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

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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 supporting document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitter's 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**
Supporting the Rapporteurs:	**Joao CARVALHO**
	Ignacio DE LA FLOR TEJERO
	Bert-Ove LUND
	Raili MOLDOV
	Michael NEUMANN

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 **10 December 2020**. The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **90 days** by the ECHA decision I(2021)0003.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted **by consensus**. [6].

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A. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter, after taking into account the comments received in the consultation, 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)	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: a. 'microplastic' means particles containing solid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 0.1 µm ≤ *x* ≤ 5 mm, or (ii), a length of 0.3 µm ≤ *x* ≤ 15 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 ≥ 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: 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. 4. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastics for use at industrial sites. b. Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/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. *In vitro* diagnostic devices f. Sewage sludge (as defined in Directive 86/278/EEC) and compost g. Food and feed h. *[OPTION A: granular infill used on synthetic sports surfaces where risk management measures are used to ensure that annual releases of microplastic do not exceed 7 g/m^2]* 5. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use. b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use, such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a).

	c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use. 6. Paragraph 1 shall apply from: a. EiF for cosmetic products (as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009) and other substances or mixtures containing microbeads. b. EiF + 6 years for medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745. c. EiF + 4 years for 'rinse-off' cosmetic products (as defined in Regulation (EC) No 1223/2009) not already included in paragraph 6(a). d. EiF + *[5/8]* years for the encapsulation of fragrances in detergents (as defined in Regulation (EC) No 648/2004), cosmetic products (as defined in Regulation (EC) No 1223/2009) or other mixtures. e. EiF + 5 years for detergents (as defined in regulation (EC) No 648/2004), waxes, polishes and air care products not already included in paragraphs 6(a) or 6(d). f. EiF + 5 years for fertilising products not regulated in the EU as fertilising products under Regulation (EC) No 2019/1009 that do not meet the requirements for biodegradability contained in that Regulation. g. EiF + 8 years for plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012. h. EiF + 5 years for other agricultural and horticultural uses including seed treatments. i. EiF + 6 years for 'leave-on' cosmetic products (as defined in regulation (EC) No 1223/2009). *j. [Either* *i. EiF + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – <u>OPTION A</u>) or,* *ii. EiF + 6 years for granular infill used on synthetic sports surfaces (if 4(h) not retained– <u>OPTION B</u>)]*

	7. From [EiF + 24 months] any supplier[1] of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastics to the environment, including at the waste life-cycle stage. The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms Where written instructions are given, these shall be in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. In addition, any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraph 4(a) shall identify, where applicable, either on the label and/or SDS and/or 'instructions for use' and/or 'package leaflet' that (i) the substance or mixture is subject to the conditions of this restriction and (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. 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: 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 microplastics released to the environment in the previous calendar year. Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for a professional or consumer end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year:

[1] 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".

	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 microplastics released to the environment in the previous calendar year. ECHA shall publish a report summarising the information received by 30 June every year.

Note 1: 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.

Note 2: The Dossier Submitter concludes that a revised lower size limit for microplastics of 100 nm is a pragmatic solution that balances risk reduction against the obvious analytical constraints and challenges of the initially proposed 1 nm limit. The Dossier Submitter still considers that particles containing solid polymer <100 nm are microplastics but, based on practical and legal certainty considerations, that the lower limit of the restriction should be set at 100nm, at least in the short-term. The Dossier Submitter notes that raw materials containing microplastics <100nm, where these can be reliably characterised, should not be intentionally added to products.

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
Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006	Entry as proposed by the Dossier Submitter above, with the following modifications: 2. For the purposes of this entry: a. 'microplastic' means particles containing solid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions ≤ 5mm, or (ii) a length of ≤ 15mm and length to diameter ratio of >3. 3. Paragraph 2a and 2b shall not apply to: b. Polymers that are (bio)degradable, according to the criteria in Appendix X. *RAC proposes modifications to the criteria in Appendix X (as described in section B.1.1.3.6 of the opinion justification)* *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.* 4. Paragraph 1 shall not apply to the placing on the market of: ~~h. *[OPTION A: granular infill used on synthetic sports surfaces where risk management measures are used to ensure that annual releases of microplastic do not exceed 7g/m^2]*~~ 6. Paragraph 1 shall apply from: *j. [~~Either~~*

	a. ~~*EiF + 3 years for granular infill used on synthetic sports surfaces (if 4(h) retained – OPTION A) or,*~~ b. *EiF + 6 years for granular infill used on synthetic sports surfaces ~~(if 4(h) not retained – OPTION B)]~~*

A.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on **intentionally-added microplastics** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified, as proposed by SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Substance (or group) identity)	Conditions of the restriction
Polymers within the meaning of Article 3(5) of Regulation (EC) No. 1907/2006)	Entry as proposed by the Dossier Submitter above, with the following modifications: 2. For the purposes of this entry: a. 'microplastic' means particles containing solid polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ *x* ≤ 5mm, or (ii) a length of 3nm ≤ *x* ≤ 15mm and length to diameter ratio of >3. 3. Paragraph 2a and 2b shall not apply to: d. Polymers without any carbon C in their chemical structure (i.e. polymer backbone or side-groups). 4. Paragraph 1 shall not apply to the placing on the market of: b. Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC[2]. e. *In vitro* diagnostic devices[3].

[2] Regarding veterinary medicinal products, EU Directive 2001/82/EC will be repealed by Regulation (EU) 2019/6. The reference to the veterinary Regulation might therefore need to be updated.

[3] *In vitro* 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 in vitro for the examination of specimens, e.g. body fluids and tissue donations from organisms".

	f. *[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/m^2]*[4]. 6. Paragraph 1 shall apply from: b. EiF + 6 years for medical devices as defined in Directive 93/42/EEC or in Regulation (EU) 2017/745. g. EiF + 8 years for plant protection products as defined in Regulation (EC) No 1107/2009, including seeds treated with such products, and biocides as defined in Regulation (EU) 528/2012. h. EiF + 5 years for other agricultural and horticultural uses not subject to (EC) No 1107/2009 and seeds treated with such products. 7. From [EiF + 24 months]: a) any supplier[5] of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastic to the environment, including at the waste life-cycle stage. The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms. Where written instructions are given, these shall be in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. b) any supplier of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraph 4(a) shall identify, where applicable, either on the label and/or SDS and/or 'instructions for use' and/or 'package leaflet' that (i) the substance or mixture is subject to the conditions of this restriction (ii) the quantity (or concentration) of microplastic in the substance or mixture and (iii)

[4] The Dossier Submitter assessed different restriction options for granular infill used on synthetic sports surfaces. These are discussed in the cost, benefit and proportionality section. SEAC concluded that a clear-cut choice for one of the scenarios can, in this case, only be taken based on policy priorities. This is outside the remit of SEAC.

[5] According to definition in Article 3(32) of REACH, 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".

	sufficient information on the polymer(s) contained in the substance or mixture for downstream users or suppliers to comply with paragraph 8. 8. From [EiF + 12 months] manufacturers of microplastics and from [EiF + 36 months], any other [industrial] actor in the supply chain, as defined in REACH article 3(17), 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 May of each calendar year: a. a description of the use(s) of microplastic in the previous calendar year, b. For each use, generic information on the identity of the polymer(s) used, c. For each use, an estimate of the quantity of microplastic released to the environment in the previous calendar year. Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for a professional or consumer end use allowed on the basis of paragraphs 4(b), 4(d), 4(e), or 5 shall send to ECHA in the format required by Article 111 of REACH, by 31 May of each calendar year: a) a description of the intended end use(s) of microplastic placed on the market in the previous calendar year, b) For each intended end use, generic information on the identity of the polymer(s) placed on the market, c) For each intended end use, an estimate of the quantity of microplastic released to the environment in the previous calendar year. ECHA shall publish a report summarising the information received by 31 October every year.

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.

Taking into account RAC's opinion, SEAC considers that the definition of microplastics should contain a lower size limit of 1 nm. However, in order to ensure that the proposed restriction is implementable, enforceable and monitorable SEAC acknowledges that there might be a temporary necessity to set a lower size limit for the conditions of the restriction at 0.1 µm (100 nm). SEAC notes that multiple stakeholders have indicated that microplastics with dimensions below 100 nm are commercially available. These should still be subject to the conditions of the restriction if they can be reliably characterised or identified (through

analytical methods or via a "document-based" enforcement).

For certain uses of microplastics the time needed to develop suitable alternatives is uncertain, therefore SEAC considers it necessary to review the availability of alternatives for these uses after entry into force and before the specific transition periods expire. For fragrance encapsulates, SEAC cannot conclude if 5 or 8 years would be the most appropriate transition period and recommends to review the need for a transition period longer than 5 years after entry into force. Also, for other uses (e.g. medical devices, plant protection products and seed coatings) a review of substitution progress and the availability of alternatives is recommended. This review could be undertaken for example 4 years after entry into force of the restriction. SEAC emphasised that the implementation of these reviews should not result in open-ended derogations for these uses being proposed, but rather that the initial transitional periods could be extended if justified by a review.

In terms of the transition period of 36 months for the reporting requirement (paragraph 8), SEAC notes that information received in the consultation of the SEAC draft opinion indicates that certain actors in the supply chains, e.g. manufacturers of microplastics or downstream users of microplastics in some supply chains (i.e. pre-production pellets), are likely to be already able to report earlier, e.g. due to efforts spent to implement voluntary industry initiatives (e.g. Operation Clean Sweep). SEAC considers that for these actors a shorter transition period, i.e. 12 months could be justified.

Please see Appendix I for an overview of the opinion-making process in SEAC.

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 and remain 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 solid[6] polymer, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 100 nm ≤ x ≤ 5 mm, or (ii) a length of 300 nm ≤ x ≤ 15 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 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 ≥ 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 5 mm 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 in paragraph 5). The scope of the proposed restriction is also targeted by the derogations set

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

1. **'solid'** means a substance or a mixture which does not meet the definitions of liquid or gas.
2. **'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.
3. **'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).

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.

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 ≥ 1% w/w of particles have:

(i) all dimensions ≤ 5mm, or

(ii) a length ≤ 15mm 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 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 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 in its evaluation identified several uncertainties 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 reduce 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 test methods included in group 4, which assess biodegradation relative to a reference material;

- the practicality and applicability of group 5 test methods to microplastic (i.e. polymer particle) 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 several sets of 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).

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 suppliers[7] 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 reasonable and well-founded.

The restriction aims at avoiding the placing on the market and intentional use of 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 concentration limit of 0.01 %, based on information collected through literature searches, the Dosser 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

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 justification for grouping is underpinned by similar intrinsic properties:

i. substance identity (i.e. REACH polymers),

ii. physical properties (i.e. solid particle with relevant dimensions, insoluble in water) and

iii. properties determining environmental fate and behaviour (i.e. 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

[7] 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".

could also be present. Polymers that are not solid particles are not 'microplastics'.

The proposed microplastic definition is based on the REACH polymer definition in combination with several additional elements, as set out in paragraph 2 of the conditions of the restriction. All 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

a) 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 is necessary for consistency. Industry stakeholders' concerns that polymers which do not contribute to the microplastic concern would also be targeted is 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 defines 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.

b) Particle (paragraph 2c)

The second element of the microplastics definition, as defined in paragraph 2c of the proposal, is the requirement for a polymer to be present as a particle[8]**.** The proposed definition of a particle, which is supported by RAC, is consistent with that previously established as part of the European Commission Recommendation on the definition of nanomaterials (2011/696/EU), which, in turn, follows the definition of particle in a relevant ISO standard (6824:2013)[9].

c) Solid (paragraphs 2e, 2f and 2g)

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, while 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

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

[9] 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 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.

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, 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.

d) Particle dimensions (paragraph 2a)

The fourth element of the definition sets the dimensions for relevant particles, comprising upper and lower size limits, and a minimum weight threshold of relevant particles in a substance or a mixture (i.e. where particles with other dimensions are also present).

The 5 mm upper limit proposed for microplastics is partly biologically selected as particles below this size are considered more likely to be ingested by biota than larger items (which are more frequently associated with physical effects, such as entanglement). There is consensus on the upper size limit (5 mm) for a microplastic (GESAMP, 2015; UNEP, 2015). This upper size limit is already used in existing microplastic regulations 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 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 this size range of particles might be expected to present different kinds of risks than larger plastic items (such as entanglement) (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).

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). Furthermore, several polymers that may fall in the scope of the proposed restriction are quoted in cosmetics list of ingredients in nano form.[10] In this list, some colourants and UV filters in nano form, like TiO_2, could be coated with polymers and fall in the scope of the

[10] 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

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 Committee considers that 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 several different analytical methods to cover the applicable size range from 5 mm to 1 nm[11].

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 1 nm (ii) the Dossier Submitter's revised lower limit of 100 nm 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 100 nm.

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

[11] 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.

conditions of the restriction based on what is practicable, according to the currently available analytical techniques. In addition, the Forum considers that it is advisable to include a review of the definition in the legal text 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 of the definition and some of them could be larger or smaller. 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*).

e) Particle containing solid polymer (paragraph 2d)

For the fifth element of the revised microplastics definition, the Dossier Submitter proposes a definition for a so-called **'particle containing solid polymer[12]'**. The Dossier Submitter identifies two types of particles that could fit the term:

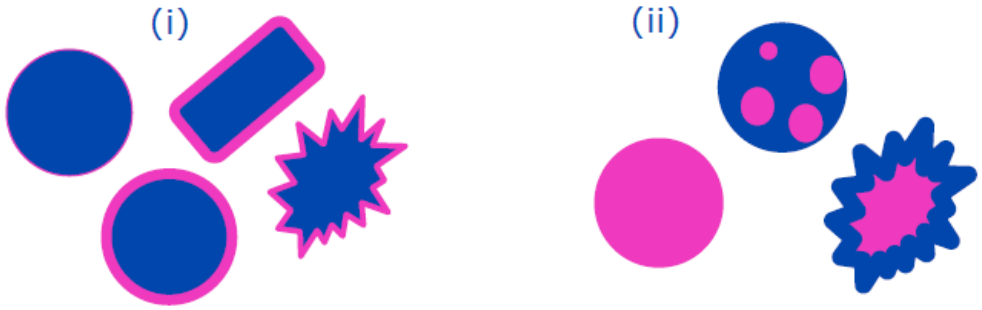
(i) A particle of any composition with a continuous solid polymer surface coating of any thickness (polymer encapsulated materials).

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 ≥ 1% w/w.

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

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



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 the proposed concentration limit corresponds to the lowest concentration at which it is 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%).

During the consultation, some Stakeholders 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).

RAC considers that it is appropriate to set the limit concentration at the lowest concentration added in products placed on the market. This is compatible with the proposed 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.

Regarding the large range of concentrations of microplastics used, 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 available information. 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 to determine a concentration limit at the level proposed.

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 suppliers[13], 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 as it entails a significant administrative burden, could lead to double counting and would require the disclosure of confidential business information. Taking these comments into consideration, the Dossier Submitter made significant revisions to the proposal to address the concerns of stakeholders. For example, the exact polymer identify is no longer proposed as mandatory information and only release quantities would be requested rather than use quantities (to avoid confidentially 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 requirements (instructions for use and reporting), respectively, are also proposed by the Dossier Submitter, who considers that it does not compromise the risk reduction capacity of the proposed

[13] 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".

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 reasonable 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 and 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 and 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 is 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. cellulose, hemicellulose, glucomannan, agar, starch, pectin, inulin, rosin, guar gum, locust bean gum, gum acacia, karaya gum, gum tragacanth, chitin, alginates, carageenans, psyllium and 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 derogated from the conditions of the restriction (unless they were demonstrated to be biodeg.

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 may break into smaller sections 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, etc. 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 biodegrade[14] in the environment since their properties would in principle not be consistent

[14] 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 CO_2 and H_2O (or CH_4 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 CO_2. As a consequence, a bi-phasic pattern with a rapid phase of CO_2 production followed by a slower secondary phase of CO_2 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

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 ($ThCO_2$) and is not generally known (Chinaglia et al 2018).

The Dossier Submitter proposed specific test methods, pass criteria and guidance on appropriate test materials[15] 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 (i.e. OECD and ISO methods); five groups of tests are identified. Some of these are screening tests, routinely used with chemical substances. Only 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 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, # 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

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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 (O_2) or the end product (CO_2) of energy metabolism. The biodegradation percentage is the ratio between the evolved CO_2 and the theoretical CO_2 ($ThCO_2$) i.e. the amount of CO_2 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.

[15] 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.

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 given environment depends on many factors such as its crystallinity, 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, it was questioned how the criteria were derived and also whether there is a need to conduct testing in all testing tiers.

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 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 had failed the more stringent but rapidly performed tests in groups 1 to 3.

Biodegradation tests

Screening tests (Groups 1, 2 and 3)

This group consists of 'ready' biodegradation tests and the included test methods are OECD TG 301 B,C,D,F and 310 with a 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 three 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 tests[16] are widely used in European regulations (Table 3 Annex C

[16] 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.

of the Background Document) and they are part of the data requirement for REACH registration. The results can be used to draw the conclusion that the substance does not meet the P and vP criteria as set out in REACH Annex XIII[17].

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 polymer 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 but 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.

ISO Methods: Group 4

Table 2 (see below) summarises the ISO tests in Appendix X specifically developed to determine the biodegradability of plastics[18]. The test methods are characterised by assessing

[17] 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.

[18] 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

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 six months in aqueous tests and 48 months in soil/sediment tests. 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/ $ThCO_2$. 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)[19]. Significantly, ISO tests are not used to derive a half-life, but to identify materials that have comparable biodegradation behaviour to biodegradable reference substances.

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.

[19] 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 tests –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 under 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 reportedly 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 they 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. Consequently, 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 on biodegradation 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 of the test results to the fate of the material in the environment.

Regarding the general scheme proposed by the Dossier Submitter, 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 the Group 4 ISO and Group 5 OECD simulation 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 simulation 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.

To assist with the further evaluation of the Dossier Submitter's proposal, the Rapporteurs together with an ad-hoc RAC working group developed a series of eight scenarios comprising

different approaches to the tests considered necessary 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':** When group 4 (ISO) tests are used, a pass should be obtained in soil, surface water and sediment, rather than in a single test as proposed by the Dossier Submitter. Validation in one or more relevant OECD simulation studies is proposed (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. If one or more of the three ISO tests does not achieve a pass, then a group 5 OECD simulation study should be performed in the failed environmental compartment(s).

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 Section B.1.4.4 of the Annex to the Background Document.

Table 3 Summary of the systematic evaluation of biodegradation scenarios

Scenario	Conclusion, including key uncertainties
1. Dossier Submitter's proposal	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. 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. 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. 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 GRAB[20] 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. 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. 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 uncertainties, and it is not possible to definitively prefer one group of tests to the other based on current knowledge.

[20] Generally regarded as biodegradable, e.g. cellulose

Scenario	Conclusion, including key uncertainties
	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. 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. 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.
2. RAC-52 proposal	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. 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) 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. 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). Acknowledging the current lack of experience with conducting group 5 tests 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

Scenario	Conclusion, including key uncertainties
	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). 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. 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.
3. 'All compartments requirement at G4/G5'	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. 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 *vice versa*). 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). 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. 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 outcome used, if necessary, as part of a review of the conditions of the derogation in the future.
4. OECD test methods only	This scenario is based on the OECD standardised tests included groups 1, 2, 3 and/or multiple (three) compartments at group 5. 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

Scenario	Conclusion, including key uncertainties
	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. 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.
5. ISO test methods only	This scenario is based on performing multiple tests in group 4 (ISO) only. No screening level tests would be included. 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.
6. Polymer testing only	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). 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. 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.
7. Confirmatory polymer data requirement at G1/G2/G3	In response to a concern that under very specific conditions the results of OECD screening tests (G1/2/3) could be disproportionally 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. 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. 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 In terms of the relative concentration of non-polymeric organic constituents to polymeric constituents of a test material, RAC

Scenario	Conclusion, including key uncertainties
	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.
8. Weight of evidence	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.

RAC considers that the long-term persistence of microplastics in the environment makes transport from one environmental compartment to another after release more likely (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 to ensure that biodegradability across different compartments, irrespective of the compartment where they are initially released to the environment, is addressed.

To summarise the analysis in Table 3 above, although each of the scenarios evaluated presents their own advantages and disadvantages, 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 and would avoid 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).

A microplastic-containing product could, according to the Dossier Submitter's exposure assessment lead to releases to several different environmental compartments. For example, a moisturiser or sun-protection product containing a microplastic, if washed-off after use (e.g. in a shower) the down-the-drain pathway means that releases 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 a minimum requirement for justifying a derogation.

The benefit of using ether 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. 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. Even with option 3, additional research would be required to 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.

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) refers to the OECD screening tests in Groups 1 to 3 and performing some form of analysis of the components of a polymer could ensure that screening tests do not generate false pass results due to the non polymeric components in a mixture.

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 microplastics[21]. Nevertheless, RAC is of the opinion that the P criteria should be preferred instead of vP.

Test material

Microplastics will frequently be mixtures comprising one or more polymers together with other substances (e.g. additives). Therefore, an 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. 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

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

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). 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 each component (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. 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 from soluble polymers. 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 (OECD, 2000) test method used to determine the solution/extraction behaviour of polymers in water, 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.

However, some 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 the concept of water solubility and concluded that it could be usefully included in the definition as long as (i) a standardised methodology was used for the measurement of solubility and (ii) that 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 identified standard test methods and conditions for measuring the water solubility of polymers for the purposes of the restriction based on existing OECD standard methods (See Appendix Y).

In terms of a suitable threshold, the Dossier Submitter explored the relevance and suitability of various existing criteria for identifying 'soluble'/'insoluble' substances[22] in relation to the microplastics concern.

Rather than corresponding with an existing criterion for solubility/insolubility, the Dossier Submitter proposed a threshold of >2 g/L which corresponds with the maximum test material concentration (as TOC) under optimal conditions specified in the test methods for assessing the biodegradation of polymers in aqueous environments (ISO 14851 and 14852). This approach 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

[22] ≥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.

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 accept the rationale of the Dossier Submitter that where microplastics (i.e. insoluble polymer particles) 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:

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) as well as 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 contaminants present in the environment.

The Dossier Submitter relied on several comprehensive assessments of the (eco)toxicity of microplastics published in recent years, such as those reported by the 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 SAPEA[23] in January 2019 as part of the European Commission Group of Chief Scientific Advisors work on microplastics[24].

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

[23] Science Advice for Policy by European Academies. www.sapea.info/topic/microplastics

[24] https://ec.europa.eu/research/sam/index.cfm?pg=pollution

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 minimum standards of taxonomic diversity required for SSD derivation were not achieved (fish and insects are notable omissions from the available dataset) and effects thresholds were normalised to LOECs instead of NOECs or EC10s. The normalisation (acute to chronic ratio) approach applied, used to facilitate the derivation of HC5 in the absence of representative long-term exposure data, while unconventional does indicate that microplastics are relatively toxic in the aquatic environment. The application of the tentative threshold values 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 any potential for remediation it is clear that the scale of these risks, is 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 is not possible to adequately assess risks using traditional quantitative risk characterisation methods. In the event that effect thresholds would become well understood (or could be 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').Because of their long-term persistence, effects thresholds that are 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 such as waste water treatment digester sludge. The absence of information to assess risks poised 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.

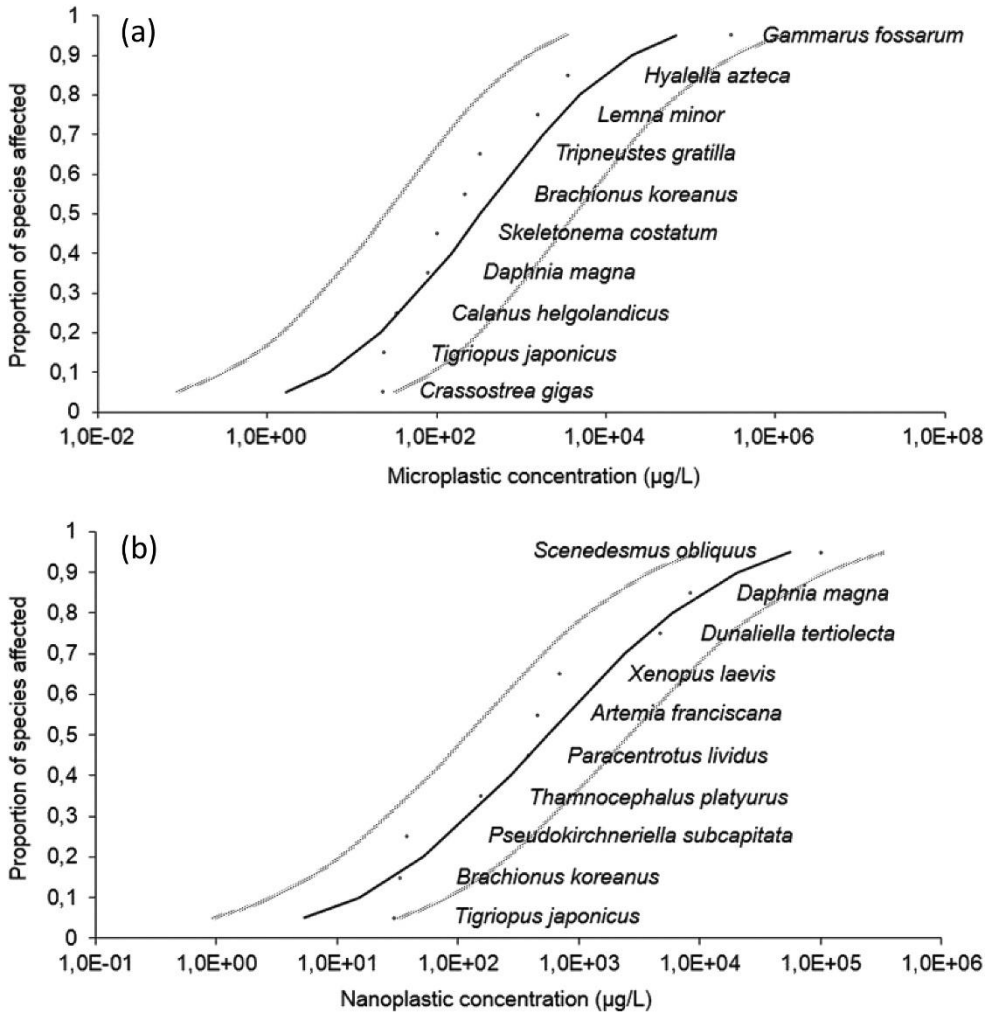

Figure 2 SSDs for microplastics (a) and nanoplastics (b), after Besseling et al. (2018)

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	6.9×10^{-9} – 2×10^{5}	0.02 - 400
		Brackish	23.5	0.04 – 0.1	6.9×10^{-9} – 1.8×10^{4}	0.4 - 313
		Marine	-	-	9.1×10^{-3} – 2.5×10^{3}	2×10^{-3} - 510
	Nano	Fresh	4 - 36	0.5 – 1.6	4.5 – 1×10^{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 bioaccumulation are not practicable for assessing particulate materials such as microplastics. The classical concepts of bioaccumulation and biomagnification, established on a molecular level, are not suitable for assessing 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 Annex I, 0.10[25], risks can be assessed by means of a 'case-by-case' approach. The Dossier Submitter describes this general approach as well suited 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 irreversible stock pollution 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 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 a range of 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 Dosser Submitter addressed conventional (eco)toxicological risk assessment based on the derivation of an effects threshold (PNEC) and quantitative risk characterisation (PEC/PNEC).

