using these reported thresholds.

The availability of additional, reliable ecotoxicity data for sufficient species, compartments and routes of exposure (in due course), or the use of (potentially large) assessment factors (e.g. up to 10 000), could be used to address the uncertainties associated with tentative PNEC values and consequently increase the confidence that exposures below such levels are safe. This may allow an assessment of whether a given exposure in a particular compartment could be considered to be either safe or result in a risk, but would not address the key fundamental issue arising from the long-term persistence of microplastics whereby any 'safe' threshold will eventually and inevitably be exceeded over time due to the cumulative nature of the exposure.

As a consequence RAC agrees that a conventional quantitative risk characterisation cannot be carried out with sufficient reliability (is currently not practicable) for microplastics to demonstrate that risks are adequately controlled.

B.1.2.2.2. PBT/vPvB

The Dossier Submitter did not propose a PBT assessment (according to REACH Annex XIII) because the criteria for identifying bioaccumulative substances in REACH Annex XIII are not practicable for particulate materials (such as microplastics), and would be unlikely to be fulfilled. The evidence that polymer particles are present in organs, tissues, cells and even organelles of organisms including top predators is indicative of a different hazard than bioaccumulation at a molecular/metabolic level.

RAC also notes that the persistence of polymer particles is such that most far exceed the current vP criteria and that the formation of environmental stocks is their most concerning aspect.

RAC therefore agrees with the Dossier Submitter and concludes that a REACH PBT assessment is not practicable for microplastics, noting that this does not diminish the concern.

The Dossier Submitter did not assess the hazard of microplastics against the SVHC criteria set out in Article 57(f), 'equivalent concern' as this was not a necessary prerequisite for a REACH restriction. However, the conclusions of the case-by-case assessment could be considered to be analogous to the concept of equivalent level concern set out in Article 57(f).

B.1.2.2.3. Case by case assessment

According to REACH Annex I, paragraph 0.10, the Dossier Submitter performed a case-by-case assessment underpinned by the available information on the effects of microplastics in biota in combination with their long-term persistence in the environment. Based on this assessment RAC notes that the risk from microplastics extends for long periods of time and cannot be reversed. RAC concludes that microplastics should, therefore, be considered as non-threshold substances with their releases used as a proxy for risk. To minimise the likelihood of adverse effects in the future all releases should be minimised.

B.1.2.2.4. Overall conclusion

RAC recognises that microplastic pollution is a global phenomenon. Relevant aspects of such

pollution from intentionally introduced microplastics are their extreme persistence, ease of ingestion, tendency for trophic transfer and expanding evidence of adverse effects on biota. RAC concludes that the risks from the use of intentionally added microplastics are not currently adequately controlled and that, therefore, releases should be minimised to minimise the likelihood of adverse effects occurring in the future.

B.1.2.3. Key elements underpinning the RAC conclusion(s)

In the comprehensive literature review provided by the Dossier Submitter, microplastics have been documented to occur in almost all environments investigated, including seawater, sea ice and sediments in polar regions (Obbard, 2018) and the deepest ocean trenches (Peng et al., 2018).

Early ecotoxicity studies were relatively limited in scope and typically focussed on the ability of organisms to ingest microplastics and their occurrence in the gut, rather than exploring adverse effects on organisms.

Ingestion in laboratory studies has since been linked to a diverse range of sub-lethal endpoints, including reduced food intake, false satiation and reduced energy reserves, as well as mortality and sub-lethal 'apical effects', such as negative effects on growth rates or reproduction (Besseling et al., 2018). Translocation of microplastics from the gut to other secondary tissues after ingestion has also been reported in some species, although in some cases translocation observed on histological sections is thought to be an artefact of sample preparation rather than true translocation (Duis and Coors, 2016, Besseling et al., 2017a).

RAC noted that endpoints included in the studies were survival, feeding, growth, reproduction, moulting, malformation, behaviour, photosynthesis, oxidative stress, enzyme activity, inflammation, gene expression and nutrient cycling.

According to the Dossier Submitter, effects are observed at different levels (cellular/tissue, individual, population). Below some relevant effects are grouped based on cellular/ tissue level and individual level observed.

Table 5 Selection of effects of microplastics observed at cellular/tissue level

Observed effect	Species	Reliability	Reference
Alterations of immunological responses; decreased lysosomal membrane stability; modulation of antioxidant systems (upregulation of <i>GPX2</i> , <i>GSTP1</i> , <i>GSTP2</i> and downregulation of <i>SOD2</i> , inhibition of catalase and selenium dependent glutathione peroxidases); neurotoxicity and genotoxicity. microplastic conc. 1.5 g/L-2.5 g/L.	<i>Mytilus sp.</i> (invertebrate)	2	Avio CG et al. 2015; Von Moos N. et al. 2012
Induction of the CYP1A (cytochrome P450); histopathology changes in the liver with signs of inflammation and lipid accumulation; signs of oxidative stress; alteration of lipid metabolism leading to increased fatty acid content; disruption of the energy metabolism with decreased content of ATP/ADP/AMP metabolites; alterations in amino acid metabolism and decreased content of amino acids; accumulation of microplastics in the gills, liver and gut.	<i>Danio rerio</i> (fish)	2	Batel A. et al. 2016; Lu, Y. et al., 2016
Glycogen depletion, fatty vacuolation and single cell necrosis in the liver	<i>Oryzias latipes</i> (fish)	2	Rochman CM. et al., 2013
Changes in the transcriptomic profiles suggesting an alteration in glucocorticoid response, insulin pathway, and fatty-acid metabolism	<i>Crassostrea gigas</i> (invertebrate)	2	Sussarellu, R. et al., 2016

Table 6 Selection of effects of microplastics observed at individual level

Observed effect	Species	Reliability	Ref.
Immobilisation	<i>Daphnia magna</i> (invertebrate)	1	Rehse et al., 2016
Weight loss, and reduction in feeding activity	<i>Arenicola marina</i> (invertebrate)	2	Besseling et al., 2013

Table 7 Selection of effects of microplastics at population level

Observed effect	Species	Reliability	Ref.
Reduction population growth	<i>Scenedesmus obliquus</i> (algae)	1	Besseling et al [*] , 2014
Severe alterations in reproduction	<i>Daphnia magna</i> (invertebrate)		
Decrease reproductive output	<i>Calanus helgolandicus</i> (invertebrate)	2	Cole et al., 2015

Notes: * effects on the growth and photosynthesis of the green alga and the growth, mortality, neonate production, and malformations of *Daphnia magna* were assessed. Nano-polystyrene (~70 nm) reduced population growth and chlorophyll concentrations in the algae *Scenedesmus obliquus*. Exposed *Daphnia* showed reduced body size and severe alterations in reproduction. Numbers and body size of neonates decreased, while the number of neonate malformations among neonates rose to 68% of the individuals. These effects were observed between 0.22 and 103 mg/L.

Regarding the aquatic compartment, extensive experimental and monitoring data demonstrate that microplastics can be ingested by a diverse aquatic species of different taxa along food chains (GESAMP, 2015, GESAMP, 2016, Lusher et al., 2017).

- Translocation reported in invertebrates (mussel) and fish in the laboratory.
- Trophic transfer in laboratory but not conclusive for the environment.
- Primary consumers ingest microplastics so a potential for trophic transfer to top levels exists. There are some evidence of low biomagnification in fish (as a result of significant gut clearance). Secondary poisoning, particularly under environmental conditions, is unknown.

Laboratory studies assessing the effect of microplastics on fish species, showed a significant decrease in the predatory performance of *P. microps* (common goby) after exposure to microplastics. (de Sá et al, 2015). Other effects observed include increased AChE activity, weight loss, altered metabolism and liver toxicity.

Moreover, regarding nanoplastics and their potential impacts, several studies have shown that uptake and toxicity depend on the intrinsic properties of the particles, such as size and surface charges, that affect their interaction with exposure media (Della Torre et al. 2014). In addition, a number of recent studies have demonstrated effects of polystyrene nanoparticles on the feeding, behaviour and physiology of early life stages, such as brine shrimp (Bergami et al. 2015) and sea urchins (Della Torre et al. 2014; Canesi et al. 2015).

Transport of indigenous species is another aspect mentioned by GESAMP (2010, 2015)²³. In the discussion the authors compare the difference between transfer by natural floating substrata and floating plastics. The distribution of plastic in the water column is different from that of natural substrata, and plastic has substantially increased the available substratum in

²³ Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection. <http://www.gesamp.org/>

oligotrophic open-ocean regions, potentially altering the distribution of marine organisms (Goldstein et al. 2012). Some examples are: plastic pellets that act as an oviposition site for marine insects such as *Halobates micans* and *Halobates sericeus* (Goldstein et al. 2012; Majer et al. 2012), having a positive effect on the population size and dispersal of this species, while Duarte et al. (2012) pointed out that the increase in human structures in the ocean may contribute to an increase in jellyfish blooms; additionally, the proliferation of microplastic particles provides substratum for the attachment and development of jellyfish hydroid life stages.

Other reviews suggests that exposure of individual aquatic organisms to microplastics may negatively impact feeding (e.g., Wegner et al., 2012; Ogonowski et al., 2016), growth (e.g., Au et al., 2015; Jeong et al., 2016), reproductive capabilities (e.g., Della Torre et al., 2014; Ogonowski et al., 2016), and survival (e.g., Booth et al., 2016; Luís et al., 2015), due to, for example, blockage of feeding structures or reduced consumption of prey (e.g., as reviewed by Wright et al., 2013b, Eerkes-Medrano et al., 2015). However, Foley et al. conclude that the effects of microplastic exposure do not appear to be consistent across studies. Some organisms may be resilient to stresses induced by microplastic exposure (e.g., Nasser and Lynch, 2016; Watts et al., 2016), and the fact that microplastics can be egested suggests that cumulative impacts may not occur. Foley et al. state that the overall potential impact of microplastic pollution in aquatic systems remains difficult to predict.

Foley et al. include a number of scientific studies assessing the impacts of microplastics on the vital rates of fish and aquatic invertebrates (e.g., Eerkes-Medrano et al., 2015; Phuong et al., 2016; Wright et al., 2013b, among others) and suggest that their results most strongly support the notion that exposure to microplastics leads to negative effects on consumption of aquatic organisms, with less compelling and consistent evidence that growth, reproduction, or survival of aquatic organisms is negatively affected by exposure to microplastics.

Foley et al. suggest that zooplankton are among the most susceptible biota to microplastic exposure, which could have broader ramifications for aquatic food webs. The tendency of these taxa to consume microplastics may promote the accumulation and transfer of plastics up the food web (e.g., Setälä et al., 2014; Farrell and Nelson, 2013).

Compared to aquatic species, effects on terrestrial biota are not well studied. Terrestrial arthropods (worms, collembolans and Oribatid mites) interact with and transport soil deposited microplastic particles (Huerta Lwanga et al. (2016). Mortality, reduced burrow construction and growth in earthworms exposed to polyethylene particles are effects observed a high exposure concentrations compared to the concentrations in the environment [Huerta Lwanga et al. (2016)]. Earthworms exposed to polyethylene microplastics (250 and 1000 µm) in laboratory showed serious histological damage of the gut, including inflammation, accompanied with immune system responses (Rodriguez-Seijo et al. (2017).

Regarding effects on human health, there are very few studies on the effect of microplastics in humans (direct or via food; EFSA 2016). Indeed, there is some evidence that exposure to certain chemicals could cause infertility, genetic disruption, poisoning, reduced feeding and increased mortality in marine organisms and in humans if ingested in very large quantities (Hollman et al., 2013, Galloway, 2015, Auta et al., 2018).

Biomonitoring shows that chemicals used in the manufacture of plastics are present in the human population [Galloway (2015)]. Leaching from plastic particles could present a long-term source of chemicals into tissues and body fluids, plastics additives of concern include

phthalates, BPA, brominated flame retardants, triclosan, bisphenone and organotins.

Additional research is required to adequately assess the risks that accumulation of micro- and nanoplastics in the body may pose (Galloway, 2015).

Therefore, based on the current knowledge, RAC concludes that the restriction should be based on environmental concerns.

B.1.2.3.1. Conventional risk assessment (PEC/PNEC approach)

RAC notes that the Dossier Submitter's hazard assessment is based on experimental data derived from "non standard" studies reported predominantly over the previous five years, during which time studies were not typically designed with regulatory purposes in mind. As such, the reliability and reproducibility of these studies may not be equivalent to datasets for substances that have been subject to standardised testing and regulatory hazard assessment over many years. This adds to the uncertainty of any classical PEC/PNEC approach to risk assessment.

Despite these uncertainties, some authors have investigated the potential for quantitative risk characterisation for microplastics, by deriving no effect thresholds and comparing these to environmental exposure concentrations (Everaert et al., 2018, Burns and Boxall, 2018, Besseling et al., 2018).

However, the Dossier Submitter proposes that these should be considered as tentative as they have not been derived in accordance with the appropriate standards required for a conventional chemical safety assessment (such according to REACH Guidance).

Besseling et al. (2018) constructed separate provisional SSDs for microplastics and nanoplastics for exposure via water using the available literature data for apical endpoints (survival, reproduction and growth). As effects thresholds were expressed in terms of either LC50, EC50, or LOEC values, and exposures varied from 'minutes to months', all effects data were converted to chronic LOEC values using extrapolation factors (acute to chronic ratios), after Diepens et al. (2017). Effects thresholds for marine, estuarine and freshwater species were combined in the same SSD (Figure 2).

RAC notes that the dataset used for PNEC derivation was not according to REACH Guidance. Minimum standards of taxonomic diversity required for SSD derivation were not achieved (fish and insects were not in the dataset). Effects normalised to LOEC, whilst ECHA Guidance requires NOECs or EC10. Normalisation (acute to chronic ratio) applied to derive HC5 is unconventional and is unlikely to be acceptable for regulatory purposes.

Although the reported effects threshold indicate, if exceeded, exposure concentrations in the environment where effects are likely to occur it is not possible to conclude that exposures below these tentative PNEC values are 'safe' (effects unlikely to occur). Therefore, it is not possible to reliably quantify the hazard for the environment using these reported thresholds.

The availability of additional reliable ecotoxicity data for sufficient species, compartments and routes of exposure (in due course), or the use of (potentially large) assessment factors (e.g. up to 10 000), could be used to address the uncertainties associated with the tentative PNEC values and consequently increase the confidence that exposures below them are safe. This may allow an assessment of whether a given exposure in a particular compartment could be considered to be either safe or result in a risk, but would not address the key fundamental issue arising from the long-term persistence of microplastics whereby any 'safe' threshold will

eventually and inevitably be exceeded over time due to the cumulative nature of the exposure.

Uncertainties (trophic-transfer, nanoplastics effects) do not allow the derivation of reliable PNECs for quantitative risk characterisation.

Based on above arguments, RAC agrees with the Dossier Submitter that a conventional threshold-based risk assessment cannot currently be carried out with sufficient reliability.

B.1.2.3.2. PBT/vPvB

RAC notes that the concept of bioaccumulation described by the criteria in Annex XIII may not be satisfied by a particle, despite the available evidence that microplastics are present in top predators and can be subject to trophic transfer.

In addition, RAC notes that the long-term persistence in the environment of microplastics could raise an equivalent level of concern as PBT/vPvB, as established in REACH Article 57(f). The Dossier Submitter did not explicitly conclude that microplastics pose an equivalent level of concern to PBT/vPvB substances. However, RAC notes that the conclusions of the case-by-case assessment (see below) suggest so and could be considered to be analogous to the concept of equivalent concern set out in Article 57(f).

B.1.2.3.3. Case by case assessment

The case-by-case approach for risk assessment under Annex I, Paragraph 0.10²⁴, recognises the (i) the long-term persistence of microplastics to lead to their wide dispersive and irreversible accumulation in the environment alongside the (ii) available evidence that exposure to microplastics results in adverse effects. These elements lead to a consideration of microplastics as non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment assumed to result in a risk. In such a case, emissions should be minimised to reduce the likelihood of adverse effects.

B.1.3. Information on emissions and exposures

B.1.3.1. Summary of Dossier Submitter's proposal

B.1.3.1.1. Uses and use volumes

The Dossier Submitter identified various consumer and professional products containing intentionally added microplastics.

The Dossier Submitter estimated that in 2017 more than 51 000 (11 000 - 63 000) tonnes of microplastics were intentionally added in products placed on the market in the EEA and that about 70% of these were subsequently emitted to environment in the same year (Table 8).

²⁴ REACH Annex I (0.10) *In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis.*

B.1.3.1.2. Releases to the environment

Releases of intentionally added microplastics to the environment arise via one or more of the following three principal release pathways:

- **Down-the-drain disposal**
- **Municipal solid waste (bin/trash) disposal** which includes disposal via contaminated tissues/wipes (or similar) as well as via residual product contained in discarded packaging.
- **Direct release to the environment**

The relative importance of each of the three pathways is dependent on the products that microplastics are used in and, in certain instances, the behaviour of consumers in relation to how the products are used and subsequently disposed.

Release estimates are based on the quantity of microplastics that are disposed of via each of the three pathways. The three pathways are, on the whole, independent, but overlap in specific circumstances, e.g. where product packaging disposed in municipal solid waste leads to wastewater releases through the washing of shredded material during recycling.

For example, 'rinse-off' cosmetic products are disposed of predominantly down the drain with wastewater, whilst some 'leave-on' cosmetic products are more likely to be disposed of in municipal solid waste (although they may also be washed-off and disposed of via wastewater). Overall, leave-on cosmetic products are disposed of to both pathways, with 50% released down-the-drain and 50% to municipal solid waste.

In contrast, microplastics used in fertilising products are dispersed directly into the environment.

The quantity of microplastics disposed of via each of these pathways has been estimated separately (quantified where possible) for each of the prioritised uses or, where relevant, for sub-uses. Additional pathways into the environment may also exist (e.g. releases via atmosphere), but are considered to be of minor importance compared to the three principal pathways; their contribution has not been assessed further.

The methodology for estimating releases comprises an EU level assessment of the fate and behaviour of microplastics after applicable waste treatment/management processes that they will be subject to after their use and subsequent disposal (e.g. wastewater treatment or municipal solid waste). The release factors used for each of the different pathways are further detailed in the Background Document (Section 1.4.2).

Releases from the use of microplastics as infill on artificial sports turf were assessed specifically and are described in the Background Document and Annex to the Background Document.

Conventional approaches for modelling exposure are not suitable to estimate the exposure, in particular for the long range transport behaviour. Once released to environmental compartments (air, soil, aquatic) microplastics will be subject to various transport and (bio)degradation processes. Microplastics are themselves sources of secondary microplastics, comprising progressively smaller particles due to embrittlement, abrasion or slow (bio)degradation of primary particles, theoretically leading to nanoplastics (GESAMP, 2015, Koelmans et al., 2015, Koelmans et al., 2017b). There is currently insufficient knowledge to

reliably model the fate and transport of microplastics across environmental compartments on a quantitative basis. Information on the fate of microplastics in soils and air are particular data gaps. Models predicting the fate of microplastics in freshwaters and river basins have been reported in the literature (Besseling et al., 2017b, Siegfried et al., 2017, Liedermann et al., 2018, Nizzetto et al., 2016, Unice et al., 2019a, Unice et al., 2019b). These studies did not specifically address intentionally added microplastics.

B.1.3.1.3. Infill material for synthetic turf sports fields

Microplastics used as performance infill in synthetic turf sport pitches are the largest contributor at a European level in terms of both quantities of intentionally-added microplastics used and released to the environment, with a central estimate of 16 000 tonnes released to the environment per year. Based on the central estimate use quantity of 100 000 t/y, this corresponds to a release factor of 0.16 (16%). In line with other uses of microplastics that inevitably result in release to the environment, the Dossier Submitter concluded that the use of microplastics as infill on synthetic turf sports pitches poses a risk that is not adequately controlled.

The Dossier Submitter proposed two options to address the risks posed by the use of in the restriction proposal:

- **Option A** – use of risk management measures to ensure that annual releases of microplastic do not exceed 7g/m² (equivalent to 50 kg/full size pitch/year) after a transitional period of three years.
- **Option B** – ban on placing on the market after a transitional period of six years.

As there is currently no list of standard risk management measures that could be specified in the conditions of the restriction, the Dossier Submitter considered that compliance with option A could be demonstrated, in due course, by implementing risk management measures that had been verified to achieve the required effectiveness of <7g/m²/year, ideally specified in a recognised international or European standard. In such a way the minimum effectiveness of standardised risk management measures would be set by the REACH restriction, but the precise risk management measures to achieve them could be established through subsequent standardisation. Different RMMs could be established for different types of pitch scenarios (e.g. newly constructed pitches vs retro-fitting RMMs to existing pitches) although the minimum standard of effectiveness would need to be the same.

The Dossier Submitter notes that over the longer term (i.e. >20 years after implementation) option A would be less effective than option B.

B.1.3.2. RAC conclusion(s)

The methodology applied by the Dossier Submitter allows a large part of the releases to different environmental compartments to be quantified. Release factors for specific uses have also been calculated (i.e. the proportion of the quantity used in products that will eventually be released to the environment). Releases to the environment have been estimated for each of the sectors of use and product groups quantitatively. Where a quantitative assessment was not possible, a semi-quantitative or qualitative approach is presented by the Dossier Submitter. Release factors were based, where available, on empirical data on the fate and behaviour of microplastics during waste treatment identified from the literature. Where such

data are not available default values from ECHA Guidance or other relevant sources were applied. In both cases, sources are clearly identified.

RAC concludes that the uses and releases are clearly identified and in the Background Document. All relevant release pathways were properly assessed and they provide a good basis for the risk characterisation. RAC agrees that the available information on microplastic properties do not allow a reliable estimation of fate and exposure level into the environment.

The down-the-drain pathway has considerable potential for releases, primarily via sewage sludge disposal to soil. Incineration (e.g. of municipal waste or sewage sludge) can effectively prevent the release of microplastics to the environment. Landfilling may also be a relatively effective risk management measure.

There are many different types of microplastics and specific information on their (bio)degradation rates is scarce. The identity of the polymer dictates, to a large extent, its physicochemical properties and (bio)degradation rates in different environments. In addition to the size and surface area of the microplastic, polymer structure, and composition, as well as environmental conditions (e.g. UV radiation, pH, temperature, moisture, amount of oxygen, and presence and diversity of degraders) are all factors that affect the (bio)degradation rate in the environment (Andrady, 2017, Klein et al., 2018, Briassoulis, 2007, Kyrikou and Briassoulis, 2007, Emadian et al., 2017).

Recent studies have demonstrated that microplastics are widely distributed in freshwater bodies in concentrations at least similar to marine systems. They have been found on the water surface, in the water column and in sediments of lakes, rivers and estuaries (Eerkes-Medrano, Thompson, & Aldridge, 2015; Li, Liu, & Paul Chen, 2018). The reported concentrations of microplastics in freshwaters vary among locations, from a few particles/m³ up to thousands of particles/m³ (Horton et al., 2017; Rezaia et al., 2018). Similarly, the concentrations of microplastics in freshwater sediments are very variable and can reach several thousands of particles/kg of sediment (Hurley et al., 2018; Rezaia et al., 2018).

RAC notes that the estimates of losses of infill material from synthetic turf pitches are underpinned by numerous assumptions, but supports the methodology used by the Dossier Submitter to estimate an average loss of 500 kg/yr per full size pitch in the EU under baseline conditions.

RAC evaluated both of the Dossier Submitter's options for the risk management of infill from an effectiveness, practicality and enforceability perspective. RAC agrees with the Dossier Submitter that a complete ban will be more effective to prevent releases of microplastics over the long term than use of RMMs.

RAC notes that the effectiveness of RMMs assumed by the Dossier Submitter of 90% relative to baseline is in agreement with recent studies, but that this is likely to be more readily achieved at sites where RMMs were planned during the initial design and construction of facilities rather than when retrofitted to existing facilities. There is limited information currently available of whether the effectiveness of RMMs that could be retro-fitted to existing pitches would achieve the stated 90% reduction relative to baseline.

RAC notes that after implementation of risk management measures annual releases of microplastics from EU pitches would still be in the order of 1 600 t/yr, which remains significant relative to other uses/releases of intentionally added microplastics.

In terms of practicality and enforceability, RAC notes that option A would be difficult to enforce

without the development of appropriate international or European standards or guidance that establishes the effectiveness of different RMMs in different pitch contexts (i.e. newly constructed vs existing) and their suitability to achieve the stated minimum effectiveness of annual losses of <7g/m². Therefore, RAC notes that the development of such guidance would be a pre-requisite for option A to be considered as practical.

RAC also considers that releases associated with the construction and end of life disposal of artificial pitches is relevant to consider, as this may lead to releases of microplastics in addition to those that occur during the service life of the pitch. It is estimated that the useful life of an artificial pitch is about 10 years. RAC considers that the re-use or recycling of the old pitch-infill granules has potential to result in large release of microplastics and should be carefully managed.

RAC has a clear preference, from an emissions reduction, practicality and enforceability perspective, for a ban on the use microplastics as infill material on synthetic sports turf pitches to be implemented as soon as possible. RAC concludes that the use of RMMs over the longer term would be unlikely to result in an adequate control of risk.

Releases of microplastics from intentional uses are lower than the total releases from unintentional sources, but the former are still significant contributors to microplastic pollution in the environment. Therefore a reduction of releases from intentionally added microplastics, estimated of about 500 000 tonnes over 20 year period, is considered significant.

B.1.3.3. Key elements underpinning the RAC conclusion(s)

Based on information received in the consultation the Dossier Submitter revised upwards its estimated releases to the environment of 36 000 (8 500 – 61 300) tonnes per year to 42 400 (13 200 to 95 000) tonnes per year. The most relevant product categories and the related releases are indicated in Table 8. The tonnages for certain product categories have been revised downwards (e.g. agriculture and horticulture) whilst the tonnage for other categories increased (i.e. detergents and maintenance products). The revised figures also include use and release tonnages for polymeric infill material used on synthetic sports pitches, which were not included in the Annex XV report.

A recent report estimated the total annual releases of microplastics from unintentional sources to EU surface waters to 176 300 ton/year (71 800 – 280 600) (Eunomia, 2018). The greatest contributors were identified as road tyre (94 000 tonnes/year), losses of pre-production plastic pellets (41 000 tonnes/year), road markings (15 000 tonnes/year), and washing of clothes (13 000 tonnes/year).

More than 145 000 tonnes of microplastics are intentionally used in the EEA per year, and about 32% of these are emitted to environment. Although lower with respect to total unintentional releases, the intentional ones are significant contributors to microplastics pollution.

B.1.3.3.1. Down-the-drain disposal

With the exception of agricultural and oil and gas, all the other identified sectors/uses release a proportion of microplastics used via the down the drain (DTD) pathway. The main contributions come from cosmetic products (3 800 t/y), detergents and maintenance products (8 500 t/y), paints and coatings (2 700 t/y) and medicinal products (1 100 t/y).

Wastewater treatment retains microplastics mainly through grit removal and sludge retention in the primary and secondary step of the process, respectively (about 97.5% retention). Tertiary treatment, where present, results in marginally more effective retention than primary and secondary treatment (99% overall efficiency of primary-secondary-tertiary treatment). A large proportion of the microplastics retained by WWTP (about 50%) subsequently goes to landfill or incineration.

Nevertheless, the down-the-drain pathway has an overall release factor of approximately 50% on the basis that a large proportion of the microplastic retained in sewage sludge will eventually be applied to agricultural soil as a fertiliser. It should also be noted that a significant percentage (about 10%) of households across Europe are not connected to wastewater treatment facilities, meaning that microplastics are discharged directly to surface water. Parts of the exposure route is thus inherently uncontrolled. For sludge applied to soil, the release factor for microplastics can be considered to be 100%. After application to soil microplastics could potentially be transported to the aquatic compartment via adjective transport processes, such as rainwater run-off or dispersal via wind.

RAC notes that the estimated release factors are subject to some uncertainties because of the assumptions made by the Dossier Submitter and the use of default release factors at some steps of the pathway, particularly for the municipal solid waste pathway.

B.1.3.3.2. Municipal solid waste (bin/trash) disposal

Releases from the municipal solid waste pathway derive mainly from landfill and incineration. Overall, the pathway has a release factor of approximately 0.5%, which is significantly smaller than the other releases pathways considered.

Municipal solid waste is a relevant release pathway for microplastics in cosmetic products or paints that are present on used tissues or wipes. Minor contributors derive from other uses like medicinal products and medical devices and *in vitro* diagnostic medical devices. Releases from municipal waste are based, predominantly, on default release factors from ECHA R.18 Guidance supplemented with data from Eurostat on the relative proportion of municipal waste disposed of via different routes, e.g. incineration and landfill.

An important sub-scenario included in the Dossier Submitter's assessment is related to releases that occur via the recycling of cosmetic product packaging containing residual product. Indeed about 5% of total product volume is assumed to be disposed in cosmetic product packaging. Taking into account that about 10% of packaging material is assumed to be recycled, all the remaining microplastics (100%) are released to wastewater during shredding/washing processes common to plastics recycling operations. A crude estimate, based on total annual use of microplastics in cosmetic products, results in a release to the environment of greater than 200 t/year. This means that this sub-scenario is probably the most relevant for the solid waste disposal pathway. This level could be expected to increase considerably in the future as greater amounts of plastic product packaging are recycled.

B.1.3.3.3. Direct release to the environment

The analysis of emissions provided makes it clear that the direct releases from agriculture to soil is one of the most significant pathway. The relevant agriculture uses are as controlled-

release fertilisers (CRFs), fertiliser additives, capsule suspension plant protection products (CSPs) and seed coatings. The polymeric material used after fulfilling its function remains in the treated soil. Minor direct releases to the environment (water and air) could rise from waxes and polishes.

The overall agriculture release is estimated at 10 000 t/y, with a range between 3 500 to 18 000 t/y. Overall the release factor is 100%.

B.1.3.3.4. Infill material for synthetic turf sports fields

Synthetic turf sports pitches (mainly used for ball sports such as football, rugby, American football, lacrosse and Gaelic sports) typically consist of a synthetic grass pile (filaments) together with a loose granular 'infill' material. Infill material is used to control the performance of the surface (Figure 2). The most common infill material in synthetic turf sports fields consists of polymeric particles of < 5mm in size (thus meeting the definition of a microplastic under the proposed restriction). The Dossier Submitter had not undertaken a detailed assessment of these intentionally added microplastics in its original proposal as insufficient robust information on this use was not considered to be available at the time of preparation. Instead, recognising that it could be a significant use of intentionally added microplastics, the Dossier Submitter included the use (by default) within the scope of the original proposal and used the consultation to obtain contemporary information on uses volumes, risk management measures and impacts (of a ban). The Dossier Submitter refined the proposed restriction in relation to infill material during opinion-development based on the information received in the consultation (refer to Annex D.13 of the Background Document).

Although several alternative synthetic turf sports pitch systems are also in use (e.g. non-infill systems or those using natural infill such as cork or coconut fibre) between 90 to 95% of synthetic turf sports pitches in the EU use styrene-butadiene rubber granules (i.e. microplastics) produced from recycled tyres as infill material. Other types of polymeric infill material (also microplastics) are also in use, but in much lower quantities, such as:

- ethylene propylene diene monomer (EPDM) rubbers: market share of ~4%;²⁵
- Thermoplastic elastomers/thermoplastic rubbers (TPE): market share of ~4%;
- Polyethylene (PE) or polypropylene (PP): market share unknown.

²⁵ According to industry information, EPDM rubber material is produced from both recycled EPDM and virgin EPDM infill material (ECHA 2017).

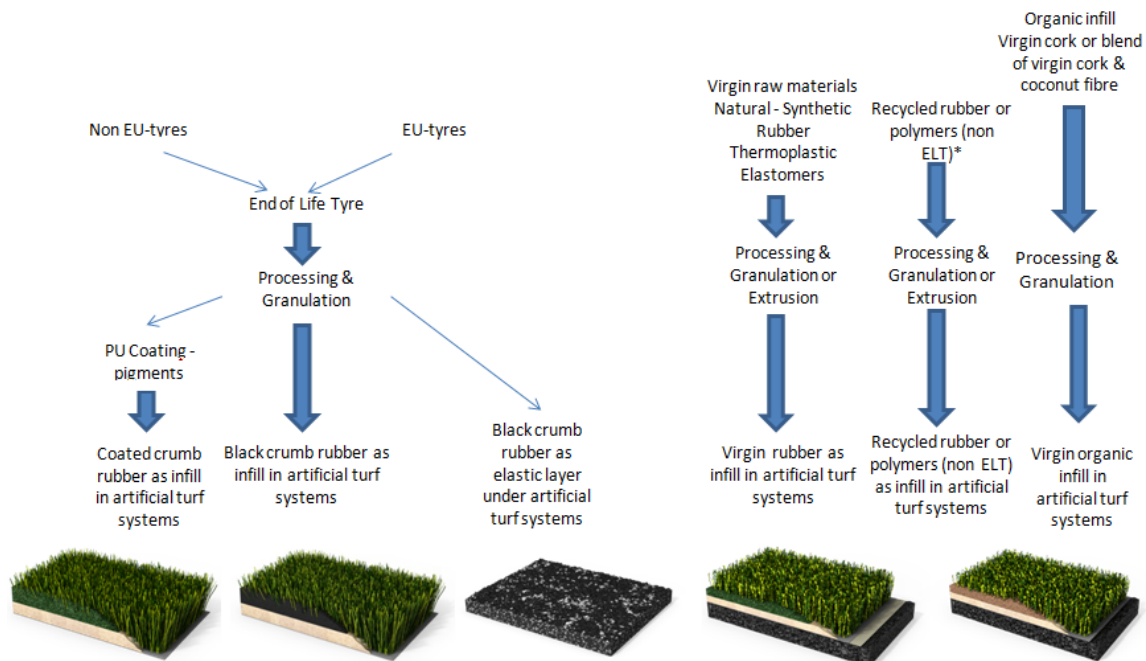


Figure 2 Schematic of 3rd generation artificial turf systems; based on information provided by ETRMA and ESTO (2016).

RAC notes that, based on the revised assessment of uses and releases provided in the Background Document by the Dossier Submitter after the consultation, rubber granules used as infill in synthetic turf sport pitches are the largest contributor at European level in terms of both quantities of intentionally-added microplastics used and released to the environment, with a central estimate of 16 000 tonnes released to the environment per year (Table 8). Based on the central estimate use quantity of 100 000 t/y, this corresponds to a release factor of 0.16 (16%).

Polymeric infill material used on synthetic turf sports fields can be inadvertently removed (also sometimes referred to as dispersed) from pitches by players (via their clothes, footwear and equipment) as well as through rainwater run-off, loss via drainage systems, wind dispersal and as a result of routine maintenance activities, including snow clearance in some countries (predominantly Northern and Eastern European Member States). Infill material may enter drainage systems or be dispersed directly to adjacent soil//grass (around the perimeter of the pitch) or surface waters (if present). A proportion of the microplastics lost from pitches will be disposed as waste (e.g. by players themselves after cleaning clothing, footwear or other equipment). Microplastics released via drains may be intercepted by WWTWs and a proportion will be prevented from reaching the environment (see 'down the-drain' pathway above). The infill on synthetic turf sports pitches needs to be periodically topped-up to maintain the performance of the surface. Refilling is necessary to replace lost infill (i.e. via dispersal), but also to compensate for the compaction of infill that occurs over time reducing its performance.

The Background Document reports the results of several studies investigating the loss of infill material from synthetic turf sports pitches. The Danish Technological Institute (DTI – cited as Løkkegaard et al. 2018 in the Background Document) reported a mass balance of infill material from synthetic sports turf pitches, with a focus on losses to the environment, including releases to water. The mass balance confirms that the main reason for infill refilling

is to compensate for a compaction effect-related loss (65 to 85%), and not losses to the environment.

According to this study, the largest loss is via migration to ground and paved areas (250 kg/yr). Losses via water discharges range from 10 to 200 kg/yr (with the quantity released to the aquatic environment ranging from 2.5 to 36 kg per year after wastewater treatment). The average annual loss per pitch from transfer to clothes and shoes is reported as 40 kg/yr. The loss from snow removal ranged from 0 to 240 kg/yr.

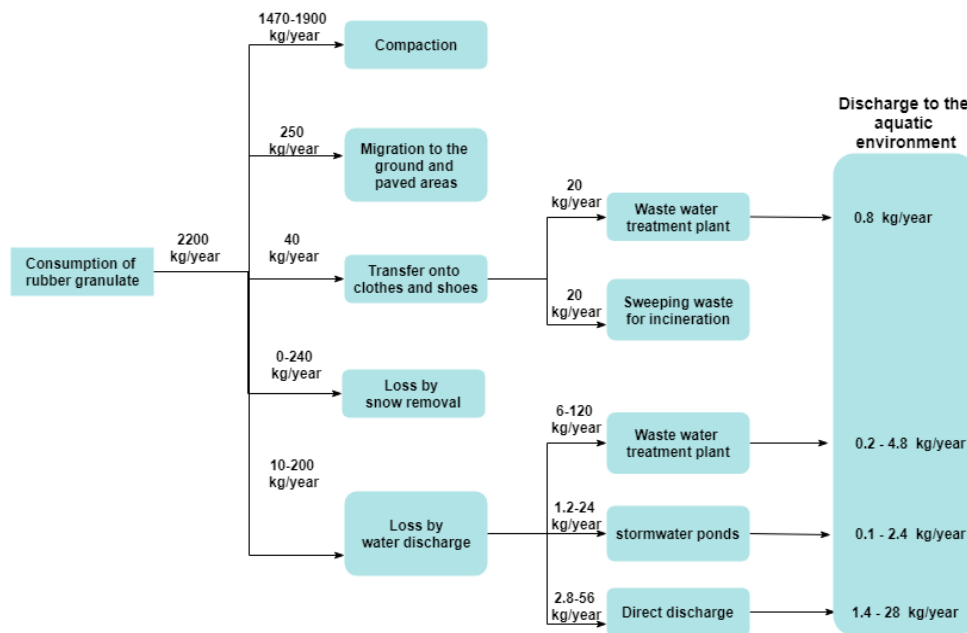


Figure 3 Different pathways for loss of rubber infill (Løkkegaard et al. 2018).

Similarly, Wijer and Knol (2017) reported that 250-325 kg of infill material per year was lost to the environment surrounding a pitch, particularly grass and pavements within a distance of two metres from the field. Wijer and Knol (2017) considered that it was relatively easy to collect this dispersed infill material by undertaking routine maintenance (i.e. sweeping) as well as to install preventive measures that would minimise any further dispersion.

The methodology used by the Dossier Submitter to estimate annual releases of infill material from EU pitches is reported in detail in Annex D.13 of the Background Document²⁶. RAC notes that the loss of infill material of 500 Kg/year per pitch, estimated by the Dossier Submitter under the baseline scenario, was based on the assumption that only a limited number of pitches in the EU (~15%) apply risk management measures (RMMs) to prevent releases of infill material. The estimated loss of 500 kg/yr per pitch is the net loss resulting from the use, on average, of two tons/year of infill to maintain performance, with 75% of refilling necessary

²⁶ The Dossier Submitter assumed, based on information from the consultation, that an average full-sized pitch contains 80 tonnes of infill material and 2.5% of infill material per year would have to be refilled. This corresponds to an annual consumption of 2 tonnes per average full-sized pitch. 75% (1.5 tonnes) of the consumption was due to compaction. The actual loss per full-sized pitch would be 500 kg per year. Forecasted full-sized pitch equivalents of 39 000 (calculated from 21 000 full-sized pitches plus 18 000 full-sized pitch equivalents estimated from 72 000 mini pitches). ~5% of pitches assumed to already use alternative infill material. ~15% of pitches assumed to already implement technical risk management measures to minimise releases. 32 000 pitches assumed to release 500 kg per full-sized pitch. 16 kt of forecasted losses of infill material per year across the EU.

to offset compaction. RAC notes that the estimates of losses of infill material are underpinned by numerous assumptions, but supports the methodology used by the Dossier Submitter to estimate an average loss of 500 kg/yr per full size pitch in the EU under baseline conditions. Site-specific considerations, such as the frequency of snow clearance, construction of drainage systems, compaction and how regular maintenance activities are performed will determine losses from individual pitches. RAC notes that the Dossier Submitter's estimate of releases of 500 kg/yr/pitch does not take into account that wastewater treatment could prevent a proportion of these releases from reaching the environment (as per the 'down-the-drain' pathway). RAC also notes that losses could have been underestimated if compaction (assumed by the Dossier Submitter to account for 75% of the need for refilling on an EU wide basis) is a less important process than assumed.