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[25] "*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* [see 0.6.1 and 0.6.2] *are impracticable, the risks associated with such effects shall be assessed on a case by case basis….*".

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), would normally 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 'safe' thresholds can 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. The Committee emphasises that this lack does not in any way diminish the concern.

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 PBT assessment is not practicable for microplastics, noting again 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

The Dosser Submitter performed a case-by-case assessment according to REACH Annex I,

paragraph 0.10, underpinned by the available information on the effects of microplastics in biota in combination with their long-term persistence in the environment. REACH Annex I, 0.10 is intended to cover unconventional risks not fitting into the typical six step hazard evaluation, exposure assessment and risk characterisation as specified in Annex I, 6.1 and 6.2. The examples given in 0.10 are sufficiently diverse for RAC to have confidence that the risks posed by microplastics are well suited to a 'case-by-case' assessment as carried out by the Dossier Submitter. RAC notes that the risk from microplastics extends for long periods of time and cannot be reversed. Given the significance and permanence of this concern and in the absence of appropriate data for a quantitative risk assessment, RAC concludes that microplastics should be considered as non-threshold substances in a similar way to PPT/vPvB substances. In such cases, the environmental releases are 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 in line with the Dossier Submitter 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 *GPX2, GSTP1, GSTP2* and downregulation of *SOD2*, inhibition of catalase and selenium dependent glutathione peroxidases); neurotoxicity and genotoxicity. microplastic conc. 1.5 g/L-2.5 g/L.	*Mytilus sp. (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.	*Danio rerio (fish)*	2	Batel A. et al. 2016; Lu, Y. et al., 2016
Glycogen depletion, fatty vacuolation and single cell necrosis in the liver	*Oryzias latipes (fish)*	2	Rochman CM. et al., 2013
Changes in the transcriptomic profiles suggesting an alteration in glucocorticoid response, insulin pathway, and fatty-acid metabolism	*Crassostrea gigas (invertebrate)*	2	Sussarellu, R. et al., 2016

Table 6 Selection of effects of microplastics observed at individual level

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

Table 7 Selection of effects of microplastics at population level

Observed effect	Species	Reliability	Ref.
Reduction population growth	*Scenedesmus obliquus (algae)*	1	Besseling et al*., 2014
Severe alterations in reproduction	*Daphnia magna (invertebrate)*		
Decrease reproductive output	*Calanus helgolandicus (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 the laboratory but not conclusive for the environment.
- Primary consumers ingest microplastics and there is some evidence (mainly from the laboratory) of a potential for trophic transfer in food chains; some species that represent key links for trophic transfer are known to ingest microplastics, e.g. small pelagic fish and copepods. There is some evidence of low level 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)[26]. The

[26] Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection. http://www.gesamp.org/

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 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. (2018) 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). 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 proposed restriction is appropriately 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, and that such 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 (e.g. 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 the limitations of the dataset as described by the Dossier Submitter.

Although the reported effects thresholds indicate, 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 reliable ecotoxicity data for sufficient species, compartments and routes of exposure with which to carry out multiple quantitative risk assessments in representative environmental compartments is not expected any time soon while emissions of intentionally added microplastics continue. On the other hand, the use of (potentially large) assessment factors (e.g. up to 10 000), which would normally be applied to address the uncertainties associated with tentative PNEC values would not have sufficient basis and consequently would

not increase the confidence that exposures below them are safe. This would also not address the key fundamental issue arising from the long-term persistence of microplastics whereby a 'safe' threshold today will may inevitably be exceeded over time due to the cumulative nature of the exposure due to further to build-up of environmental stocks.

Other uncertainties such as trophic-transfer and nanoplastics effects do not allow for the derivation of reliable PNECs for quantitative risk characterisation.

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

B.1.2.3.2. PBT/vPvB

RAC notes that the concept of bioaccumulation on a molecular level, as described by the criteria in Annex XIII is not suited to the assessment of polymer particles, despite the available evidence that microplastics are present in top predators and are possibly subject to trophic transfer.

While the PBT and vPvB criteria are not met, RAC notes that the long-term persistence in the environment of microplastics could raise an equivalent level of concern to PBT/vPvB, as established in REACH Article 57(f). The Dossier Submitter did not conclude that microplastics pose an equivalent level of concern to PBT/vPvB substances, concluding instead that the case-by-case assessment (see below) 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 0.10, recognises the (i) the long-term persistence of microplastics that leads to their wide dispersive and irreversible accumulation in the environment alongside (ii) the available evidence that exposure to microplastics results in various 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. RAC supports this approach to risk assessment as best fitting this particular case.

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).

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 largely 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 an estimated 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 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/m^2 (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 RMMs retro-fitted 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). 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 as identified from the literature. Where such data are not available default values from ECHA Guidance or other relevant sources were applied.

RAC concludes that all relevant release pathways were properly assessed and provide a good basis for the risk characterisation and agrees that the available information on microplastic properties does not allow a reliable estimation of fate and exposure level in the environment.

The down-the-drain pathway has considerable potential for release, 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/m^3 up to thousands of particles/m^3 (Horton et al., 2017; Rezania 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; Rezania et al., 2018).

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 at about 500 000 tonnes over a 20 year period, is considered significant.

Synthetic turf pitches

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 and considers that a complete ban will be more effective to prevent releases of microplastics over the longer term than the use of RMMs.

RAC notes that the effectiveness of RMMs assumed by the Dossier Submitter of 90% relative to the 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, for which there is limited information. 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.

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, large versus small clubs, etc) and their suitability to achieve the stated minimum effectiveness of annual losses of <7g/m^2. Therefore, RAC notes that the development of such guidance would be a pre-requisite for option A to be considered as practical. **RAC does not endorse the stated level of <7g/m^2/year as any sort of acceptable threshold, as this on its own still implies substantial releases to the environment on a continuing basis**. After implementation of such 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. RAC considers that the smallest microplastic fraction (<100 µm) from pitch infill material, which is the most critical in terms of its potential for environmental effects, is also the most likely to escape through traps and filters adding an uncertainty to the effectiveness of such risk management measures.

RAC also considers that releases associated with the construction and end of life disposal of artificial pitches may lead to release of microplastics in addition to those that occur during the service life. 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.

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 turf sports pitches, which should 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.

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

Based on information received during the consultation, the Dossier Submitter revised its estimated releases to the environment of 36 000 (8 500 – 61 300) tonnes per year upwards 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 original Annex XV report.

A recent report estimated the total annual releases of microplastics from **unintentional sources** to EU surface waters at 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).

Approximately 145 000 tonnes of microplastics are intentionally used in the EEA per year, and about 29% - 42 400 (13 200 to 95 000) tonnes per year - of this is emitted to the environment. Although lower at roughly one quarter of total unintentional releases, the intentional releases are substantial contributors to microplastic pollution.

B.1.3.3.1. Down-the-drain disposal

With the exception of the 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).

The Dossier Submitter cites numerous studies on the effectiveness of wastewater treatment to remove microplastics (See section 1.4.2.2 of the Background Document). Wastewater treatment retains microplastics mainly thorough grit/grease removal and sludge retention in the primary and secondary step of the process, respectively (the Dossier Submitter calculated an average of 97.5% retention after secondary treatment from the available studies). Tertiary treatment, where present, results in marginally more effective retention that primary and secondary treatment (the Dossier Submitter estimated an average of 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 contributions 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 release from agriculture to soil is one of the most significant pathways. 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 arise 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, hockey, 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 1). 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).

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%;[27]
- Thermoplastic elastomers/thermoplastic rubbers (TPE): market share of ~4%;
- Polyethylene (PE) or polypropylene (PP): market share unknown.

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

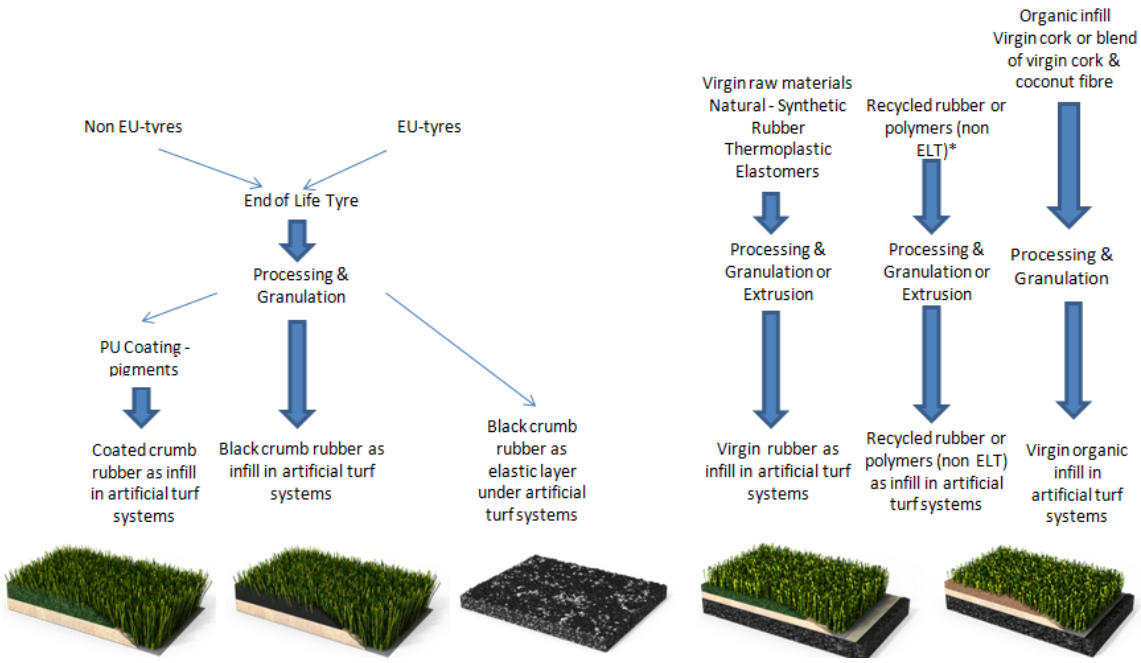

Figure 1 Schematic of 3rd generation artificial turf systems; based on information provided by ETRMA and ESTO (2016).

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 a European level in terms of both quantities of intentionally-added microplastics used (100 000 t/y) and released to the environment (16 000 tonnes) per year (Table 8). Based on central estimates, this corresponds to a release factor of 0.16 (16%).

Polymeric infill material used on synthetic turf sports fields can be inadvertently removed (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, i.e. to replace lost infill, but also to compensate for compaction that occurs over time.

The Background Document reports the results of several studies investigating the loss of infill material from synthetic turf sports pitches. Løkkegaard et al. (2018) 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.

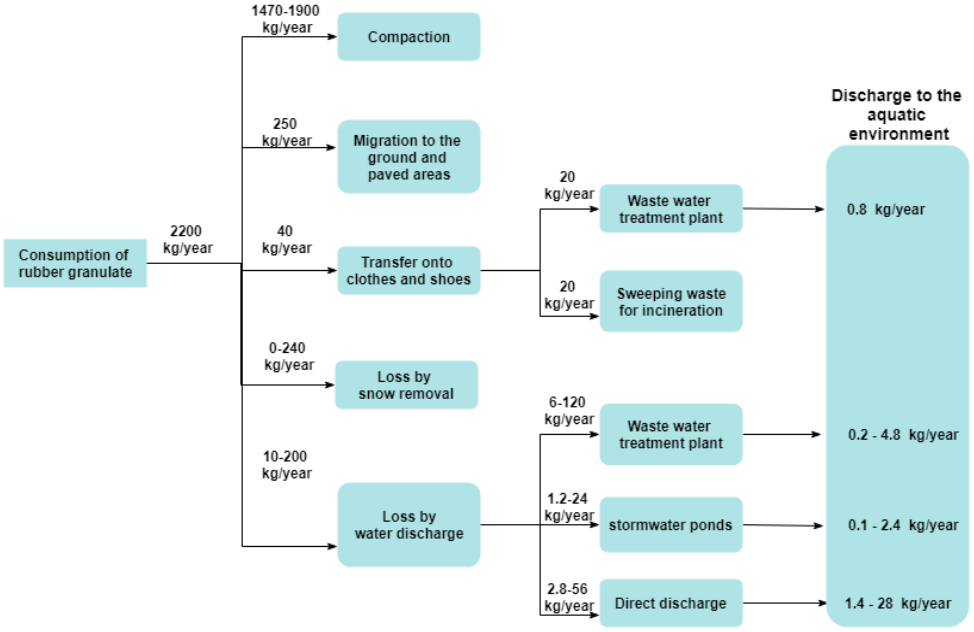

Figure 2 Different pathways for loss of rubber infill (Løkkegaard et al. 2018).

Similarly, Wiijer 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. They 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 Document[28]. 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 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.

[28] 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 pitches 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.

Site-specific considerations, such as the frequency of snow clearance, construction of drainage systems, compaction and how regularly 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*[29] 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 the environment, the guideline includes examples of what they consider to be good practice, some of which are:

- Use of raised perimeter edge details;

[29] 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.

- 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 stich 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 adequately evaluated and documented. The effectiveness of risk management measures was recently reported in a one year study of a newly installed synthetic turf at Bergaviks IP sports ground in Kalmar, Sweden (Regnell, 2019. 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
- A sealing layer under the pitch was installed to collect all drainage water
- Granular traps were fitted in all stormwater drains around the pitch (>200 µm filter)
- Granular filters were fitted 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 critical fine 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). The Committee points out that the smallest microplastic fraction (<100 µm) from pitch infill material, which is the most critical in terms of its potential for environmental effects, is also the most likely to escape through traps and filters adding an uncertainty to the effectiveness of such risk management measures.

Based on information provided in the consultation, the Dosser 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 m^2), this annual release is equivalent to or lower than 7 g/m^2/year. The magnitude of this release is put into context further below.

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/m^2 (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/m^2/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 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 by Regnell (2019) for the Kalmar case study correspond to a value of >99%[30]. 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 substantial 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/m^2. 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

[30] 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.

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 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. Risk management measures such as drainage sinks and filters will not typically be effective for the smallest microplastic fraction (<100µm) from pitch infill material, i.e. the most critical in terms of its potential for environmental effects. RAC also notes that after implementation of risk management measures, at 90% effectiveness, annual releases of microplastics from EU pitches would still be in the order of 1 600 t/yr.

RAC notes that, associated with Option B, 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 be phased out completely in newly constructed or refurbished pitches after a certain transitional period expired[31]. This option is not preferred by RAC as it would still result in releases of

[31] Microplastics shall not (i), from [entry into force (EiF)], be used as granular infill in synthetic sports surfaces

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.

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] - Other rinse-off - Leave-on	107 6 500 (2 900 – 10 000) 2 100 (1 100 – 3 000)	55 3 100 (1 400 – 4 900) 600 (300 – 900)
Detergents and maintenance	17 000 (11 100 – 23 000)	8 500 (5 600 – 11 600)
- Detergents containing microbeads[c] - Fragrance encapsulation - Other detergents - Waxes, polishes and air care products	95 400 (260 – 540) 15 200 (9 440 – 20 960) 1 300	50 200 (0 – 150) 7 700 (4 800 – 10 650) 585
Agriculture and horticulture	10 000 (3 500 – 18 000)	10 000 (3 500 – 18 000)
- Controlled release fertilisers - Fertiliser additives - Treated seeds - Capsule suspension PPPs	5 000 (1 000 – 10 000) 4 000 (2 000 – 6 000) 500 (250 – 1 000) 500 (250 – 1 000)	5 000 (1 000 – 10 000) 4 000 (2 000 – 6 000) 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 - Professional uses	5 300 (4 900)	2 700 (2 500)
Construction products	Not known	Not known
In vitro diagnostic devices [e]	50 (0.5 – 100)	0.27 (0.25 – 0.29)

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/m^2/y; (iii), from [EiF + 6 years] be used as granular infill on sports surfaces installed (newly constructed or refurbished) after EiF + 6.

Sector / Product group	Use [a] (tonnes/year)	Release to the environment [b] (tonnes/year)
Medical devices (MD)		
- (substance-based) MD - MD other than (substance-based)	Not known ~10	Not known -
Medicinal products	2 300 (800 – 3 700)	1 100 (400 – 1 800)
- Ion exchange resins - Matrix or polymer film for controlled release - Immediate release	700 (300 – 1 000) 1 600 (500 – 2 700) Not known	300 (100 – 500) 800 (300 – 1 300) 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;
[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]
[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;
[f] Assumes 21 000 full-sized and 72 000 small-sized pitches in the EU by 2020;
[g] All figures are rounded so may not add up precisely to the totals presented.

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 notes that a similar approach has been applied in its recent opinions on e.g. decaBDE (2015), PFOA (2015), lead in PVC (2017) and lead in gunshot (2018).

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 of releases from different uses and to 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) [32]. SAM (2019) report 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 and mentioned in RAC analysis of these aspects in preceding sections of this opinion. For instance, a significant proportion of the studies conducted to date

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

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 most 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 allowing the Committee 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 a range of relevant environmental compartments.

Should safe thresholds be derived in the future for all the necessary compartments (which may take decades to undertake sufficiently representative laboratory studies) this would not address the fundamental key 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 were ever 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 are associated with an environmental 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'[33] 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 innovation[34].

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

[33] http://europa.eu/rapid/press-release_IP-18-5_en.htm

[34] 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.

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.

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

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
			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 proposal:

The primary reason for regulatory action on a Union-wide basis is that a REACH restriction provides the means to effectively reduce emissions of intentionally-added 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 Member State may receive microplastic emissions released in another Member State. The Dossier Submitter considers EU-wide measures to be required to address the transboundary nature of microplastics pollution and 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.

As substances and mixtures containing microplastics are produced, marketed, transported and used throughout the EU in a variety of sectors leading to transboundary pollution (meaning that one EU Member State may receive microplastic emissions released in another), action should be taken on a Union-wide basis.

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with intentionally added microplastics should be implemented in all Member States.

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:

i. The need to ensure a harmonised high level of protection of the environment;
ii. The fact that 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.

The Dossier Submitter identified a risk from the EU-wide use of intentionally added microplastics that was not adequately controlled. Emissions of intentionally added microplastics, which unlike other plastic uses, cannot be readily collected, recycled or remediated once released to the environment, leads to accumulation and persistence for hundreds to thousands of years. Environmental pollution caused by microplastic releases gives rise to social costs in terms of adverse effects on aquatic, terrestrial and marine organisms. Hence, any measure aiming to effectively reduce/address this risk and correct this market failure needs to be taken in all Member States of the EU (as well as the EEA members: Norway, Iceland and Liechtenstein).

Another argument showing the necessity of an EU-wide action is the transboundary nature of microplastic pollution. One EU Member State may receive microplastic emissions released in other Member States. While intentionally added microplastics add, in relative terms (i.e. comparing volumes of primary and secondary microplastics[35] in the environment), only a small part to the overall environmental burden of microplastics, SEAC notes that this restriction proposal effectively reduces environmental emissions of microplastics, which results in environmental benefits.

Based on evidence provided by the Dossier Submitter, SEAC recognises that the placing on the market and use of substances and mixtures containing microplastics takes place Union-wide.

The Dossier Submitter presents information that microplastics are used, as such or in mixtures, in the following product groups, applications or sectors (non-exhaustive list):

Table 10 Microplastic use by sector (sectors marked in italics were analysed in depth in the Background Document)

Cosmetic products	*Detergents and maintenance products*
Agriculture and horticulture	*In vitro diagnostic devices*
Medicinal products for human and veterinary use	*Food additives*
Paints, inks and other coatings	*Oil and gas*
Plastics	Technical ceramics
Media for abrasive blasting	Adhesives
3D-printing	Printing inks
Infill material	*Medical devices*

The sectors marked in italics in the above table were analysed in more depth by the Dossier Submitter, highlighting how widespread the use of microplastics is. Where information permitted and when impacts within a sector were likely to vary substantially, further subdivisions into product groups were made. For example, cosmetic products were subdivided

[35] The majority of microplastics found in the environment are so-called secondary microplastics formed through degradation of larger articles containing polymers (e.g. tyres, clothes, plastic bags). Secondary microplastics are not in the scope of the restriction, but other actions on an EU-wide basis are currently being considered by the EU Commission to address some sources of secondary microplastics (see EU Plastics Strategy). According to comments made by SCHEER (#2244) during the consultation on the Annex XV report, the percentage of primary microplastics in the environment is never higher than 10%, but that stock effects need to be taken into consideration (continuous emissions and persistence of the material).

into three product groups: rinse-off with microbeads, other rinse-off (i.e. without microbeads) and leave-on. The same was done for the detergent and maintenance, agriculture and horticulture sectors.

From this table and the in-depth analysis of different sectors, SEAC concurs that microplastics are used in a wide variety of applications, which are targeted to consumers and professionals across the EU. Union-wide action is therefore necessary in order to maintain a level playing field within the internal market.

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 11 and Table 12.

SEAC notes that the Dossier Submitter's proposal was revised during opinion making based on submissions to the consultation. This opinion relates to the revised proposal. All revisions to the proposal are documented in the Background Document.

Table 11 Proposed derogations from the restriction by the Dossier Submitter

Para.	Derogation from restriction	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) as well as 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 that would inevitably and immediately lose their particle form in the environment are different from microplastics that would retain their particle form in the environment. The criteria are set out in an Appendix to the entry (currently referred to as Appendix Y) and are described in Section 2.2.1.7 of the Background Document. The derogation is required to ensure that the restriction is targeted to the substances contributing to the identified risk.
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.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 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).
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.

Table 12 Proposed derogations from the ban only (i.e. conditional derogations) by the Dossier Submitter

Para.	Derogation from ban only (i.e. conditional derogations)	Explanation
4.a	Substances or mixtures containing microplastics for **use at industrial sites**.	This is required to allow continued use at industrial uses, as previously described. As there could be releases of microplastics under reasonably foreseeable conditions of use the downstream users benefiting from this derogation shall be required to report the quantities released to the environment 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	Derogation from the scope of the restriction on use to avoid potential double regulation and any risk that the availability of medicines could be affected. The Commission is also developing a strategy on pollution from the use of medicines. As there could be some releases of microplastics under reasonably foreseeable conditions of use the importers or downstream users placing medicinal products

Para.	Derogation from ban only (i.e. conditional derogations)	Explanation
	Directives 2001/83/EC and 2001/82/EC, and in EU Regulation (EC) No. 726/2004.	on the market, and benefiting from this derogation shall be required to report the quantities released to the environment 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 include appropriate use and disposal instructions to minimise releases to the environment (paragraph 7).
4.d	Substances or mixtures containing **food additives** as defined in EU Regulation (EC) No. 1333/2008.	Derogation from the scope of the restriction on use to avoid potential double 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 released to the environment to the Agency (paragraph 8), so the legislator can decide on any further EU action if needed. In addition, products shall be required to include 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 released to the environment to the Agency (paragraph 8). This requirement sends a clear signal that the substitution of microplastics or the implementation of containment measures is encouraged without disrupting market access to IVDs. In the event that the reporting requirement does not lead to minimisation of releases, further regulatory action could be initiated by the EU Commission. In addition, products shall be required to include instructions on appropriate use and disposal 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. *In vitro* 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 *in vitro* for the examination of specimens, including blood and tissue donations, derived from living organisms".
[4.h]	**Infill** used at pitches with RMMs to achieve minimal releases.	The Dossier Submitter concluded that two restriction options could be considered as proportionate: Option A (mandatory RMMs) and Option B (ban on the placing on the market). This derogation would be needed in the event that Option A was preferred by the decision-maker over Option B to address infill material as states the minimum performance of RMMs required to be derogated from the ban on placing on the market.
5.a	Substances, mixtures or articles containing microplastic where the microplastic is **contained by technical means to prevent releases** to the environment.	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. This derogation is generic but is primarily intended to cover uses of microplastics in non-industrial professional or consumer settings, including water purification applications (cartridges containing Ion Exchange Resins), incontinence pads, nappies or menstrual pads. Therefore, uses benefiting from this derogation shall be required to include appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities released to the Agency (paragraph 8).
5.b	Substances or mixtures containing microplastics **where the physical**	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

Para.	Derogation from ban only (i.e. conditional derogations)	Explanation
	properties of the microplastic **are permanently modified** when the mixture is used such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a).	irreversible. 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). However, as there could be some releases of 'unconsumed' microplastics under reasonably foreseeable conditions of use, these releases should be minimised. Therefore, uses benefiting from this derogation shall be required to include appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities released to the environment to the Agency (paragraph 8).
5.c	Substances or mixtures containing microplastics where the microplastic are **permanently incorporated into a solid matrix** when used.	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. 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. 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. Therefore, uses benefiting from this derogation shall be required to include appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities released to the environment 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.

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 monitorabilty 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 an extension of the derogation

(# 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.

Justification for the opinion of SEAC

SEAC conclusion(s):

Scope of the proposed restriction

SEAC agrees in general with the scope of the restriction as proposed by the Dossier Submitter including the modifications and refinements made during opinion development. All revisions are described in the Background Document.