Effectiveness of risk management measures

The Dossier Submitter, and the numerous stakeholders taking part in the consultation, consider that microplastic releases from synthetic turf pitches can be significantly reduced by applying appropriate risk management measures. Risk management measures can be both technical (i.e. containment by fences, grids, mats, gates and interceptors/filters in drainage systems), behavioural (i.e. educating players to clean boots and clothing before leaving the boundaries of pitches) as well as organisational (e.g. requiring the use of football boots with integrated socks, undertaking regular sweeping of pitch boundaries and the appropriate management of snow cleared from pitches). Many types of RMMs were brought to the attention of the Dossier Submitter during the consultation (See Annex D.13.4.1 of the Background Document). RAC considers that technical risk management measures are potentially simple to implement if foreseen during the design and (re)construction phase of synthetic turf sport pitches. They are considered less easy to implement (retro-fit) to existing pitches.

Professional football associations (e.g. SVFF, FIFA, UEFA), recommended risk management measures to be implemented in order to decrease the release of infill material from pitches into the environment. The set of risk management measures is reported to be specifically designed to target different pathways of dispersal, including migration to the ground and paved areas, transfer via players' clothes and shoes, loss by snow removal, and loss through water discharge.

The ESTC (Synthetic turf council) together with the European Standards Committee (CEN) have advocated that *CEN/TC 217 – Surfaces for sports areas*²⁷ develop a CEN Technical Report to promote the design and maintenance features that will minimise or eliminate infill migration from sports fields. The Technical Report would support European Standard *EN 15330-1: Specification for Synthetic Turf Sports Surfaces*. RAC understands that the European Standards Committee is currently seeking approval of the National Standards Bodies to approve the new work item and intends to publish the technical report in 2020.

The ESTC published a guidance document in 2017 outlining various ways of control infill migration from synthetic turf surfaces. Besides instructions on minimising infill emissions to

²⁷ Technical standardisation body in the field of surfaces for indoor and outdoor sports areas with a special regard to safety and performance requirements, test methods and environmental aspects.

the environment, the guideline includes examples of what they consider to be good practice, some of which are:

- Use of raised perimeter edge details;
- Use of entrance mats and metal foot-grills to capture infill that escaped a field;
- Use of slit traps or special filter areas in the drainage devices around the boundaries of fields and in changing rooms, etc.;
- Use of synthetic turf systems that either have a lower potential for infill movement using yarn profiles and stitch rates that are designed to restrict infill movement and or the use of synthetic turf systems that require less infill;
- Use of infills that are less prone to movement and migration.

RAC notes that, despite widespread advice that they are implemented, the effectiveness of different risk management measures has not been comprehensively evaluated and documented. The effectiveness of risk management measures was recently reported in a one year study by Ragn- Sells (Sweden) on a synthetic turf installed at Bergavik's IP (Kalmar, Sweden). The artificial turf was constructed according to the recommendations of the Swedish Football Association, supplemented with several additional measures. The following risk management measures were installed:

- Surface water and drainage water were separated
- Sealing layer under the pitch was installed to collect all drainage water
- Granular traps in all stormwater drains around the pitch (>200 µm filter)
- Granular filter for both surface water and drainage water (>100 µm filter)
- ➔ covering the pitch during winter to decrease the chance of releasing the granules during snow clearance.
- Installation of brushing stations and signage for players when entering and leaving the pitch
- Cleaning maintenance vehicles after use.

Preliminary results of this one-year study showed that the migration of microplastics from the artificial pitch to the environment amounted to about 0.3 kg/year. Releases to water were about 0.1 kg per year. Stormwater drains were the largest potential source of losses, where approximately 15.5 kg per year were captured in the granular traps in the drains.

RAC considers that this study is likely to represent best practice for containment, but notes that, despite promising results, there remain some uncertainties in the study. As it was not possible to quantify microplastics < 10 µm in size (due to limitations in the analytical methods used) losses from this fraction could have been underestimated. RAC also notes that the size of the pitch was not indicated in the study and the dispersal route via wind was not quantified because it was not considered to be relevant because of the mass of the particles (RAC considers that small particles of infill could be readily dispersed by the wind).

RAC notes that risk management measures implemented are similar to those employed at plastic manufacturers and compounders as part of Operation Clean Sweep (OCS) for pellet loss mitigation; traps for drains both inside and out, good housekeeping with spills regularly cleaned up and a site designed to prevent infill from migrating outside of the pitch area, are

all simple but effective measures (EUNOMIA 2018).

Based on information provided in the consultation, the Dossier Submitter estimates that when risk management measures are applied to a full-sized football pitch, releases of infill material can be reduced to around 50 to 100 kg/year per pitch. Loss of 50 kg/yr corresponds to an effectiveness of 90% compared to the baseline release per EU pitch of 500 kg/yr and an overall release factor of 0.016 (1.6%). Taking into account the standard surface area of a full-size football pitch (c.a. 7 600 m²), this annual release is equivalent to or lower than 7 g/m²/year.

Proposed restriction options by the Dossier Submitter

Based on the information received in the consultation, the Dossier Submitter assessed the effectiveness and impact of various restriction options (ROs) to address the releases of infill material from synthetic turf pitches.

- RO1. Restriction on placing on the market of polymeric infill (no transitional periods)
- RO2. Restriction on placing on the market of polymeric infill (six year transitional period)
- RO3. Derogation conditional on providing mandatory instructions for use and introducing a reporting obligation
- RO4. Derogation conditional on implementation of risk management measures (three year transitional period).

The Dossier Submitter concluded that both RO2 and RO4 could be considered to be proportionate restrictions, but that a recommendation for the most appropriate option could only be made based on political considerations (i.e. the weight placed on emission reduction relative to costs). The Dossier Submitter therefore included both as options in the restriction proposal:

- **Option A** – use of risk management measures to ensure that annual releases of microplastic do not exceed 7g/m² (equivalent to 50 kg/full size pitch/year) after a transitional period of three years.
- **Option B** – ban on placing on the market after a transitional period of six years.

As there is currently no list of standard risk management measures that could be specified in the conditions of the restriction, the Dossier Submitter considered that compliance with option A could be demonstrated, in due course, by implementing risk management measures that had been verified to achieve the required effectiveness of <7g/m²/year, ideally specified in a recognised international or European standard. In such a way the minimum effectiveness of standardised risk management measures would be set by the REACH restriction, but the precise risk management measures to achieve them could be established through subsequent standardisation. Different RMMs could be established for different types of pitch scenarios (e.g. newly constructed pitches vs retro-fitting RMMs to existing pitches) although the minimum standard of effectiveness would need to be the same.

RAC evaluated both of the Dossier Submitter's options from an effectiveness perspective. RAC notes that both of the options were considered by the Dossier Submitter to have equivalent effectiveness (i.e. total microplastic releases) over the 20 year analytical period considered. The shorter transitional period of three years proposed for option A (versus six years for

option B) was selected to compensate precisely for the greater relative releases of option A after the full ban entered into effect. However, the Dossier Submitter notes that over the longer term (i.e. >20 years after implementation) option A would be less effective than option B. RAC agrees with the Dossier Submitter that a complete ban will be more effective to prevent releases of microplastics over the long term than use of RMMs.

RAC notes that the effectiveness of RMMs of 90% assumed by the Dossier Submitter is in agreement with recent studies, but that this is likely to be more readily achieved at sites where RMMs were planned during the initial design and construction of facilities rather than when retrofitted to existing facilities. There is limited understanding of the effectiveness of RMMs that could be retro-fitted to existing pitches.

The effectiveness of risk management measures reported at the Kalmar case study correspond to a value of >99%²⁸. However, RAC considers that it is unlikely that under normal operating conditions microplastic releases <1 kg/year (>99% effectiveness), such as those claimed at the Kalmar site, will be achieved. In addition, RAC considers that drainage filters will not typically be effective for small microplastics <100µm in size.

RAC notes that after implementation of risk management measures annual releases of microplastics from EU pitches would still be in the order of 1 600 t/yr, which remains significant relative to other uses/releases of intentionally added microplastics.

In terms of practicality and enforceability, RAC notes that option A would be difficult to enforce without the development of appropriate international or European standards or guidance that establishes the effectiveness of different RMMs in different pitch contexts (i.e. newly constructed vs existing) and their suitability to achieve the stated minimum effectiveness of annual losses of <7g/m². Therefore, RAC notes that the development of such guidance would be a pre-requisite for option A to be considered as practical.

In addition, as a substantial amount of releases are likely to arise from shoes and clothing, as well as from maintenance operations, the effectiveness of risk management measures will largely depend on individual behaviour (e.g. to remember to clean footwear before leaving pitches) and the climatic conditions where the pitch is located (i.e. frequency of snow clearance required).

RAC considers that the lower size granules are those with a higher environmental concern. This could support the introduction of a lower size limit for rubber granules used as infill, only allowing the use of infill granules with a size above 1 mm. This could avoid release of the smallest particles, that are the most likely to migrate. Nevertheless, the introduction of a lower size limit should also take into account aspects related to the technical feasibility and the practicality.

RAC also considers that the construction phase and end of life disposal of artificial pitches is relevant to consider, as this may lead to releases of microplastics in addition to those that occur during the service life of the pitch. It is estimated that the useful life of an artificial pitch is about 10 years and there are four main end of life options: re-use, landfill, incineration and recycling. Re-use is when the turf (or its component parts) are removed and re-used in a new

²⁸ This estimate does not include losses that occurred during the installation of the pitch or which could occur at the end of life of the pitch.

installation with the same, or similar function. In contrast, recycling of materials generally involves some form of processing before the material can be used again. Both incineration and landfill exist in many countries although the dominant method of waste disposal is landfill in most of Eastern Europe while, in Western Europe rely more strongly on incineration. In any case, recycling of artificial football turf is not widespread. However, there is insufficient information to evaluate the specific environmental releases for each option. RAC considers that the re-use or recycling of the old pitch-infill granules has potential to result in potentially large release of microplastics and should be carefully managed.

Conclusion

Based on these considerations RAC expressed a clear preference, from an emissions reduction perspective, for a ban on the use microplastics as infill material on synthetic sports turf pitches to be implemented as soon as possible. RAC concludes that the use of RMMs over the longer term would be unlikely to result in an adequate control of risk. RAC notes there are likely to be other environmental benefits associated with Option B, particularly associated with the use of organic alternatives. Organic infills can have a smaller environmental impact than polymer infills (depending on end of life disposal) including lower global warming potential (FIFA, 2017). In RAC's view, a six-year transitional period, from the Entry into Force, would facilitate a managed transition to artificial turf systems that either use organic infill material or are infill-free. RAC notes that some alternatives to polymeric infill (i.e. cork or other organic blends that include coconut fibres) are certified by the FIFA Quality Programme (FIFA, 2017).

Nevertheless, as part of its evaluation, RAC considered an alternative (hybrid) restriction option where existing (or constructed in the near future) microplastic-based pitches could continue to be used for the remainder of their useful service lives conditional on the progressive implementation of strict RMMs, but that microplastic infill material would eventually be phased out completely in newly constructed or refurbished pitches after a certain transitional period expired²⁹. This option is not preferred by RAC as it would still result in releases of microplastics over the lifetime of pitches (typically at least 10 years) installed before the final implementation date, and would still require the development of international/European standards for appropriate RMMs, but might be usefully considered should the impacts of a full ban be considered to be disproportionate.

B.1.4. Characterisation of risk(s)

B.1.4.1. Summary of the Dossier Submitter's proposal

On the basis of the conclusions of the hazard assessment the Dossier Submitter proposes that intentionally-added microplastics are considered as non-threshold substances and that releases to the environment are considered as a proxy for risk.

This is consistent with recent restrictions on substances where it is not possible to derive a threshold, such as decaBDE, PFOA and lead (in PVC and in gunshot), etc.

²⁹ Microplastics shall not (i), from [entry into force (EiF)], be used as granular infill in synthetic sports surfaces unless [list of simple RMMs] are implemented; (ii), from [entry into force (EiF)] + 3 years, be used as granular infill synthetic sports surfaces, unless technical risk management measures are implemented to limit releases to < 7g/m²/y; (iii), from [EiF + 6 years] be used as granular infill on sports surfaces installed (newly constructed or refurbished) after EiF + 6.

The Dossier Submitter revised the quantities of intentionally-added microplastics used and released in the EU based on updated information received in the consultation. The revised values are reported in the Background Document (and Annexes) and in Table 8, below.

Table 8 Use and releases of intentionally-added microplastics in EU/EEA

Sector / Product group	Use ^a (tonnes/year)	Release to the environment ^b (tonnes/year)
Cosmetic products	8 700 (4 100 – 13 100)	3 800 (1 800 – 5 900)
- Rinse-off containing microbeads (exfoliators/cleansers) ^c	107	55
- Other rinse-off	6 500 (2 900 – 10 000)	3 100 (1 400 – 4 900)
- Leave-on	2 100 (1 100 – 3 000)	600 (300 – 900)
Detergents and maintenance	17 000 (11 100 – 23 000)	8 500 (5 600 – 11 600)
- Detergents containing microbeads ^c	95	50
- Fragrance encapsulation	400 (260 – 540)	200 (0 – 150)
- Other detergents	15 200 (9 440 – 20 960)	7 700 (4 800 – 10 650)
- Waxes, polishes and air care products	1 300	585
Agriculture and horticulture	10 000 (3 500 – 18 000)	10 000 (3 500 – 18 000)
- Controlled release fertilisers	5 000 (1 000 – 10 000)	5 000 (1 000 – 10 000)
- Fertiliser additives	4 000 (2 000 – 6 000)	4 000 (2 000 – 6 000)
- Treated seeds	500 (250 – 1 000)	500 (250 – 1 000)
- Capsule suspension PPPs	500 (250 – 1 000)	500 (250 – 1 000)
Oil and gas	1 200 (300 – 2 000)	270 (-0 – 550)
Paints and coatings ^d	5 300 (10 200)	2 700 (5 200)
- Consumer uses	5 300	2 700
- Professional uses	(4 900)	(2 500)
Construction products	Not known	Not known
<i>In vitro</i> diagnostic devices ^e	50 (0.5 – 100)	0.27 (0.25 – 0.29)
Medical devices (MD)		
- (substance-based) MD	Not known	Not known -
- MD other than (substance-based)	~10	
Medicinal products	2 300 (800 – 3 700)	1 100 (400 – 1 800)
- Ion exchange resins	700 (300 – 1 000)	300 (100 – 500)
- Matrix or polymer film for controlled release	1 600 (500 – 2 700)	800 (300 – 1 300)
- Immediate release	Not known	Not known
Food additives	Not known	Not known
Infill material for synthetic pitches ^f	100 000 ^g (15 400 – 184 800)	16 000 (2 000 – 52 000)
Total (excluding infill material)^g	44 600 (19 800 – 70 000)	26 400 (11 200 – 43 000)
Total (including infill material)^g	144 500 (35 200 – 254 800)	42 400 (13 200 – 95 000)
Notes:		
^a Releases via down-the-drain (wastewater), municipal solid waste (trash/bin) and/or direct application/deposition to soil pathways;		
^b eventual release to the environment;		
^c represents values for 2017. The use is expected to be phased out by 2020 and therefore the restriction is not expected to have an impact on the use and emissions;		

Sector / Product group	Use ^a (tonnes/year)	Release to the environment ^b (tonnes/year)
<p>^d most microplastics in paints and coatings will be bound in a solid matrix (film) once correctly applied, however a residue on brushes/rollers is assumed to be disposed down the drain. The tonnage reported in the table represents the quantity disposed down the drain^e</p> <p>^e during use, microplastics are typically contained in equipment or cartridges and treated as hazardous waste/incinerated at their end of life, hence the limited release to the environment;</p> <p>^f Assumes 21 000 full-sized and 72 000 small-sized pitches in the EU by 2020;</p> <p>^g All figures are rounded so may not add up precisely to the totals presented.</p>		

A recent project for the European Commission estimated the scale of annual releases of microplastics from unintentional sources to EU surface waters (Eunomia, 2018). The study reports releases of 176 300 tonnes per year, with a lower and upper range of 71 800 to 280 600 tonnes per year. The greatest contributors were identified to be road tyres (94 000 tonnes per year) and losses of pre-production plastic pellets (41 000 tonnes per year), followed by road marking (15 000 tonnes per year) and the washing of clothes (13 000 tonnes per year). Therefore, although lower with respect to total annual releases of microplastics from unintentional sources, the release of intentionally added microplastics are comparable to some unintentional sources and should be considered as significant, i.e. need to be addressed, particularly when the ‘stock’ effects of microplastics are considered. RAC notes losses of pre-production pellets is a large potential source of microplastics to the environment.

B.1.4.2. RAC conclusion(s)

RAC agrees that microplastics should be considered as non-threshold substances and pose environmental concerns similar to that associated with PBT and vPvB substances. Therefore releases to the environment are considered as a proxy for risk.

RAC agrees with Dossier Submitter that quantitative risk assessment is not appropriate and the aim of the risk characterisation is therefore to demonstrate the magnitude to releases from different uses and determine whether releases have been minimised. All environmental compartments are relevant to consider.

Taking into account their long-term persistence, reported adverse effects on biota, and the increasing environmental concentration, RAC concludes that uses of microplastics that inevitably result in releases to the environment are not adequately controlled and pose a risk that needs to be addressed.

B.1.4.3. Key elements underpinning the RAC conclusion(s)

The presence of microplastics has been reported in almost all of the environmental compartments, including aquatic (fresh and marine water and sediment), the terrestrial environment and the air. Ecotoxicity studies with a range of organisms have demonstrated that exposure to microplastics results in adverse effects (see earlier sections of this opinion). In addition, microplastics can be transferred to humans through the food chain.

RAC notes the opinion of the European Commission’s Group of Chief Scientific Advisers on the environmental and health risks of microplastic pollution (SAM, 2019) ³⁰. SAM (2019) report

³⁰ https://ec.europa.eu/info/sites/info/files/research_and_innovation/groups/sam/ec_rtd_sam-mnp-opinion_042019.pdf

that there is growing scientific evidence that microplastics pose, irreversible, and long-term ecological risks in some coastal waters and sediments and that, although microplastic pollution does not constitute a widespread risk at present, business-as-usual would lead to concentrations thresholds being exceeded in the near future and the occurrence of widespread risk within a century.

Microplastics are highly persistent and any releases will contribute to the environmental stock over time. Microplastics can be transported between compartments after release. Microplastics are considered by RAC to be non-threshold substances, and a 'safe' concentration in the environment cannot be established using the data that is currently available. As a result, quantitative risk characterisation cannot be used to demonstrate that risks are adequately controlled. Should safe thresholds be derived in the future for all the necessary compartments this would not address the key fundamental issue arising from the long-term persistence of microplastics whereby any 'safe' threshold will eventually and inevitably be exceeded over time due to the cumulative nature of the exposure.

The Dossier Submitter considers that a restriction under REACH should minimise releases of intentionally added microplastics to the environment and reduce the likelihood of adverse effects arising as a consequence of the exposure concentrations arising today, or that would arise in the future based on continued use. Minimisation of release would also reduce the potential for cumulative effects arising from the presence of both primary (intentionally added) and secondary microplastics in the environment.

B.1.4.4. Uncertainties in the risk characterisation

The risk assessment of microplastics is complicated by current uncertainties in relation to their hazard, environmental fate and exposure. These are described in the respective sections of the Background Document. For instance, a significant proportion of the studies conducted to date document the occurrence and concentration of microplastics in different environmental compartments with fewer focusing on hazard assessment and even fewer still reporting the dose-response relationships for apical endpoints (e.g. survival, growth or reproduction) in relevant flora and fauna that typically underpin regulatory risk assessments. Of particular note is the paucity of hazard data for terrestrial species (especially relevant to intentionally introduced microplastics disposed of down the drain), information on secondary poisoning and for nanoplastics (breakdown products of microplastics), in general.

Although existing information is considered to be insufficient to establish safe concentrations in the environment (i.e. PNEC values) for microplastics, 'tentative' threshold of adverse effect have been reported in the scientific literature for some compartments (see Background Document).

Given the knowledge of the quantity of intentionally added microplastics released to the environment and their potential to contribute to an irreversible environmental stock, the likelihood that 'real' effects thresholds will be exceeded in the environment in the future increases with continued use and releases. However, it remains uncertain where and when precisely these thresholds will be exceeded and what the relative contribution of intentionally-added to secondary microplastics will be to this exposure. Effects thresholds have already been reported to be exceeded in certain marine hot-spots (most likely as a result of secondary microplastics) but it may be that effects thresholds are also exceeded in other environmental compartments, but without our knowledge.

The relative contribution from intentionally-added microplastics to total microplastic exposure (i.e. including secondary sources) also remains an uncertainty. RAC notes that recent research (Lindeque et al. 2020) has highlighted that concentrations of smaller microplastics in the environment are likely to be underestimated in previous studies because of the sampling methods used (i.e. net mesh size). The contribution of intentionally-added microplastics in the marine environment (compared to marine litter) is likely to be minor, but the contribution of intentionally-added microplastics to overall microplastic exposure in the terrestrial compartment (the key receptor of the down-the-drain pathway as well as direct releases through agricultural and horticultural uses) is less easy to dismiss.

RAC notes that the Dossier Submitter did not estimate releases for several of the identified consumer/professional uses of intentionally added microplastics (e.g. uses in construction products) or for uses of microplastics at industrial sites (e.g. use of pre-production pellets to manufacture articles). Therefore releases of microplastics could be greater than reported by the Dossier Submitter. The reporting element of the proposed restriction will allow these uncertainties to be addressed.

Therefore, RAC considers that the underlying uncertainties identified above do not prevent a sufficiently complete understanding of the risks of microplastics to arrive at a robust conclusion on the need for risk management. RAC considers that releases of microplastics should be minimised to avoid, as far as possible, effects thresholds from being exceeded in the future in relevant environmental compartments.

Should safe thresholds be derived in the future for all the necessary compartments (which may take many years to undertake sufficiently representative laboratory studies) this would not address the key fundamental issue arising from the long-term persistence of microplastics whereby any 'safe' threshold will eventually and inevitably be exceeded over time due to the cumulative nature of the exposure resulting from continued use. Given this, the consequence of inaction would be additional releases of microplastics to the environment leading to greater likelihood of adverse effects.

Whilst the role of microplastics in facilitating the bioaccumulation of hydrophobic organic contaminants (particularly POPs) would appear to be less significant than initially considered, understanding the role of plastic additives (such as fillers, UV stabilisers and plasticisers) to observed (eco)toxicity of microplastic remains an important data gap. Conventional risk assessment of these substances is unlikely to have considered exposure to organisms via a microplastic vector.

While the full extent of the risks posed by microplastics in the environment (and humans) are currently considered as uncertain, the Dossier Submitter expects that the understanding of risks will increase significantly over the next 10 years as microplastics, nanoplastics, and their impacts continue to be further studied.

The available information on environmental fate and exposure is also limited. Conventional approaches for modelling exposure and long-range transport, which would normally be applied in chemical risk assessment in the absence of information on measured concentrations, are not applicable to microplastics.

Very little published literature has examined the effect of microplastics in humans (direct or via food; EFSA (2016)). Given their long-term persistence in the environment of many

polymers, additional research is required to adequately assess the risks that accumulation of micro- and nanoplastics in humans may pose (Galloway, 2015).

There are uncertainties related to hazard, fate and exposure of the different substance that are grouped as microplastics in this proposal. However, such uncertainties are not in the view of RAC, solved by taking a polymer-specific approach and attempting multiple quantitative risk assessments.

The more or less direct release of microplastics to the environment, e.g. seed coatings, fertilisers and plant protection products also make it difficult to minimise releases by specific technical means, i.e. suitable risk management measures do not exist.

B.1.5. Risk management measures and operational conditions implemented and recommended by manufactures / importers

B.1.5.1. Summary of Dossier Submitter's proposal

Based on the assessment of releases reported by the Dossier Submitter in Section 1.4.2 of the Background Document, uses of consumer and professional products containing microplastics will result in microplastics being released to the environment. Some of these uses will inevitably result in releases of microplastic to the environment, whilst others could be minimised through the use of additional risk management measures or by adopting more appropriate conditions of use and disposal at end use.

On the basis of the conclusions of the risk assessment reported in the Background Document, these releases are considered to pose a risk to the environment that is not adequately controlled.

B.1.5.2. RAC conclusion(s)

RAC notes that any risk management measure applied depends on the specific pathway through which microplastics are released. For the majority of uses no specific risk management measures to prevent emission to the environment are envisaged, principally as suppliers placing microplastics on the market in products have not considered that their release could pose a risk to the environment or human health.

Therefore RAC concludes that appropriate operational conditions and risk management measures have not been implemented to control the risk.

B.1.5.3. Key elements underpinning the RAC conclusion(s)

Microplastics have a concern similar that posed by the PBT/vPvB substances with non-threshold effect level. In this case, according to REACH regulation, manufacturers and importers shall minimise releases by applying the best risk management measures and OC throughout the life-cycle of the substance. The use of microplastics in consumer products, that are 'widely dispersed' is not consistent with the concept of minimisation.

B.1.6. Existing regulatory risk management instruments

B.1.6.1. Summary of Dossier Submitter's proposal

The Dossier Submitter conducted an analysis of diverse risk management options (RMOs) to identify the most appropriate option for addressing the identified risks, including various

permutations of a REACH restriction. The Dossier Submitter reported that various European countries have adopted legislation to regulate the use of microplastics (Table 9).

The Dossier Submitter notes that the Commission's choice to address the intentional use of microplastics by means of a restriction under the REACH regulation was part of the recently published 'European strategy for plastics in a circular economy', often simply referred to as the 'plastics strategy'³¹ that included a raft of both legislative and non-legislative initiatives to address plastic pollution and the long-term sustainability of plastic use in the EU, whilst also fostering growth and innovation³².

As a REACH restriction was specifically identified in the plastics strategy, the assessment of alternative novel union-wide legislative risk management options (RMOs), e.g. the relative merits of an EU specific legislation on intentionally added microplastics, were not specifically considered by the Dossier Submitter. Instead, it was presumed that during the development of the plastics strategy due consideration was given to the most appropriate means to effectively achieve the strategy's objectives; resulting in the conclusion that a REACH restriction was most appropriate.

In support of this presumption, it should be noted that the preferred legislative approach in other parts of the strategy were via EU Directives, for example to address improvements to port reception facilities (to prevent marine littering), ban on certain 'single-use' plastic articles (i.e. disposable plates, drinking straws and cutlery) and improvements to packaging and packaging waste regulation. Various non-legislative initiatives have been included in the strategy as well, ranging from the development of quality standards for sorted plastic waste and recycled plastics, to a pledging exercise to encourage manufacturers to use recycled plastic in their products, to funding R&D through a Strategic Research Innovation Agenda.

In addition, the Dossier Submitter compared the relative merits of the proposed restriction with risk management via existing union-wide legislation, such as the Water Framework Directive (WFD), Marine Strategy Framework Directive (MSFD), and the Urban Wastewater Treatment Directive (UWWTD), as per the requirements of Annex XV of REACH.

The possibility for existing or proposed Union-wide legislation, as well as other possible Union-wide RMOs, to address the risks posed by microplastic was explored. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors (particularly fertilising products) these were considered to be inappropriate to address *all* of the sectors and products identified to be contributing to risk that is not adequately controlled.

³¹ http://europa.eu/rapid/press-release_IP-18-5_en.htm

³² For example, by setting targets to increase the recycling and the recyclability of plastic packaging (by 2030 all plastic packaging should be designed to be recyclable or reusable), legislating to ban (by means of an EU Directive) certain 'single use' plastics, preventing the loss or abandonment of fishing gear in the marine environment as well as improving the availability of port reception facilities for maritime waste, to prevent its dumping at sea.

Table 9: Overview of European regulatory action on intentionally added microplastics

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
Belgium			Plan to ban plastic particles (microbeads) in all rinse-off cosmetic products and toothpastes by 2019.
Denmark		X	Plan to ban the placing on the market of rinse-off cosmetic products containing microplastics. Microplastics are defined as plastic in a solid state that are less or equal to 5 mm in all dimensions and that are insoluble in water, and that do not meet the criteria of being easily biodegradable according to OECD Test Guideline 301. TRIS consultation: Q3-2019
France		X	Ban the placing on the market of rinse-off cosmetic products for exfoliation or cleaning that contain solid plastic particles (define as microbeads smaller than 5 mm made of plastic in whole or in part, obtained by a hot-shaping process). Exemption for particles of natural origins (i) not persisting in the environment, (ii) not releasing active or biologic substance, (iii) not affecting animal food chain Entry into force: 1 January 2018
France		X	Plan to ban the placing on the market of substances or mixtures containing microplastics in concentration above 0.01%. Transitional periods are proposed for different product types (MD, IVD, cosmetics, detergents, other products type). In addition, the sites manufacturing, using and transporting plastic pellets (nurdles) shall be equipped and have procedures in place to avoid the loss of plastic pellets into the environment. Draft law – expected entry into force January 2024
Ireland	X	X	Plan to prohibit the manufacture and use of certain products containing plastic microbeads (rinse-off cosmetic products and household cleaning products). Public consultation in 2018. Not yet in force.
Italy		X	Ban the marketing of exfoliating rinse-off cosmetic products or detergents containing microplastics. No exemption. Entry into force: 1 July 2020
Sweden		X	Ban the placing on the market of cosmetic products that are intended to be rinsed off or spat out and contain microplastics (defined as 'solid plastic particles that are smaller than 5 mm in any dimension and insoluble in water') which have been added to cleanse, exfoliate or polish. Exemption might be given to microplastics that have been manufactured using naturally occurring polymers as a raw material, are quickly broken down into monomers in the aquatic environment, and do not pose any risk to aquatic organisms. Entry into force: July 2018
United Kingdom	X	X	Ban the use of microbeads (defined as 'any water-insoluble solid plastic particle of less than or equal to 5mm in any dimension') as an ingredient in the manufacture of rinse-off personal care products and the sale of any such products containing microbeads. Entry into force: January 2018 (manufacturing), and June 2018 (sales)

B.1.6.2. RAC conclusion(s)

RAC agrees with the Dossier Submitter's analysis and conclusion that the existing regulatory risk management instruments are not sufficient to address the risk of intentionally added microplastics.

B.1.6.3. Key elements underpinning the RAC conclusion(s)

The proposed restriction has been compared with existing risk management instruments based on union-wide legislation, such as the Water Framework Directive (WFD), Marine Strategy Framework Directive (MSFD), and the Urban Wastewater Treatment Directive (UWWTD). As a first step, the Dossier Submitter examined the possibility to address the risks posed by the use of intentionally added microplastics under (i) other REACH regulatory measures, (ii) under existing or forthcoming Union-wide legislation and, (iii) other possible Union-wide RMOs.

Whilst it was recognised, and taken into account that some existing or forthcoming EU legislation or other measures could have an impact on the risk management of certain sectors, such as the recast of the fertilising products regulation (FPR), these were assessed as insufficient to address all of the sectors and products identified as contributing to the risks that are not adequately controlled.

Moreover, RAC noted that several EU MS have only banned specific types of products, such as rinse-off cosmetic products containing 'microbeads' with an exfoliating or cleaning function, and that most of the EU countries have not yet taken action with regard to the microplastics concern through their national regulations (cf. Background Document section 1.1.3).

B.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

B.2.1.1. Summary of Dossier Submitter's proposal

The primary reason to act on a Union-wide basis is to effectively reduce emissions of microplastics across all EU Member States. European-wide measures to minimise emissions are appropriate because mixtures containing microplastics produced in one Member State may be transported to and used in other Member States. In addition, one EU Member State may receive microplastic emissions arising from other Member States. This means that it is appropriate to consider EU-wide measures for risk reduction. This offers the most effective way to implement controls efficiently and uniformly within the EU.

In addition, Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

B.2.1.2. SEAC and RAC conclusion(s)

Microplastics are highly persistent materials with a potential for environmental long-range transport via waterways, and thus becoming transboundary pollution problem. It is practically

impossible to remove pollution once it has occurred. National regulatory action cannot adequately minimise emissions, so EU wide action is necessary to eliminate emissions.

B.2.1.3. Key elements underpinning the SEAC and RAC conclusion(s)

The RAC conclusion on the need to address on a Union-wide basis the risks associated with EU manufactured or imported mixtures containing microplastics, is based on the reasons provided by DS:

- i. to ensure a harmonised high level of protection of the environment,
- ii. some Member States have enacted national measures on microplastics, mainly in wash-off cosmetic products, but only Union-wide measures will curb microplastic emissions effectively, and
- iii. to ensure the free movement of goods within the Union.

B.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of RAC

B.3.1. Scope including derogations

B.3.1.1. Summary of Dossier Submitter's proposal

In response to the identified risk, the Dossier Submitter conducted an analysis of a range of diverse risk management options (RMOs) to identify the most appropriate risk management measure to address these risks. These included REACH regulatory measures other than restriction, other existing EU legislation, and other possible Union-wide RMOs. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures have an impact on the risk management of certain sectors, such as the new fertilising products regulation (FPR), these were assessed as inappropriate to address *all* of the sectors and products contributing to the identified risk.

The Dossier Submitter also assessed six alternative restriction options, alone and in combination, but settled on the restriction presented in Table 1. In summary, the proposed restriction comprises three types of measures:

- a **ban on the placing on the market** of microplastics on their own or in mixtures where their use will inevitably result in releases of microplastics to the environment, irrespective of the conditions of use. For some of these uses, a transitional period is proposed to allow sufficient time for stakeholders to comply with the restriction. (See paragraph 6 in Table 1.)
- an **"instructions for use and disposal" requirement** to minimise releases to the environment for uses of microplastics where they are not inevitably released to the environment, but where residual releases could occur if raw materials or products are not used or disposed of appropriately. This instruction could be placed, for example, on a label, packaging information leaflet, or safety data sheet.

- a **reporting requirement** to improve the quality of information available for assessing potential risks from some uses in the future.

The Dossier Submitter proposes definitions for several terms such as microplastic, microbead, particle, particle containing solid polymer, solid, gas, liquid, and (bio)degradable polymers to improve the clarity of the proposed restriction. A concentration limit is proposed to clearly define the intentional use of microplastics in consumer or professional applications.

A number of derogations are proposed to ensure the proposal is targeted to the risk. These are summarised in Table 10:

Table 10 Proposed derogations by the Dossier Submitter

Para.	Derogation	Explanation
3.a	Natural polymers that have not been chemically modified.	To clarify that natural polymers, as long as their chemical structure has not been chemically modified, are exempt from the restriction as they are inherently biodegradable and therefore do not contribute to the microplastics concern. This is consistent with Annex V of REACH and the Guidance on monomers and polymers (April 2012 Version 2.0) and the Single Use Plastic Directive. The derogation is required to ensure that the restriction is targeted to the substances contributing to the identified risk.
3.b	Polymers that are (bio)degradable , as set out in the criteria in Appendix X.	To clarify that (bio)degradable polymers are exempt from the restriction on the basis that they do not contribute to the microplastic concern, even though they could remain in the environment for some time after use/release. The criteria are set out in an Appendix to the entry (currently referred to as Appendix X) and are described in Section 2.2.1.6 of the Background Document. The derogation is required to ensure that the restriction is targeted to the substances contributing to the identified risk.
3.c	Polymers with solubility > 2 g/L	To clarify that that microplastics particles that would inevitably and immediately lose their particle form once in the environment are different from microplastics that would retain their particle form once released to the environment. The derogation is required to ensure that the restriction is targeted to the substances contributing to the identified risk.
4.a	Substances or mixtures containing microplastics for use at industrial sites .	This is required to prevent regulation on industrial uses as previously described. As there could be some releases of microplastics under reasonably foreseeable conditions of use the downstream users benefiting from this derogation shall be required to report the quantities used and released to the market to the Agency (paragraph 8), so the legislator can decide on any further EU action if needed. Instructions on appropriate use and disposal should also be communicated down the supply chain to minimise releases to the environment (paragraph 7).
4.b	Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC, and in EU Regulation (EC) No. 726/2004.	Derogation from the scope of the restriction on use to avoid potential double regulation, and the risk to affect the availability of medicines. The Commission is also developing a strategy on pollution from medicinal products. As there could be some releases of microplastics under reasonably foreseeable conditions of use the importers or downstream users placing medicinal products on the market, and benefiting from this derogation, shall be required to report the quantities used and released to the market to the Agency (paragraph 8), so the legislator can decide on any further EU action if needed. In addition, medicinal products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7).
4.c	Substances or mixtures that are regulated in the EU under Regulation (EC) No. 2019/1009 on Fertilising Products .	Complete derogation of EU regulated fertilisers from the scope of the restriction to avoid double regulation. The Fertilising Products Regulation includes provisions to phase out the use of non-biodegradable polymers in EU Fertilising Products.
4.d	Substances or mixtures	Derogation from the scope of the restriction on use to avoid potential double

Para.	Derogation	Explanation
	containing food additives as defined in EU Regulation (EC) No. 1333/2008.	regulation, and market-distortion (food supplements or medical food containing food additives might be regulated by different type of legislation in EU). As there could be some releases of microplastics under reasonably foreseeable conditions of use the importers or downstream users placing products on the market containing food additives, and benefiting from this derogation, shall be required to report the quantities used and released to the market to the Agency (paragraph 8), so the legislator can decide on any further EU action if needed. In addition, products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7).
4.e	In vitro diagnostic devices (IVD).	Derogation from the scope of the restriction on use based on cost-effectiveness and socio-economic considerations. As there could be some releases of microplastics under reasonably foreseeable conditions of use the importers or downstream users placing IVD devices and components (e.g. IVD kits, calibration kits) on the market, and benefiting from this derogation shall be required to report the quantities used and released to the market to the Agency (paragraph 8). This action also sends a signal that substitution of microplastics or implementation of containment measures can be sought and encouraged without disrupting the access to IVDs. This could be made via 'voluntary' actions from the sector. In the event, the information gathered via the reporting would reveal that the voluntary measures put in place by the sector do not lead to progressive reduction of release of microplastics into the environment, further regulatory action could be initiated by the EU Commission. In addition, products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7). As IVDs might be used in many areas (e.g. human health, animal health, pest control, research and development field etc.), the wording of the derogation should remain generic and should not refer to in vitro diagnostics undertaken under any specific regulation. <i>In vitro</i> diagnostic devices could also be defined as "reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, whether used alone or in combination, intended by the manufacturer to be used <i>in vitro</i> for the examination of specimens, including blood and tissue donations, derived from living organisms".
4.f	Sludge and compost.	Complete derogation from the scope of the restriction as this was not intended to be part of the scope. Microplastics are indeed not intentionally added into sludge and composts. However, they might be present in industrial sludge and compost supplied or sold to professionals (e.g. farmers) or consumers as a result of water treatment (where microplastics will be removed from the water effluents and partition in sludge) or composting process (where secondary microplastics might be present due to the non-degradability of some composting inputs e.g. partially degradable plastics). These microplastics will be present unintentionally and it is not the intention of this restriction to prevent the placing on the market of these products.
4.g	Food and feed.	A REACH restriction can cover food and feed. As these can unintentionally contain microplastics above the specific concentration limit then it is prudent to ensure that they are specifically derogated.
[4.h]	Infill used at pitches with RMMs to achieve minimal releases.	Option A (as described in Table 1) to address infill material.
5.a	Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use	Generic derogation from the restriction for uses where OC and RMM are implemented that are appropriate to adequately control the risk from the use of microplastics. Includes a requirement that appropriate OCs and RMMs are identified on product labelling, leaflet or instructions for use (IFU). This derogation is generic but is primarily intended to cover uses of microplastics in non-industrial professional or consumer settings, including <i>in vitro</i> medical diagnostic uses at clinical laboratories (e.g. at healthcare centres or hospitals), or water purification applications. Therefore, uses benefiting from this derogation shall be required to