The Dossier Submitter performed a thorough review of the different definitions for the term *'microplastic'* in existing national legislation, as well as those put forward by academic and research organisations. SEAC finds that the definition[36] proposed by the Dossier Submitter is clear, based on a critical assessment of all information available, and takes into consideration various issues raised by stakeholders in the Dossier Submitter's call for evidence or the Annex XV report consultation. It is outside of the remit of SEAC to comment on the validity and appropriateness of the definition itself, but the overall approach is considered to be well-justified by the Committee. SEAC notes that the updated definition[37] is fit for purpose, i.e. it is in line with the objectives set out by the Dossier Submitter and the request by the Commission.

The proposed restriction adopts a three-pronged approach to address the concerns raised by the placing on the market and intentional use of microplastics.

A **ban** is proposed for sectors, product groups and applications where the evidence on uncontrolled releases to the environment is sufficiently robust and where these releases would inevitably occur despite the existence of RMMs.

Where the Dossier Submitter considered that releases to the environment could only happen in case of inadequate use or disposal, and that risks could therefore be minimised by appropriate conditions of use and disposal[38] '**instructions for use and disposal' requirements**[39] are proposed instead of a ban.

Where the Dossier Submitter found there was insufficient information on uses of substances and/or mixtures containing microplastics as well as the effectiveness of current risk management measures, then a **reporting requirement** is proposed as a means to gather information to support future action if necessary. In order to enable downstream users to fulfil their reporting obligations, suppliers are required to inform downstream users on substances or mixtures containing microplastics (generic polymer identity and concentration). In this respect, stakeholders expressed concerns in regard to the leaking of Confidential Business Information (CBI). SEAC finds these concerns valid, because the disclosure of CBI cannot be entirely excluded. However, SEAC considers that there are possibilities to prevent CBI disclosure, e.g. by using an identifier for polymer identity or concentration ranges. An identifier could be for instance a code number, where the polymer identity is only disclosed to ECHA and not to other actors within the supply chain. If such a solution does not prove to be practical, SEAC notes that it would also be possible to claim polymer identity as confidential and still provide information on the relevant concentration of microplastics (which could be used by a downstream user for reporting purposes).

The scope of the restriction proposal is intentionally wide. Any use that is not derogated in the conditions of the restriction or associated with specific transitional periods will be banned

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[36] Including sub-definitions for microbead, particle, particle containing solid polymer, solid, gas, liquid, (bio)degradable polymers, natural polymers etc.

[37] See 'Key Elements' section.

[38] In other words, when releases of microplastics are not considered to be inevitable.

[39] Includes instructions for proper use and disposal in the SDS (as an example) or on the label .

from the entry into force date of the restriction. The Dossier Submitter considered a comprehensive approach to be important given the breadth of identified uses and also to prevent new uses. The Dossier Submitter indicates that it is possible, albeit unlikely, that specific uses were not identified during either the Annex XV report preparation or opinion development. Given the generic nature of the conditions of the restriction unidentified uses that would not result in releases would be derogated from the ban (i.e. by means of the paragraph 5 derogations), but would not have transitional periods. Since RAC concluded that the releases of microplastics to the environment are a proxy for risk, all emitted microplastics pose a risk to the environment. SEAC therefore supports the wide coverage of the restriction proposal.

Specific derogations were proposed to avoid regulating substances or mixtures that are not associated with a microplastic concern, such as natural polymers, (bio)degradable polymers and soluble polymers (water solubility >2 g/L). Additionally, microplastics that are contained during their use and are therefore not released into the environment, microplastics that are modified during their end use and lose the physical properties of microplastic (i.e. there is no microplastic released into the environment) and microplastics that are permanently embedded into a solid matrix during end use minimising releases, are also derogated. Other derogations are proposed to avoid double regulation (e.g. fertilising products covered by Regulation (EU) 2019/1009) or to exclude the non-intentional presence of microplastics (food/feed, sewage sludge and compost).

SEAC acknowledges the necessity for these derogations and finds the Dossier Submitter's reasoning to be sound.

During the consultation, stakeholders from the (rubber) infill industry (tyre recyclers, pitch manufacturers) as well its downstream users indicated that a full ban of infill material, which is covered by the microplastics definition, is not proportionate in their view. The Dossier Submitter performed an assessment based on the information submitted in the Annex XV report consultation and concluded that a derogation (under the condition that specific risk management measures are implemented) or specific transitional arrangements (prior to a ban taking effect) are warranted. As is detailed later in this opinion, SEAC finds this to be justified[40].

SEAC considers that the approach taken by the Dossier Submitter is reasoned and well-founded. It allows immediate action to be taken where that action would be most effective and the collection of information to inform the assessment of possible future action. Since the Commission wished to focus on consumer and professional uses of microplastics, the Dossier Submitter did not propose to ban any industrial uses. In this respect, SEAC notes that there is information on releases of intentionally added microplastics for some industrial uses, indicating that further action on these uses may be appropriate. SEAC supports the instructions for use and reporting requirements to inform possible future action in this regard.

SEAC also supports the approach taken for setting different transitional periods for different product groups balancing the need to provide stakeholders with sufficient time to implement the proposed restriction and the objective to minimise emissions and impacts on the environment. SEAC considers the proposed transitional periods generally as a reasonable timeframe for implementation of the restriction. The Committee based this conclusion on the analysis performed by the Dossier Submitter in regard to the availability of alternatives, the

[40] See the key elements and costs section for SEAC's analysis.

need for reducing microplastics emissions, and the expected costs to society. SEAC also took into consideration comments received during the Annex XV report and SEAC draft opinion consultations and, where relevant, reflects these comments and SEAC's own considerations in the analysis of the transitional periods (see key elements section).

RMO analysis

The majority of the possible risk management options (RMOs) discussed by the Dossier Submitter are variations of different REACH restrictions: restricting all uses without any derogations or transitional periods, restricting specific uses only, restricting specific polymer types used as microplastics, or adjusting the size characteristics of the microplastic definition. SEAC agrees with the Dossier Submitter's reasoning for rejecting these options. Some would indeed be less proportionate[41] and/or less practical in comparison with the proposed restriction; others would have been (significantly) less effective in terms of risk reduction. While SEAC agrees that the discarded RMOs are less appropriate and acknowledges that the Dossier Submitter was thorough in identifying different possible RMOs, the Committee considers that their assessment was rather concise and sometimes lacked well elaborated justification (see key elements section).

In addition to these variations on the same RMO, the Dossier Submitter also considered the use of non-legislative measures (voluntary agreements and information campaigns), action under legislation other than REACH (e.g. sector specific legislation, product safety directive and taxation) and action through other REACH processes (authorisation and using REACH Article 68(2)). While SEAC notes that in the specific case of microbeads in wash-off cosmetic products voluntary measures proved to be effective, similar actions will prove to be extremely difficult to implement effectively on a more general basis due to the wide scope of the restriction proposal and, thus, the vast number of stakeholders involved. Therefore, SEAC agrees that non-legislative measures can be rejected based on their ineffectiveness in terms of risk reduction or the practicality of the measure. Legislative measures other than those under REACH are, in general, also considered to be less effective or not effective at all in addressing the EU-wide risks identified. SEAC further notes that action through other REACH measures[42] is not possible since microplastics are currently neither classified nor identified as SVHC.

SEAC acknowledges that the Commission specifically requested ECHA to prepare an Annex XV dossier to reduce possible risks associated with the placing on the market and intentional use of microplastics in products for consumer and professional use. SEAC notes that non-legislative measures, legislative measures and other actions under REACH were discussed nonetheless to decide on the appropriateness of a restriction. As a REACH restriction was specifically identified in the 'European strategy for plastics in a circular economy', the Dossier Submitter did not assess other novel union-wide legislative RMOs, e.g. the relative merits of an EU Directive/Regulation on intentionally added microplastics. The Dossier Submitter presumed that during the development of the 'plastics strategy' due consideration had been given to the most appropriate means to effectively achieve each of the strategy's objectives. Nevertheless, SEAC would have preferred to have had an assessment of the appropriateness of a stand-alone legislation to address intentionally added microplastics.

Overall, and considering the above, the analysis conducted by the Dossier Submitter has

[41] Both in terms of cost vs benefits as well as in regard to technical feasibility.

[42] Such as authorisation and article 68 §2 restrictions.

provided sufficient justification for SEAC to agree that the proposed restriction is the most appropriate EU-wide measure to address the risk arising from the placing on the market and intentional use of microplastics within the scope of the request from the Commission. SEAC agrees with the Dossier Submitter's conclusion that the other risk management options assessed are not as appropriate as a restriction under REACH due to limitations in scope, effectiveness, practicality and/or proportionality.

Key elements underpinning the SEAC conclusion(s):

Scope of the proposed restriction

a) Microplastic definition

Original proposal:

> '***microplastic***' *means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ x ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ x ≤ 15mm and length to diameter ratio of >3.*

The Dossier Submitter notes that various other definitions for microplastic have been proposed in the scientific literature, but that there is no standardised understanding. SEAC agrees that in order for the proposed restriction to work as intended the term 'microplastic' needs to be defined clearly. To do that, the Dossier Submitter screened existing national and international legislation, as well as activities by academic and research organisations for suitable definitions.

A first important point to note is that there does not seem to be a consensus on what the term '**plastic**' means. Since REACH already contains a definition of the term '**polymer**' and the term 'plastic' is deeply connected to it, the Dossier Submitter decided to use **REACH Article 3 point 5 (i.e. definition of 'polymer') as the basis for the proposed restriction**. SEAC agrees with this clear, practical and pragmatic approach. SEAC notes that using the polymer definition under REACH creates a harmonised understanding of the term plastic, which is not the case in existing legislation or research, even within the EU[43]. During the consultation on the Annex XV report, industry indicated that the restriction should include a list of all the polymers that are specifically within the scope of the restriction. SEAC notes that this would be very impractical considering the wealth of polymers that are or could be used in microplastic form. Industry stakeholders' concerns that polymers which do not contribute to the risk would also be targeted seem unfounded due to the scope reflecting the risks to be addressed and the incorporation of full and partial derogations from the restriction for polymers where there are no reasons for concern (see further in the opinion).

Secondly, not all polymers are considered to be microplastics. A clear **delineation of what polymers should be defined as microplastics** is therefore the next important step. The Dossier Submitter concluded that certain other aspects of existing microplastic definitions appear almost universally, for example: 'particle', 'solid' and 'dimensions of 5 mm or less'.

[43] Although it should be noted that the recent Single Use Plastics Directive does use the REACH Polymer definition as part of its definition of plastic.

- The term '**particle**' was previously defined as part of the Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU). The Dossier Submitter adopted this definition. SEAC notes that this alignment creates a harmonised understanding of the term. In 2018, the Joint Research Centre of the EU (JRC) prepared draft guidance on the implementation of the EU definition of nanomaterial in which it is specified that a '*minute piece of matter*' is only called a particle if this piece of matter has defined physical boundaries. During opinion development the Dossier Submitter decided to include additional aspects of JRC's recently published guidance on the implementation of the nanomaterial definition as part of the particle definition, specifically that single molecules are not particles. This would not only create a harmonised definition of the term 'particle', but also be coherent with the implementation of the nanomaterial definition and take into account current scientific understanding. RAC agreed with this inclusion.
- The term '**solid**' (and therefore also the terms 'liquid' and 'gas') is already defined under CLP and the Dossier Submitter adopted this for their definition of microplastics. SEAC notes that this creates a harmonised understanding of the term. However, RAC and the Dosser Submitter both acknowledged that the CLP definition is not fully fit-for-purpose when it comes to polymers without a melting point and have therefore adapted the definition accordingly. The Dossier Submitter indicated that in many definitions water insolubility has been included and that stakeholders are also in favour of this[44]. The Dossier Submitter did not include such an element in its original proposal since from a practical and empirical perspective "*it is open to interpretation and is not as straightforward as would be initially thought*"[45]. Furthermore, "*Polymer solubility can be understood differently depending on the context the term is used*". SEAC understands that in the interest of clarity, the Dossier Submitter had initially chosen not to include this concept in their proposal for a definition. SEAC also notes that, in a practical sense, the use of the term 'particle' replaced the need to consider solubility in the definition itself. Nevertheless, during the consultation on the Annex XV report it became clear that a specific derogation for highly water soluble polymers might be warranted (see further in this opinion).
- The Dossier Submitter discusses particle size and morphology in detail. Several elements are important to discuss according to SEAC.
    - The Dossier Submitter states that there is a consensus on the **upper size limit** (5 mm) for particles considered as microplastic. SEAC finds it justified to set an upper size limit of 5mm as part of the definition, since it seems to represent the size at which the relevant exposure of organisms in the environment changes from ingestion (microplastics) to physical effects such as entanglement (larger plastic items).
    - A **lower size limit** was originally proposed by the Dossier Submitter to be 1 nm in order to include both nano- and sub-micron sized particles. During the consultation on the Annex XV report many stakeholders indicated that a lower size limit smaller than 100 nm would cause considerable technical problems from an analytical standpoint, indicating, for example, that the presence of

[44] This was reiterated by multiple stakeholders during the consultation on the restriction dossier.

[45] As an example, polymers can swell in a solvent while non-polymeric substances do not. Swelling can be the final stage in a polymer's interaction with a solvent, but can also be the first step towards dissolution.

'molecular particles' (particles comprising single molecules), detergent micelles and other particles comprised of several molecules with dynamic surface structure could confound the interpretation of particle characterisation at the nanoscale. It was also stated that it would be difficult to ascertain the size through regular testing methods. The FORUM echoed these concerns. The Dossier Submitter acknowledged the practical difficulties associated with the 1nm limit and, whilst acknowledging that particles <100 should not be deliberately used in products where they can be adequately characterised, proposed to revise the lower limit in the conditions of the restriction from 1nm to 100 nm. However, whilst agreeing with the concerns raised, RAC did not consider it necessary to set a lower size limit for the microplastic definition at all as enforcement would not necessarily need to be based on analysis of samples. SEAC notes that a definition should delineate a group of substances with similar concern/hazard and should not take into account considerations regarding enforceability and practicality. Difficulties in relation to determining the size of submicron particles, should be dealt with through adequate targeting of the restriction, rather than modifying the underlying definition of a microplastic. As such, SEAC finds RAC's rejection of the 100 nm limit in the definition of "microplastics" to be justified. However, SEAC does not agree to set no lower size limit at all. In that case the definition would not provide a fully fit-for-purpose delineation of the group of substances that need to be regulated (i.e. the scope of the proposed restriction). SEAC therefore proposes to include in the definition the lower limit of 1 nm originally proposed by the Dossier Submitter. SEAC also notes that in light of the risk identified by RAC and the Dossier Submitter (which also includes particles at the nano-scale), it is unfortunate that an unrefined term such as "microplastics" was used to define the conditions of the restriction proposal. This can lead to confusion and discussions based on semantics instead of the underlying scientific reasons for proposing this restriction. SEAC notes that the term should perhaps not be used as the basis for any Annex XVII entry resulting from this proposal, but rather the relevant physical and chemical criteria could be used by themselves.

- The size limit should be assessed for **all dimensions of the material** since, as an example, plastic bags and films with a large surface area could otherwise also be covered by the restriction. SEAC agrees with the Dossier Submitter that these types of material should not be considered as intentionally added microplastics.

  Some stakeholders have expressed concerns regarding the size cut-offs for **fibres**[46]. The Dossier Submitter has therefore included upper and lower limit values for length as well as a length-to-diameter ratio to address these concerns. The basis for these additional elements was the WHO fibre aspect ratio criteria. A lower size limit had been proposed by the Dossier Submitter of 3 nm and upper one of 15 mm, as well as a length-to-diameter ratio that needs to be larger than 3. As was the case for the particle size cut-off, RAC did not find it necessary to set one. SEAC does not agree with this (see detailed

[46] It is important to note that some, but not all, fibres can be considered as articles. If a type of fibre is considered to be an article then it is outside of the scope of this restriction. E.g.: man-made textile and non-woven fibres are considered articles (see guidance on substances in articles), but fibres used for reinforcement are considered as substances or mixtures.

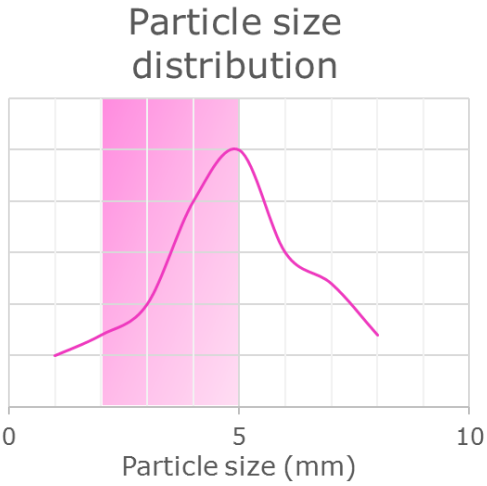
discussion above). SEAC therefore proposes to include in the definition the originally proposed lower limit of 3 nm. Previous considerations on the targeting of the restriction apply here as well.

Besides these almost universally accepted parts of the microplastics definition, the Dossier Submitter also considered some additional terminology and characteristics.

- While the term '**microbead**' is sometimes interchangeably used with the term 'microplastic', in most cases it is defined as a microplastic with exfoliating or cleansing functions added to cosmetic or detergent products. SEAC notes that the need for a definition for this subset of microplastics is necessary to set different transitional periods (see later in this opinion). The Dossier Submitter has clarified that if a microplastic also has another function besides as or additional to being an abrasive (e.g. opacifying, encapsulation) then it is still considered as a microbead for the purposes of this restriction. SEAC notes that this is not readily apparent from the wording of the restriction, which could potentially be clarified.
- Before a 'particle' can even be considered to be a microplastic, it first needs to be ascertained if it contains a polymer (with or without additives). In the context of this restriction a microplastic particle does not refer only to particles consisting solely of polymers. SEAC notes that in order to adequately control releases of microplastics into the environment it is indeed appropriate to be inclusive in regard to what could be a microplastic. The Dossier Submitter therefore proposes a definition for a so-called '*particles containing solid polymers'*. The Dossier Submitter identifies two types of particles that could be consistent with this term:
    - A particle of any composition with a solid polymer content of ≥ 1% w/w. SEAC finds it justified to propose this specific value, since it is consistent with the impurity level threshold under REACH.
    - 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 material. SEAC 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, but due to size difference, the relative weight percentage will be different.

All of the above terminology pertains (or can pertain) to a single particle. In order to ascertain if a sample of a substance or mixture containing a variety of particle sizes can be considered to be a microplastic, a threshold for the presence of particles containing solid polymer within the relevant size range needs to be set. Based on stakeholder input, available scientific methods, and practical considerations, the Dossier Submitter proposed 1% w/w as the limit value. In practice, this means that if more than 1% w/w of relevant particles (**particle weight-based size distribution**) in a sample are within the size range given in the definition for 'microplastics', the substance/mixture as a whole is considered to be a microplastic.

SEAC notes that the Dossier Submitter has indicated several reasons to choose this specific limit value



- It is a conservative value which takes into account the inherent skew towards larger particles in weight-based distributions.
- There is analogous precedent in the nanomaterial definition and international legislation regarding nanomaterials.
- It was seen as a feasible and pragmatic value that takes into account current methods for separating microplastics (e.g. sieving methods).

SEAC wishes to note that the microplastics definition was discussed thoroughly with stakeholders and that the Dossier Submitter updated the definition during the opinion making phase to reflect relevant comments.

It is outside of the remit of SEAC to comment on the validity and overall appropriateness of the microplastic definition, but the approach taken to arrive at it is considered to be reasoned and well-justified by the Committee. SEAC also wishes to note that the updated definition is fit for purpose, i.e. it is in line with the objectives set out by the Dossier Submitter and the request from the Commission.

b) Targeting of the proposed restriction

The Dossier Submitter states that the proposed restriction aims to address the risks from microplastics in uses that are not adequately controlled. Therefore, the restriction proposal entails a ban on all microplastics that meet the definition unless their specific use is explicitly derogated from the ban. Specifically targeting the intentional use of microplastics can be done via different means. The Dossier Submitter proposes a concentration limit of 0.01% w/w in order to achieve this. SEAC notes that this threshold is based on information collected through literature searches and the Call for Evidence. For certain uses, the percentage of microplastics added to achieve a specific function, i.e. intentionally added microplastics, is available. SEAC understands that this specific threshold was chosen since it seems to correspond to the lowest concentration at which it is generally assumed that the addition of microplastics has an effect on the function of the product.

During opinion development it became clear that there are technological barriers that make identifying microplastics <100 nm challenging. In certain cases, it might however be possible that raw material suppliers can reliably characterise materials <100 nm as microplastics and

that formulators can then avoid the use of microplastics <100 nm even if they cannot be resolved analytically in final products. However, this does not necessarily ease enforceability concerns at the present time. SEAC stated earlier in this opinion that practicality and enforceability should have no bearing on the microplastics definition, but that these issues should be taken up when defining the target of the restriction. SEAC therefore sees some merit in including a **temporary** lower size limit of 100 nm **when the reliable characterisation or identification of microplastics is not self-evident** (through analytical methods or via a "document-based" enforcement)[47]. This will help both compliance by industry and enforcement by the competent authorities. SEAC notes that supporting measures are needed to remove the aforementioned technological barriers in analysing the size of microplastics as soon as possible (e.g. funding for research to remove technological barriers regarding analytical methods). This is seen as important to remove current risks associated with emissions of particles with a size below 100 nm. SEAC arrives to this conclusion taking into account RAC's view that no lower size limit should be set from a risk assessment point of view, but that considering the current state of the art in analytical methods, certain practical considerations could be used to set a temporary lower size limit (see section on enforceability). SEAC notes that multiple stakeholders have indicated that microplastics with dimensions below 100 nm are commercially available and are used. Regrettable substitution is therefore possible if the difference in size does not significantly affect the functionality of the microplastics.[48] CEFIC has indicated that there is no likelihood of this happening, but SEAC agrees with other stakeholders that it is an issue that needs to be taken into account. Equally, it is important to note that setting a temporary lower size limit of 100 nm could mean that relevant information on particles <100 nm that can be identified and characterised would not be gathered through the instructions for use (paragraph 7) and reporting (paragraph 8) requirements.

Targeting the placing on the market and use of a substance or mixture is a tried and tested approach in restriction proposals. SEAC notes however that due to the wide targeting of the restriction, certain elements need to be discussed more in-depth.

i. <u>Ban – instruct[49] – report</u>

For this restriction proposal the Dossier Submitter adopted a three-pronged approach to address the concerns raised by the placing on the market and intentional use of microplastics.

A complete **ban** on the placing on the market is proposed for sectors, product groups and applications where the evidence base is sufficiently robust that releases are inevitable despite RMMs being implemented. This means that the Dossier Submitter considered releases of microplastics due to their use as unavoidable and that the subsequent risks to the

[47] When the reliable characterisation or identification of microplastics is possible though, then the restriction should also be targeted at microplastics <100nm.

[48] Changing the size of a particle can also change the characteristics and properties of that particle. This is why nanomaterials are considered differently to "macro" materials in chemicals legislation. Below a threshold of ±50 nm questions such as "Is it still a polymer?" or "Is it still a solid?" become very important. It follows that reducing the size of a microplastic in a substance/mixture to avoid the proposed restriction would not always be technically possible as the properties of the smaller particle could adversely affect the properties of the substance/mixture to such an extent that it would not have the desired functionality.

[49] Includes instructions for proper use in the SDS (as an example).

environment should be curtailed. It also means that the Dossier Submitter considered there to be sufficient socio-economic information available covering the whole breadth of the scope in order to assess the impact[50] and justify a ban.

When the Dossier Submitter considered that risks from unintended, but not inevitable, releases could be minimised by appropriate conditions of use and disposal then the ban does not apply, but '**instructions for use and disposal requirements'** were proposed instead. This is notably the case for the placing on the market of the substances and/or mixtures containing microplastics listed below.

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

SEAC agrees that in order to be most effective the 'instruction for use and disposal requirement' should indeed cover end uses as well as preceding life-cycle steps, including those at industrial sites. Every actor within the supply chain needs to have sufficient information to be able to take appropriate action in order to minimise releases, including accidental releases.

Additionally, if the Dossier Submitter found there to be insufficient information on these substances and/or mixtures containing microplastics, then a **reporting requirement** is put forward as a way to increase the evidence base[51]. It is intended to be complementary with the 'instruction for use and disposal requirement'. The substances and/or mixtures containing microplastics for which this is the case are:

- For use at industrial sites (Downstream User only);
- Supplier placing on the market a substance or mixture for consumer or professional use:
    - Medicinal products for human and veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC;
    - Food additives as defined in EU Regulation (EC) No 1333/2008
    - *In vitro* diagnostic devices
    - Where the microplastic is contained by technical means to prevent releases to the environment during end use;

[50] See section on costs, benefits.

[51] Which not only includes releases to the environment, but also generic polymer identity and information on specific uses.

- Where the physical properties of the microplastic are permanently modified during end use. As such the polymers no longer can be defined as microplastics;
- Where microplastics are permanently incorporated into a solid matrix during end use.

SEAC notes that based on the restriction wording, the reporting requirement applies to any Downstream User using microplastics at industrial sites as well as any supplier placing derogated products for consumer/professional use on the market (i.e. not for use at industrial sites). The Dossier Submitter has indicated that this does not include professional users and consumers. SEAC finds the focussed targeting of the reporting requirement appropriate since it tries to exclude double counting and it only seems to apply when it is considered useful to inform possible future action (either through separate legislation or through review of the currently proposed restriction). Based on comments made during the Annex XV report consultation, the Dossier Submitter clarified and updated the wording of the Background Document to address some of the issues raised by stakeholders (e.g. double counting of emissions, disclosure of CBI). SEAC notes that industrial stakeholders have still expressed concerns in regard to the leaking of Confidential Business Information (CBI) when informing downstream users on substances or mixtures containing microplastics (generic polymer identity and concentration). SEAC finds these concerns valid, because the disclosure of CBI cannot be entirely excluded. However, SEAC considers that there are possibilities to prevent CBI disclosure, e.g. by using an identifier for polymer identity or concentration ranges.

SEAC considers the approach taken by the Dossier Submitter as reasoned and well-founded. It allows immediate action to be taken where most effective and the collection of information to inform possible future action.