Para.	Derogation	Explanation
		communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the Agency (paragraph 8).
5.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).	<p>Generic derogation from the restriction for uses of microplastics as a substance or in a mixture where the microplastics are 'consumed' or otherwise permanently cease to exist at the point of end use; this principally corresponds to the loss of the particulate nature of the microplastic through various physico-chemical processes or chemical reactions. The change must be permanent and irreversible.</p> <p>This would derogate film-forming functions of microplastics in all sectors, including those in cosmetic products, detergents and maintenance products and in paints/coatings; as well as any products where the microplastic particles cease to exist at the point of end use, such as in instances where they 'dissolve' (e.g. polyelectrolytes or certain detergents).</p> <p>However, as there could be some releases of 'unconsumed' microplastics under reasonably foreseeable conditions of use, these releases should be minimised.</p> <p>Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the market to the Agency (paragraph 8).</p>
5.c	Substances or mixtures containing microplastics where the microplastic are permanently incorporated into a solid matrix during end use.	<p>Generic derogation from the restriction for uses of microplastics as substances or mixtures where the microplastics are permanently 'contained' at the point of use. Permanence is intended to relate to the useful (service) life of the solid matrix, not the waste life-cycle stage.</p> <p>This would derogate certain applications of microplastics in paints/coatings and in materials used in construction (concrete and adhesive). It is not considered to apply to any use that could be considered as temporary, such as use in cosmetic products. Any necessary preceding steps (e.g. mixing before the matrix becomes solid) should also be derogated from paragraph 1.</p> <p>However, as there could be some releases of 'uncontained' microplastics under reasonably foreseeable conditions of use (e.g. during the preparation, application and curing/setting of a solid matrix), these releases should be minimised.</p> <p>Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the market to the Agency (paragraph 8). Appropriate use instructions could include advice to avoid disposal of unused material to drains and watercourses and to clean up areas thoroughly after use. Releases that would occur at the end of the service life of the solid matrix (e.g. when it becomes waste at some undefined point in the future) shall be considered as part of the paragraph 8 reporting obligation.</p>

For selected sectors specific transitional periods are proposed to allow sufficient time:

- to develop or identify alternatives, reformulate and transition to alternatives: agricultural and horticultural products, other rinse-off and leave-on cosmetic products, detergents and maintenance products. No such transitional arrangement was necessary for microbeads in rinse-off cosmetic products or detergents as these uses are expected to be phased out by 2020;
- to implement technical means where microplastics would be contained throughout their use.

Reformulations are expected to constitute the largest economic impact of the proposed

restriction, requiring considerable time and other resource investments. Therefore, the Dossier Submitter tried to align the transitional period of the proposed restriction with the time required by industry to switch to alternatives in order to minimise the negative economic, social and distributional impacts of the restriction, and at the same time to ensure its effectiveness in terms of reduction of microplastics emissions. Factors that were taken into account in the determination of the transitional periods were sector (product group) emissions to the environment and their overall contribution of emissions of intentionally added microplastics, other stakeholder readiness to comply with the restriction (e.g. enforcement authorities to put in place the necessary protocols to monitor the compliance with the restriction), cost-effectiveness, non-monetised impacts as well as practicality and monitorability of the proposed restriction.

The Dossier Submitter is proposing a requirement to communicate relevant instructions for use and disposal (aka 'instruction for use and disposal' requirement), e.g. by labelling, to downstream users and consumers for specific uses, where it is expected that behaviours of the users can be successfully influenced by providing relevant instructions for use (e.g., in relation to the correct disposal of wastes arising from the use for example to brush/roller residues of paints/coatings) in order to minimise releases to the environment.

The Dossier Submitter also proposes that all suppliers placing on the market mixtures containing microplastics that are derogated under paragraph 4 (a), 4 (b), 4 (d), 4 (e) or 5, have to report key information to ECHA to allow the tracking of the quantities of microplastics released to the environment. This reporting requirement is proposed to, among others, monitor the effectiveness of the restriction and to ensure that significant emissions are not occurring from derogated uses.

During the opinion development, the following changes were made to the proposed conditions of the restriction by the Dossier Submitter in response to comments received from the Forum, the consultation and on request of RAC and SEAC:

- Editorial changes to use names to improve clarity;
- Lower size limit of the microplastics in the scope of the restriction increased from 1nm to 100nm;
- Term 'particle-containing polymer' replaced with the term 'polymer-containing solid polymer';
- Clarification added that single molecules are not particles;
- Term 'naturally-occurring polymer' replaced with the term 'natural polymer';
- Additional derogation for polymers with solubility >2 g/L added as paragraph 3(c);
- Additional derogations added to paragraph 4 for food additives (4.d), *in vitro* diagnostics (4.e), sludge and compost (4.f), food and feed (4.g) and infill material (4.h);
- Wording of paragraph 5(a) revised to remove the need for incineration;
- Wording of paragraph 5(b) and 5(c) revised to refer to 'end uses' to distinguish more clearly from the uses at industrial sites referred to in paragraph 4(a);
- Various revisions to durations of the transitional periods proposed;

- Paragraph 7 revised to improve clarity and to align more closely with the intention of the Dossier Submitter, termed 'instructions for use and disposal';
- Paragraph 8 revised to re-focus the information requirements onto the key information required for monitoring the effectiveness of the restriction.

B.3.1.2. RAC conclusion(s)

RAC agrees with the Dossier Submitter's conclusion that a restriction under REACH should minimise releases of intentionally added microplastics to the environment, similarly to PBT/vPvB substances under REACH, in order to minimise the likelihood of adverse effects. The proposed restriction would also minimise the potential for cumulative effects arising from the presence of both primary (intentionally added) and secondary microplastics in the environment.

RAC's conclusions is also justified by the consideration that microplastics have long-term persistence in the environment, are practically impossible to remove once released (irreversibility) and are associated with adverse effects.

RAC agrees that these derogations are warranted taking into account that releases from these uses are not considered to be inevitable and could be minimised by appropriate conditions of disposal. Furthermore, when the microplastics definition criteria are not fulfilled during the use of the substance or mixtures, this use should be derogated.

B.3.1.3. Key elements underpinning the RAC conclusion(s)

B.3.1.3.1. Derogation 4c: Mixtures regulated in the EU under Fertilising Products Regulation

Regulation 2019/1009 provides that from 16 July 2026, the polymers shall comply with the biodegradability criteria established by delegated acts referred to in Article 42(6). In Article 42(6) that by 16 July 2024, the Commission shall assess biodegradability criteria for polymers and test methods to verify compliance with those criteria. Such criteria shall ensure that:

- a) the polymer is capable of undergoing physical and biological decomposition in natural soil conditions and aquatic environments across the Union, so that it ultimately decomposes only into carbon dioxide, biomass and water;*
- b) the polymer has at least 90 % of the organic carbon converted into carbon dioxide in a maximum period of 48 months after the end of the claimed functionality period of the EU fertilising product indicated on the label, and as compared to an appropriate standard in the biodegradation test; and*
- c) the use of polymers does not lead to accumulation of plastics in the environment.*

With these requirements, the release of persistent polymers is avoided even if the biodegradation criteria seem to be less stringent than those proposed in the derogation 3b of this microplastics restriction.

B.3.1.3.2. Derogation 5a: Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use

The Dossier Submitter initially proposed a derogation for substances/mixtures containing microplastics with no release to the environment over the whole life-cycle (requiring disposal

as hazardous waste). Uses benefiting from this derogation would be required to communicate appropriate instructions for use and disposal to minimise releases to the environment (paragraph 7) and report the quantities used and released to the market to ECHA (paragraph 8). The derogation was intended to be applicable to non-industrial uses of *in vitro* diagnostics (note that this use was subsequently proposed for derogation by the Dossier Submitter during opinion-development – See SEAC opinion).

RAC notes that the Forum considered that the derogation as initially proposed could pose challenges in term of enforceability due to the difficulty to ensure that the release of microplastics from a product over its lifecycle is prevented. Also, it would be difficult to ensure that such a product would be incinerated and disposed of as hazardous waste.

During the consultation, stakeholders asked for clarification and derogation extension (# 2118, # 2695). The Dossier Submitter revised the wording of this derogation for “Substances, mixtures or articles where microplastics are contained by technical means to prevent releases to the environment”, to avoid issues with some consumer articles and difficulties with describing microplastic waste as ‘hazardous’. As the restriction’s aim is to avoid environmental release, RAC considers this derogation to be justified.

B.3.1.3.3. Derogation 5b: 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)

The Dossier Submitter proposed this generic derogation from the restriction for uses of microplastics as a substance or in a mixture where the microplastics are ‘consumed’ or otherwise cease to exist at the point of use; this principally corresponds to the loss of the particulate nature of the microplastic through various physico-chemical processes or chemical reactions.

This would derogate film-forming functions of microplastics in all sectors, including those in cosmetic products, household care and maintenance products, medical devices (e.g. certain dental moulds) and in paints/coatings; as well as any products where the microplastic particles cease to exist at the point of use, such as in instances where they ‘dissolve’ (e.g. polyelectrolytes or certain detergents) or permanently ‘swell’ in contact with water to such an extent that they can no longer be considered to be particles as they have lost their interface (e.g. super absorbent polymers; SAPs.) or exceed the relevant size dimensions (e.g. >5mm). Temporary (i.e. reversible under reasonably foreseeable conditions of use) loss of microplastic form is not intended to be derogated.

As releases of ‘unreacted’ microplastics could feasibly occur during end use the derogation requires that suppliers include relevant instructions for use and disposal (para. 7) to minimise the extent of releases and that information on uses and releases are reported (para. 8).

RAC is of the opinion that as solid particles are part of the microplastic definition the loss of the solid form and/or particle boundaries, by e.g. film-forming, is an appropriate exclude the polymer from the restriction scope. However, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the market to ECHA (paragraph 8). Forum stated that this derogation would be difficult or even impossible to enforce, due to the complexity of the issue and considered that an elaboration of the criteria by means of guidance would be helpful. During the consultation, stakeholders requested that

solubility criteria should be added in the definition 5b (#2434) (see earlier in the opinion for a discussion on polymer solubility).

B.3.1.3.4. Derogation 5c: Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use

The Dossier Submitter proposed a generic derogation from the restriction for uses of microplastics as substances or mixtures where the microplastics are permanently contained in a solid matrix (including a solid film) at the point of end use. The intended use of the microplastics is considered to have inherently limited potential for releases to the environment, although releases could occur during the use phase similarly to film-forming applications, via the inappropriate disposal of residual product to wastewater or the cleaning of tools. Releases may also occur during the waste life cycle stage of the solid matrix.

This would derogate certain (non-film-forming) uses of microplastics in paints/coatings (e.g. pigment extenders) and in materials used in construction (fibre-reinforcement of concrete and adhesive). It is not considered to apply to any use that could be considered as temporary, such as use in cosmetics.

However, as there could be some releases of 'uncontained' microplastics under reasonably foreseeable conditions of use, these releases should be minimised. Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the market to the Agency (paragraph 8).

The Forum suggested to clarify if the meaning of "permanently incorporated" extends to the waste lifecycle stage or not. The Dossier Submitter subsequently clarified that the term 'permanently' related to the intended service life of the solid matrix, rather than during any subsequent waste life-cycle stage. RAC notes that [the potential] releases from solid matrices during the waste life-cycle state could be requested in the reporting requirement for uses derogated under paragraph 5c.

During the consultation, stakeholders stated that fibres are articles and should be outside of the scope of this derogation and this restriction (#2544). The Dossier Submitter confirmed that fibre-like particles are intended to be included in the scope of the restriction, irrespective to whether they are considered articles or not. RAC agrees that fibre-like particles with dimensions consistent with a microplastic should be included in the scope of the restriction, potentially by restricting polymers in specific types of articles (fibres used to reinforce concrete/adhesive).

To improve the derogation understanding, RAC considered the merit of combining derogations 5b and 5c. However, after further consideration it was clear that their basis was not similar. 5b is based on the loss of the microplastic identity and 5c is based on the absence of release due to the incorporation of a microplastic in a matrix.

B.3.2. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

B.3.2.1. Summary of Dossier Submitter's proposal

The Dossier Submitter assessed the effectiveness, practicality and monitorability of each of

the following five restriction options identified and analysed prior to selecting its preferred option.

- A restriction on the placing on the market and use of all mixtures intended for consumer and professional use containing intentionally added microplastics (≥ 0.01 % w/w) (without derogations (except for industrial uses or to avoid double regulation) or transitional periods)
- Labelling of all mixtures for consumer and professional use containing intentionally added microplastics (≥ 0.1 % w/w) with the phrase 'contains microplastics > 0.1%', with a requirement for user instructions to minimise releases to wastewater e.g. dispose to municipal waste
- Restriction on the placing on the market and use of specifically identified mixtures or articles for consumer and professional use containing intentionally added microplastics (≥ 0.01 % w/w) (with derogations)
- Restriction on the placing on the market and use of all mixtures for consumer and professional use containing intentionally added microbeads (≥ 0.01 % w/w) (without derogations)
- Restriction on the use of microplastics in consumer and professional products ($\geq 0.01\%$) in a size range of $1\mu\text{m} \leq x \leq 1\text{mm}$.
- Restriction on thermoform and thermoset organic polymer 'plastics' only ($\geq 0.01\%$ w/w).

As a result of this assessment, the current restriction option is supported, whilst the others were discarded. The detailed rationale for not proposing the discarded restriction options is presented in Annex D. In summary, the proposed restriction was found to fulfil the criteria for effectiveness, practicality and monitorability better than the other evaluated restriction options.

The proposed restriction is estimated to result in a cumulative emission reduction of approximately 500 thousand tonnes of microplastics (central scenario) over the 20-year period following its entry into force. This is a reduction of 70% of the quantified emissions of intentionally added microplastics that would have occurred in the absence of the restriction entering in effect over the 20 year analytical period. The annual emission reduction after all transitional periods have expired is calculated to be >90% (Figure 4).

In terms of infill material, if the estimated baseline releases of 16 000 tonnes per year would continue throughout the 20 year analytical period this would result in total releases of 320 thousand tonnes. However, this is likely to be an overestimate as this does not take into account that risk management measures to reduce infill loss are likely to be progressively implemented as a matter of best practice (irrespective of any restriction) as pitches reach the end of their service life and are replaced.

Similarly, the estimate does not include releases of microplastics that are currently occurring from industrial sites that would be reduced as a result of the implementation of the 'instructions for use and disposal' (para 7) and 'reporting' (para 9) elements of the proposed restriction. Losses of microplastics from certain industrial sites can be significant, for example losses of pre-production pellets (nurdles).

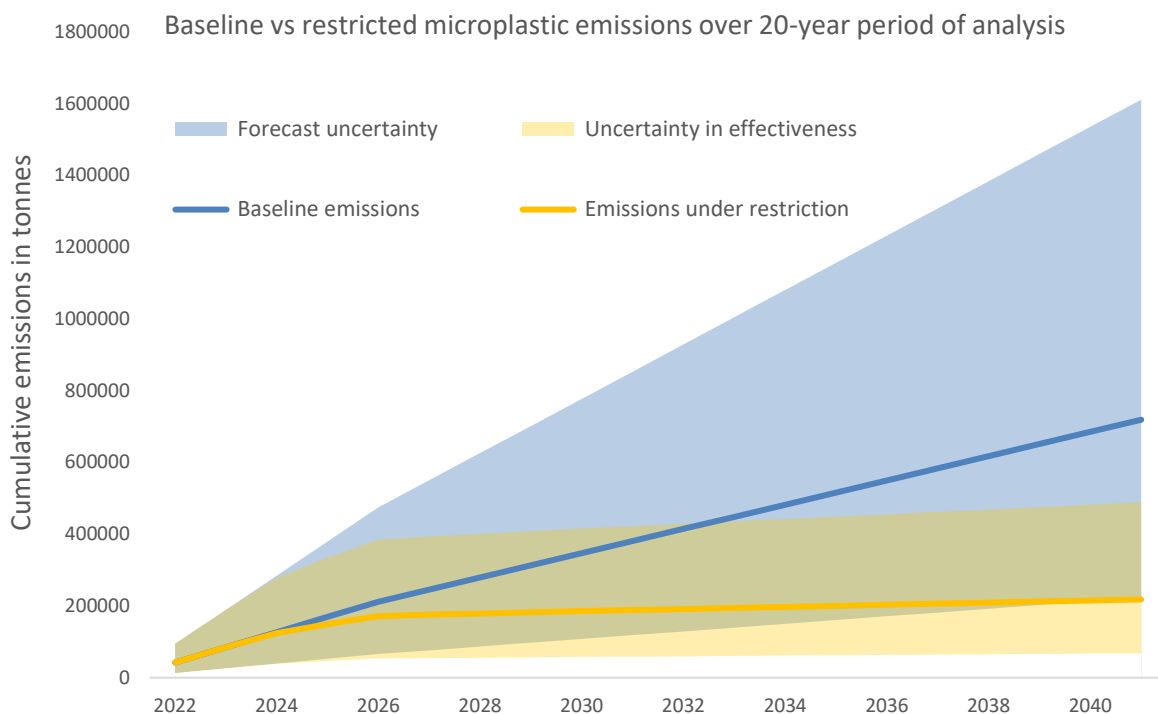


Figure 4 Effect of the proposed restriction on cumulative releases over the period of analysis

B.3.2.2. RAC conclusion(s)

RAC agrees with the Dossier Submitter that the proposed restriction is the most effective option to reduce the identified risks.

RAC concludes that the estimated reduction in the total releases into the environment achieved by the proposed restriction can be used as an estimate of the effectiveness (risk reduction capacity) of the proposed restriction.

B.3.2.3. Key elements underpinning the RAC conclusion(s)

RAC notes that the proposed restriction aims to address the risks from microplastics in certain products that are not adequately controlled. The proposed restriction entails a ban on all microplastics that meet the definition proposed (unless their specific use is derogated from the ban). The ban on use will enter into force at different times for different uses depending on the transition period assessed as necessary to avoid disproportionate socio-economic impacts (see Annex D).

Paragraph 1 of the proposal deliberately captures all uses of intentionally added microplastics, irrespective of sector or technical function; certain sectors or technical functions are derogated.

The restriction applies to microplastics that are substances on their own or in mixtures.

The Commission's request was to investigate the restriction of intentionally added microplastics. However, as the wording 'intentionally added' could lead to enforcement issues, the Dossier Submitter instead has included a concentration limit to discourage intentional

addition of microplastics and an exemption for industrial uses (that take place at industrial sites). The Dossier Submitter considers that a concentration limit of 0.01% w/w would be appropriate to prevent intentional use. This is the concentration of microplastics that are reported to be present in a number of different product categories: detergents, waxes and polishes as well as in fertilisers.

RAC notes that the estimated annual loss of pre-production plastic pellets to the environment in the EU is significant (41 000 tonnes per year). The proposed restriction does not prevent the placing on the market of these materials, but does oblige suppliers placing these substances/mixtures on the market to provide appropriate 'instructions for use and disposal' to Downstream Users to prevent releases to the environment. Downstream Users of these microplastics will also be obliged to report the quantity of releases occurring to the environment on an annual basis. Given the likely scale of these releases compared to those from other intentionally-added microplastics, RAC encourages additional efforts that could further reduce industrial releases of pre-production pellets.

B.3.3. Socio-economic impact

Justification for the opinion of SEAC

B.3.3.1. Costs

B.3.3.1.1. Summary of Dossier Submitter's proposal

See SEAC opinion

B.3.3.1.2. SEAC conclusion(s):

See SEAC opinion

B.3.3.1.3. Key elements underpinning the SEAC conclusion(s)

See SEAC opinion

B.3.3.2. Benefits

B.3.3.2.1. Summary of Dossier Submitter's proposal

See SEAC opinion

B.3.3.2.2. SEAC conclusion(s)

See SEAC opinion.

B.3.3.2.3. Key elements underpinning the SEAC conclusion(s)

See SEAC opinion.

B.3.3.3. Other impacts

B.3.3.3.1. Summary of Dossier Submitter's proposal

See SEAC opinion.

B.3.3.3.2. SEAC conclusion(s)

See SEAC opinion.

B.3.3.3.3. Key elements underpinning the SEAC conclusion(s)

See SEAC opinion.

B.3.3.4. Overall proportionality

B.3.3.4.1. Summary of Dossier Submitter's proposal

See SEAC opinion

B.3.3.4.2. SEAC conclusion(s)

See SEAC opinion.

B.3.3.4.3. Key elements underpinning the SEAC conclusion(s)

See SEAC opinion.

B.3.3.5. Uncertainties in the proportionality section

See SEAC opinion

B.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

B.3.4.1. Summary of Dossier Submitter's proposal

The Dossier Submitter considers that the proposed restriction is practical because it is implementable, enforceable and manageable. The proposal gives sufficient time to the impacted supply chains to transition to alternatives and, on the basis of the proposed regulatory definition of a microplastic, the restriction clearly defines which mixtures are in its scope and where transitional arrangements could be justified to apply.

The Dossier Submitter considers that the restriction is implementable and enforceable, although harmonised analytical methods for detecting microplastics in products are yet to be agreed and a framework of test methods and criteria for identifying (bio)degradable 'microplastics' will likely need to be adapted in due course in response to scientific and technical progress.

This conclusion is on the basis that various existing analytical methods can be readily applied to establish if microplastics are present in mixtures, and that these can be applied in a tiered way, as necessary, to avoid unnecessary testing costs. Furthermore, the use of these analytical methods can be supported by contractual measures to ensure that only non-microplastic polymers are used in products that inevitably lead to releases to the environment.

The restriction is designed so that enforcement authorities can set up efficient supervision mechanisms to monitor compliance with the proposed restriction and is practically implementable for companies. The Dossier Submitter considers that it is possible to determine

if a product includes polymer-containing particles with all dimensions less than 5mm, or fibre-like particles with length <15mm. For the cases where the particle is mainly non-polymer, there is also a need to determine the amount of polymer present in the particle. The Dossier Submitter considers that applied method for determining the amount of polymer will need to be decided on a case-by-case basis, but that suitable methods are available.

B.3.4.2. RAC and SEAC conclusion(s)

Taking into account, among other elements, information in the Background Document, the consultation and the advice given by the Forum, RAC and SEAC are of the view that the proposed restriction options are practical and enforceable. However, the Committees as well as Forum stress that a prerequisite for the validity of this conclusion is that parts of the microplastics definition are clarified, derogations are further explained and extensive guidance for industry and national inspectors is provided. It is clear that for a well-thought-out, but broad and complex, restriction, flanking measures to support the implementation are necessary.

B.3.4.3. Key elements underpinning the RAC and SEAC conclusion(s)

The Committees agree with the Forum that due to the broad scope and complexity of the restriction proposal the elaboration of dedicated guidance would be advisable. This would benefit both national inspectors and industry.

Several issues that are of importance to the practicality and implementability of the proposed restriction need to be discussed. These are analysed below.

B.3.4.3.1. Wording of the restriction

While the Committees have concluded that the wording and scope of the restriction is clear and fit-for-purpose, some clarifications are necessary. Several stakeholders provided comments to that effect during the consultation as well as Forum in its advice.

According to Forum's advice and comments received in the consultation, the following terms needed to be better defined or clarified:

- "industrial sites" in paragraph 4a: insufficient information on how this should be interpreted. During the consultation several industry stakeholders indicated that this should be changed to "industrial installations" in order to be consistent with other restrictions.
- "medicinal products for human or veterinary use" (paragraph 4b): should refer directly to the corresponding Union legislation. This has already been taken into account by the Dossier Submitter during the opinion development (see section B.3.5).
- "other mixtures" in paragraph 6a: it should be explained if this only refers to other cosmetic mixtures or to all mixtures containing microbeads.
- "legible" in paragraph 7: a precise definition should be provided since this seems to be an ongoing issue from a practical enforcement point of view.
- "relevant instructions" in paragraph 7: should be clarified according to Forum.

The Forum (implicitly) asks for these clarifications to be provided in the restriction wording itself. SEAC and RAC note that some of these issues could also be solved through a dedicated

guidance document for the restriction proposal.

B.3.4.3.2. Implementing the restriction

The Dossier Submitter indicates that the implementation of the restriction should prove to be rather straightforward. The Annex XV dossier is however very brief when it comes to providing justifications for this. In the Committees' view the restriction dossier does not capture difficulties that may arise for both companies and national inspectors during the implementation phase of the proposed restriction. In certain instances possible barriers to compliance are not discussed and in other instances they are dismissed even though the characteristics of a sector, or of the way different Member States inspect compliance, are not taken into account³³.

As was indicated previously, RAC and SEAC agree with Forum that sufficient guidance should be provided to both industry and national inspectors in order to maximise implementability of the proposed restriction.

According to the Committees and Forum an essential part of this guidance would be a detailed decision tree that further elaborates on the tiered approach³⁴ mentioned in the restriction dossier. This decision tree could provide a step-by-step guide in order to assess if a polymeric substance is covered by the microplastics definition. Including possible analytical methods in order to assess if a polymer fits the definition and exceeds the concentration limit of 0.01%, is also considered advisable. The Dossier Submitter has however indicated that these methods are available and should therefore be able to provide, at the very least, general information. It is acknowledged that it would be impossible to provide guidance for every situation that would arise for every sector or product group covered. Furthermore, it is also considered advisable to provide a decision tree on the obligations for different actors in the supply chain, address the links with other Community legislation (sectors, emissions and/or product groups) and further clarify the derogations. These decision trees are part of the Background Document (developed by the Dossier Submitter during opinion development), but should be presented to industry and inspectors in a dedicated and more accessible document.

This type of guidance, including both decision trees and further detailed explanations, would not only help companies identify their obligations and test in an efficient and cost-effective way, but also improve the overall implementability, especially for smaller companies.

Several specific issues that warrant further attention are analysed below.

Sampling, preparation and analysis

Forum agrees with the Dossier Submitter that analytical methods are available, but indicates that due to the wide variety of products covered by the restriction different sample preparation techniques will need to be applied as well as normalisation efforts. Applying the most appropriate one in a specific situation will be key for the implementability and enforceability of the proposed restriction.

³³ As an example, in certain Member States joint REACH – Cosmetics/detergents/PPP inspections are carried out, in others not.

³⁴ E.g.: Does the mixture contain solid particles? What is the size and morphology of these particles? Do these particles contain polymeric material? What is the concentration of these particles in the mixture? Are the microplastics biodegradable?

Forum also indicates that the measurement of nanoplastics will be problematic (impossible or at extremely high testing cost). This is echoed by several comments made during the consultation. It should however be noted again that due to the broad scope of the proposed restriction a multitude of analytical methods will need to be applied.

RAC and SEAC acknowledge current technological barriers in identifying microplastics <100 nm. Discussions with the JRC have indicated that, at the moment, this size limit is the cut-off for performing reliable analyses on individual particles. SEAC therefore proposes to limit the targeting of the restriction to microplastics >100nm until the aforementioned technological barriers have been resolved.

There appears to be microplastic particles in sizes down to at least 50 nm on the market, and as these might be the most toxic, it would be strange from a risk assessment point of view to exclude those from the restriction. On the other hand, the analytical methods may not be straight-forward until reaching sizes of 1µm or even larger (especially if present in complex mixtures). Thus, from a regulatory enforcement point of view, limits of 1nm, 50nm, or 100 nm may all be equally challenging and there are neither analytical nor other scientific reasons for choosing one of them. RAC therefore proposes not to set a lower limit in order that microplastics that cannot be analytical determined are not inadvertently excluded from the restriction. RAC notes that the revised paragraph 7 requirements for 'instructions for use and disposal' require upstream suppliers to identify if the products they place on the market for industrial use (i) contain microplastics and would therefore be subject to the conditions of the proposed restriction and (ii) the mass or concentration of microplastics present. On this basis formulators should be able to avoid using raw materials containing microplastics in products (and demonstrate this to enforcement authorities if necessary) irrespective of the possibility to detect them analytically in final formulations.

However, as restrictions usually have limits, and some FORUM members advocated using a lower limit, the following factors should be considered if setting a lower limit;

microplastic particles down to sizes of 50 nm are used on the market, and should thus be included. Limits of 50 or 100nm would probably be equally efficient as it is sufficient that 1% of the particles exceed the size limit (if at all possible to measure in products) for the restriction to kick in.

In theory, there are analytical methods that are appropriate for microplastics >100 nm. However, the analytical methods are probably equally bad in the 50-100 nm size range for complex products.

The Committees assume that companies themselves know what they put in their products and also know how to analyse them for quality and compliance purposes, which should in theory ease enforcement. This statement does however not imply that internal procedural and organisational changes will not be necessary.

It remains clear that, unless enforcement can be performed by checking raw materials, the analysis of mixtures containing microplastics will be the key factor affecting the implementability and enforceability of the proposed restriction.

Transitional periods

The choice of the transitional period has already been discussed, but from an enforcement standpoint it should be noted that the identification of the most appropriate analytical methods for the different products within the scope of the proposed restriction will be key.

Since the Dossier Submitter has indicated that methods are already available and reliable for microplastics >100 nm (confirmed by JRC), the Committees consider that the currently proposed transitional periods should afford inspection services and industry enough time to prepare for future compliance checking.

The implementability for certain sectors, such as the agri- and horticultural sector, will heavily depend on biodegradable polymers becoming available during the transitional period. If this is not the case than SEAC considers that the proposed restriction cannot be considered implementable. Since the Committees cannot predict the future evolution of this technology, a review of the state of play at or just before the end of the transitional period is warranted in this case.

In conclusion, RAC and SEAC find the restriction to be practical and enforceable if clarifications and guidance are provided to both industry and inspectors. It is clear that for a well-thought-out, but broad and complex, restriction, flanking measures (e.g. guidance documents) to support the implementation are necessary.

B.3.5. Monitorability

Justification for the opinion of RAC and SEAC

B.3.5.1. Summary of Dossier Submitter's proposal

The Dossier Submitter concludes that it is possible to monitor the implementation of the proposed restriction via calculating emissions and, potentially, through monitoring studies of certain types of relevant microplastics in waste water and sludge (e.g. microbeads, which tend to be fairly large). For uses derogated from the restriction on use, the proposed reporting requirement will allow information on them to be gathered and, where necessary, future additions to the restriction could be considered. For imported mixtures, the compliance control can be accomplished by border authorities and notifications of any violation of the restriction can be reported in the RAPEX system.

B.3.5.2. RAC and SEAC conclusion(s)

Based on the information in the Background Document and the Forum advice on this aspect SEAC concludes that the proposed restriction option for intentionally added microplastics is monitorable with following caveats:

- appropriate flow of information between the different public services responsible for REACH and sector specific legislation (e.g. cosmetics, detergents, agro-industry) is achieved;
- appropriate guidance is available for all private and public stakeholders.

B.3.5.3. Key elements underpinning the RAC and SEAC conclusion(s)

The Dossier Submitter indicates that monitoring of certain sectors and/or product groups covered by the proposed restriction can be done through inspection campaigns also checking compliance with specific Community legislation (cosmetics, detergents, etc.). This presumes that every piece of chemicals legislation is enforced jointly or by the same national inspectorate in every Member State, which is not always the case in every Member State. Organisational choices made within Member States may therefore sometimes hamper proper

monitoring of the effectiveness of the proposed restriction.

The Committees consider that the proposed reporting requirement is not a measure to monitor the effectiveness of the proposed restriction. Reporting only gives information on (the evolution of) emissions to the environment from uses not covered by the ban, not overall emissions of microplastics. However, it is considered to be relevant in order to assess if additional measures are needed in the future to reduce microplastics emissions that are not addressed with the current proposal.

RAC and SEAC wish to stress that, as is the case for the practicality, the monitorability of the proposed restriction will depend on the availability of proper guidance for both inspectors and industry.

B.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

B.4.1. Summary of Dossier Submitter's proposal

The uncertainties related to risk assessment of microplastics are described in the respective sections on hazards, fate, exposure and risks. Of particular note are the paucity of hazard data for terrestrial species and for nanoplastics, in general. The non-threshold based approach to risk assessment (and the minimisation approach to risk management) was adopted in response to these uncertainties.

Assumptions and uncertainties relevant for the socio-economic analysis of the individual sectors in the scope of the restriction proposal are detailed in their respective sector-specific assessment presented in Annex D and highlighted in the opinion sections above. The main uncertainties in the analysis are due to ambiguity regarding the tonnages of microplastics affected by the proposed restriction and, where relevant, the number of reformulations that can be expected to be induced.

To test these and other uncertainties and assumptions, sensitivity analysis was performed. (See Annex D.) As summarised in the preceding sections, the conclusions on the proportionality of the proposed restriction hold also when worst-case values for key assumptions are applied.

However, for some sectors (e.g., agriculture and horticulture, detergents with encapsulation technology), the conclusion on proportionality is conditional on biodegradable alternatives with the same or similar functionality becoming available in the medium term. If this were not the case, then this would cast doubt on the proportionality of the proposed restriction, as the benefits of non-degradable polymers used in some sectors (e.g., agriculture and horticulture) can be substantial.

When considering the optimal length of transition before the (bio)degradability requirement becomes binding, several aspects need to be balanced against each other. On one hand, more time for adoption allows a smoother transitioning which may be particularly important for SMEs; on the other hand, a shorter period is more effective in curbing emissions and may thus be preferable from an emission-reduction point of view.

B.4.2. RAC conclusion(s)

- The effectiveness (in relation to emission reduction) of the instructions for use and disposal will be dependent on the measures proposed by suppliers and how readily they are implemented by downstream users, consumers and professionals.
- Uncertainties remain in relation to the criteria proposed for derogating biodegradable polymers from the restriction. The key uncertainty relates to the potential for the derogation to continue to allow the placing on the market of materials that biodegrade so slowly in the environment that they contribute to the microplastic concern.
- A key uncertainty relates to the analytical challenges of detecting, characterising and quantifying the very smallest (<1µm) microplastics. These are legitimate uncertainties, which could introduce challenges in relation to enforcement. Enforcement through supply chains will address many of the uncertainties introduced by analytical methods.

B.4.3. Key elements underpinning the RAC conclusion(s)

RAC has elaborated on the uncertainties in relation the risk assessment, and their significance, in preceding sections of the opinion. RAC notes various other uncertainties associated with the proposal in relation to effectiveness and practicality (including enforceability).

In relation to effectiveness, RAC considers that there are several uncertainties the merit highlighting. The restriction is based on three elements (i) a ban on placing on the market for uses where releases are inevitable, (ii) a requirement for instructions for use and reporting where releases are possible, but there is scope for them to be minimised and (iii) a reporting requirement. The effectiveness of the ban on placing on the market is clear. However, the effectiveness of the instructions for use and disposal will be dependent on the measures proposed by suppliers and how readily they are implemented by downstream users, consumers and professionals. Manufacturers are familiar and experienced with recommending appropriate OCs and RMMs to Downstream Users as part of their existing REACH registration obligations. Downstream Users are less familiar with this process, which could lead to inappropriate or inconsistent recommendations of 'appropriate conditions of use and disposal' to Downstream Users but are likely build upon their experience with SDS over time.

If the instructions for use and disposal requirements are coordinated by sector associations or under existing certification or product stewardship schemes (e.g. Plastic Europe's Operation Clean Sweep), as envisaged by the Dossier Submitter, there is less potential for inconsistent or information of limited usefulness to pass through supply chains. The spERC (specific environmental release category) concept developed by sectors for use in REACH registration can be used as a template for how appropriate conditions of use and disposal could be developed on a sector level. The proposal was set out by the Dossier Submitter to be intentionally flexible allowing industry actors to research and implement the most effective measures for their particular uses. Such an approach puts the burden on industry to make robust and effective recommendations, and therefore introduces some uncertainties as to the effectiveness that will be achieved in practice, but allows innovative approaches to be developed and adopted where these are likely to be more effective. It is consistent with existing REACH concepts and the reversal of the burden of proof.

Downstream Users are used to following safety advice from suppliers. The effectiveness of the instructions passed by suppliers to consumers is less well understood, although the

Dossier Submitter cites several studies in the Background Document supporting their effectiveness, particularly for mixtures that are used infrequently and which are considered as potentially dangerous by consumers. There is less information available on the effectiveness of warnings and instructions on everyday products, which remains an uncertainty. Importantly, the reporting obligation is complementary to the instructions for use and disposal requirement and, indirectly, will provide information on the effectiveness of the instructions for use and disposal requirements, addressing the uncertainties identified above, over time. The implementation of the reporting requirement itself is also relatively uncertain as the requirements, as set out in paragraph 8 of the proposal, are only briefly described. The implementation of the format by ECHA will address uncertainties with respect to the level of detail required for polymer identity. The development of the reporting is likely to follow, and build upon, recent developments and innovations implemented as part of the harmonisation of poison centres reporting.

Uncertainties remain in relation to the criteria proposed for derogating biodegradable polymers from the restriction. These are elaborated in detail earlier in the opinion. The key uncertainty relates to the potential for the derogation to continue to allow the placing on the market of materials that biodegrade so slowly in the environment that they contribute to the microplastic concern. The modifications to the criteria recommended by RAC partially address these uncertainties, but not entirely. It should be noted that all of the derogated materials **will** have inherent potential to undergo biodegradation. In this respect they will differ from conventional plastics, such as PP, HDPE, LDPE and PVC, which do not. Further research will be needed to address all the identified uncertainties. Polymers that meet the OECD screening criteria are already available on the market in some applications (notably for cosmetic products). However, it is not currently known if polymers for all relevant microplastic applications can be found that will achieve the revised criteria for Appendix X proposed by RAC.

In terms of practicality, RAC notes several areas of uncertainty, RAC acknowledges that the definition of a microplastic is complex and generic. The advantages of a generic approach are considered to outweigh the difficulties in interpretation. In the majority of cases it will be clear if a substance or mixture contains a microplastic, but there will remain uncertainties in interpretation as it is not possible to foresee all permutations.

Clearly, a key uncertainty relates to the analytical challenges of detecting, characterising and quantifying the very smallest (<1µm) microplastics. These are legitimate uncertainties, which could introduce challenges in relation to enforcement. However, the majority of microplastics are much larger particles that are readily characterised. The transitional arrangements proposed by the Dossier Submitter are considered to be sufficiently long to allow significant analytical progress to be made prior to a requirement for enforcement. RAC notes that concerted efforts for analytical method development for microplastics only began relatively recently (i.e. within the last five years) consistent with the growing interest in the topic in academia. Rapid progress has already been made and RAC expects this to continue into the future, building upon the work on nanomaterials. Enforcement through supply chains will address many of the uncertainties introduced by analytical methods.

Similarly, derogation in paragraph 5b may cause some difficulties. Although the concept is clear, further practical guidance and examples would be likely to help both industry and enforcement authorities.