In the Background Document the Dossier Submitter states: "*Nevertheless, if there was considered to be sufficient residual uncertainty about unidentified uses, the conditions of the restriction could be re-framed to postpone the 'blanket ban' element of the restriction from the initial entry into force date (approximately 2022), to a later date, potentially the final entry into force date (EiF plus 8 years). If reporting of these 'newly identified' uses was required during the implementation period, this would allow the Commission to decide if further derogations would be justified after the blanket-ban came into force.*"

SEAC is confident that all significant sectors of use and product groups, and therefore potential releases, are covered by the market analysis of the Dossier Submitter. As such, the Committee thinks that the risk management choices made (ban, instruct and report) can be considered appropriate since they seem to strike a balance between data availability and the risks identified. SEAC therefore sees no reason to postpone the 'blanket ban' element of the restriction from the initial entry into force.

ii. <u>Derogations from the restriction</u>

Some substances were derogated to avoid regulating microplastics that are not considered to pose a risk to the environment. These are discussed more in-depth below:

- <u>Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)</u>

The Dossier Submitter indicates that the identified concerns regarding microplastics are, in general, related to synthetic polymers[52]. The justification for excluding natural polymers that have not been chemically modified is stated to be that these are inherently "benign" as nature has evolved in its presence. SEAC notes that nature has a finite capacity to deal with natural polymers efficiently. Initially, the Dossier Submitter proposed to use the term "occur in nature" to define such polymers, implying that only certain processes (see REACH article 3 (39)) can be used to obtain these polymers in order to benefit from the derogation. This was subsequently seen by the Dossier Submitter as overly stringent for the purposes of the proposed restriction, which is only interested in the nature of the polymer not the way it was obtained (i.e. which extraction method was used). The Dossier Submitter has therefore proposed to change the wording of the derogation to "natural polymers" (as defined in the guidance on monomers and polymers[53]) that have not been chemically modified (as defined in REACH article 3 (40)). SEAC finds it justified to include a derogation for "natural polymers" (again, as defined in the aforementioned guidance document), especially since the Committee has been assured by the Dossier Submitter that polymers produced by a living organism (e.g. bacteria) within an industrial setting are not covered and neither should they be. SEAC notes that the terminology is also used in the Single-Use Plastics Directive. Using it in this restriction would therefore assure consistency among legislation.

- Polymers that are (bio)degradable

  Microplastics raise concern due to their persistence characteristics. SEAC therefore finds it justified to include an exemption for polymers that (bio)degrade since these polymers would in principle not exhibit the aforementioned concerns. SEAC notes that the choice of biodegradation testing methods and pass/fail criteria will impact the effectiveness of the final restriction[54]. As such, a review of the biodegradability criteria (including testing costs and time needed to assess alternatives) might be needed after entry into force.

- Polymers with a solubility > 2 g/l

  While use of the term 'particle' was initially considered by the Dossier Submitter to replace the need to consider water solubility in the definition, it became clear during the Annex XV report consultation that including an additional derogation for water soluble polymers would improve the targeting of the restriction since soluble polymers do not contribute to the identified risk[55], even if in particle form during certain stages of the supply chain. Test methodology was proposed by the Dossier Submitter and evaluated by RAC. RAC finds the addition of this derogation justified under the

[52] Including natural polymers that have been chemically modified (e.g. certain types of chemically modified lignins).

[53] "Natural polymers are understood as 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."

[54] If the biodegradability criteria mimic real environmental conditions then the effectiveness of the restriction will be higher.

[55] It is important to note that this does not necessarily mean that certain soluble polymers could not pose a risk to the environment.

proposed condition.

- Polymers without any carbon C in their chemical structure (i.e. backbone and side-groups)
  Microplastics are targeted by the proposed restriction because of their persistence in the environment. The tools that REACH provides to define persistence (Annex XIII criteria) are not considered to be suitable for polymers without any carbon in their chemical formula because of their sometimes radically different physical properties (which is also the reason that regrettable substitution seems highly unlikely[56]). It is therefore justified to derogate them from the restriction. **However, this would need to be confirmed by a full evaluation by RAC.**

Certain biological products/materials that may contain microplastics (as contaminants) >0.01% w/w are also derogated from the scope of the restriction, i.e. food and feed as well as sludge and compost.

iii. Derogations from the ban only

Uses at industrial sites were derogated from the ban, because the mandate from the Commission focussed on consumer and professional uses of microplastics. SEAC notes that industrial uses contribute significantly to environmental releases and that further action on these uses may be justified. As uses at industrial sites fall under the reporting requirement better data on uses and releases will become available in the future. SEAC therefore supports the proposed reporting for downstream industrial users and the instructions for use and disposal.

Some uses were derogated from the ban to avoid double regulation:

- Medicinal products
- Fertilising products if regulated under Fertilising Product Regulation (where microplastics will be banned unless biodegradable)
- Food additives: Food supplements or medical food containing food additives might be regulated by different type of legislation in EU. In the Annex XV consultation industry requested a derogation (similar to medicinal products) or longer transition period to allow for substitution of microplastics. SEAC agrees with the Dossier Submitter that a derogation from the ban, but having 'instructions for use and disposal' and reporting requirements, is the ideal way to deal with the concerns raised.

SEAC considers these derogations to be appropriate, but also observes that medicinal products as well as food additives also contribute to environmental releases of microplastics.

iv. Derogation requests received in the consultation of the SEAC draft opinion for (i) polymer dispersions (#641) and (ii) lubricants (#660):

SEAC considers that insufficient information was provided to assess the need to derogate polymer dispersions. Furthermore, statements made in the submission seem to indicate that these products might already be covered by other derogations (e.g. soluble polymers, use at industrial sites, permanently incorporate in solid matrix during end use, permanently

[56] Confirmed by RAC Rapporteurs.

modified). SEAC considers that insufficient information was provided to assess the need to derogate lubricants.

- Infill material

The Dossier Submitter performed an analysis of the information submitted during the Annex XV report consultation regarding polymeric infill material used in artificial sports pitches. Emissions of microplastics to the environment from this use are estimated to amount to 16 000 tonnes per year.

The Dossier Submitter analysed four possible scenarios wherein action is taken to reduce or eliminate the emissions of infill material to the environment.

1. RO1: Full ban without transition period
2. RO2: Full ban with transition period (6 years after EiF)
3. RO3: Derogation from ban, but instructions for use and reporting requirements
4. RO4: Derogation conditional on technical risk management measures being implemented (with transition period) [57]

A fifth option emerged from discussions in RAC:

5. RO5: Hybrid option – existing pitches implement RMMs, ban on new/refurbished pitches

Costs and benefits of these options are assessed in detail in the relevant sections of this opinion. SEAC's main conclusion is that all restriction options might be proportionate based on a (semi-)quantitative and/or qualitative assessment.

Based on the available cost and benefit information and SEAC's analysis of that information, a clear advice on which scenario should be preferred is however not possible. A clear-cut choice for one of the scenarios can, in this case, only be taken based on policy priorities. This is outside the remit of SEAC. The only scenario that might be easily excluded from consideration is the derogation from the ban with instructions for use and reporting requirements, since emission reduction is considered minimal and the scenario as a whole is likely to be significantly less effective than the other four scenarios.

RAC proposed a hybrid option (RO5) where existing pitches could be used for their remaining lifetime conditional on strict RMMs being implemented[57]. Newly constructed or refurbished pitches would then be banned from using infill material altogether. This option was not

[57] SEAC notes that both of the proposed restriction options for infill prohibit the "*placing on the market*" of microplastic infill material rather than its use. The Dossier Submitter confirmed that when developing Option A (RO4 – mandatory use of RMMs) the working assumption was that maintenance activities (i.e. regular "top-up" of infill) would continue as normal on all existing pitches after the end of the transitional period; necessitating the implementation of RMMs at all existing pitches in order to obtain infill from the market. However, SEAC notes that as the wording of the proposed restriction does not prohibit the use (or presence) of microplastic infill on sports surfaces, pitch owners/operators could stockpile microplastic infill material before the end of the transitional period for use in maintenance activities after the end of the transitional period without being legally obligated to implement RMMs. Similarly, existing pitches could avoid implementing RMMs after entry into force if they did not undertake any further maintenance activities with synthetic infill (although the performance of the pitch would eventually be compromised).

preferred by RAC unless a full ban would not be proportionate. During the consultation on the SEAC draft opinion, both public and private stakeholders indicated that this option should not be preferred as well. SEAC also does not prefer this option since a full ban (with or without transition period) could be considered to be proportionate, thereby negating the reason RAC proposed RO5 in the first place. Further to that, ESTC (European Synthetic Turf Council) indicated in its comments to the SEAC draft opinion consultation that, if RO4 was implemented it could be subsequently repealed after review, which calls into question the added value of RO5 even more.

SEAC wishes to stress that if under the microplastics restriction a derogation is introduced for polymeric infill material conditional on technical risk management measures being implemented (RO4), this should be limited to its use as infill material on synthetic turf pitches. Derogating other uses of infill (loose application on children's playgrounds, in gardening and landscaping) is not effective from the viewpoint of emission reduction, implementability and enforceability. It is worthwhile to note that there are indications that indoor pitches (about 5% of total pitches) also present a potential for emissions to the environment and as such should be covered by the restriction.

If the option of derogating polymeric infill material conditional on technical risk management measures being implemented is chosen, there is a clear need for guidance on the most suitable technical RMMs to implement. The Dossier Submitter proposes to include an annual emission limit in the derogation for infill material (7 g/m^2) corresponding to emissions of 50 kg per standard football pitch and year. It is then left up to pitch owners to decide what measures to implement to achieve this goal. Sports associations can play a crucial role in guiding pitch owners. The recently approved CEN technical report (CEN/TR 17519[58]) might provide the basis for this guidance. The technical report's effectiveness in limiting emissions and the economic impact associated with its implementation, is discussed later on in the opinion (cost and benefit section). Additionally, during the Annex XV report and SEAC draft opinion consultations valuable information was provided by a diverse range of stakeholders (pitch owners, users, manufacturers and NGOs) which might be useful when trying to limit emissions as well. Stakeholders (pitch owners and users mostly from Germany) indicated that a transition period would be needed for stakeholders to implement suitable RMMs. Based on an assessment by the Dossier Submitter, 3 years (from entry into force) would be needed to strike a balance between the minimisation of socio-economic impacts and a timely and efficient reduction in emissions. Both the guidance and the transition period will mitigate associated costs and improve the implementability and enforceability of the derogation. Forum has indicated that enforceability of RO4 using the CEN technical report as a basis for compliance, would take considerable efforts from the different actors in the Member States involved in the enforcement of the REACH Restriction (some of whom are usually not impacted by REACH)[59].

- *In vitro* diagnostics (IVD)

Initially, the Dossier Submitter intended to derogate IVD products on the condition that

[58] CEN/TR 17519:2020 lays out the technical measures by which the releases of infill to the surrounding environment can be reduced.

[59] "Construction", "maintenance" and "disposal" of sports facilities is typically not within the remit of the REACH inspectors in the Member States.

microplastics are contained by technical means and then disposed as hazardous waste (para 5a of the initial Annex XV proposal). IVD products are used by healthcare professionals in hospitals and laboratories, but also in research and development (various fields), and in veterinary and pest control applications. During the Annex XV report consultation information was received on the costs to implement measures to ensure containment of microplastics during use and disposal of IVDs. Based on this information, the Dossier Submitter developed different scenarios to assess the impact of different RMO for the use of microplastics in IVD products (BD D.7):

1. Full ban without transition period
2. Derogation conditional on incineration of microplastic-containing solid waste
3. Derogation conditional on containment of microplastics throughout their use and incineration of solid and liquid waste
4. Full ban with a transitional period long enough to allow the IVD sector suppliers to minimise the releases of microplastics to the environment[60]
5. 'instructions for use and disposal' and an annual reporting requirement

Given that releases of microplastics from IVD products are very low (estimated to be 270 kg per year), the Dossier Submitter concluded that that RO 3 and RO 4 would be disproportionate and considered RO 5 to be the most appropriate measure. SEAC agrees with this conclusion.

v. Transitional periods

The ban on placing on the market will enter into force at different times for different uses depending on the transition period assessed as necessary to avoid disproportionate socio-economic impacts, without unnecessary delays in emissions reduction.

Table 13 Proposed transitional periods

Sector or product group	DS proposed Transitional period (TP)	DS summary justification	SEAC conclusions
Mixtures containing microbeads (e.g. cosmetics and detergents)	No transitional period	Voluntary agreements to phase out this use by 2020 at the latest are widespread.	SEAC finds this justified since industry is on track to phase out the use by EiF of the restriction proposal.
Medical devices (where microplastics cannot be contained during end use)	6 years	Many of the medical devices affected are so-called substance-based and have similarities to cosmetics (e.g. creams applied on skin, medical toothpaste etc.). Therefore, a transition period of 6 years is considered to allow for sufficient time to reformulate and transition to alternatives.	In principal, SEAC finds a longer TP justified considering the complexity of the product development of these products (including certification). However, the information on the potential impact on substance-based medical devices is very limited. SEAC considers that the similarities to cosmetics per se do not provide sufficient justification for the TP. More specific information on the substitution

[60] either by substitution or containment of microplastics in the product

Sector or product group	DS proposed Transitional period (TP)	DS summary justification	SEAC conclusions
			process in substance-based medical devices would be needed to substantiate that six years TP is appropriate. Based on available information (including information received in the consultation on the Annex XV report as well as the SEAC DO), SEAC cannot draw a final conclusion on the appropriateness of the TP.
Other rinse-off cosmetic products	4 years	Reformulations are the most important factor in this case. The typical reformulation process takes 2.5-4.5 years. Alternatives are widely available.	SEAC finds this justified since it allows sufficient time to find and implement alternatives.
Detergents and other maintenance products without microbeads	5 years for microplastics used in detergents as well as for maintenance products	Reformulations are the most important factor in this case. According to industry the majority of products could be reformulated in 5 years, although some companies would require up to 10 years. The Dossier Submitter proposes a 5-year transitional period since this minimises the socio-economic impacts on society while still allowing releases to the environment to be reduced as fast as possible.	SEAC finds the transition period justified since the proposed transitional period strikes a balance between the minimisation of socio-economic impacts and a timely reduction in emissions. Based on available information 5 years should be sufficient to substitute microplastics banned in detergents and maintenance products.
Fragrance encapsulates[61]	5 or 8 years for polymeric fragrance encapsulates	During the Annex XV consultation industry provided information on the substitution process of microplastics in fragrance encapsulation systems, which the Dossier Submitter found may justify a longer transition period of 8 years for this use. The Dossier Submitter updated the impact assessment considering both a 5- and an 8-year transition period. The Dossier Submitter concluded that the	Main argument in favour of extending the transitional period for fragrance encapsulation is the fact that there is currently no alternative, non-microplastic fragrance encapsulation technology and that industry is working on developing alternatives. However, the information available is insufficient for SEAC to conclude that a longer transition period (i.e. 8 years) would be necessary considering the work already being done by industry and on-going research initiatives. Therefore, SEAC cannot

[61] While the majority of fragrance encapsulates are used in the detergents sector, a small part is also used in rinse-off and leave-on cosmetics. It should be noted that these cosmetic applications are also covered in the assessment of fragrance encapsulates, even though fragrance encapsulates are presented as part of the detergents and maintenance sector.

Sector or product group	DS proposed Transitional period (TP)	DS summary justification	SEAC conclusions
		proposed restriction would be proportional for this product category both under a 5- and an 8-year transitional period.	conclude whether a 5 or 8 year TP would be most appropriate and recommends to review the need for a transition period longer than 5 years after entry into force. The impacts in case no alternatives were available when the transition period ends (higher use of perfume, profit losses, rewashing of textiles) are discussed in the section on costs.
Agricultural & horticultural uses: Controlled release fertilisers (CRF) & fertiliser additives	5 years, to be aligned with the Fertilising Products Regulation (FPR)	Time is required for the development of biodegradable polymers. The transitional period is intended to align with the new Fertilising Products Regulation, which contains provisions regarding biodegradability.	SEAC finds this justified in order to create regulatory consistency, but notes the uncertainty regarding the ability to actually develop alternatives in the proposed transitional period. After entry into force, progress on the development of biodegradable polymers should therefore be monitored. Depending on the situation after entry into force, a review of the transitional period might be necessary in order to avoid significant socio-economic impacts. However, according to comments in the Consultation 95% of CRFs and additives would already be restricted by the FPR. The current proposal would therefore only affect 5% of fertilising products (those that are non-CE marked).
Agricultural & horticultural uses: Capsule suspension PPPs (CSPs) & coated seeds	Plant protection products as defined in Regulation (EC) No 1107/2009, including seeds treated with such products: 8 years (justified by information received in the consultation) Other agricultural and horticultural uses not subject to (EC) No 1107/2009: 5 years	Time is required for the development of biodegradable polymers, whose functionalities might be different from products covered under the FPR (see above). Furthermore, the CSP products would have to be re-authorised as PPP, which takes 2-3 years. Therefore, the Dossier Submitter found an extension of the transition period to 8 years to be justified. For coated seeds it was found that alternative coatings are already on the market and therefore a	SEAC finds this justified since the proposed transitional period strikes a balance between the minimisation of socio-economic impacts and a timely reduction in emissions. The Committee does wish to note the uncertainty regarding the ability to actually develop alternatives in the proposed transitional period (as stated above). Deviation from the transitional period for other agri- and horticultural uses (5 years, see above) seems justified since in the case of CSPs a re-authorisation process would be necessary in addition to the development of alternatives.

Sector or product group	DS proposed Transitional period (TP)	DS summary justification	SEAC conclusions
		transition period longer than 5 years is not justified.	
Leave-on cosmetic products	6 years	Reformulations are the most important factor in this case. According to industry it would take approximately five years for leave-on cosmetic products, stressing the higher complexity of these formulations compared to rinse-off cosmetic products. The Dossier Submitter proposes a 6-year transitional period since this minimises the socio-economic impacts on society while still allowing releases to the environment to be reduced as fast as possible.	SEAC finds a longer transitional period than for rinse-off cosmetic products justified due to the complexity of the formulations. The Dossier Submitter based six years on information on the average length of the reformulation process (~four years) and added two years to account for the complexity of the formulations of leave-on cosmetics. Given that there is only scarce and partly conflicting information SEAC considers this approach reasonable, but cannot fully assess the appropriateness of a specific transition period (please see text on proportionality for further details). SEAC notes that for product groups that are predominantly removed using tissues/wipes and disposed of as solid waste rather than by washing off (i.e., make-up, lip and nail products) a longer transition period or a derogation from the ban might also be considered as being proportionate, because (i) releases from these uses are comparatively low (and might also be effectively managed by a requirement to include instructions for use and disposal) and (ii) the potentially high number of reformulations could be difficult to manage for industry within the proposed TP of 6 years as reported in the consultation. However, the uncertainties related to the different impacts (impacts on industry and releases) do not allow for SEAC to conclude whether these other options would be more appropriate (see text under proportionality).
Instructions for use and disposal	24 months	TP will provide sufficient time to actors to implement the requirement and to keep the economic impact involved limited, because instructions for use and disposal can be integrated in the regular revision	SEAC agrees with the proposed transition period (see text under proportionality)

Sector or product group	DS proposed Transitional period (TP)	DS summary justification	SEAC conclusions
		process of labels or safety data sheets.	
Reporting	36 months	TP will provide sufficient time to actors to implement a reporting scheme. Information from instructions for use and disposal can be used to facilitate reporting.	SEAC agrees with the proposed transition period (see text under proportionality)
Other uses (not mentioned in this table)	No transitional period	Prevent new uses of intentionally added microplastics.	SEAC finds this justified in light of the request of the Commission and the overarching goal of the restriction, to minimise microplastics emissions. During the opinion development no sufficiently substantiated requests have been received indicating that transition periods would be needed for applications not covered by this table.

SEAC supports the approach taken for setting different transitional periods for different product groups. In general, SEAC considers the proposed transitional periods as a reasonable timeframe for implementation of the restriction. The Committee based this conclusion on the analysis performed by the Dossier Submitter in regard to the availability of alternatives, the need for reducing microplastics emissions and costs to society.

RMO analysis

The majority of the possible risk management options (RMOs) discussed and discarded by the Dossier Submitter are variations of different REACH restrictions:

i. **All uses** – restriction on the placing on the market and use of all mixtures or articles 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);
ii. **Labelling** – **instruction for use** of all mixtures and articles for consumer and professional use containing intentionally added microplastics (≥ 0.01% w/w) with the phrase "contains microplastics > 0.01%", and a requirement for user instructions to minimise releases to wastewater e.g. "dispose to municipal waste");
iii. **Specific uses** – restriction on the placing on the market and use of specifically identified mixtures for consumer and professional use containing intentionally added microbeads (≥ 0.01% w/w) (with derogations);
iv. **Microbeads** (abrasive uses) – restriction on the placing on the market and use of all mixtures or articles for consumer and professional use containing intentionally added microplastics as an abrasive (≥ 0.01% w/w) (without derogations);
v. **Narrower size range** – restriction on the use of microplastics in consumer and professional products (≥ 0.01% w/w) with a size range of 1 µm ≤ x ≤ 1 mm;

vi. **Thermoform and thermoset plastics** – restriction on thermoform and thermoset organic polymer 'plastics' only (>0.01% w/w);

Table 14 gives an overview of different RMOs and includes a summary of the Dossier Submitter's assessment and SEAC's conclusions.

Table 14 An overview of different RMOs

Dossier Submitter Assessment				SEAC remarks
RMO discarded	**Considerations**	**Costs/benefits** (compared to proposed restriction)	**Practicality + monitorability** (compared to proposed restriction)	
All uses (no derogations)	Reduces emissions to the environment as quickly as possible. Exemptions are necessary to avoid double regulation or to maintain the scope as set out by the Commission.	Costs: Significant increase. Increased number of products in scope and lack of time to develop alternatives (no transitional periods). Benefits: Emission reduction higher than the proposed restriction. Additional uses in this RMO have significantly less emissions than the uses already captured by the proposed restriction. Proportionality: Not considered to be proportional. Costs are significantly higher than the proposed restriction and likely to outweigh additional benefits.	Practicality: Lower due to the lack of transitional periods and the increased scope. Industry and enforcement authorities cannot plan for the implementation of the restriction. Monitorability: More complicated due to the entry into effect of the requirements for several sectors at the same time, among others.	Based on SEAC's assessment of the proposed restriction, the Committee agrees with the Dossier Submitter that this restriction cannot be seen as the most appropriate EU-wide measure. This is due to the fact that it does not take into account the identified risks which differ among sectors and/or product groups, harmful impacts on industry (lack of transitional periods) and disadvantages to society (loss of critical functionality).
Instruction for use	Not all emissions can be minimised via instruction for use (e.g., detergents, agricultural uses, rinse-off and several leave-on cosmetics, etc.).	Costs: If aligned with normal relabelling cycles costs would be minimal. If a significant number of consumers change their purchasing habits then profits would be reduced and reformulation necessary. This would lead to high costs (no transition time to move to alternatives).	Practicality: Lower due to the lack of transitional periods and the increased scope. Companies cannot plan for the implementation of the restriction. Enforcement would be more complicated. Monitorability: More complicated.	SEAC agrees that in light of the identified risks and the persistent nature of microplastics, the effectiveness of instruction for use/labelling as a standalone measure can be considered low, as it cannot address all intentionally added uses.

		Benefits: If enough consumers change habits, then a reduction in emissions would occur. It is however unlikely to have the same risk reduction effect as the proposed restriction. Proportionality: Lower because of high costs and low benefits.		Even if a significant change in consumer behaviour would take place, it is, at present, uncertain if consumers and professionals would be able to switch easily and immediately to alternatives in all sectors and for all product groups covered by this RMO.
Specific uses	Reduces likelihood of capturing significant uses of microplastics that are unknown to the Dossier Submitter. This is considered unlikely due to the extensive investigation that was undertaken. A disadvantage is also that future uses would not be captured.	Costs: Similar to current proposal since the Dossier Submitter is confident that they have captured all significant uses in their assessment. The consultation has confirmed this. Benefits: Risk reduction would be similar or lower. Proportionality: Probably lower (due to possible decreased benefits).	Practicality: Similar to the proposed restriction. Monitorability: Similar to the proposed restriction.	It is difficult to conclude on the necessity of covering possible future uses of microplastics since it is not clear what the probability is of this actually occurring. This means that it is also difficult to state unequivocally that the benefits for and proportionality of this RMO are lower. While including future uses is not specifically mentioned in the request by the Commission, it does not conflict with it. When taking into account the persistent-like nature of microplastics, it may indeed also be advisable to include future uses. As such SEAC agrees that it is justified to discard this RMO.
Microbeads	Limited effectiveness in reducing the identified risk.	Costs: Reduced costs since industry has already voluntarily phased out the majority of such uses. Benefits:	Practicality: High, since industry is already implementing a voluntary agreement similar to this RMO. Monitorability:	SEAC agrees with the dossier Submitter's assessment and finds it justified to discard this option since it would not cover all uses linked

		Limited risk reduction and therefore also benefits since industry has already voluntarily phased out the majority of such uses. Concern raised by risk assessment is not addressed. Proportionality: Proportional but not effective.	High.	to the identified risk.
Smaller size characteristics	Potential increase in implementability since stakeholders state that it is challenging to perform measurements for lower size ranges (<1µm). Restricting the upper size ranges would exclude certain plastic raw materials (e.g. 'nurdles').	Costs: Would be similar, but there are potential savings from the reduced scope and less costly testing methods. Benefits: Reduced risk reduction and therefore reduced benefits. Does not capture nanoparticles for which there is already a concern. Some microplastics would also not be covered. Proportionality: Not clear if increase in proportionality.	Practicality: Higher since testing methods are more accessible. Monitorability: Lower since there would be no additional information on nanoplastics.	SEAC agrees with the Dossier Submitter that it is not clear that the proportionality of this RMO would be higher since the relative changes in costs and benefits are unknown. SEAC agrees that practicality would be higher. This is also confirmed by several stakeholders during the consultation as well as by Forum. SEAC does however not agree that monitorabilty would be lower. The Dossier Submitter presumes this based on the fact that they would not get information on smaller sized particles. Monitorability of an RMO should not be based on what is not covered by the scope, but on what is covered by the actual RMO. This RMO can however be discarded based on it not addressing all identified risks/concerns. Excluding certain plastic raw materials from the scope seems

				unjustified since the proposed restriction already includes an exclusion from the microplastics ban for these types of materials (use in industrial sites).
Thermoform and thermoset plastics	Several stakeholders proposed to only cover these types of organic polymers.	Costs: Since less companies are effected costs would be reduced. Benefits: Unlikely to have the same risk reduction effect and therefore benefits as less polymers are in scope. Proportionality: Not clear if increase in proportionality.	Practicality: Similar to the proposed restriction Monitorability: Same as the proposed restriction.	SEAC agrees with the Dossier Submitter that it is not clear that the proportionality of this RMO would be higher since the relative changes in costs and benefits are unknown. This RMO can however be discarded based on it not addressing all identified risks. Based on the information at hand microplastics are not limited to these types of polymers and therefore the identified risks aren't as well.