REFERENCES

References not in the Background Document

- Elert, A.M., Becker, R., Duemichen, E., Eisentraut, P., Falkenhagen, J., Sturm, H. and Braun, U. (2017) Comparison of different methods for MP detection: What can we learn from them, and why asking the right question before measurements matters? *Environmental Pollution*, 231(Part 2), 1256-1264.
- FIFA 2017. Environmental Impact Study on Artificial Football turf. FIFA, Zurich, Switzerland. Available online https://football-technology.fifa.com/media/1230/artificial_turf_recycling.pdf. Accessed 22/06/2020
- HERNANDEZ, L. M., YOUSEFI, N. & TUFENKJI, N. 2017. Are there nanoplastics in your personal care products. *Environmental Science & Technology Letters*, 2017, 4, 7, 280-285.
- Lindeque, P.K., Cole, M., Coppock, R.L., Lewis, C.N., Miller, R.Z., Watts, A.J., Wilson-McNeal, A., Wright, S.L. and Galloway, T.S., 2020. Are we underestimating microplastic abundance in the marine environment? A comparison of microplastic capture with nets of different mesh-size. *Environmental Pollution*, p.114721.
- Wolf, J.R., 2016. radiolabelled polymers containing covalently bound ³H and ¹⁴C. *Journal of Labelled Compounds and Radiopharmaceuticals*, 59(2), pp.38-47.
- Zumstein, M.T., Schintlmeister, A., Nelson, T.F., Baumgartner, R., Wobken, D., Wagner, M., Kohler, H.P.E., McNeill, K. and Sander, M., 2018. Biodegradation of synthetic polymers in soils: Tracking carbon into CO₂ and microbial biomass. *Science advances*, 4(7), p.eaas9024.

ANNEX 1

Table A1.1 Scenario 1 - Dossier Submitter's proposal

Element to evaluate	1. Dossier Submitter's proposal
Summary of scenario	<p>The Dossier Submitter's proposal (detailed in Table 22 of the Background Document) requires that a microplastic achieve the pass criteria in one of the listed test methods to be derogated from the proposed restriction. Where microplastics are deliberately applied to soil or foliage (e.g. controlled-release fertilising products) test methods applicable to this compartment shall be used. The test material (including additives and other substances were relevant) should be comparable to either (i) the particles produced, or if not technically feasible, (ii) the particles released at the point of use. Where the test material consist of more than one polymeric component (i.e. it is a blend), in addition to demonstrating the (bio)degradation of the microplastic, the biodegradation potential of each of the polymeric components in the blend must also be demonstrated. Tests shall be conducted by laboratories accredited to ISO 17025 or certified to GLP.</p>
Advantages	<p>The proposal is straightforward with clear 'exit' criteria; achieving the pass criteria in any of the permitted test methods specified in groups 1 to 5 is sufficient to demonstrate that a test material should be derogated from the restriction. G1,2,3 and 5 contain the tests already used for assessing biodegradability under REACH and CLP regulations and, therefore, there is extensive experience of their performance (for soluble substances at least). G4 contains a group of tests specifically developed for plastics, which are assumed to be well suited for testing the biodegradation behaviour microplastics.</p> <p>The producer of the microplastic can choose from a range of different test methods based on the properties of the microplastic and how (and where) they are used (a soil-specific test in groups 4/5 is required if the microplastic is intended to be directly applied to soil or foliage). The inclusion of relatively conservative, but simple/rapid, screening tests in groups 1 to 3 of the scheme means that longer term testing will not be needed in all cases if a test material can achieve the pass criteria for these tests (but it is acknowledged that the pass criteria for these tests will be too stringent for many microplastic test materials). Therefore, the time and resources necessary to demonstrate that a polymer is derogated from the proposed restriction can be limited in some cases.</p> <p>The simplicity of the proposal provides certainty and at least some predictability for manufacturers and users of microplastics, therefore presumably supporting innovation to biodegradable alternatives to persistent microplastics.</p> <p>The requirement for ISO 17025 or GLP quality assurance ensures that the data generated will be reliable and reported in sufficient clarity for enforcement to take place.</p>
Disadvantages	<p>The disadvantages of the Dossier Submitter's proposal can be grouped as follows:</p> <ol style="list-style-type: none"> 1. Comparability, in terms of underlying rationale, of the different test methods 2. Adequate consideration of relevant environmental compartments and conditions

Element to evaluate	1. Dossier Submitter's proposal
	<p data-bbox="573 280 987 309">3. Requirement for case-by-case testing</p> <p data-bbox="483 331 1216 360"><i>Comparability, in terms of underlying rationale, of the different test methods</i></p> <p data-bbox="483 383 2101 552">With the exception of the group 5 (OECD simulation) tests, the pass criteria of the different tests are not directly related to the environmental half life values used to define environmental persistence of concern under REACH (i.e. P and vP criteria included in Annex XIII of REACH). Instead, the test methods are used to demonstrate that test materials are either (i) sufficiently rapidly biodegradable that they can be assumed to not be persistent in the environment under any conditions (G1,2,3 screening tests) or (ii) that they have inherent biodegradation potential similar to reference materials that are 'generally regarded as biodegradable' e.g. cellulose (G4 ISO tests) .</p> <p data-bbox="483 574 2107 711">Therefore, it is clear that the different test methods do not provide equivalent information and are not directly comparable to one another, despite all being used to justify derogation. Whilst the pass criteria associated with the indirect assessments performed in the screening tests included in G1,2,3 are generally accepted to mean that a test material would not be persistent in the environment (as measured against the criteria in Annex XIII of REACH), the relevance of the indirect assessment of biodegradation performance relative to a reference material, at least in relation to the P and vP criteria in Annex XIII of REACH, in the group 4 tests is not known.</p> <p data-bbox="483 734 2101 938">Although G4 tests provide relevant information, the comparability of the results of the G4 tests with the results of other tests is challenging as there is no common reference point between them and the other tests. Achieving the pass criteria in an ISO test would mean that a material has similar biodegradation behaviour as a biodegradable reference substance (under the conditions of the test) but its degradation half-life in the environment would not be known. The implications of this, from the perspective of ensuring that derogated materials do not persist over the long-term in the environment (one of the key microplastic concerns), is not fully clear. Although relatively standard for the assessment of soluble substances, there is limited practical experience of performing G5 tests with microplastics. It is also pertinent to note that the availability and practicality of undertaking G5 tests with microplastics (non-soluble particulate test materials) should not be assumed.</p> <p data-bbox="483 960 1115 989"><i>Adequate consideration of relevant environmental compartments</i></p> <p data-bbox="483 1011 2101 1254">Where G4 and G5 tests are used to demonstrate biodegradability (i.e. the pass criteria in G1,2 and 3 tests cannot be achieved), and with the exception of the requirements for microplastics applied to soil or foliage, as only a single passing test is required it is possible that a producer would choose the test where the MP is most likely to pass, without due consideration of the compartment's relevance (e.g., a material may be more likely to pass a terrestrial compartment test but is released to the environment via the aquatic compartment). Equally, as the fate and behaviour of microplastics in the environment are likely to result in them being transferred between compartments after they are released, the appropriateness of requiring testing G4 or G5 tests for only a single compartment can be considered to have questionable effectiveness (in terms of the objective of the derogation) as microplastics may not achieve pass criteria (and could therefore be very persistent) in other relevant compartments.</p> <p data-bbox="483 1276 853 1305"><i>Requirement for case-by-case testing</i></p>

Element to evaluate		1. Dossier Submitter's proposal
		The Dossier Submitter's proposed requires case-by-case assessment of all of the different microplastics that are placed on the market. Given the large number of potential microplastic formulations (polymers + additives) this could require large amounts of testing to be undertaken.
Uncertainties		<p>MPs derogated using ISO tests are inherently biodegradable, but the tests do not give an indication of environmental half life.</p> <p>Furthermore, by passing only a single test from groups 4 and 5 (representing one environmental compartment), the microplastic may be derogated, but it may not degrade sufficiently quickly across all relevant compartments. In addition, the applicability of P and vP criteria to particulate materials is subject to uncertainty (P and vP criteria were calibrated for soluble chemicals) and will, in all likelihood, be challenging to achieve for particulate materials, even particulate materials of reference materials such as cellulose (depending on particle size).</p>
REACH Action 10 uncertainties	(i) what information is needed to address the uncertainties	There is a need for a comparative study or studies on the relationship between testing approaches underpinned by using a reference material and those using radiolabelled material to establish environmental half lives. The results of the comparison will shed light on the environmental relevance of both ISO-tests and G5 tests undertaken using particulate test materials. Information on the performance of particulate reference materials in G5 testing (relative to Annex XIII P and vP criteria).
	(ii) the timeline for generating such information, who could generate the data	As both ISO and OECD simulation tests are relatively long to perform (6 months to two years), it may take 5-10 years (assuming funding) to get sufficient data. Industry is most likely to be able to design such a project considering their access to relevant microplastic test materials. However, in this scenario, Industry is not under obligation to produce these data.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		Passing this scenario will ensure that the microplastic has an inherent possibility to be biodegrade. However, the rate of biodegradation in the environment is unclear if the derogation is based on passing a G4 test (the test compares biodegradation with that of a reference substance), and if derogated based on G4 or G5 tests in one compartment, the overall biodegradation across different environmental compartments (the overall environment) is unclear. Thus, although ensuring biodegradation would be likely to occur in at least some environmental compartments, the proposal may not ensure that all derogated materials would biodegrade in all relevant environmental compartments.
Practicality, including enforceability		<p>The tests are already performed, so the main practical problem concerns the long testing duration of the group 4 and 5 tests and the lack of experience of testing microplastic test materials in G5 simulation tests, including the feasibility of synthesising radio-labelled polymers/microplastics.</p> <p>The scenario is enforceable, but it requires experience in assessing the outcome of the biodegradation tests that the derogation is based on.</p>

Element to evaluate	1. Dossier Submitter's proposal
Stringency	Not very stringent. As only a single test needs to be passed (including at G4/G5).
Conclusion	The proposal provides clarity to industry and enforcement authorities, but may not fully prevent derogated materials contributing to the microplastic concern as although derogated materials are demonstrated to biodegrade in one compartment they may not degrade sufficiently rapidly in all environmental compartments.

Table A1.2 – RAC-52 proposal

Element to evaluate	2. RAC-52 proposal
Summary of scenario	<p>Modified Dossier Submitter proposal:</p> <ul style="list-style-type: none"> - Tests included in G1,2,3 and Dossier Submitter's proposal - G4 testing modified to require a pass in three ISO tests with derogation conditional on also achieving a pass in three (G5) OECD simulation studies against P half-life (within 10 years from placing MP on the market). - Intended to be time limited (could be reviewed if sufficient information/understanding is achieved or if sufficient information/understating is available from another source).
Advantages	<ul style="list-style-type: none"> - This scheme offers high level of environmental protection by explicitly addressing relevant identified uncertainties within the scheme itself: - Comprehensive testing requirement ensures protection of all environmental compartments - Uncertainties are addressed by those undertaking to place biodegradable polymers on the market (consistent with the principle of the reversal of the burden of proof under REACH)- - The specificity of microplastics acknowledged with the integration of G4 tests - Addresses ISO tests uncertainties and the transferability of their results to the environment with the inclusion of OECD simulation testing and a requirement to test all compartments. - Relevant for either P or vP evaluation (or other pass/fail criterion) since DT50 is obtained - Would avoid the placing on the market of materials that may achieve the pass criteria in G4 (ISO tests) but would not degrade sufficiently rapidly in the environment to avoid a microplastic stock in the environment

Element to evaluate		2. RAC-52 proposal
		<ul style="list-style-type: none"> - Allows sufficient time for the development of technical expertise and capacity to perform the G5 tests with microplastics by only requiring these tests to be performed after an extended period after placing a G4 derogated microplastic on the market.
	Disadvantages	<ul style="list-style-type: none"> - Assumes that G5 tests and pass criteria based on P/vP are appropriate to address the microplastic concern and will be technically possible to perform as they are mandatory if G1,2,3 tests pass criteria are not met (i.e. feasibility to radiolabel polymers/microplastics), whilst this is subject to considerable uncertainty. - Many (at least 6) relatively long tests are required if G1,2,3 pass criteria cannot be achieved and thus a long time period is necessary to perform them. - Testing will be time, resource and economically intensive – considerable adverse predictability and certainty for industry if G4 is used as the basis for a derogation (at least until G5 testing is performed and passed). Industry may choose to skip G4 tests completely to mitigate these uncertainties and proceed directly to G5 testing, despite inherent uncertainties. - To carry out these tests, MPs should be radiolabelled. To use the simulation tests and their results, the DT50, setting the thresholds to obtain the derogation is necessary.
	Uncertainties	<p>Although the aim of this scheme is to minimise the uncertainties linked to the transferability of the ISO tests to the environment there are some key remaining uncertainties. The principle uncertainty being the technical feasibility of performing G5 testing with microplastics. G5 testing is optional under the Dossier Submitter's proposal, but becomes mandatory under this revised proposal if G1,2,3 test pass criteria are not achieved. Should G5 testing prove to be impossible then only microplastics that pass G1,2,3 test pass criteria can be derogated from the proposed restriction. In addition, the applicability of P and vP criteria to particulate materials is subject to uncertainty (P and vP criteria were calibrated for soluble chemicals) are will, in all likelihood, be challenging to achieve for particulate materials, even particulate materials of reference materials such as cellulose (depending on particle size)..</p>
REACH Action 10 uncertainties	(i) what information is needed to address the uncertainties	<ul style="list-style-type: none"> - Information on the practical application of G5 testing methods to microplastics. Information on the performance of particulate reference materials in G5 testing (relative to Annex XIII P and vP criteria). - Only ISO tests seem tailored for MPs, but there are uncertainties in relation to their representativeness to the environmental conditions. OECD simulation tests are more environmentally representative. There is a lack of correlation between the results of ISO and OECD tests. Testing with both G4 and G5 tests, as proposed in this scheme, deals with this uncertainty.
	(ii) the timeline for generating such information, who could generate the	<ul style="list-style-type: none"> - 10 years would be a sufficient time to perform the tests and fulfil the uncertainty linked to the ISO tests

Element to evaluate		2. RAC-52 proposal
	data	
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		<ul style="list-style-type: none"> - Passing this scenario will ensure that derogated microplastic are not persistent across various different environmental compartments.
Practicality, including enforceability		<ul style="list-style-type: none"> - Testing will be time, resource and economically intensive. - Technical feasibility of undertaking G5 testing with microplastics is currently unknown; scenario assumes that technical progress will occur before G5 testing results are required.
Stringency		Very stringent. Scheme intended to provide a high level of protection to the environment. Assumes that confirmatory testing with G5 with P or vP criteria is fit-for-purpose for assessing the persistence of particulate materials, but these criteria could prove to be very difficult to achieve, even for particulate reference materials. On this basis the scheme could be overly stringent by failing to derogate materials that would not contribute to the microplastic concern.
Conclusion		This scheme is environmentally relevant and will ensure that derogated materials will not contribute to the microplastic concern but it is time and resource intensive for industry and, at present, its technical feasibility (because of G5 testing experience with microplastics) is unknown. There are also uncertainties regarding the appropriateness of using the P and vP half-life criteria as G5 pass criteria and considerable challenges for industry in relation to certainty and predictability until G5 testing is completed.

Table A1.3 – All compartments at G4/G5

Element to evaluate		3. 'All compartments' at G4/G5
Summary of scenario		DS scheme modified such that, if G1,2,3 pass criteria are not achieved, three ISO (G4) test passes are required to justify derogation (rather than one as proposed by the DS). G5 testing (against P or vP criteria) is not mandatory but corresponding G5 test(s) may be used to justify derogation should an equivalent G4 level test not achieve the pass criteria. Acknowledges that based on the relative uncertainties G4 and G5 are not part of a hierarchy, but both are equally acceptable means upon which to justify a derogation – note: on this basis, and for the purposes of this scenario, it is assumed that a corresponding G4 test could equally be used justify a derogation where G5 pass criteria are not met.
Advantages		<ul style="list-style-type: none"> - Having a requirement to pass 3 ISO-tests that represent different environmental compartments (soil, aqueous environment, marine water/sediment) will increase the likelihood that microplastic particles will biodegrade in the environment (after taking into account relevant fate and transport processes). - Differently from OECD tests, ISO tests are specifically developed for microplastics. - The testing strategy is simpler to perform and less time consuming with respect to scenario 2 (above). No OECD simulation tests are needed to confirm ISO test results. ISO tests and OECD G5 tests are on the same level in the strategy
Disadvantages		<ul style="list-style-type: none"> - ISO tests are performed in different environmental compartments, but there is incomplete understanding of their relevance to actual environmental conditions, specifically in relation to DT50. - ISO-tests can take a long time to perform (up to 2 years). - G5 tests will need to be performed for any compartment that fails corresponding G4 tests. If these tests are run sequentially then could be a long process.
Uncertainties		Environmental relevance of the ISO-tests, but also the technical feasibility of G5 tests (radiolabelling of polymers/microplastics) and appropriateness of vP/P criteria for particulate materials.
REACH Action 10 uncertainties	(i) what information is needed to address the uncertainties	<p>Same as scenario 1:</p> <p>Technical feasibility of undertaking G5 tests with microplastics, including feasibility of radiolabelling polymers/microplastics.</p> <p>There is a need for a comparative study or studies on the relationship between testing approaches underpinned by using a reference material and those using radiolabelled material to establish environmental half lives. The results of the comparison will shed light on the environmental relevance of both ISO-tests and G5 tests undertaken using particulate test materials.</p> <p>Information on the performance of particulate reference materials in G5 testing (relative to Annex XIII P and vP criteria).</p>

Element to evaluate		3. 'All compartments' at G4/G5
	(ii) the timeline for generating such information, who could generate the data	As the ISO-and OECD tests are rather long, it may take 5-10 years (assuming funding) to get sufficient data to enable a firm conclusion on the environmental relevance of the ISO-tests. Data could be generated by industry or academia.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		As described above, the environmental relevance of the ISO-tests is not clear, but OECD simulation tests, mandatory for a G4 fail, are more representative of actual environmental conditions, but there are uncertainties in relation to the appropriateness of P and vP criteria for particulate substances, such as microplastics.
Practicality, including enforcability		Unless pass criteria are achieved in G1,2,3 screening tests, G4/G5 testing will be time and resource intensive. Technical feasibility of undertaking G5 testing with microplastics is currently unknown.
Stringency		Stringent. Scheme requires a test material to pass either a conservative screening test or achieve pass criteria in multiple ISO or OECD simulation studies.
Conclusion		The scheme is implementable. Comprehensive testing requirements for different environmental compartments is likely to ensure derogated materials do not contribute to the microplastic concern, but there will be some remaining uncertainty with respect to environmental half-lives of degraded microplastics if G5 testing is not performed. Similar timeline as Dossier Submitter proposal, but greater resources as more testing at G4 and G5 is needed. Nevertheless, this scheme does not solve the ISO tests uncertainties by itself and research into the relationship between reference substance and simulation testing biodegradation tests would be a high priority.