While SEAC considers that the Dossier Submitter was thorough in identifying different possible RMOs, the Committee considers that the assessment of the options was overly concise and sometimes lacked sufficient justification. In general, however, SEAC does agree that the discarded RMOs are less appropriate than the proposed restriction. This is mostly linked to lower effectiveness and/or lower proportionality.

In addition to these variations on the same RMO, the Dossier Submitter also considered the use of non-legislative measures, action under legislation other than REACH and action through other REACH processes. Even though the Commission specifically requested ECHA to prepare an Annex XV restriction dossier[62], the Dossier Submitter still briefly discussed options besides a REACH restriction. Based on the assessment performed, SEAC agrees that a restriction is the most appropriate EU-wide measure for intentionally added microplastics.

i. Non-legislative measures
    a. *Voluntary industry agreement to restrict microplastics use*: SEAC agrees that due to the sheer number of stakeholders belonging to different sectors and industry groups, negotiating a voluntary agreement covering the scope of the

[62] Which should imply that a complete RMO analysis looking at different (non-)legislative options, has been performed during the preparation of the EU Plastics strategy. This is also what the Dossier Submitter presumed.

proposed restriction, is very unlikely to succeed. Furthermore, the effectiveness in addressing the identified risk is considered questionable by the Committee.

b. *Voluntary industry agreement to label*: SEAC agrees that this RMO shares many of the disadvantages linked to the previous non-legislative measure and the discarded labelling restriction option.
c. *Information campaign to consumers*: SEAC agrees that the effectiveness of this as a stand-alone measure is questionable. At present it is also very difficult for consumers to identify which products contain microplastics and which do not.

ii. Action under legislation other than REACH

Legislative measures other than those under REACH are, in general, considered by the Dossier Submitter to be less effective or not effective at all in addressing the identified EU-wide risks.

This is due to the fact that other legislation has a very specific scope which does not cover all of the identified risks (e.g. sector specific legislation), targets life cycle stages that are not linked to the majority of the emissions (e.g. IED, Water Framework Directive), would conflict with the primary objectives of specific legislation (e.g. Sewage Sludge Directive) or would lead to non-harmonised situations (e.g. 'microplastics tax').

iii. Action through other REACH processes

a. *REACH authorisation*: SEAC agrees with the Dossier Submitter that this is not a viable option at all since microplastics are not classified as CMR 1a or 1b and not identified as PBTs, vPvBs or substances of equivalent concern.
b. *REACH article 68 §2*: SEAC agrees with the Dossier Submitter that this is not a viable option at all since microplastics are not classified which is a prerequisite for action to be taken under this provision.

Taken into consideration all of the above, SEAC agrees that the proposed restriction is the most appropriate EU-wide measure.

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 (≥ 0.01%) in a size range of 1µm ≤ x ≤ 1mm.

- Restriction on thermoform and thermoset organic polymer 'plastics' only (≥ 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 3).

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).

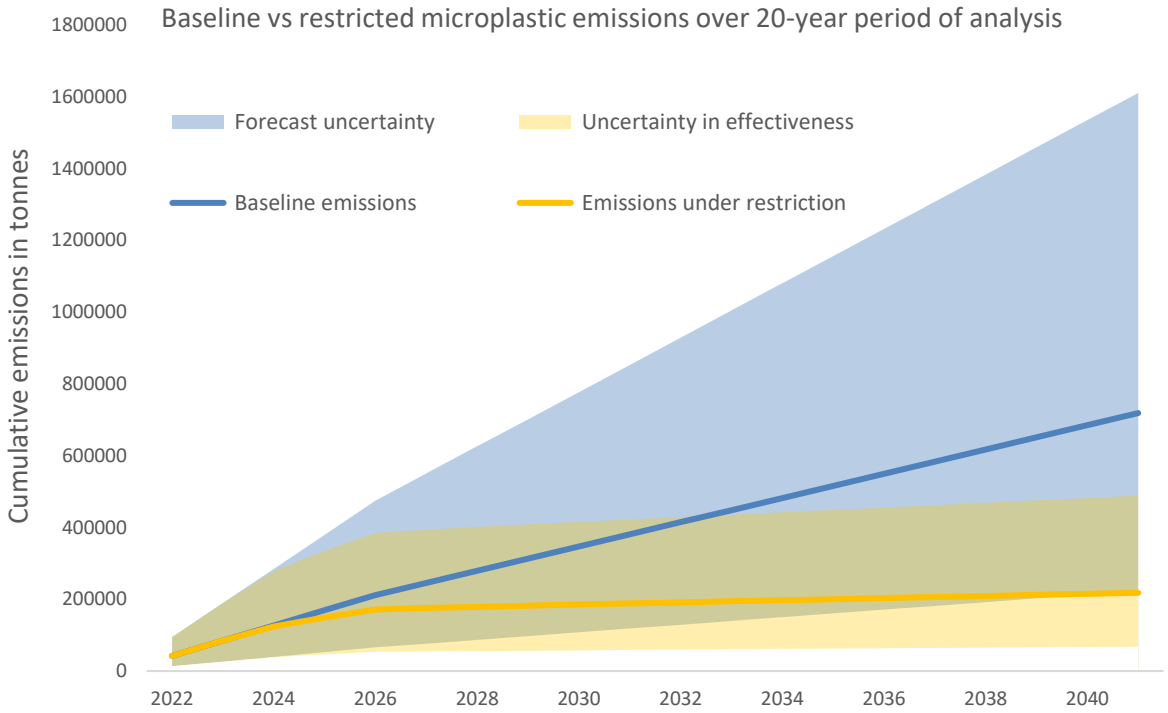


Figure 3 Effect of the proposed restriction on cumulative releases over the period of analysis

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

Summary of proposal:

General approach

The Dossier Submitter anticipates that the main economic impact resulting from the proposal will be associated with the costs of replacing microplastics in selected products falling under the ban of placing on the market (i.e. agricultural and horticultural products, cosmetics, detergents and maintenance products). For these sectors affected by the ban, a quantitative cost assessment[63] was presented.

In this quantitative assessment, the Dossier Submitter estimated the costs of the proposed restriction on a product-group basis for each of the industry sectors concerned, because important factors affecting the costs to substitute microplastics such as functionality, use conditions, and availability of alternatives vary across the uses covered by the proposed restriction and therefore can result in diverse impacts for supply chains and society as whole. Where the available information permitted, and where the socio-economic impacts within a product group were likely to vary substantially, the analysis was further differentiated.

The Dossier Submitter reviewed the figures and assumptions used in the assessment based

[63] The geographical scope of the impact assessment is the European Economic Area (EEA) as the proposed restriction would take effect over the territory of the EEA, recognising that there is considerable uncertainty related to the future status of the United Kingdom. The temporal scope of the analysis is 2022 (as the first potential full year of entry into force of the proposed restriction) plus 20 years. Unless otherwise specified all costs are in 2017 price levels, discounted with 4% discount rate to the study reference year of 2017, in Net Present Value (NPV).

on information gained during the consultation on the Annex XV report and revised the assessment when sufficiently justified. All revisions are detailed in the Background Document.

Furthermore, the Dossier Submitter assessed the costs to implement technical means to reduce emissions, which are proposed for other non-industrial uses that lead to releases to the environment (i.e. polymeric infill material) based on information received during the consultation on the Annex XV report.

The Dossier Submitter concluded that in comparison to substitution costs the costs to comply with the 'instructions for use and disposal' and reporting requirements as well as enforcement costs would be minor. For sectors, where 'instructions for use and disposal' and reporting requirements are proposed, a largely qualitative analysis was presented. However, comments submitted by industry in the consultation on the Annex XV report indicated that these costs could be considerable. Considering the information received the Dossier Submitter elaborated on the costs to fulfil the 'instructions for use and disposal' and reporting requirements including a review of cost figures given in the scientific literature.

Substitution costs

The Dossier Submitter assessed the economic impacts of substituting microplastics in the principal sectors that would be affected by a ban on placing on the market, namely agriculture/horticulture, cosmetic products, detergents and maintenance products[64]. While there are already equivalent alternatives on the market for some microplastic uses (e.g. for microbeads), for other uses the supply of microplastic-free products is currently not sufficient to meet demand for products with similar functions. Also, alternative products may not achieve the same performance as products containing microplastics. For some uses or functions, e.g. microencapsulation used in agriculture and horticulture and fragrance encapsulation in detergents and cosmetics, there are no equivalent microplastic-free products (i.e. using biodegradable polymers) on the market yet. Therefore, alternatives would need to be identified, developed, tested and, in certain uses such as that in plant protection products, authorised. Addressing the uncertainties with regard to the availability and feasibility of alternatives was one of the motives for the Dossier Submitter to recommend a review of the socio-economic implications of the proposed restriction 5 years after entry into force.

The major economic impact of substituting microplastics is the reformulation of tens of thousands of products. Hence, the main cost element is reformulation costs, whereas raw material costs are less important in comparison. Both are summarised for the different sectors affected in Table 15.

Reformulation costs

The Dossier Submitter estimated the number of products that would be reformulated in response to the proposed restriction as well as average costs of reformulating relevant products in the different sectors, mainly based on information from industry. These costs, estimated at €9.3 billion over a period of 20 years (ranging from €1 to €18 billion in NPV), represent the majority of quantified impacts of the proposed restriction.

[64] In addition, substitution costs were estimated for synthetic infill material as well as for *in vitro* diagnostics with the conclusion that a ban (without transitional period) would not be the most appropriate EU-wide measure for the use of microplastics in these applications.

Raw material costs

Alternatives to microplastics are assumed to be of higher costs, accordingly raw material costs were assessed for cosmetics, detergents and maintenance products. The Dossier Submitter estimates these costs at €200 million over a period of 20 years (€20 – €430 million in NPV, see Table 15).

Table 15 Overview of sectors covered by the ban of the proposed restriction and related substitution costs over 20 years

Sector	Volumes used at EiF (tonnes/annum)	Raw material costs (€$_{2017}$ million)	Reformulation/R&D costs (€$_{2017}$ million)
Agriculture and Horticulture			
Controlled-release fertilisers (CRF)	5 000 (1 000 – 10 000)	n/e[b]	60 – 1 200
Fertiliser additives	4 000 (2 000 – 6 000)	n/e	10 - 62.5 [a]
Capsule suspension plant protection products (CSPs)	500 (250 –1 000)	n/e	12.5 - 150
Seed coatings	500 (250 – 1 000)	n/e	25 - 250
Cosmetics			
Other rinse-off cosmetic products (excl. microbeads)	6 500 (2 900 - 10 000)	34 (15 – 53)	1 047 (36 - 2 057)
Leave-on cosmetic products	2 100 (1 100 - 3 000)	9 (5 – 13)	7 300 (1 600 – 13 300)
Detergents and maintenance products			
Fragrance encapsulates[c]	400 (260 – 540)	86 (0 – 183)	440 (293 – 554)
Other detergents	15 200 (9 440– 20 960)	63 (0 – 173)	67 (43 – 1 059)
Waxes, polishes and air care products	1 300	5 (0 – 11)	0.7 (0.4 – 7.9)
Total		197 (20 – 434)	9 307 (2 088 – 18 001)

[a] These are reformulation costs attributable to the restriction proposal and do not include reformulation costs attributable to the Fertilisers Product Regulation.
[b] n/e – not estimated
[c] These cost estimates are based on a 5-year transition period for fragrance encapsulates. The Dossier Submitter has also undertaken an analysis of the impacts under an 8-year transition period for fragrance encapsulates, which is outlined in Annex D6 of the BD.

Profit losses and loss in product performance

Apart from reformulation and raw material costs, other possible economic impacts of the ban on the placing on the market include potential performance loss of tangible or perceived product benefits to consumers or at the worst-case profit losses in the event successful reformulations are delayed and there is no sufficient critical mass of microplastic-free products on the market to take over their market share. The latter costs have been quantified by the Dossier Submitter for four product groups (in the cosmetics and detergents sector) in the high scenario under worst-case assumptions (see Table 16). These costs are estimated to be less than €2.1 billion (NPV).

Table 16 Profit losses estimated for the high scenario (worst case) in € million

Cosmetics	Detergents and maintenance products		
Leave-on cosmetic products	Fragrance encapsulates	Other microplastics used in detergents	Waxes, polishes and air care products
1 900	74	98	0.7

Cost of different options to reduce emissions from synthetic infill material

The cost for retrofitting existing artificial sports fields with technical risk management measures was indicated in the consultation to be in the range of €3 000 to €29 000 per pitch (depending on the measures already in place). EU-wide, an average cost of €20 000 per full-sized pitch may be incurred for implementing recommended risk management measures. Assuming that today around 5% of the existing ~40 000 full-size pitch equivalents do not use any of the polymeric infill materials and that a fraction of pitches in Nordic countries and Germany have already measures in place (about 20% of artificial turf pitches using polymeric infill material), one may assume that some 32 000 pitches would require additional measures to be taken; and if those measures cost on average €20 000 per pitch, then the overall cost of this requirement would be in the order of €640m. However, older pitches would have to be replaced anyway and with a sufficiently long transitional period granted the cost of retrofitting can be expected to be succinctly lower.

Notwithstanding the significant costs of implementing proposed risk management measures across the EU, a rough cost-effectiveness analysis suggests that the cost of preventing polymeric infill emissions to the environment is relatively low. Similarly, the downtime for retrofitting is relatively limited. Based on the Dossier Submitter's assessment an average full-sized pitch, without RMMs, loses around 500 kg of infill per year. If that loss were to be reduced by 90% to 50 kg per year at the one-off expense of €20 000, then the cost-effectiveness over an average remaining lifespan of 5 years (the midpoint of the 10-year life expectancy of a 3rd generation artificial sports field) would suggest an abatement cost of less than €10 per kg of emission avoided.

The Dossier Submitter assessed the implementation costs for options RO2 (ban with 6-year transitional period after EiF) and RO4 (technical RMMs) in detail with the premise that a transition period for RO4 should limit emissions over a 20-year analytical horizon to the same extent as RO2. As long as RMMs cannot fully abate emissions this can only be achieved if a transition period for RO4 is shorter than the 6 years after EiF foreseen for RO2. Based on this premise, the Dossier Submitter constructed a stylised comparison between RO2 and RO4 using the implementation cost estimates reported in Table 17. It should be stressed that whilst these assumptions are subject to some uncertainty (relating to their representativeness for all artificial turf pitches in the EU), the general conclusions reached in terms of implementation cost vs emission abatement are considered to be robust by the Dossier Submitter.

Table 17 Assumptions maintained for the investment cost comparison.

	Best estimate	Range	Unit
Maintenance cost	10 000	[6 000-12 000]	€/pitch and year
Emission control cost	20 000	[3 000-29 000]	€/pitch
Replacement cost	200 000	[100 000-200 000]	€/pitch
No. affected pitches in EU28	32 000	n/a	Pitches in EU
Lifetime of an average pitch	10	[10-15]	Years
No. pitches to be replaced in an average year	3 200	n/a	No. pitches per year
Baseline emissions per field	500	[250-1 000]	kg/pitch and year
Effectiveness of measures	90	[80-95]	per cent
Residual emissions per field	50	[25-200]	kg/pitch and year
Cost multiplier for non-polymeric field	150	[125-200]	per cent

A simple model of implementation cost IC_i for option i is devised as follows:

$$IC_i = \sum_{t=1}^{20} \frac{(RC_{i,t}+MC_{i,t}+CC_{i,t})}{(1+r)^t} - \sum_{t=1}^{20} \frac{(RC_{0,t}+MC_{0,t}+CC_{0,t})}{(1+r)^t} \text{ for } i=\{RO2,RO4\}$$

$$\text{s.t.} \sum_{t=1}^{20} RE_{RO4,t} = \sum_{t=1}^{20} RE_{RO2,t}.$$

In summary, the model sums the differences between cost streams (RC=replacement cost, MC=maintenance cost, CC=control cost, r=social discount rate) accruing under business as usual and the respective restriction option subject to the constraint that both RO2 and RO4 would emit the same quantities of polymeric infill material (RE=restriction effectiveness). Given the assumptions on implementation costs reported in Table 17, and the fact that RO2 foresees a transition period of 6 years after EiF, RO4 would require the implementation of RMMs appropriate in reducing annual emissions to 10% within 3 years after EiF. This then permits to obtain cost-effectiveness ratios of 33.3 €/kg of emissions avoided for RO2 and 2.2 €/kg of emissions avoided for RO4, respectively. As the residual emissions over the analytical horizon of 20 years (80 000 tonnes) are required to be the same under both options, one may directly compare the present value of implementation costs which amounts to €9.6bn for RO2 and €1.3bn for RO4, respectively. This finding supports the Dossier Submitter's qualitative restriction option analysis and suggests that a swift implementation of technical RMMs may be the most proportionate restriction option.

Table 18 Cost estimates for different restriction options for synthetic infill material

Restriction option	Total enforcement cost € million
Ban with 6 years TP (RO 2)	**9 591**
Incremental replacement cost	5 510
Incremental maintenance cost	4 081
Incremental control cost	0
Technical measures to reduce releases (RO 4)	**1 282**
Incremental replacement cost (RO4)	0
Incremental maintenance cost (RO4)	0
Incremental control (RO4)	1 282

The Dossier Submitter concludes that i) all restriction options analysed are practical and monitorable, and ii) RO4 is likely to emerge as the best option unless the decision maker favours emission reduction much more than any of the other key dimensions, in which case RO2 is the most proportional option.

Costs of 'instructions for use and disposal' and reporting requirements

Sectors also using microplastics but not covered by the ban, e.g. construction products, medical devices, medicinal products, paints and coatings or printing inks, are required to inform users how to minimise microplastic emissions to the environment as well as to report key information to ECHA.

The requirement to communicate 'instructions for use and disposal' along the supply chain in order to avoid releases of microplastics to the environment, e.g. by labelling or updated SDS, may generate incremental costs to industry actors. The Dossier Submitter expects these costs to be minor, as requirements for product labelling (or updates of SDS) exist for almost all sectors under existing legislation (e.g. CLP, CPR and medicinal products regulation). They are updated on a regular basis, both due to regulatory requirements and due to periodic market-driven changes to products (reformulations).

The proposal also includes requirements for downstream users of microplastics at industrial sites as well as importers or downstream users placing a substance or mixture containing microplastics on the market for an end use, to report each year the identity and emissions of the microplastics used to ECHA via a prescribed electronic format. This requirement will entail annual administrative reporting costs for industry (and authorities to process the information reported), which were not quantified in the assessment. The one-time costs for developing a reporting system for authorities (ECHA) were estimated at €50 000.

According to the Dossier Submitter, the two requirements are complementary and sufficient time is given to stakeholders to comply with both, which is anticipated to minimise impacts.

However, during the consultation on the Annex XV report many comments were received indicating that the requirement to provide 'instructions for use and disposal' as well as to report to ECHA could entail substantial costs to industry. Based on information received, the Dossier Submitter assessed the economic impact in more detail.

Enforcement costs

The costs to enforcement authorities and industry consist of administrative (staff salaries, materials, equipment and overhead) and analytical (to develop testing methods and test products for compliance) costs for enforcement. The Dossier Submitter has estimated enforcement costs of the restriction based on the approach developed by ECHA[65] also recognising the limitations of this approach. In the absence of other estimates of enforcement costs, it is assumed that each of the product groups for which a restriction on the placing on the market is proposed would result in administrative enforcement costs of €55 000 per year. Consequently, the enforcement costs of the proposed restriction to authorities were estimated at about €3 million for the duration of the study period (NPV).

Table 19 Estimates of total enforcement costs of the proposed restriction

Product group	Total enforcement cost € million
Controlled-release fertilisers (CRF) & Fertiliser additives	0.4
Capsule suspension plant protection products (CSPs) & Seed coatings	0.4
Other rinse-off cosmetic products (excl. microbeads)	0.5
Leave-on cosmetic products	0.4
Fragrance encapsulates[c]	0.4
Other detergents	0.4
Waxes, polishes and air care products	0.4
Total	**2.9**

The Dossier Submitter points out that compliance can be ensured solely on the basis of labelling for many products, because information on their ingredients are already required under existing legislation (e.g. under the cosmetic product regulation, detergents regulation, medicinal products regulation or medical devices regulations). The restriction itself proposes measures that will facilitate enforcement by requiring that key information is included on the label (or SDS or instructions of use) enabling information to be passed down the supply chain. Therefore, it can be assumed that the need to test for the presence of microplastics in materials or final products will be minimal for both industry and enforcement authorities.

SEAC conclusion(s)

SEAC agrees with the cost assessment performed by the Dossier Submitter as an appropriate and pragmatic approach to assess the economic impacts of the proposed restriction.

SEAC highlights that the presented cost estimates cannot be regarded as precise figures, because the data to underpin the cost assessment are limited and significant uncertainties to assess the economic impact of the proposal remain. Therefore, the cost figures rather

[65] ECHA (2017) estimates the incremental administrative costs for restrictions at approximately €55 000 per year using the fixed budget approach (i.e. that enforcement authorities have a limited budget for enforcement, which they allocate to enforcing restrictions on the basis of the expected risk of non-compliance).

illustrate the range of costs that may result from the proposed restriction.

SEAC notes that, as reported by the Dossier Submitter, for cosmetics, in particular for leave-on cosmetic products, the costs to substitute microplastics are significantly higher than for the other sectors.

In addition, for some functions of microplastics, i.e. for encapsulation, substitution seems to be significantly more complex and costly to be achieved, because alternatives still need to be developed. For these uses, the costs resulting from the proposed restriction ultimately depend on the availability of alternatives before the end of the transition period.

For synthetic infill material the implementation of technical measures to reduce releases is likely to entail significantly lower costs than the substitution of microplastics.

SEAC agrees that the costs incurred by sectors derogated from a ban of microplastics to provide 'instructions for use and disposal' is likely to be moderate, in particular as cost-effective communication tools are available, the extent of information required is limited and the transition period give actors sufficient time to smoothly implement the requirements.

For the reporting, the total costs of reporting could be substantial as the number of companies affected is likely to be large. SEAC considers that there are different options to reduce the costs of the requirement, e.g. by excluding certain actors (small or micro-sized companies) from the requirement or by setting a threshold for microplastics volumes used or released to be reported. However, these options might compromise the value of information obtained and hence its usefulness for future risk management (see discussion on proportionality).

Key elements underpinning the SEAC conclusion(s):

A. Cost assessment: Overall view

Substitution costs

SEAC considers the approach taken by the Dossier Submitter – i.e. to structure the cost assessment by industry sector and product group – to be appropriate taking into account the multiple applications and functions of intentionally added microplastics, and resulting impacts of the proposed restriction.

Available data to assess the costs of the proposed restriction is scarce, meaning that there was limited evidence to derive essential parameters used in the assessment, e.g. the number of products and tonnages affected or the cost per reformulation. Therefore, the Dossier Submitter had to make assumptions and generalisations, which seem plausible and underpinned by available information. However, even though SEAC considers the assumptions made are appropriate to assess the economic impact of the proposal, it is not possible for SEAC to make a final judgement on their validity due to the limited data available. SEAC notes that the assumptions made in the assessment for the different sectors covered by the ban (agriculture/horticulture, cosmetic products and detergents/maintenance products) partly diverge from each other without always giving the reasons for doing so, e.g. assumptions on the coordination of R&D activities and baseline reformulations, on the replacement of affected products by microplastic-free products already on the market or on the incurrence of raw material costs. Generally, a more harmonised approach to assessing substitution costs would have been desirable.

To account for the uncertainties resulting from the limited data, the Dossier Submitter defined a low and high scenario for each sector assessed based on sensitivity values for the different assumptions made. This results in a broad range of possible costs presented in the dossier.

SEAC notes that some assumptions made for the low and high scenario may lead to under- or overestimation of costs. Some assumptions made in the cost assessment were revised based on information received in the consultation on the Annex XV report. As a result, the cost ranges were narrowed down for some sectors. Overall, it is difficult for SEAC to draw a final conclusion on the exact level of the costs of the proposed ban. However, SEAC considers that the range of costs estimated by the Dossier Submitter is likely to illustrate the order of magnitude of costs to be expected from the proposal.

The Dossier Submitter estimated the costs (as well as the benefits) over a 20-year period. SEAC considers this a reasonable timeframe to assess the impacts of the proposed restriction.

The main cost elements of the substitution costs – reformulation and raw material costs as well as a potential loss in product performance– are discussed below.

Reformulation costs

SEAC agrees with the Dossier Submitter that the cost of reformulating products in response to the proposed ban of the placing on the market can be expected to be the main socio-economic impact of the restriction. SEAC points out that for some product groups (e.g. cosmetics) the proposed restriction will not create a need to reformulate *per se*, because they are currently reformulated at regular intervals, but will bring reformulation efforts, and the associated costs, forward to an earlier point in time (i.e. during the transition period)[66]. For other product groups, e.g. capsule suspension plant protection products, genuinely new formulations will be required to comply with the proposed restriction. In the former case, it can be expected that the reformulation efforts triggered by the proposed restriction will be coordinated with baseline reformulations.

The magnitude of reformulation costs induced by the restriction depends on the number of microplastic-containing products on the market, in which microplastics will be replaced (i.e. the number of reformulations), and on the cost per reformulation. The Dossier Submitter used different data sources to estimate these parameters. To estimate the **number of reformulations**, the Dossier Submitter used product databases (cosmetic products) and information provided by industry (detergents, cosmetic products, agriculture and horticulture) complemented by making assumptions where no information was available. It is difficult to evaluate the reliability of the figures applied by the Dossier Submitter, when these were based on assumptions or on limited information received from industry. However, SEAC considers that the figures and assumptions used are a reasonable approach to the assessment taking into account the limited information available. The use of product databases, as available for the cosmetics sector, is the most transparent approach to estimate the number of products potentially affected. However, there are still significant uncertainties related to the number of reformulations triggered by the proposed restriction, for instance as products may be included in the cost calculations that are not covered by the ban, because the polymers or uses are derogated from the ban on placing on the market (e.g. biodegradable or liquid polymers or polymers with film-forming function that lose their microplastic form at the point of end use). The Dossier Submitter addressed these uncertainties by developing low and high scenarios, which result in the broad range of cost estimates.

Another important factor to consider is that the number of products containing microplastics is not equal to the number of reformulations that will actually occur in response to the

[66] This is in line with SEAC opinions on other restrictions, e.g. D4, D5 in wash-off cosmetic products.

proposed regulatory action. SEAC agrees with the Dossier Submitter that not all products containing microplastics will be reformulated in response to the proposed restriction. Depending on the market conditions of a specific product (e.g. when there is sufficient supply of microplastic-free products), the functionality of the microplastic in the product and the capacity of a company to reformulate, industry may choose to rather discontinue its production. This possibility is reflected in the underlying assumptions of the cost assessment for the cosmetics sector and was underpinned by contributions received from industry during the consultation (see below). SEAC notes that for other sectors (agriculture, detergents) such a differentiation was not included, either because of missing data (agriculture) or because information on the expected number of reformulations provided by industry was used (detergents).

The **cost per reformulation** was estimated by the Dossier Submitter for each sector or product group based on information received from industry. SEAC notes that the costs per reformulation vary considerably (ranging from €10 000 to more than €1 million) among the different industry sectors. Some differences in costs are plausible, because of different product requirements determining the resources needed to complete the reformulations as well as the differences in the current availability of alternatives and R&D budgets. However, SEAC also observes that the functions of microplastics in different products are partly similar (e.g. encapsulation or opacifying)[67], which makes it difficult to judge the validity of these differences in costs based on available information.

SEAC highlights that the cost per reformulation is likely to decrease with an increasing number of products that need to be reformulated because of both learning effects and economies of scale. Total spending on R&D to develop alternatives is largely uncertain. Furthermore, it is difficult to quantify R&D costs per product, because the number of products to be reformulated capitalising the R&D investment needs to be known. In terms of the net impacts of the restriction proposal, it is important to take into account that a share of product reformulations may be coordinated with ongoing R&D activities and product development meaning that for these baseline reformulations no extra cost is induced by the proposed ban. For some sectors (cosmetic products, detergents) the Dossier Submitter took this into account in the underlying assumptions of the cost assessments by estimating the share of baseline reformulations. SEAC considers this approach to be useful in order to derive a more realistic number of reformulations induced by the proposed restriction.

During the consultation on the SEAC draft opinion, there were comments raising the potentially high costs of biodegradability testing resulting from the criteria proposed by RAC including cost estimates to accomplish ISO tests (group 4) and OECD simulation tests (Group 5) (e.g. #663, #784, #785). SEAC considers biodegradability testing an integral part of R&D spending to develop alternatives, hence in principle the testing requirements resulting from biodegradability criteria influence reformulation costs. The cost data received in the consultation provide an indication of potential testing costs for one polymer[68]. However, based on this information it is not possible to provide a reliable estimate of total testing costs

[67] For instance, for detergents the estimates of the cost per reformulation ranges from €10 000 to €50 000, for cosmetics a major reformulation is estimated to be €365 000(rinse-off) to €547 500 (leave-on), an order in magnitude higher. Some of the functions of microplastics in cosmetics and detergents are similar, e.g. opacifying or encapsulation technology.

[68] OECD Screening test € ~5 000, ISO test € ~20 000 and OECD simulation test (307, 308, 309) € ~100 000.

resulting from the biodegradability criteria, because (i) the number of polymers to be tested in response to the restriction proposal and (ii) the average number of the different types of tests that will be performed per polymer is unknown . Therefore, SEAC cannot conclude on the overall magnitude of biodegradability testing costs.

Raw material costs

Besides the reformulation cost, the Dossier Submitter also estimated the raw material cost of replacing microplastics for some sectors (cosmetics, detergents) based on use volumes, price data on microplastics and the estimated increased price (price premium) of alternatives. Based on this assessment raw material costs are generally much lower than reformulation costs. SEAC agrees with this conclusion.

SEAC notes that the assumptions made in the assessment of raw material costs partly diverge between the different sectors. For example, no incremental material costs are estimated for the agriculture/horticulture product groups, whereas for detergents and cosmetics 50% price increase was assumed for alternatives as per information from industry. It would have been desirable if the Dossier Submitter had provided further justification of the different approaches to address raw material costs for the different sectors. However, given that reformulation costs are the main economic impact to be expected it is unlikely that raw material costs would change the overall order of magnitude of the costs of the proposed restriction.

Loss in product performance

SEAC points out that the replacement of microplastics in products as well as ceasing production of certain products as a reaction to the proposed restriction may entail a loss in product performance, and hence in consumer surplus. The Dossier Submitter did not quantify these impacts. Therefore, SEAC cannot draw a firm conclusion on the magnitude of the losses in product performance. The Dossier Submitter however assumes profit losses for some sectors in the worst-case scenario (some detergents and leave-on cosmetics) in the event some reformulations are unsuccessful.

In general, the existence of microplastic-free products within a product category suggests that the performance of alternatives is acceptable to replace microplastics, e.g. in rinse-off cosmetics. In cases where the share of alternatives is small, e.g. in some leave-on cosmetic categories or for encapsulation technologies, SEAC considers that impacts on performance may be significant. However, this is highly uncertain as for several sectors alternative ingredients are yet to be identified and their performance is to be evaluated.

Cost of implementing technical means to reduce emissions

The Dossier Submitter estimated the costs to implement technical means to reduce emissions for relevant sectors, i.e. polymeric infill material and *in vitro* diagnostics. These are discussed further below.

Costs of 'instructions for use and disposal' and reporting requirements

The Dossier Submitter did not quantify the costs of the requirements to provide 'instructions for use and disposal' and to report on the uses and releases of microplastics incurred by industry based on the arguments that the effort needed to fulfil these requirements is expected to be limited and that the length of the transitional periods is sufficiently long to coordinate these requirements with other changes to the product labels (regulatory or market-driven) and to establish the organisational structure needed. Therefore, these costs would be minor compared to the substitution costs.

The Dossier Submitter's assessment and information received in the consultation are further discussed below.

Enforcement costs

Similarly, enforcement costs were not assessed in detail by the Dossier Submitter apart from the default figure on enforcement costs of a restriction. SEAC considers that given the different sectors and multitude of products covered by the proposal, proper enforcement is likely to be quite resource intensive, which is reflected in the cost assessment by estimating the enforcement cost to €3 million. However, it is uncertain if additional budget for enforcement would actually be allocated for the implementation of the proposed restriction.

A major uncertainty is related to the resources industry will invest for testing in order to ensure compliance with the proposed restriction. If many products will be tested, this would entail significant costs considering that the test methods that are already available are quite expensive. However, SEAC in general agrees with the Dossier Submitter that for the products that will be covered by the proposed restriction information on their ingredients should already be available based on current regulation. Also, imported products play a minor role in these sectors. Therefore, SEAC considers it unlikely that industry would undertake large-scale analytical testing. Nevertheless, additional administrative costs for intensified supply-chain communication will still be required. The magnitude of this cost is uncertain, but it is likely to be minor compared to other economic impacts of the proposed restriction.

B. Sectors affected

Cosmetic products

Among the different product groups and sectors affected, the Dossier Submitter's assessment (Annex D5) shows that by far the largest share of costs will be incurred by the cosmetics industry, in particular to substitute microplastics in leave-on cosmetic products. These costs arise from the large number of products that are assumed to require reformulation to comply with the proposed restriction and the relatively high cost per reformulation.

A major uncertainty in the estimation of costs to the cosmetic sector is the **number of reformulations** in response to the proposed restriction due to the lack of specific quantitative information on the uses of microplastics (as defined by the restriction proposal) in cosmetics. The Dossier Submitter addressed this uncertainty by defining a low and high scenario when estimating the number of formulations containing polymers. Using the CosmEthics database the Dossier Submitter extracted all products that contained (i) polymers that are considered to be microplastics according to industry (a selection of 19 polymers) for the low scenario and (ii) all polymers for which there was information that they can be used in cosmetics in the high scenario (520 polymers). SEAC considers that the high scenario overestimates the number of products containing microplastics, because not all polymers used in cosmetics will be covered by the proposed restriction, either because they do not fall under the definition of a microplastic (e.g. because they are liquid, soluble or biodegradable polymers) or they have film forming properties (derogated by Paragraph 5 b) [69]. Information received from industry

[69] About 40% of all polymers used fall in the scope of the ban based on information from industry submitted during the consultation on the Annex XV report, e.g. #2220, #2361) This is of particular importance for leave-on cosmetic products, where it was difficult to estimate which INCI (International Nomenclature of Cosmetic Ingredients) uses fall into the scope of the proposed restriction based on available information.

in the consultation on the Annex XV report substantiate that the total number of formulations covered by the proposed restriction is likely to be at the lower end of the range estimated by the Dossier Submitter[70]. As stated previously, not all cosmetic products containing microplastics are likely to be reformulated in response to the restriction, for some it is likely that production will be discontinued instead. This was addressed in the cost assessment by assuming different shares of products that will be reformulated for each specific product category depending on the share of the number of products containing polymers compared to the share of alternative (polymer-free) products on the market[71]. The assumptions made by the Dossier Submitter are underpinned by experiences from the phase out of microbeads in cosmetics[72] and therefore, reasonable in the absence of specific information on the products concerned. However, SEAC notes that the decision to reformulate a product will also depend on the specific performance of microplastics in the product and the equivalence of alternative products already on the market to achieve this performance, which is not necessarily reflected by their market share. Furthermore, reformulation is conditional on the availability and suitability of biodegradable polymers or other materials as alternatives, which according to comments received in the consultation may not be the case for all functions of microplastics used in cosmetics (#2107, #2172, #2375). SEAC recognises that these factors are difficult to address quantitatively in the assessment. Nevertheless, the information received by industry during the consultation on the Annex XV report (e.g. in #2361 as well as confidential contributions) indicates that the number of reformulations expected by industry is within the lower end of the range estimated by the Dossier Submitter in the different cost scenarios assessed.

Microplastics are used in cosmetics to achieve many different functions. Simple drop-in alternative solutions are often not available. In particular for leave-on cosmetics, the **cost per reformulation** is expected to be substantial. This is supported by the fact that these products often contain more than one type of microplastic increasing the costs per reformulation compared to rinse-off cosmetics[73]. The Dossier Submitter reflected this complexity and the additional effort to develop alternatives to substitute microplastics by using a higher estimate for the average cost per reformulation for leave-on cosmetics compared to rinse-off products[74].

The estimates used by the Dossier Submitter for the cost per reformulation were challenged by industry stakeholders during the consultation on the Annex XV report (e.g. #2220, #2361, #2375, confidential submissions) as well as the SEAC draft opinion indicating that the cost

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[70] For leave-on cosmetics, the Dossier Submitter estimates between 11 000 (low scenario) and 92 000 (high scenario) reformulations in response to the proposed restriction. Industry expects about 13 000 formulas to be impacted as stated in the consultation of the SEAC draft opinion (#806).

[71] The Dossier Submitter assumed that (i) 5% of the estimated microplastic-containing formulations would be reformulated as a result of the proposed restriction, if they constitute < 30% of all products on the market, (ii) 50% if they constitute between 30 and 70 % and (iii) 95% if they constitute > 70% of all products in the specific product category. The same assumptions were applied to all cost scenarios (low, central and high).

[72] Only about 50% of all products containing microbeads were reformulated.

[73] On average rinse-off products contain between 1.1 (low scenario) and 1.3 (high scenario) polymers, leave-on products between 1.4 (low scenario) and 1.6 polymers (high scenario) (based on CosmEthics 2018).

[74] The Dossier Submitter estimated €365 000 (€42 000 for SMEs) for rinse off and €550 000 (€63 000 for SMEs) for leave-on based on information available from the restriction on D4 and D5 in wash-off products (RTI, 2002).

would be much higher for products where there are no alternative ingredients available yet suggesting a significantly higher average cost than assumed by the Dossier Submitter[75]. Also, the representativeness of the estimate used by the Dossier Submitter was questioned by Cosmetics Europe, who provided their own assessment in the consultation of the Annex XV report and the SEAC draft opinion (#806).

SEAC considers that the estimate of the cost per reformulation provided by industry is likely to be overestimated and may reflect the marginal, but not the average cost to reformulate. This conclusion is based on the following elements:

- There is evidence that alternatives are on the market already for most functions of microplastics (see Bertling et al. (2018), summarised in BD, Annex D5, pp. 206). Furthermore, functions where the availability of alternatives seems to be limited are either excluded from the ban such as film-forming (based on derogation 5b) or information was received from industry in the consultation suggesting that also for these functions some alternatives exist (confidential submission), e.g. skin conditioning. Therefore, the number of reformulations that will require extensive initial R&D to develop alternatives is likely to be limited.

- Not all reformulations can be expected to be equally resource-intensive. This conclusion is confirmed by information provided by industry indicating that usually cosmetic products are composed of specific raw material mixtures, which contain one or more microplastic ingredient(s) (confidential submission). Hence, microplastics will be replaced in raw material mixtures, which are used in several final formulations meaning that the costs to substitute microplastics in the mixture have to be allocated among the final products that will be reformulated in response to the restriction. It is not clear to what extent these raw material mixtures actually would be reformulated or if a company would switch to another supplier who already provides microplastic-free raw material mixtures instead.

- Inconsistent information was submitted by industry during the consultation on the Annex XV report also suggesting that the cost per reformulation could actually be within the range or much lower than estimated by the Dossier Submitter (confidential submissions). Insufficient details were provided to evaluate the different cost estimates given by industry, hence SEAC cannot assess their validity and representativeness to reflect the average cost to substitute microplastics in cosmetics.

Overall, SEAC notes the estimates used by the Dossier Submitter is based on independent information sources and strike a balance between inconsistent information received in the consultation on the Annex XV report and can be considered appropriate to reflect the average reformulation costs to be expected.

In the consultation on the Annex XV report, industry raised concerns about further costs entailed by the proposed restriction, namely patent costs, lost profits as well as export losses. The Dossier Submitter addressed these potential impacts by revising the high cost scenario. SEAC considers that the likelihood of these impacts to occur very much depends on the number of reformulations and the performance of reformulated products compared to products containing microplastics.

[75] Cosmetics Europe (#806) assumes that the average reformulation cost will be €820 000.

Apart from the costs to reformulate, a loss in product performance was raised as a significant economic impact of the proposed restriction in both consultations, in particular for leave-on cosmetic product categories such as skin care, sunscreen and make-up. For sunscreen, it was also stated that the benefits in terms of skin protection could be negatively affected. SEAC acknowledges that a loss in product performance could be a possible impact of the restriction. However, evidence to assess its significance is scarce. Some information on the performance of alternative products may be derived from the Nordic Swan ecolabel criteria, which prohibit the use of microplastics and at the same time demand products to fulfil certain performance standards. The number of products certified in each product category on the market may provide some indication on the possibilities to replace microplastics without a major performance loss. Based on these figures, SEAC notes that several hundred products are certified in some leave-on product categories, e.g. skin care or sunscreen, indicating a satisfactory performance, however significantly less in others, e.g. make-up products. Overall, SEAC does not have sufficient information to conclude on the significance of a loss in product performance resulting from the proposed restriction.

Information received during the consultation (#2361, confidential submissions) confirmed that particularly high costs can be expected for some product groups of leave-on cosmetics, i.e. **make-up, lip and nail products**. These costs mainly result from the large number of reformulations to be expected in response to the proposed restriction. The conclusion that there could be particularly many reformulations within make-up, lip and nail products is supported by the fact that the current share of polymer-free products that may absorb the market of products containing polymers is much lower compared to other product groups of leave-on cosmetics such as skin care products. In addition, the substitution of microplastics is likely to require more resources compared to other product groups, because make-up, lip and nail products on average seem to contain a greater number of different microplastic ingredients (to achieve different functions). Also, comments received in the consultation on the Annex XV report indicated that the substitution process could be more costly, e.g. in terms of additional testing (#2360, confidential submissions). SEAC considers that the costs to substitute microplastics in make-up, lip and nail products are critical for assessing the proportionality of the restriction proposal for cosmetic products (discussed in the section on proportionality B.3.3.4). However, the uncertainties in the estimation of the number of reformulations required are even more relevant for these product groups pointing to greater overestimation than for the remaining leave-on categories. The main factors include: i) the film forming function (which is even more prevalent use of polymers in these leave-on categories) is not excluded when estimating the number of reformulations required to comply with the restriction, ii) the high number of products[76] characterised by small differences, e.g. on the basis of colour, within the same brand name and product series[77].

SEAC points out that there is an overlap of the cost estimates with the cost assessment of the restriction proposal on D4, D5 and D6 in cosmetic products. This is due to a share of the products (mainly leave-on cosmetics) that contain D4, D5 and D6 as well as microplastics,

[76] The Dossier Submitted estimated the number of required reformulations to comply with the proposed restriction based on the unique barcode used in the CosmEthics database.

[77] Therefore, for example, for cosmetic eye-shadow series of the same brand, consisting of 10 different colours with otherwise similar list of ingredients, the analysis would treat them as unique formulations, i.e., requiring 10 separate reformulations, while it is likely that industry would approach their reformulation as a group, likely identifying one alternative for all these separate reformulations.

meaning that they are affected by both restriction proposals. Accordingly, the costs of reformulating these products would need to be distributed between the two to avoid double-counting of costs. The Dossier Submitter assessed the potential overlap of products affected by both restriction proposals and concluded that up to 30% of products (primarily in the leave-on category) on the market could contain both, microplastics and D4, D5 or D6 (see Background Document).

Detergents and maintenance products

A considerable number of detergent and maintenance[78] products can be expected to be reformulated in response to the proposed restriction (see Annex D6 of the Background Document for details on the uses and functions of microplastics in detergents, waxes, polishes and air care products). The Dossier Submitter estimated the number of reformulations based on information received from industry during the preparation of the Annex XV report and updated these figures based on information received in the consultation on the Annex XV report. In general, the range of the number of reformulations derived from the estimates used in the different scenarios (low, central, high) was supported by information submitted to the consultation on the Annex XV report. Furthermore, the range of costs per reformulation estimated by the Dossier Submitter was generally confirmed by information received in the consultation on the Annex XV report, although there were comments stating that more complex reformulations would cost significantly more. Therefore, the Dossier Submitter updated the upper estimates of reformulation costs used in the cost assessment based on the information received. Where more specific information was submitted, the Dossier Submitter took this information into account when updating the assumptions made, e.g. a higher number of reformulations for polymeric fragrance encapsulates (which were covered by the assessment on detergents) as it was indicated that more products than originally assumed would be affected by the proposed restriction (#2421). The Dossier Submitter also developed additional sensitivity scenarios to assess the effect of impacts raised during the consultation, which seemed not entirely plausible or credible (see Section 3.6.7 in the Annexes to the Background Document). For example, industry claimed that the majority of reformulations to be expected in response to the proposed restriction would be undertaken in order to avoid the 'instructions for use and disposal' and reporting requirements. SEAC considers this to be unlikely, because based on the information available the cost to reformulate can be expected to be substantially higher than the cost to provide instructions for use and reporting.

Fragrance encapsulation

For one application of microplastics, the encapsulation of fragrances (used in detergents and to a small extent also in cosmetics), substitution seems to be more difficult and no alternatives are available yet according to information received in the consultation on the Annex XV report. This difficulty was addressed by the Dossier Submitter by assuming higher costs per reformulation compared to other uses in detergents as well as additional expenses for R&D. Industry stated in the consultation on the Annex XV report that reformulation costs, in particular R&D costs to develop alternatives, would be even higher. The Dossier Submitter took the information received into account by updating the upper values used in the cost assessment.

[78] Maintenance products include air care products (i.e. aerosol, electric, gel and liquid air fresheners as well as scented candles and car air fresheners), waxes and polishes (i.e. shoe, floor, furniture and metal polishes).

The costs resulting from the ban of microplastics in fragrance encapsulates essentially depend on whether suitable alternatives will become available in time to allow for replacing microplastics before the end of the transition period. As there is insufficient evidence available to conclude on the time needed to develop alternatives (see Section B 3.3.4), SEAC considers this a major uncertainty of the cost assessment for fragrance encapsulates. To reflect this uncertainty, the Dossier Submitter estimated the costs of using greater amounts of perfume as well as profit losses in case alternative materials for encapsulation would not be available yet at the end of the transition period. The Dossier Submitter assessed the costs in different scenarios, depending on how long it would take industry to develop and implement alternatives (5, 8 or 10 years after entry into force) and the length of the transition period (please refer to Section B 3.4.4 for the discussion on 5 vs 8 years transition period). As another potential impact of a lack of (equivalent) alternatives, industry raised the issue that textiles would be washed more frequently in the event that fragrance encapsulation was no longer available resulting in increased releases of secondary microplastics (as fibres) as well as increased detergent and energy use. In the consultation of the SEAC draft opinion industry further substantiated these potential impacts (#663). Based on the information provided, SEAC considers more frequent washing to be a possible reaction to a loss in product performance. However, the available evidence is not sufficient to assess the likelihood of these impacts in more detail or to derive reliable, quantitative estimates of the costs associated with them.

Agriculture and horticulture products

In agriculture and horticulture, microplastics are used in fertilisers (controlled-release fertilisers (CRF) and fertiliser additives, such as anti-caking agents) as well as in plant protection products (capsule-suspension plant protection products (CSP)) and seed coating.

For fertiliser products (CRF and fertiliser additives) the order of magnitude of costs to substitute microplastics estimated by the Dossier Submitter was generally confirmed by industry during the consultation (e.g. #2047, 2116). However, industry indicated that a much higher share of fertiliser products than originally assumed by the Dossier Submitter (95% compared to 50%) is placed on the market across the EU, and is therefore subject to the biodegradability criteria set in the new EU Fertiliser Products regulation (EU) 2019/1009. This means that only 5% of the substitution costs (and accordingly 5% of the reductions in microplastic emissions) are actually attributable to the proposed restriction. The Dossier Submitter updated its assessment in the Background Document accordingly.

For plant protection products, industry provided further information during the consultation on the Annex XV report on the number of reformulations to be expected in response to the proposed restriction as well as on the cost per reformulation, which industry considers to be significantly higher than estimated by the Dossier Submitter (#2082). One argument to substantiate these higher costs was the need to re-authorise the products concerned under plant protection products regulation. The Dossier Submitter revised the cost estimates taking into account the information received.

Infill material on synthetic turf pitches

SEAC has evaluated the costs, where possible on a (semi-)quantitative basis, for several possible restriction options for managing the risks from microplastics used as infill on synthetic turf pitches. This evaluation reflects all of the information available to SEAC, including costs information received during the consultations (which was broadly in line with the estimates provided by the Dosser Submitter). SEAC notes that an assessment of the end-of-life of

artificial pitches, or other policy and environmental issues related to this (such as the end-of-life of tyres), falls outside of the scope of the evaluation of this restriction proposal, but is likely to be a relevant factor to consider in the decision-making process.

The restriction options considered were:

1. **RO1: Full ban of infill material covered by the microplastics definition (from entry into force i.e. no transitional period)**

SEAC notes that this scenario covers infill material in general. In other words, it is a full ban for all infill material covered by the microplastics definition irrespective of use (i.e. not limited to sport pitches and playgrounds[79]).

A full ban of infill material under the microplastics restriction would lead to an end-of-market scenario similar to the one discussed in the SEAC opinion on the proposed restriction of PAHs in granules and mulches. Several important differences however need to be borne in mind:

- Although the proposed restriction of PAHs in granules and mulches also covers virgin infill material, the end-of-market scenario only impacted infill derived from end-of-life tyres (ELT) since, according to the available information, virgin infill (TPE, EPDM, etc.) would not contain PAHs. However, under the microplastics restriction virgin infill would also be impacted.
- The microplastics restriction identifies a risk to the environment while the proposed restriction on PAHs in granules and mulches dealt with a human health risk.

From a cost perspective these differences mean that the impacts for the infill industry would be higher for the proposed restriction on microplastics than for the proposed restriction of PAHs in granules and mulches.

Since the market share of ELT-derived rubber infill is 90-95%, the cost estimates linked to the end-of-market scenario described in the proposed restriction of PAHs in granules and mulches are considered to be a realistic low-end approximation of the actual impact to the infill industry from RO1[80]. The overall societal costs of a full ban on infill material can therefore be estimated to be around €3 000 million to €3 500 million over a 10-year period[81] (market impacts to society). Further information on the calculation of these impacts are contained in the SEAC opinion of the proposed restriction of PAHs in granules and mulches and the associated Background Document.

Further to these costs, SEAC acknowledges that there are certain environmental benefits[82] associated with the re-use of end-of-life tyres as infill material. Landfilling of end of life tyres is not an option due to EU legislation and there is limited capacity for energy recovery (i.e. incineration[83]). There are however alternative markets where this excess infill material could be put to use such as the manufacture of flooring, athletic tracks and other surfaces or in

[79] Which is the scope of the "PAH granules restriction".

[80] It has to be noted that the cost of virgin infill material is, at the moment, significantly higher than of ELT-derived infill and will therefore represent a higher percentage of the total impact to industry than their market share might indicate.

[81] 10 years is the duration of the analytical period used in the socio-economic analysis supporting the proposed restriction of PAHs in granules and mulches, which corresponds to the typical lifetime of an artificial turf pitch.

[82] Resource efficiency: reuse of tyres as a secondary raw material and reduced energy need compared to manufacture of virgin material.