Table A1.4 - OECD test methods only (G1, 2, 3 and/or 3 x G5)

Element to evaluate	4a.OECD test methods only (G1, 2, 3 and 5)
Summary of scenario	Scheme based on OECD test methods only (G1,2,3,5)
Advantages	<ul style="list-style-type: none"> - OECD tests are required in REACH and/or CLP regulations and used widely for all substances. In this case microplastics will be assessed according to the standard methods. The testing strategy will be consistent among substances in REACH regulation There is a lot of experience with the OECD tests, making interpretation of data easier, e.g. with respect to environmental relevance of the data. Due to the specificity of microplastics, the standards with an extended test duration are accepted (similar to P, vP criteria). - This scheme permit to capture the biodegradable and the not persistent alternatives. - Passing the screening tests is considered enough to demonstrate that the polymer is not persistent in the environment. - Lack of degradation in an inherent biodegradability test equivalent to the OECD TG 302 series would provide sufficient information to confirm persistence without the need for further simulation testing. - Testing scheme requires to test microplastics in all three compartments in OECD simulation tests and would thus provide ideally information on the persistency of the particles in the real environment conditions as well as handle the concern of microplastics best possible way.
Disadvantages	<ul style="list-style-type: none"> - The OECD screening tests are considered as stringent for polymers and not tailored for microplastics. - No enough experience that OECD simulation tests are easy to apply to microplastic. A critical point is the interaction between bacteria (normally in liquid phase) and microplastics in solid phase. - A long time period is necessary to perform the OECD simulation tests and to derogate definitely to the restriction. To use the simulation tests and their results, the DT50, setting the thresholds to obtain the derogation is necessary. - The amounts of test item introduced in the test vessels may lead to limitations on the shape and the size of the item to be tested
Uncertainties	<p>Group1 to 3 are OECD tests designed for soluble substances and not for microplastics. OECD screening tests are conservative leading to a possibility to return negative results (materials that will not pass the screening tests but would not be persistent in the environment). In this case, OECD simulation tests could be useful to perform.</p> <p>Group 5 tests are not designed for microplastics and it is also unknown how feasible it will be to produce radiolabelled polymers/microplastics. Particulate test material could fail P or vP, but not be persistent over the long-term in the environment (particulate cellulose may not pass P/vP criteria (depending on particle size).</p> <p>Furthermore, the pass levels required for the tests (60 or 70%) do not allow to assess biodegradation of components present in small amounts.</p> <p>Care should be taken in the interpretation of OECD data as they are not designed for microplastics, for example a very low solubility of a test substance in the inherent</p>

Element to evaluate		4a.OECD test methods only (G1, 2, 3 and 5)
		biodegradability tests may reduce the availability of the substance for the inoculum.
REACH Action 10 uncertainties	(i) what information is needed to address the uncertainties	<p>Studies on how different microplastic particles behave in the OECD tests provide information to address the uncertainties as it would be possible to compare the biodegradability behaviour to the microplastics in different compartments and representing real environmental conditions (e.g. OECD simulation tests).</p> <p>Biodegradation data for individual components present at concentrations below 10 %.</p> <p>A critical review of the available information.</p>
	(ii) the timeline for generating such information	OECD screening tests take long time. It will most likely take many years to generate sufficient data to fully understand how the OECD tests can be used to fully predict the biodegradation of microparticles.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		<p>OECD screening tests are considered stringent as passing the threshold is considered to indicate that the substance will not be persistent in the environment. OECD simulation tests are environmentally relevant and will provide information on the rate and transformation pathway of microplastics.</p> <p>Passing this scenario will ensure that the microplastics most likely biodegrade in the environment, thus provide high level of protection.</p>
Practicality, enforceability		<p>The tests are already performed, so the main practical problem concerns the long testing duration of the OECD simulation tests, availability of radio-labelled microplastics for the simulation tests as well as lack of experience of testing microplastics in G5 tests. Preparation of the sample to be tested is also challenging.</p> <p>The scenario is enforceable, but it requires experience in assessing the outcome of the biodegradation tests that the derogation is based on.</p>
Stringency		Stringent. OECD simulation tests provide information on the possible degradation potential of the microplastic in the environment and with the DT50 it is possible to obtain degradation half life values.
Conclusions		This scenario provides the possibility to a apply standard testing scheme and to work in the longer term to build up information regarding the applicability of the OECD test methods to microplastics as well as to the real environmental conditions also to be able to decide whether the concern of microplastics can be eliminated with the described derogation criteria.

Table A1.5 – ISO test methods only (3 x G4)

Element to evaluate		4b.ISO test methods only
Summary of scenario		Scheme based on ISO test methods only (3 x G4)
Advantages		<ul style="list-style-type: none"> - Straightforward derogation – easy to understand - Standard ISO test methods have been specifically developed for assessing the biodegradability of plastic materials and could be suitable for microplastic particles.
Disadvantages		<p>The ISO tests are performed in different environmental compartments, but there is lack of knowledge on the environmental relevance of the test conditions (the size of the inoculum, the longer test period, the difference of kinetic between the reference and the tested item) and results with regards to microplastic particles. Thus, even though a test material may achieve the pass criteria e.g. a 'soil ISO-test', there is some uncertainty whether the derogated material would still contribute to the microplastic concern under real environmental conditions.</p> <p>No pass level is given in the ISO standards to conclude on the biodegradability of the test item. It has been proposed in the restriction to apply, for all tests developed by ISO/TC 61, the criteria described in EN 13432: 2000 (Packaging — Requirements for packaging recoverable through composting and biodegradation — Test scheme and evaluation criteria for the final acceptance of packaging), i.e. at least 90 % in total or 90 % of the maximum degradation of a suitable reference substance after a plateau has been reached for both test material and reference substance. One should be kept in mind that EN 13432 specifies the requirements and procedures to determine the compostability and anaerobic treatability of packaging and packaging materials. In any case, EN 13432 has been developed for assessing the ultimate biodegradation of packaging materials.</p> <p>The ISO-tests take a long time to perform (<2 years).</p>
Uncertainties		<p>Microplastics derogated using only ISO tests are inherently biodegradable, but as the tests do not give an indication of environmental half life the environmental relevance of the test conditions and pass criteria (inoculum amount, temperature conditions) is unknown.</p> <p>Degradation will be very much affected by the particle size, so the results of any tests will be greatly affected by mean particle size and size distribution.</p>
REACH Action 10	(i) what information is needed to address the uncertainties	Same as 1 and 3. There is a need for comparative studies, where preferably the degradation of microplastic particles (or possibly natural fibres) are studied both in ISO-tests and tests representing real environmental conditions (e.g. OECD simulation tests). This comparison will shed light on the environmental relevance of the ISO-tests. A faster, but uncertain, option both be to review all ISO-tests that have been conducted so far, to see if some ideas of the environmental relevance can come out of that review.

Element to evaluate		4b.ISO test methods only
	(ii) the timeline for generating such information	ISO-tests are rather long, it may take 5-10 years (assuming funding) to get sufficient data to enable a firm conclusion on the environmental relevance of the ISO-tests.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		ISO tests alone are not suitable for assessing the biodegradability of microplastic particles in the real life environmental conditions, thus passing this scenario would have remaining uncertainties.
Practicality, enforceability		<ul style="list-style-type: none"> - Practicable, laboratories able to perform ISO tests but there is limited experience from testing microplastics. - Long duration - The scenario is enforceable.
Stringency		Stringent. Derogated materials are inherently biodegradable, may continue to contribute to the microplastic concern if they do not degrade sufficiently rapidly under environmental conditions. Pass must be achieved in multiple compartments.
Conclusions		Although demonstrating inherent biodegradability ISO tests are not considered to be as stringent as OECD screening or simulation tests and may have limited environmental relevance (until proven otherwise).

Table A1.6 – Polymer only

Element to evaluate	5. polymers only
Summary of scenario	Testing scheme modified such that only data on polymer(s) present in microplastics is needed. Testing of the microplastic placed on the market is not necessary.
Advantages	<p>The polymer only scenario reduces significantly the numbers of necessary tests and consequently the necessary resources and time for completing the required testing. Currently more scientific knowledge exists on the biodegradation of polymers compared to the high number of different microplastics. Especially the representativeness of laboratory test systems on the degradability in the environment is easier for polymers than for microplastics as there is less potential for interferences from other substances in the polymer matrix. .</p> <p>Testing only the polymers separately and in a standard particle size would allow to demonstrate that the main contributors to the persistence concern are biodegradable. The microplastic which falls in the derogation would be composed only from polymers which proved to be degradable. Consequently, it would not be possible, that very persistent polymers are part of a microplastic blend. The Dossier Submitter's proposal ensures that microplastics cannot contain additives (or other substances) that meet PBT/vPvB criteria. Overall the largest advantage of the polymer only scenario is the easy and cost-effective enforcement.</p>
Disadvantages	<p>Testing only the polymers separately and in a standard particle size does not taken into account that microplastic as it is placed on the market including the blend, additives and the form, size and the surface area of the microplastic. Consequently, we do not gain scientific understanding on the biodegradation of the different microplastics as they are placed on the market or released to the environment.</p> <p>In addition to test standard particle size it could be necessary to also test the particle as it is placed on the market, as size and shape are key parameters for polymer biodegradation.</p> <p>In addition to testing the polymer only it could be necessary to evaluate the effect of any relevant additives. Many of these have the technical function to provide durability and consequently make the microplastic as it is placed on the market less biodegradable. Consequently, testing the polymers only may underestimate the fate and behaviour of the microplastic under relevant environmental conditions.</p>
Uncertainties	<p>Testing only the polymers separately and in a standard particle size gives a transparent and comparable test results but would not address uncertainties related to the effect of additives/other substances in the polymer matrix on biodegradability. The representativeness of the degradability of each polymer in the different environmental compartments under relevant environmental conditions is scientifically much easier.</p> <p>The surface area is significantly correlated with biodegradation. If the standard size tested is significantly smaller than the microplastic placed on the market there is uncertainty as to the environmental relevance of the standard test data. If on the other hand the polymer is only tested as 5 mm particles an important parameter specific for each microplastic would be missed in the derogation scheme. The polymer only scenario does not consider the variety of size of the microplastic placed on</p>

Element to evaluate		5. polymers only
		<p>the market</p> <p>Standard particle size (or a range of standard particle sizes) needs to be defined.</p>
REACH Action 10 uncertainties	(i) what information is needed to address the uncertainties	In addition to testing only the polymers separate and in a standard particle size it might be necessary to address the uncertainties resulting from the microplastics as it is placed on the market, including the blend and the form, size and the surface area of the microplastic.
	(ii) the timeline for generating such information	For many polymers the test results are already available. It might be necessary to perform new test with a standard size or with a lower test temperature more relevant for environmental conditions. New testing requires the same timeline as in the other scenarios.
Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)		The environmental relevance is unclear of testing polymers in separate and in a standard particle size as it is different from the forms that are released on the market. Testing of the polymers only without additives might not be protective for the environment. Additives might significantly decrease the biodegradation of microplastics.
Practicality, including enforceability		<p>The polymer only scenario requires testing of the polymers separately and in a standard particle size. Since the derogation would only apply to microplastic which is composed from only degradable polymer it is fully applicable. Other microplastic would be outside the derogation.</p> <p>The polymer only scenario cause the lowest number of necessary tests, is resource effective and relatively easy to implement and to enforce. It will be straightforward to set transparent and well justified criteria for the standard size to test. Overall, to justify the derogation with the polymer only scenario is very practicable.</p> <p>The necessary effort for the enforcement seems to be significant lower with this polymer only scenario.</p>
Stringency		If small particle sizes are testing then then derogation may not be very stringent as , although efficient, additives and other substances in the polymer matrix may significantly decrease the biodegradability of microplastics as placed on the market, which would not been considered by this derogation. If relatively large particles are tested the derogation could be considered to be very stringent as biodegradation is acknowledged to be a surface-limited process.
Conclusions		Derogation based on testing only polymers separately and in a large e.g. (5 mm) standard particle size would have significant advantage. This derogation would cause the lowest number of necessary tests, would be practicable and easy to enforce. The derogation would be stringent, since the microplastic as

Element to evaluate	5. polymers only
	it is placed on the market only contains polymers for which it has been proven that they are degradable in the different environmental compartments under relevant environmental conditions. However, an effect of the composition (e.g. additives) on the biodegradability is not taken into account so the fate and behaviour of the microplastics in the environment under relevant environmental conditions may be underestimated.

Table A1.7 – Confirmatory polymer data

Element to evaluate	7. Confirmatory polymer data *Testing scheme modified such that additional information on the polymer itself is needed where there is some potential for the interpretation of screening test results to be confounded by another (biodegradable) constituent (e.g. additive).
Summary of scenario	Testing scheme modified such that where a derogation for a MP comprising a single polymer is justified on the basis of the results screening tests (G1 to 3) additional data demonstrating the biodegradation of the polymer itself (without additives) in the same tests is also needed (this could be additional testing or analytical data demonstrating the degradation of the polymer). The Dossier Submitter approach already requires data on polymer degradation where there is a blend comprising >1 polymer in the test material. This modification would apply where there is a single polymer in the test material and would address the concern that pass criteria are achieved in screening tests because of the degradation of other constituents in the test material (e.g. additives) rather than the polymer itself. Most relevant to G1 to G3 test methods (because it is acknowledged that they have limitations when testing mixtures). G4 tests are designed for plastics, which are typically mixtures of polymers and additives, and have more conservative pass criteria.
Advantages	The screening tests are not designed for mixtures, such as a MP containing polymers and different additives, and requiring additional information on the polymer itself will rule out that additives are interfering with the tests and therefore provide clarity as to the biodegradation of the polymer.
Disadvantages	Additional data requirements may delay testing and, consequently, innovation. It may be difficult to predict if other components of the microplastic (than the polymer) affect the tests. And the content of other components (e.g. additives) may not be fully known. The amount of other constituents in a test material may be so low in relation to the content of polymers that it could not affect the result of testing, and a requirement to test the polymer as such may complicate testing while not really being needed.

Element to evaluate		7. Confirmatory polymer data *Testing scheme modified such that additional information on the polymer itself is needed where there is some potential for the interpretation of screening test results to be confounded by another (biodegradable) constituent (e.g. additive).
Uncertainties		Will the content of additives be so high that it affects the outcome of testing ³⁵ .
REACH Action 10 uncertainties	(i) what information is needed to address the uncertainties	Information is needed on what 'other constituents (and the concentration) are used in MPs to get an indication whether they may affect the outcome of testing. Data from testing MPs with and without other constituents is needed for a firm conclusion as to the possibilities of other constituents to affect the results of testing MPs. Information from the MP producers may become available within a few years, but it will most likely take many years to get test data allowing a firm conclusion.
	(ii) the timeline for generating such information	Information from the MP producers may become available within a few years, but it will most likely take many years to get test data allowing a firm conclusion.
Relevance to the environment		Depending on the concentrations of other constituents used in microplastics, the environmental relevance of test data for MPs may be questioned.
Practicality, including enforceability		It will be an industry task to decide to perform additional polymer testing and to provide a rationale for why other constituents may affect the testing of the microplastic as released on the market. It may be difficult to enforce if dependent on expert judgement (i.e. interpretation of analytical data).
Stringency		If other constituents decrease the biodegradation of microplastics in laboratory tests, they will also decrease biodegradation of the microplastics in the environment.
Conclusions		The need for such a testing regime is unclear to RAC. If allowing derogations based on additional testing of the polymer itself, the consequences as the environmental protection is unclear and may lead to build up of the microplastic in the environment.

³⁵ Colwell, J. M. et al. Lifetime prediction of biodegradable polymers. Prog. Polym. Sci. 71, 144–189 (2017); Kjeldsen A., Price, M., Lilley C, Guzniczak, E. 2019. A Review of Standards for Biodegradable Plastics. Industrial Biotechnology Innovation Centre (IBIOIC)

Table A1.8 – weight of evidence approaches

Element to evaluate	09. Weight of evidence
Summary of scenario	Testing Scheme modified to allow the use of (i) non-testing or (ii) 'non-standard' test method data to waive Appendix X testing requirements e.g. based on QSAR, read-across (including between different sizes of the same MP), use pattern or environmental fate information (to justify lack of exposure in a particular compartment)
Advantages	A weight of evidence (WoE) approach is a case-by-case decision and consequently allows flexibility to prove that a microplastic would biodegrade in the environment. The use of non-testing or 'non-standard' test data to waive standard testing would reduce the burden of laboratory testing.
Disadvantages	<p>A weight of evidence (WoE) approach is impossible to compare between different types of microplastics. The robustness and the confirmability of the WoE is extremely low. Furthermore, the WoE only depends on expert judgement, which is legally difficult to prove, to challenge and to enforce. MS enforcement authorities would need access to all information which was considered during the WoE. On the one hand this causes for industry a huge burden of preparing a detailed documentation of the WoE. On the other hand, the evaluation of this would causes extremely high effort for enforcement.</p> <p>For each single waiving of standard tests with non-testing or 'non-standard' test data the scientific validity must be proven and must be established. This causes huge effort and has not been established yet for e.g. QSAR-models or simulation studies. The level of quality and reliability of each information used might be extremely different and is very difficult to assess.</p> <p>In case of monitoring data or simulation studies the result must be representative and should not be specific for a use or a site. It is difficult to correlate monitoring data with a source or use over time and space compromising the possibility of reaching reliable conclusions on persistency. The lack of adequate analytical methods for field studies in comparison to standard test systems must be considered.</p>
Uncertainties	<p>A weight of evidence (WoE) approach results in a high degree of uncertainty in every single aspect of the decision. It depends mainly on combining uncertain aspect using expert judgement, which can result in an uncertain overall conclusion. In consequence different experts will come to different WoE even if the available information is the same. Also, a WoE does not depend on transparent criteria and the expert judgement used in the WoE is usually not transparently justified.</p> <p>A WoE approach can only be implemented in a scientific area where a lot of scientific experiences and well documented investigations is available. In the case for assessing the degradability of microplastic in the different environmental compartments under relevant environmental conditions (e.g. temperature, microorganisms, fungi etc.) the available different sources for information are low (lack of knowledge) and consequently the implementation of a weight of evidence (WoE) approach is difficult or even impossible.</p> <p>In general uncertainties are higher if standard tests are waived. Although monitoring data could be more illustrative for relevant environmental conditions, uncertainties</p>

Element to evaluate	09. Weight of evidence	
	<p>may remain from quality of the sampling and analytical techniques as well as about its representativeness (geographic and time scales) across Europe.</p> <p>The general lack of understanding of the fate and behaviour of a particular microplastics in the environment causes a lack of adequate simulation models to predict the fate and transport of microplastics in the environment.</p> <p>The relevance of size and surface area for the degradation of microplastic can hinder the implementation of a read across. On the other hand, it may be justified to read across from larger particle sizes of identical microplastics to smaller particle sizes.</p> <p>QSAR models and simulation models to assess the degradability of polymers and microplastics in different environmental compartments under relevant environmental conditions do not exist. However if they become available the uncertainty is expected to be extremely high, because of the low number of standard test results available.</p>	
<p>it's extremely difficult to correlate monitoring data with a source (in time and in space) so, this undermines the possibility to REACH Action 10 uncertainties</p>	<p>(i) what information is needed to address the uncertainties</p>	<p>To decrease the uncertainty and increase the transparency, there would be a need to establish criteria for how to weight different types of information and criteria for how to combine them into an overall WoE conclusion.</p> <p>Before it is scientifically justified to waive standard tests more standard test results and a better understanding of the fate and transport of microplastics in the environment, including better methods for microplastics sampling and quantification in the environment as well as better simulation models need to become available.</p>
	<p>(ii) the timeline for generating such information</p>	<p>To implement the weight of evidence (WoE) approach, there is a need for a common view on how to weight and combine different types of information. This is not available and it is likely to take a long time to get this experience.</p> <p>The WoE itself needs to consider all available relevant information and does not request a specific type of information. However, it is extremely likely that a WoE would require new testing with standard test system just like in the other approaches.</p>
<p>Relevance to the environment (level of protection / effectiveness / probability that persistent MPs used/released)</p>	<p>The weight of evidence (WoE) approach would allow to consider all relevant information for assessing biodegradability and fate of microplastics in the environment and therefore could be protective for the environment. However, the disadvantages and uncertainties are much more significant than the advantages and consequently a WoE is very likely not protective for the environment. However, it is crucial, that the WoE is protective and conservative enough that the outcome must not be overruled in future by standard testing-data, if they come available. A WoE depends strongly on the individual expert judgement and does not follow transparent criteria which have been agreed by the society to define the level of protection for the environment.</p>	
<p>Practicality, including enforceability</p>	<p>The scientific complexity to allow non-testing or non-standard testing in a WoE is very high. To set up QSAR models, simulation models or field monitoring studies causes</p>	

Element to evaluate	09. Weight of evidence
	a much higher effort than to perform standard tests in the laboratory. Overall the practicality and enforceability of the weight of evidence (WoE) approach is considered low.
Stringency	The weight of evidence (WoE) approach would be quite flexible and would allow all relevant information. This would include low quality data. It can be expected that for many microplastics the derogation could be justified with a WoE and consequently the level of stringency is low.
Conclusion	A weight of evidence (WoE) approach including the use of (i) non-testing or (ii) 'non-standard' test method data to waive Appendix X testing requirements e.g. based on QSAR, read-across (including between different sizes of the same MP), use pattern or environmental fate information (to justify lack of exposure in a particular compartment) would not be protective for the environment and would be extremely difficult to enforce. While reducing the burden of standard testing it would significantly increase the uncertainty of the derogation.