[83] Incineration typically takes place at cement kilns.

pyrolysis and black carbon manufacture. It is unknown to what extent these alternative markets could absorb the excess infill currently used on artificial pitches[84]. It is therefore also unclear if and to what extent these lost benefits are a significant factor from a cost perspective. SEAC re-iterates this is only part of a larger policy and environmental discussion (e.g. end-of-life) surrounding end of life tyres and artificial pitches which falls outside of the evaluation of the proposed restriction on microplastics. Potential lost benefits should be considered as costs additional to the already mentioned costs due to market impacts. However, these lost benefits could not be monetised.

During the consultation on the Annex XV report various national football associations submitted estimates for the "social return on investment" (SROI) from participation in football (both on natural and artificial pitches), essentially attempting to monetise the benefits for public health and wellbeing, the economy and society at large. These associations assessed these social opportunity costs using a model developed by UEFA.. While SEAC was not able to assess the methodological underpinnings of the UEFA SROI model, SEAC acknowledges that RO1 would create significant social opportunity costs. However, these will certainly not be as large as the costs mentioned in some of the comments submitted in the consultation (i.e. several billion euros). A full ban on infill material covered by the microplastics definition would in the short-term lead to some pitches being less playable or, in a worst-case scenario, unavailable for play at all, but it will not lead to a complete collapse of football participation (especially in the long term). Not all pitches need to comply with the high-quality standards for professional play. Since it is impossible to estimate the loss in football participation, SEAC can also not estimate the social opportunity costs associated with this restriction option. The short-term social opportunity costs might however be considerable.

2. RO2: Full ban of infill material covered by the microplastics definition (with a transition period of 6 years)

During the Annex XV report consultation multiple respondents from Germany indicated that a 6-year transitional period would allow for a gradual transition to artificial turf systems that either use natural infill material or are infill-free (e.g. comment #2131). This claim was echoed by UEFA (Comment #2362). Alternatively, many other respondents stated that some alternatives will not be suitable under certain circumstances (climate, professional or amateur play, etc) and also questioned the availability of alternative infill material and infill systems.

SEAC agrees with the Dossier Submitter that a sufficiently long transition period would mitigate most immediate impacts of a ban since time is given to find/implement suitable alternative infill material and turf systems and increase their availability[85]. During the consultation on the draft SEAC opinion further evidence was provided showing that several non-microplastic alternatives are available and could in certain cases even fulfil the high technical requirements for professional play (such as cork[86]). Most of these alternative infill materials are at the moment significantly more expensive, except cork which is however not available in sufficient quantities to be used ubiquitously across the EU.

The Dossier Submitter provided an indicative cost assessment. SEAC notes that there does

[84] Although research is on-going to find other applications for infill material (e.g. pyrolysis).

[85] Certain producers have indicated that production of non-microplastic alternatives could be ramped up during the 6-year transition period.

[86] It is important to note that different types of cork with different types of behaviour (e.g. in cold and/or wet climates) are available.

not seem to be enough information available to arrive at a sufficiently robust and meaningful cost assessment. The Committee also considers the costs provided by the Dossier Submitter (€9 600 million) to be an overestimation of the costs associated with RO2. This is due to the fact that the Dossier Submitter includes the difference in the replacement cost for different pitch systems for all existing pitches (32 000 full size pitch equivalents). This implies that even incremental replacement costs that accrue before the phase out date would be counted toward the total cost of RO2. However, due to the proposed transition period only a limited number of pitches (10-20%) should need to be prematurely replaced.

SEAC therefore prefers to make the following qualitative statements which use the costs of RO1 as a baseline:

- The societal cost estimate (€3 000 million - €3 500 million over a 10-year period) needs to be adjusted downward due to the following reasons:
    - As mentioned earlier, 80-90% of the pitches can be refurbished/replaced at the end of their foreseen lifespan. Considering the fact that the average lifespan of an artificial pitch is 10 years SEAC finds this plausible. SEAC does however recognise that, at the moment, alternative pitches are more expensive than ELT pitches.
    - During the transition period the availability of alternative infill material and infill systems will increase. While some of these alternatives are at the moment more expensive, it is in principle to be expected that prices would reduce because of greater availability.

As was the case under RO1 (full ban without transition period), potential lost benefits due to not-reusing end-of-life tyres as infill material should be considered as costs additional to the already mentioned costs due to market impacts. These costs are not mitigated by the transition period, but would only delay them. The same comments under the RO1 discussion regarding the larger policy context also apply here.

Social opportunity costs (see discussion under RO1) might also arise here, but due to the transition period these are highly uncertain, but will in any case be significantly lower than for RO1 (or even non-existent).

Overall SEAC finds it clear that the costs linked to RO2 to be (significantly) lower compared to those for RO1.

3. **RO3: Derogation from ban, but reporting and instructions-for-use requirements**

Since the Dossier Submitter did not provide a cost assessment, SEAC cannot provide an in-depth analysis on the impact of this restriction option.

It is however clear that labelling and IFU requirements would not be prohibitive for this type of low-tech product (e.g. no complex and very variable formulations).

Higher costs might be associated with the reporting requirement (especially in regards to estimating annual releases).

Overall, the impacts on both costs and emission reduction from this restriction option will be significantly lower compared to RO1, 2 and 4.

4. **RO4: Derogation from ban conditional on technical Risk Management Measures being implemented to prevent releases the environment (with or without the proposed 3-year transitional period)**

During the Annex XV report and SEAC draft opinion consultations a wealth of information was submitted on means to limit infill release to the environment. Based on this it is clear to SEAC that ways to limit or even eliminate releases of infill material into the environment are widely available. Effective measures can be and are already implemented on existing fields. More far-reaching measures are then ready to be implemented when synthetic pitches have reached the end of their lifetime and need to be refurbished/replaced.

Furthermore, a CEN technical report (CEN/TR 17519) was recently approved (after the adoption of the RAC opinion on the microplastics proposal) that lays out technical measures by which the releases of infill to the surrounding environment can be reduced. Magnusson & Macsik (comment #686) reviewed the available published studies and estimated the effectiveness of existing RMM measures as detailed in CEN /TR 17519. On the basis of this study, RAC Rapporteurs have informally indicated to SEAC that it appears reasonable to assume that CEN/TR 17519 can limit the infill dispersion to levels below 7g/m^2, set out in RO4, provided that they are adhered to in the fields of new construction and retroactively implemented in the pre-existing fields. **However, this would need to be confirmed by a full evaluation by RAC.**

During the different consultations, very disparate information was submitted on the costs for implementing these technical measures (e.g. those included in CEN/TR 17519). Based on the comments received, the Dossier Submitter indicates that costs for retrofitting existing artificial sports fields to be in the range of €3 000 to €29 000 per full-sized pitch (average cost proposed by Dossier Submitter: €20 000). SEAC notes that other comments (e.g. #2139 and #2364) report higher costs. SEAC therefore suggests to adapt the costs range: €3 000 - €83 000 (average cost proposed by SEAC: €30 000). It is important to note that the upper cost limit contains worst-case estimates and costs that may not be necessary in certain countries (e.g. related to snow deposit area). It is however useful to include as a sensitivity test when discussing cost-effectiveness and proportionality (see further in this opinion).

Using an average cost of €20 000 per pitch and assuming that 32 000 of the existing 39 000 full-size pitch equivalents use polymeric infill material and have no measures in place to limit emissions to the environment, the Dossier Submitter arrives at an overall cost for this restriction option of €640 million (PV). Using an average cost of €30 000 per pitch this overall cost estimate increases to €960 million (PV). A transition period of 3 years would mitigate most of these costs since 80-90% of the pitches can be refurbished/replaced at the end of their foreseen lifespan. Considering that the average lifespan of an artificial pitch is 10 years SEAC finds this plausible. During the opinion development UEFA stated that investments in pitches are already being made now, which indicates that the cost estimated presented above should be seen as an upper bound.

The European Synthetic Turf Council (ESTC) in any case indicates that costs for mitigating emissions are not prohibitive and less than the cost of switching to alternatives (comment #686). ESTC have also indicated that, if RO4 was favoured, the measure should in time be reviewed and if necessary repealed.

Noteworthy, is a 2019 Dutch court decision which found a field owner to be in breach of the "Duty of Care" article in the Dutch Soil Protection Act. The owner was found guilty of not having done more to prevent granules from spreading to and contaminating the surrounding soil. It is outside of the remit of SEAC to analyse possible legal and policy implications of this decision on the currently proposed restriction (in regards to infill material). However, if a field owner already has a specific "Duty of Care" requirement under national legislation related to

infill material[87] then any costs made to fulfil this requirement cannot be considered part of the costs of this restriction option. As such, the costs mentioned in this opinion might be overestimated.

5. RO5: hybrid restriction option

RAC proposed a hybrid option (RO5) where existing pitches could be used for their remaining lifetime conditional on strict RMMs being implemented. Newly constructed or refurbished pitches would then be banned from using infill material.

No specific cost information is available to SEAC, but the Committee considers the cost assessment under RO4 to be applicable here. This is due to the fact that the only relevant costs for this restriction option are those associated with the implementation of RMMs. While SEAC acknowledges that currently alternative infill materials/systems are more expensive, it is in principle to be expected that prices would decline because of greater availability. Allowing the use of existing pitches until they reach the end of their lifetime should mitigate the surplus costs associated with alternatives.

This option was not preferred by RAC unless a full ban would not be considered to be proportionate. During the consultation, both public and private stakeholders indicated that this option should not be preferred as well. SEAC also does not prefer this option since a full ban (with or without transition period) might be proportionate, thereby negating the reason that RAC proposed RO5. Further to that, ESTC indicated that they would be receptive to RO4 being a time-limited derogation (review clause), which similarly question the added value of RO5.

Medical devices

Microplastics are used in a multitude of products used for medical purposes such as equipment like adsorbers for blood treatment or ion-exchange resins but also in mixtures such as dental filling material or sunscreen. During the preparation of the Annex XV report the Dossier Submitter was not fully aware of these substance-based medical devices[88] and expected that medical devices would be derogated from the ban of the proposal, because microplastics are contained (derogation 5a) or permanently modified (derogation 5b) suggesting a limited economic impact ('instructions for use and disposal' and reporting requirements).

Information received during the consultations on the Annex XV report and the SEAC draft opinion indicated that medical devices would also include products that would contribute to microplastic releases and hence would be covered by the ban. These products are very similar to cosmetic products (e.g. skin cream or toothpaste) and microplastics have the same functions as in cosmetic products. Therefore, the Dossier Submitter proposed the longest transition period proposed for cosmetic products, i.e. 6 years, referring to the similarities to cosmetics formulation. The proposed transition period takes into account the time needed for the reformulation and the regulatory (re)certification (self-certification or assessment by the authorities depending on the classification of medical device) of such medical devices (Annex XV report consultation #2098, #2126, #2432, and SEAC DO consultation e.g. #715). Reformulation costs for those medical devices that would be affected by the ban were not specifically estimated.

SEAC considers that more information on the economic impact of the ban on medical devices

[87] Which might or might not be the case in member states other than the Netherlands.

[88] In this context, 'substance-based medical device' should be understood as 'mixture medical device'.

would be desirable. Even though SEAC agrees that there are a lot of similarities to cosmetic products, there may also be differences in terms of reformulation process and testing required as well as regulatory requirements. Comments received during the consultation on the Annex XV report indicate that the cost per reformulation could be higher for medical devices than for cosmetic products. However, the information received in the consultation of the SEAC draft opinion is not sufficient to estimate the costs resulting from a ban of microplastics in substance-based medical devices. Therefore, SEAC considers that a review of the substitution of microplastics in medical devices before the end of the transition period would be useful to assess the associated socio-economic impacts.

***in vitro* diagnostic devices (IVD)**

Initially, the Dossier Submitter intended a derogation for IVD devices conditional on the containment of microplastics throughout the lifecycle of these products (derogation 5a). During the consultation on the Annex XV report industry provided further information on the costs to implement technical means in order to ensure the containment of microplastics as well as on the costs to substitute microplastics from IVD assays.

The Dossier Submitter estimated the costs of (i) collection and incineration of all liquid and solid waste generated during the use of IVD products, which is the main source of releases from IVD devices and (ii) substitution of microplastics in IVD assays (see SectionD.7 in the Background Document). According to this assessment, the economic impact would be in the order of magnitude of billions of Euros over the 20-year analytical period. Main drivers of the costs are (i) the number of hospitals and laboratories that will have to implement and operate technical solutions to prevent microplastic releases (estimated ~23 000) and (ii) the reformulation cost per IVD assay (estimated at €4.5 million for one assay). Based on proportionality considerations (see section on proportionality) the Dossier Submitter now proposes 'instructions for use and disposal' and reporting requirements for IVD devices containing microplastics (see below).

Overall, SEAC considers that the Dossier Submitter's assessment illustrates the range of costs that could be expected from a ban or containment of microplastics in IVD products, even though uncertainties remain due to the lack of specific information. SEAC points out that there is an overlap in impacts with IVD products covered by applications for authorisation for octylphenol ethoxylates, which however would only be relevant, if containment of microplastics would be required (by imposing the collection and incineration of the wastes generated from the IVD uses) and/or if respective applications for authorisation would be rejected by the decision-maker.

Sectors affected by 'instructions for use and disposal' and reporting requirement

For products containing microplastics that are derogated from the ban (under paragraphs 4a, 4b, 4d, 4e and 5) mandatory 'instructions for use and disposal' are proposed in order to ensure releases from these uses are minimised as far as possible in all lifecycle stages (paragraph 7). Furthermore, the Dossier Submitter proposed an obligation for industrial users and suppliers[89] of the products concerned to provide annual reports on releases of microplastics used including generic information on polymer identity and a description of the use(s) (paragraph 8). Examples of the sectors covered by these requirements are:

- *in vitro* diagnostic devices (IVD)

[89] placing a microplastic on the market for consumer or professional use for the first time

- other medical devices (if not covered by ban)
- cosmetic products (if not covered by ban)
- detergents and maintenance products (if not covered by ban)
- medicinal products
- food additives
- paints and coatings
- construction products
- toners and printing inks
- 3D printing
- Any other industrial use, e.g. oil and gas
- manufacturers of microplastics

During the consultation on the Annex XV report as well as on the SEAC draft opinion many stakeholders commented, in particular on the reporting requirement, indicating that the administrative cost could be substantial (e.g. #2027, #2040, #2057, #2058, #2065, #2068, #2073, #2074, #2092, #2102, #2148, #2236). The comments received indicated the need for guidance to clarify what is required from the actors involved along the supply chain. In this respect, SEAC notes that the variability in cost estimates provided by industry during the consultations may also result from different interpretations of the efforts needed to fulfil the requirements.

With regard to the requirement to provide **'instructions for use and disposal'**, information received in the consultation suggests that the costs to industry to fulfil this requirement could be substantial. The Dossier Submitter performed a qualitative analysis on the costs to be expected considering the contributions received from industry (see Background Document 2.5.4). Accordingly, costs estimated by stakeholders tend to focus on the more costly measures to implement the requirement, e.g. assuming that the instructions have to be presented in an additional package leaflet rather than on the label itself or via an SDS. The Dossier Submitter complemented the information received by industry with literature sources. According to this, the range of costs of relabelling would be between about €300 and €3 000 per product. The Dossier Submitter highlights that the obligation leaves flexibility to the actors involved to choose the most appropriate and cost-effective solution to fulfil the obligation, including pictograms. SEAC considers that the analysis carried out by the Dossier Submitter illustrates the range of costs to implement the instructions for use and disposal requirement on a 'per label' basis. However, based on this information, it is not possible to estimate the total economic impact of providing 'instructions for use and disposal', because the number of companies and products covered is unknown for most sectors. Nevertheless, SEAC notes that products are relabelled on a regular basis and that the longer transition period of 24 months as is now proposed (compared with 12 months) will reduce the additional costs of relabelling triggered by the 'instructions for use and disposal' requirement and also prevent unintended impacts such as recall of products with long shelf-lives. During the consultation of the SEAC draft opinion, some stakeholders confirmed that the costs to implement the instructions for use and disposal requirement down the supply chain are likely to be proportionate (e.g. #539, #550).

The second element of the instructions for use and disposal requirement (paragraph 7) obliging industrial users to pass information on to downstream users in order to enable them to report microplastic uses and releases was considered much more costly to implement in the comments received (please see discussion on reporting below).

With regard to the **reporting requirement**, many comments were received during the Annex

XV report consultation highlighting the potentially high administrative costs of this obligation, in particular if it will apply to all actors of the supply chain including professional users and consumers. Addressing these comments, the Dossier Submitter clarified what exactly the reporting requirement would include and to whom it would apply (see section 2.2.1.5 of the Background Document). Hence, (i) all downstream users of microplastics at industrial sites as well as (ii) suppliers of other products containing microplastics who place these products on the market for consumers or professionals for the first time would have to report annually the estimated releases of microplastics as well as generic information on polymer identity and a description of the use(s). Furthermore, the Dossier Submitter revised the reporting requirement in response to the consultation comments to focus onto key information (description of use(s) and environmental releases) and highlighted how industry sectors can collaborate to develop cost-efficient means to estimate releases, e.g. by using Specific Environmental Release Categories (spERCs).

SEAC considers that this clarification shows that professional users[90] as well as consumers are not affected by the requirement so that a more limited number of actors will be obliged to report. When it comes to the resources needed to prepare the report, SEAC agrees with the Dossier Submitter that there are possibilities to do it cost-efficiently, e.g. by applying available standards to derive release estimates such as 'environmental release categories' provided in REACH guidance.

Comments received from stakeholders during the consultation on the SEAC draft opinion still indicated that the total costs of reporting could be significant. Some comments provided cost estimates for implementing reporting obligations, without specifying what the quantified costs related to (see Table 25 in the Background Document). While the submitted cost estimates varied, most comments indicated that the reporting requirement would entail a one-off cost for setting up a software/system (the non-confidential cost estimates ranged from €5k to €220k per company) and an annual cost related to the actual reporting (the non-confidential estimates ranged from 0.3 to 2.5 FTEs required per company and year). Some comments stated that there would be additional annual costs related to the maintenance of the software and to maintaining a list of microplastics releases for the site and/or consumers/professional users. SEAC considers that the ranges of the estimates provided demonstrate the variability of costs the reporting requirement may entail and that overall costs ultimately depend on how it is implemented.

There was only limited evidence available to evaluate the cost information received by industry and to derive an estimate of the total cost of reporting. Cost estimates derived for harmonised notifications under poison centres legislation could provide some indications (Section 2.5.5 in the Background Document) as in the consultation of the SEAC draft opinion, it was indicated that the reporting requirement could entail costs in a similar order in magnitude. However, SEAC considers that the obligations are not directly comparable, because poison centre notifications are submitted per product (not per use) and in all EU languages, which indicates that the effort spent is likely to be significantly greater. SEAC notes that other available evidence of the administrative costs of environmental reporting

[90] It was a major concern by sectors involving many professional users such as paints and coatings that these would have to comply with the reporting obligation, in terms of costs, but also in terms of double counting of emissions.

obligations (e.g. in EU EMAS[91] or EU ETS[92]) indicates average costs at the lower end of the range of costs estimated by industry in the consultations[93]. Overall, SEAC concludes that the upper end of the range of cost estimates received is likely to be exaggerated.

Considering the different supply chains covered by the reporting requirement, SEAC notes that the number of companies obliged to report their uses of microplastics is likely to be large, in particular in terms of small and micro-sized enterprises. However, the exact number of companies affected cannot be determined based on the available information[94].

SEAC examined if the available information would allow a reliable estimate of the total costs for certain sectors to be derived. However, the uncertainties with regard to the costs per company as well as the number of companies affected are significant. Taking these uncertainties into account, SEAC considers that providing an estimate of the total costs of reporting would not be very meaningful.

In the consultation of the SEAC draft opinion, there were requests for changes in the reporting requirement to reduce the costs to industry, e.g. by setting a threshold for the volume of microplastics that would need to be used or released before the reporting was required. The Dossier Submitter also discussed the possibility to introduce a threshold for reporting, or to limit the obligation to manufacturers/importers to reduce costs (cf. Section 2.2.1.5 in the Background Document). Also, the option to exclude companies covered by other environmental reporting schemes (e.g. OSPAR) from the reporting obligations to reduce costs was brought up in the consultation of the SEAC draft opinion. SEAC considers that these options would be likely to reduce overall costs, because they will reduce the number of uses and releases to be reported. However, SEAC cannot assess the extent of this reduction as no specific scenario for a modified scheme was proposed by the Dossier Submitter.

Furthermore, the practical implementation of the requirement may also influence the costs to industry. In the consultation of the SEAC draft opinion, there were comments that the annual reporting deadline should be later in the year, i.e. in May, e.g. to avoid clashes with other reporting obligations.

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[91] EU Eco-Management and Audit Scheme - https://ec.europa.eu/environment/emas/index_en.htm

[92] EU Emissions Trading Scheme - https://ec.europa.eu/clima/policies/ets_en

[93] In EMAS, administrative costs to companies were estimated to be € 56 000 (price-adjusted) for the first year and 30 400 (price-adjusted) for each consecutive year. The effort needed to implement EMAS can be considered to require significantly more resources compared to the reporting requirement of the proposed restriction.
https://ec.europa.eu/environment/emas/pdf/other/costs_and_benefits_of_emas.pdf

In EU ETS, the administrative costs for companies for monitoring and reporting to MS was estimated to amount to 20 000 – 60 000 €. As this obligation includes further activities (e.g. verification) it is very likely that it requires more resources compared to the proposed restriction
https://op.europa.eu/en/publication-detail/-/publication/f6a49ec5-c35c-11e6-a6db-01aa75ed71a1

[94] SEAC considered Eurostat data on the number of companies in different supply chains affected.

B.3.3.2. Benefits

Summary of proposal:

Microplastics, as defined in this restriction proposal, are extremely persistent and, therefore, accumulative in the environment. As with PBT/vPvB substances, a quantification of environmental impacts of microplastics is currently not possible. Therefore, the Dossier Submitter adopted a similar approach for assessing the benefits of the proposal as recommended by SEAC for evaluating PBT/vPvB (-like) substances[95]. The approach rests on the assumption that emission reduction is a reasonable proxy for risk reduction, i.e. the benefits of the restriction are measured as emission abatement.

The proposed restriction is estimated to reduce 70%[96] of cumulative emissions (over the 20 year analytical period considered) or more than 90% of annual emissions (once all transition periods have expired) of intentionally added (primary) microplastics that would occur in the absence of the restriction entering in effect (see Table 2 for an overview of releases). This is equivalent to a cumulative emission reduction of about 500 000 tonnes of microplastics over 20-years (central scenario) following the entry into force of the proposed restriction (see Table 2 for an overview of releases).

The reduction in releases will contribute to minimising releases of (primary) microplastics to the environment, where they persist over long periods and are associated with various adverse effects on organisms and with accumulation in food. The proposed restriction will reduce the quantity of microplastics in wastewater effluents and sludge, reducing the likelihood that organisms in the environment will encounter and possibly ingest these materials either directly, or via their food.

This measure will help to reduce the growth of environmental stocks of microplastics, which may lead to local risk to ecosystems and contribute to the potential for widespread risk if current trends of microplastic releases continue in the future. However, the impacts of the proposed restriction are uncertain in isolation from other measures on plastics, including secondary microplastics, which the EU is undertaking.

SEAC conclusion(s):

The approach taken by the Dossier Submitter is a reasonable way to assess the benefits of the proposed restriction as microplastics are stock pollutants characterised by **extreme persistence in the environment** and by an incomplete understanding of their effects on the environment and human health. Therefore, SEAC agrees that emission reduction is a useful quantitative proxy of the benefits of the proposed restriction.

While microplastics are a global pollution problem, SEAC notes that also local effects are possible as microplastics do not spread homogenously in the environment like other stock pollutants such as greenhouse gases. Therefore, the reduced emissions resulting from the proposed restriction would predominantly affect the environmental stock of microplastics in

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95 https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf

96 Range dependent on assumed effectiveness of 'instructions for use and disposal' requirements and scenario assumptions.

the EU.

While recognising that the environmental impacts of the proposed restriction are uncertain, SEAC underlines that RAC confirmed that microplastics constitute an intrinsic hazard and that releases should be minimised. When assessing the benefits of the restriction, it is important to take into account that **microplastic pollution is irreversible** and the growing pollution stock in the environment may lead to adverse effects in the future. There is growing evidence that addressing microplastic pollution of the environment is likely to lower losses to the value of the EU's natural capital that can occur as a result of irreversible pollution.

Key elements underpinning the SEAC conclusion(s):

The proposed restriction will significantly reduce emissions of intentionally added (primary) microplastics covering all known major emission sources. While the impact of this emission reduction is unknown, SEAC notes that RAC has confirmed that – analogous to PBT(-like) substances - emissions from all sources of microplastics should be minimised to reduce the overall risks to the environment due to their extreme persistence and potential to accumulate in the environment. In addition, there is evidence suggesting that adverse effects of microplastics may already occur in pollution hot spots (e.g. in the marine environment). Concerning the geographical scale of potential impacts, SEAC notes that potential effects may occur on local, regional as well as on global scale. To assess the impacts of emission reduction in more detail further information would be needed on the pollution stock, stock dynamics and the effects of microplastics in the environment (information that is currently not available).

It is important to consider the option value of an unpolluted environment when assessing the benefits of the proposed restriction. Microplastic pollution is irreversible and hence likely to lower the value of the EU's natural capital and the ecosystem services it provides to society. Apart from the possibility of widespread adverse effects on organisms, populations or ecosystems that may occur in the future, SEAC points out that the accumulation of microplastics in the environment may also affect its aesthetic value. The irreversibility of the potential impacts of microplastic pollution means that early action to reduce emissions can be worthwhile from a social welfare perspective, even though the direct benefits of the emission reduction are not known. This conclusion is supported by research submitted during the consultation of the SEAC draft opinion (#648) on the willingness-to-pay to invest in wastewater treatment plants in order to reduce microplastics emissions, even though the impact of the emission reduction was unknown. The results show that respondents were willing to pay significantly more for emission reduction measures than for research funding to better understand the impacts of microplastics on the environment highlighting a general preference for avoiding microplastic emissions.

When considering the overall benefits of the proposed restriction, SEAC notes that emissions of intentionally added (primary) microplastics contribute to a smaller extent to the pollution stock compared to secondary microplastics. However, sources of secondary microplastics are much more difficult to control. Therefore, SEAC considers that the proposed restriction will tackle microplastics emissions, which are easier to manage compared to other sources or to remediation measures (they are an example of 'low hanging fruit'). This conclusion is supported by comments received from the water industry in the consultation on the Annex XV report indicating that microplastics are already a problem in water treatment, which is very difficult and costly to manage (#2435 and #2725). The proposed restriction targets emissions from uses that—because of their size—cannot be addressed via measures under

discussion for reducing sources of secondary microplastics, such as recycling, collection and proper disposal of plastic waste.

Similarly, SEAC notes that the impact of the proposed restriction on emission sources outside the EU is limited, although some reduction in the use of microplastics is likely because the restriction will apply to mixtures imported to the EU. As microplastics are transboundary pollutants with the potential for long-range environmental transport emissions occurring outside the EU can contribute to the environmental stock of microplastics within the EU. In this respect, global action on (micro)plastics would be more effective to tackle the pollution problem over the long term. However, this does not affect the benefits of the proposed restriction because, (i) as the bulk of microplastics emissions is expected to remain in the EU, the proposed restriction will effectively contribute to reduced growth of environmental stocks within the EU irrespective of uses outside of the EU, e.g., in riverine and terrestrial compartments and (ii) as microplastics are stock pollutants, comparable to PBT(-like) substances, any reduction in emissions ought to be considered a benefit, even though other emission sources may remain.

Infill

Based on a thorough assessment of comments on the Annex XV report, and other available information, the Dossier Submitter estimates average annual EU emissions of infill material to be approximately 16 000 tonnes. It is important to note that an assessment of the end-of-life of artificial pitches, or other policy and environmental issues related to this, falls outside of the scope of the evaluation of this restriction proposal, but is an important factor in the decision-making process, especially when it comes to the benefits of the discussed restriction options.

Under RO1 and RO2 (full ban without and with a 6-year transition period, respectively) these emissions will be avoided which represents a clear benefit to the environment. An additional benefit to the environment of a ban on ELT-derived infill is related to the chemical constituents in this type of infill, some of which are known to be hazardous to the environment. The very high concentration of zinc oxide contained in the rubber granules is a particular source of concern (RIVM 2018). However, SEAC reiterates that there are potential lost environmental benefits (related to the use of ELT waste as a secondary raw material) associated with the fact that at least 100 000 tonnes of ELT waste per year will not be re-used as infill material. Depending on cement kiln capacities a larger part of ELT waste may end up being incinerated. However, there are alternative markets where this excess infill material could be used such as the manufacture of flooring, athletic tracks and other surfaces or in pyrolysis and black carbon manufacture. It is unknown to what extent these alternative markets could absorb the excess infill currently used on artificial pitches. It is therefore also unclear if and to what extent these lost benefits are a significant factor. A key and important difference between these restriction options is that RO2 would still allow the irreversible emission of microplastics to the environment during the transition period.

Under RO3 (instructions for use and reporting requirement) avoided emissions are uncertain but expected to be low (in absolute terms and relative to the other restriction options). Leaching of chemicals in ELT-infill material, such as zinc oxide, is not avoided in this scenario.

Under RO4 (technical measures to limit emissions) benefits are expected to be maximized without outright banning the use of synthetic infill material, at least when compared to the other restriction options. If sufficiently effective technical measures are implemented then

annual emissions can be reduced to (practically) zero (reduction to at least 50 kg/y/pitch or roughly 10% of current emissions). This was stated many times during the consultations on the Annex XV report and the draft SEAC opinion. A CEN technical report (CEN/TR 17519) was recently approved that lays out technical measures by which the releases of infill to the surrounding environment can be reduced. Magnusson & Macsik (comment #686) reviewed the available published studies and have estimated the effectiveness of existing RMM measures being used in a full-size pitch as detailed in CEN TR 17519. The main conclusion of their study is that when all the proposed RMM in CEN TR 17519 are correctly applied, the cumulative infill migration losses could be reduced to 15 kg/year (2 g/m^2)[97], below the 50 kg/year (7g/m^2) considered as a limit value proposed by the DS (90% reduction relative to baseline releases) and analysed by ECHA's committees. **However, this would need to be confirmed by a full evaluation by RAC.** Furthermore, there are no lost environmental benefits since recycled end-of-life tyres can be re-used as infill material (even though these might be small). Leaching of chemicals in ELT-infill material, such as zinc oxide, is not or only partly avoided in this scenario, but lower than under RO3. It is important to note that this restriction option would still allow average annual EU emissions of 1 600 tonnes (10% of the original emissions) or potentially 480 tonnes (3% of the original emissions) if the RMMs in CEN TR 17519 are followed strictly.

Under RO5 (RMMs during lifetime of pitch, ban of microplastic infill afterwards) annual emissions can be reduced to (practically) zero (reduction to at least 50 kg/y/pitch or roughly 10% of current emissions) during the lifetime of the artificial pitches. When pitches are replaced or refurbished, emissions will cease since microplastic infill will be prohibited.

B.3.3.3. Other impacts

Summary of proposal:

The Dossier Submitter discussed other impacts such as **social impacts (employment), impacts on SMEs, and impacts on trade and competition** for individual sectors in the scope of the proposed restrictions. Employment in companies engaged in supply chains of microplastic-containing products may be negatively affected by the proposed restriction. On the other hand, positive employment effects may be expected for businesses producing alternative products. For the purpose of illustrating worst-case impacts, loss of employment was quantified in the High costs scenario for leave-on cosmetic products, i.e. for the share of reformulations where delays have been assumed. The Dossier Submitter estimated that these would not exceed €300 million (NPV) over the study period of 20 years (€70 million for impacts on employment and €230 million for impacts on trade)

The proposed restriction impacts multiple sectors. Within the EEA economy, the majority of companies are SMEs, which tend to have limited resources. In some sectors, where a large number of reformulations may be required to be completed within the transitional period, e.g. make-up, lip and nail products, SMEs may face challenges.

The requirements of the proposed restriction that would impact a broad range of sectors entail activities such as 'instructions for use and disposal' or reporting requirements, which is not expected to require substantial resources. (See also Section B 2.2.1.50) The requirements that would likely incur the largest costs to industry relate to the proposed restriction on the

[97] Informally confirmed to SEAC by RAC rapporteurs.

placing on the market of products containing microplastics (see paragraph 6 of the proposed restriction entry in Table 1). They are introduced after transitional periods designed to allow sufficient time to comply and therefore, minimise the costs to society, including SMEs, without undue delay of minimisation of microplastic emissions to the environment. SMEs currently focusing on microplastic-free products could directly benefit from a restriction on microplastic-containing products as they already have on the market formulations that meet the requirements of the proposed restriction.

The EEA market is one of the largest markets in the world for many of the impacted supply chains. Manufacturers, importers and downstream users of microplastic–containing and alternative products are dispersed throughout Europe and internationally. Industry has expressed concerns that the restriction may lead to the expatriation of manufacturing leading to potentially lower EEA value added and lower exports. The Dossier Submitter has attempted to minimise these effects by proposing sufficient time to comply with the restriction requirements, in particular to reformulate microplastic-containing products. Therefore, while it is possible that in the worst-case scenario these impacts may materialise, it is also likely that value-added and exports of alternative (microplastic-free) products would increase. Hence, some of the negative impacts on trade and competition for microplastic-containing products may be offset by positive impacts in the markets for alternative products; with the net effect being uncertain. As any impact on exports is highly uncertain, wider economic effects are monetised only for leave-on cosmetic products. Under the worst-case assumptions they are estimated at €230 million (NPV).

SEAC conclusion(s):

Based on the information available SEAC does not consider it to be substantiated that major other net impacts will result from the proposed restriction.

Key elements underpinning the SEAC conclusion(s):

During the consultation on the Annex XV report, stakeholders raised concerns about the impact of the proposal on SMEs, exports and employment (in particular for the cosmetics sector). SEAC acknowledges that it is possible that the proposal would negatively affect some SMEs considering that SMEs operate to a large extent as suppliers for larger companies but also as producers of final products in the market in the cosmetics sector. However, information received in the consultation also indicated that the producers of alternative products are also often SMEs, which in turn may benefit from the restriction. Hence, the impact on SMEs could be more of a distributional impact than a net impact.

Similarly, a potential impact on employment could be distributional. SEAC considers it to be plausible that the overall demand for the products mainly affected by the ban, e.g. cosmetics, is unlikely to decrease. Therefore, it is uncertain if and to what extent net effects on employment are to be expected.

B.3.3.4. Overall proportionality

Summary of proposal:

Cost-effectiveness of abatement of microplastic emissions

As the benefits of reducing environmental emissions of microplastics cannot be robustly quantified, the Dossier Submitter conducted a cost-effectiveness analysis of emission abatement in line with the approach for evaluating the proportionality of restriction proposals

for PBT/vPvB (-like) substances recommended by SEAC[98].

For sectors with restrictions on the placing on the market of microplastics, the Dossier Submitter calculated, where possible, separate cost-effectiveness ratios for each sector/use. The estimates were revised taking into account updates to the cost and release information received during the Annex XV report consultation (see Table 20 for a summary).

Table 20 Summary of cost-effectiveness of proposed restriction

Sector	low	central	high
Agriculture and Horticulture			
Controlled-release fertilisers (CRF) & Fertiliser additives	1	7	42
Capsule suspension plant protection products (CSPs) & Seed coatings	4	30	188
Cosmetics			
Other rinse-off cosmetic products (excl. microbeads)	2	22	27
Leave-on cosmetic products	380	870	1 300
only make-up, lip and nail products	800	2 200	3 300
Other Leave on (excluding make-up, lip andnail products)	70	460	750
Detergents and maintenance products			
Fragrance encapsulates	5 years TP: 71 8 years TP: 89	5 years TP: 173 8 years TP: 128	5 years TP: 337 8 years TP 329
Other detergents	<1	1	9
Waxes, polishes and air care products	<1	1	2
Synthetic infill material			
Ban with 6 y TP (RO 2)	-	33	-
Technical measures (RO 4)	-	5	-

The cost-effectiveness of the proposed restriction on the placing on the market range from < €1/kg to €2 200/kg in the central case, with the lowest cost-effectiveness (highest cost per kilogram emission abatement) estimated for make-up, lip and nail products (sub-set of leave-on cosmetic products).

The ranges reflect the considerable uncertainty associated with both the emission estimates (see section on emissions) and the costs that can be expected to be induced (see section on costs).

The estimated cost-effectiveness values for the various sectors/uses included in the proposed restriction are within the range of cost-effectiveness estimates for adopted REACH restrictions on substances posing a risk to the environment, e.g. PBT/vPvB(-like) substances. This is supported by Oosterhuis et al. (2017). Their study concludes that, although cost estimates of

98 https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf

previously adopted regulatory actions do not allow to derive a value of society's willingness-to-pay for reducing PBT/vPvB presence, use, and emissions, the available evidence suggests that measures costing less than €1 000 per kilogram of emission reduction would usually not be rejected for reasons of disproportionately high costs, whereas for measures with costs above €50 000 per kilogram PBT such a rejection is likely (Oosterhuis et al., 2017). Based on this reasoning, the Dossier Submitter concluded that the costs associated with the proposed restriction can be viewed as acceptable for society to reduce microplastic emissions to the environment.

Other considerations on proportionality

Even though the costs of the proposed restriction are substantial, the Dossier Submitter concludes that the proposed restriction is affordable. This conclusion is based on the finding that the substitution costs only amount to a minor share of the estimated average profit per product, e.g. for leave-on cosmetics the monetised restriction costs represent less than 20% of the estimated average profits per reformulation, which according to the Dossier Submitter demonstrates the **affordability** of the restriction.

With regard to the **costs and benefits** of the proposed restriction, the Dossier Submitter underlines that the emissions of microplastics into the environment potentially cause irreversible effects. Irreversibility poses a challenge to conventional policy analysis, especially if the consequences are poorly understood and cannot be reliably quantified and monetised (Traeger, 2014). In such situations, restricting an activity can be the optimal strategy even if the expected costs of regulation outweigh the direct/quantifiable benefits (Gollier et al., 2000). Hence, the fact that microplastic emissions to the environment cannot be reversed – or only at a very high cost – is a key factor to be taken into account when assessing the proportionality of the proposed restriction.

The Dossier Submitter concluded that on the basis of cost-effectiveness, affordability and other cost-benefit considerations, the proposed restriction can be seen as a proportionate measure to reduce the risk of irreversible releases of microplastics to the environment for uses where (i) there are currently no viable means to collect, properly dispose of or remediate once in the environment, and (ii) where alternatives already exist or there is information that these can be developed in the medium term.

SEAC conclusion(s)

SEAC agrees that cost-effectiveness analysis is an appropriate approach to support the proportionality assessment of the proposed restriction on microplastics taking into account the similarities to PBT/vPvB substances. The cost-effectiveness of the proposed restriction lies within the range of other REACH restrictions. However, these should not be considered to be scientifically-based benchmarks for SEAC to conclude on proportionality.

As the impacts of microplastics, as well as the potential welfare loss related to these impacts, are yet to be understood, SEAC underlines that the proportionality of the different options included in the proposal ultimately depends on policy-based benchmarks or emissions targets and cannot be demonstrated by comparing the costs and benefits (since in this case there is no meaningful way to monetise the benefits of the proposal). Without clear guidance on what the policy priorities in terms of microplastics are, SEAC cannot draw a final conclusion on the proportionality of the proposal (or elements of the proposal).

Examining other aspects that are relevant to proportionality, SEAC considers that the **irreversibility of microplastic emissions** is a key argument in support of the proportionality of the proposed restriction. Even if the impacts of emission reduction are uncertain, early action can still be worthwhile from a social welfare perspective. This conclusion is supported by recent research on the willingness-to-pay of citizens for early action to reduce microplastic emissions.

Furthermore, the conclusion that the proposed restriction would be proportionate is supported by the fact that **alternatives** to microplastics are already **available** for most uses, indicating that microplastics can be substituted within the proposed transitional periods.

For **capsule suspension plant protection products** SEAC considers that a transition period of eight years (in order to account for the time needed for re-authorisation under the plant protection products regulation) could improve the proportionality of the restriction, also taking into account the potential positive environmental impact of this use and that it seems to take more time to develop alternatives than in other uses.

SEAC considers that there is currently insufficient justification to exclude certain types of cosmetic products from the proposed ban. For leave-on cosmetics that are mainly disposed via solid waste, i.e. **make-up, lip and nail products**, SEAC finds that other measures to manage microplastic emissions from these uses (such as informing consumers on proper use and disposal) or a longer transition period (i.e. > 6 years) could also be considered as proportionate measures taking into account the low contribution to overall emissions as well as the potentially large impact on industry of a ban in these products.

With regard to polymeric **fragrance encapsulation**, SEAC cannot draw a robust conclusion on the most appropriate transition period due to lack of information on the time needed to develop alternatives. An option to ensure a smooth transition to alternatives and timely reduction of releases would be a review of the availability of alternatives in due time before the end of the transition period, e.g. 4 years after entry into force of the restriction. For **infill material**, all options assessed by the Dossier Submitter that effectively reduce releases could be considered to be proportionate.

In terms of the '**instructions for use and disposal**' requirement SEAC points out that the costs of its implementation are likely to be moderate and the benefits in terms of lower releases (along the supply chain) seem likely.

For **reporting,** SEAC considers the need for a better evidence base to facilitate future risk management has to be balanced carefully against the cost of collecting this information. As reporting will place a significant burden on companies, the information requested should be only that which is strictly necessary (to achieve a sound evidence base) and the practical implementation of the reporting scheme should be as efficient as possible (to minimise the resources needed for both industry and authorities to comply). In this respect, it could be an option to exclude small and micro-sized companies from the obligation to make it more cost-effective. However, SEAC cannot draw a firm conclusion on how the different options to reduce the costs of reporting would compromise the value of information obtained and hence the benefits of reporting in terms of facilitating better risk management. Moreover, SEAC considers that for certain actors in the supply chain, e.g. manufacturers of microplastics, a shorter transition period, i.e. 12 months, seems to be justified.

Key elements underpinning the SEAC conclusion(s):

Due to their extreme persistence, microplastics are stock pollutants similar to PBT/vPvB-substances. Like PBT/vPvB-like substances, microplastics are characterised by the incomplete understanding of their environmental effects, which hampers measuring the impacts of emission abatement. Also, there is only limited evidence to estimate society's willingness-to-pay for abatement of microplastic emissions. As a consequence, a quantitative comparison of costs and benefits of the restriction is not meaningful.

Therefore, estimating **cost-effectiveness** is a suitable approach to support the proportionality assessment of the proposed restriction. In this respect, the finding that the cost-effectiveness of the proposed restriction lies within the range of former regulatory measures of PBT/vPvB(-like) substances is considered to be relevant to conclude on proportionality. SEAC points out that the cost-effectiveness of reducing microplastic emissions varies significantly depending on the sector/use as well as on the proposed measure (e.g. ban or technical measures to reduce releases).

SEAC underlines that cost-effectiveness analysis (CEA) does not per se allow for a final conclusion on whether the proposed regulatory action is proportionate or not. It can facilitate decision-making by providing information on the relative cost of emission reduction measures, also in comparison to the costs of past measures on environmental pollutants with similar properties such as PBT/vPvB substances, but it cannot lead to a definite conclusion on proportionality. As the impacts of microplastics on the environment as well as the potential welfare loss related to these impacts are yet to be understood, proportionality ultimately depends on policy priorities. Unless these priorities are clear, e.g. by setting a fixed emission reduction target or a benchmark of acceptable cost-effectiveness, CEA cannot be employed to establish what actions would impose acceptable or unacceptable costs to reduce microplastic emissions.

Therefore, it is difficult for SEAC to draw a robust conclusion on the proportionality of the proposal. The environmental impacts of the emission reduction achieved are uncertain – in particular as other sources of microplastic emissions will remain – and at the same time the proposed restriction is likely to involve substantial costs. However, a key argument in support of proportionality is the **irreversibility of emissions**. The pollution stock of microplastics is permanent and not possible to remove from the environment with current technological capabilities. If remediation would be at all possible, SEAC considers it likely to be much more costly compared to the costs of the proposed restriction. However, the long-term impacts of the growing stock of microplastics in the environment cannot be evaluated in any quantitative way.

Concerning alternatives, the available information indicates that **alternatives** already exist or are likely to be developed in the foreseeable future for the majority of uses. SEAC considers that the availability of alternatives is another important argument in favour of the proportionality of the proposal. The transition periods proposed by the Dossier Submitter in general are appropriate to allow for the transition to alternatives in order to facilitate the smooth replacement of microplastics while attaining a timely reduction of emissions.

Even though the costs of the restriction are substantial, SEAC tends to agree with the Dossier Submitter that, overall, these costs seem affordable to the actors involved, taking into account the average profit margins of the product groups involved. However, these margins could vary significantly and there could be situations, where it could be more difficult for the actors

involved, e.g. SMEs, to bear the costs to substitute microplastics in their products as indicated in comments received during the consultations on the Annex XV report and the SEAC draft opinion. However, it should be noted that the information submitted to assess affordability was limited, meaning that there is insufficient evidence for SEAC to draw a clear-cut conclusion on affordability.

Notwithstanding that there are strong arguments for the restriction being a proportionate measure to reduce microplastic emissions, SEAC points out that some changes or specifications of the original scope of the proposal might improve proportionality (depending on policy priorities as stated earlier). SEAC elaborates on the different uses and sectors concerned below.

Cosmetic products

As explained in the section on costs (B.3.3.1), the substitution of microplastics in leave-on cosmetics is likely to involve substantial costs. The major part of these costs will be related to product groups that contribute to a relatively lesser extent to microplastic releases than others, i.e. make-up, lip and nail products[99]. Therefore, replacing microplastics in these products is much less cost-effective than in other product groups (see Table 11). However, SEAC underlines that the average costs per kg emission reduced derived for make-up, lip and nail products are likely to be overestimated, in particular because they include polymers (soluble, liquid or film-forming) that are excluded from the ban (see cost section). In addition, there are indications that releases could be greater than estimated by the Dossier Submitter. This means that it could be more cost-effective to substitute microplastics in these product groups than estimated by the Dossier Submitter (€800 - €3 300 per kg).

Taking into account that this level of cost was considered proportionate in some restrictions on PBT(-like) substances (see Oosterhuis et al., 2017) and that there is no established proportionality benchmark for cost-effectiveness, SEAC considers that there is currently insufficient justification to exclude make-up, lip or nail products from the proposed ban on the basis of cost-effectiveness.

Table 21 Impacts of the proposed restriction of make-up, lip and nail products compared to other leave-on cosmetic products

Product group	Emission reduction (t)	Costs (million €)	cost-effectiveness (€ per kg)
Make-up, lip and nail	2 200	4 500	2 200 (800 – 3 300)
Other leave on	6 250	2 900	460 (70 – 750)

Comments received from industry in the consultation claimed that the resources required to replace microplastics in leave-on cosmetic products would exceed the available reformulation capacity, which could be particularly difficult for SMEs operating in the sector. In the consultations on the Annex XV report and the SEAC draft opinion there were requests for a longer transition period, in particular for certain product categories, i.e. skin care, sunscreen and make-up, mainly based on the current lack of suitable alternatives. SEAC agrees that the investments needed to develop alternatives to microplastics in these products are likely to be

[99] Make-up, lip and nail products are predominantly (~70 %) removed from skin with tissues or wipes and disposed of via solid waste as indicated by data from consumer surveys according to industry (#2361). Other surveys indicate significantly higher releases (of up to 50%) for make-up and lip products (YouGov, 2017). Details can be found in Annex D 5.5 of the Background Document.

substantial, but also notes that in principle there are alternatives to microplastics in all cosmetic products categories. Given the uncertainties associated with the resources and investments that the reformulation of products containing microplastics will actually require and considering that it is also likely that producers of alternative products would benefit from the proposed restriction, it is difficult to draw a firm conclusion on the overall net impact on industry, including SMEs.

Depending on the impact on industry and on releases, SEAC points out that the following restriction options might also be considered proportionate:

- Derogation of leave-on products with relatively low releases (such as make up, lip and nail products) provided that information that the products contain microplastics and instructions for use and disposal is given to consumers in order to reduce releases as far as possible. Furthermore, these uses should be covered by the reporting obligation in order to obtain better evidence on releases and to take further action (such as a ban on the placing on the market) in the event emissions do not sufficiently decline. The excessive costs claimed by industry would be avoided whilst some emission reduction could be expected (starting from an earlier date: within 2 years of EiF for instructions for use vs the proposed ban with a transitional period of 6 years). However, the overall effectiveness of this option to reduce releases is likely to be significantly lower than a ban.
- Ban with longer (i.e. > 6 years) transition period for leave-on products with relatively low releases: This option would give more time for industry to substitute microplastics and to spread reformulation costs over a longer time period. In the consultation on the Annex XV report, industry claimed that much more time (up to 15 years) would be needed to replace microplastics in leave-on cosmetics. Whereas it is unlikely that such a long time period would be needed (considering the evidence that in principle alternatives already exist in all product categories), also the Dossier Submitter acknowledged the possibility (in the high scenario) that not all reformulations would be finalised by the end of the six year transition period proposed. SEAC highlights that there is insufficient information to determine the optimal transition period. On the other hand, a longer transition period would mean more releases of microplastics to the environment. In order to minimise releases during the transition , complementary 'instructions for use and disposal' on product packaging could be required .

The uncertainties related to the different impacts (impacts on industry and releases) do not allow SEAC to conclude on whether one of these options is likely to be more appropriate than the proposed restriction. As mentioned above, proportionality depends on policy priorities to reduce microplastic emissions.

Detergents and maintenance products

For polymeric **fragrance encapsulation**[100] it is more costly to replace microplastics than for other uses in detergents, because alternatives have not been developed yet. Also, uncertainty remains as to whether alternatives for polymeric fragrance encapsulation will become available within the transition period originally proposed by the Dossier Submitter (i.e. five years). Industry stakeholders commented during the Annex XV consultation that the proposed transition period is too short to develop alternatives and that up to 10 years would be needed

[100] A minor percentage of polymeric fragrance encapsulation is reported to be used in cosmetic products (< 1% of production volumes).

to substitute microplastics (#2160 #2239). The additional costs that would be incurred if alternatives would not be available were estimated by the Dossier Submitter in the high cost scenario (including additional perfume use and profit losses) and therefore reflected in the cost-effectiveness estimates (see Table 12). These estimates do not include other potential impacts, e.g. resulting from potentially increased washing frequency of textiles in response to the reduced performance of alternatives.

A longer transition period for the use of microplastics in polymeric fragrance encapsulation is likely to decrease the costs of the proposed restriction, in particular if the impacts arising in the event that alternatives would not be available before the end of the transitional period could be prevented (such as profit losses and the use of additional perfume oils). The Dossier Submitter assessed the impact of an eight year transition period on cost-effectiveness, indicating a ~30% reduction of the cost per kg of microplastic emissions abatement as compared with a five year transition period (from €173 to €128 per kg). Again, SEAC points out that a longer transition period would result in greater emissions (~600 t) of microplastics in total and hence reduce the effectiveness of the proposed restriction (see Annex D.6.7 in the BD).

Table 22 Fragrance encapsulates: Impacts of 5 and 8 year transition period.

Transition period	Emissions reduction (t)	Raw material costs (€$_{2017}$ million)	Reformulation/R&D costs (€$_{2017}$ million)	Cost effectiveness (€ per kg)
5 year transition period	3 000 (2 000 – 4 100)	86 (0 – 183)	440 (293 – 554)	173 (71 – 337)
8 year transition period	2 400 (1 600 – 3 300)	1 (0 – 79)	311 (293 – 522)	128 (89 – 329)

The Dossier Submitter does not make any recommendation on whether five or eight years would be the most appropriate transition period for polymeric fragrance encapsulation. SEAC considers that based on cost-effectiveness s it cannot be concluded that it would be disproportionate to phase out microplastics used for polymeric fragrance encapsulation after a five year transition period. Noting the changes in both costs and emission reduction, both transition periods could be considered to be proportionate. To conclude on the most appropriate transition period the development of suitable alternatives is a key argument. In this respect, SEAC notes that information on the time needed to develop alternatives is not consistent. During the consultation of the SEAC draft opinion, stakeholders reaffirmed their requests for a longer transition period and submitted further information on potential alternatives and on the substitution process (#663). They argued that the overall time for the substitution of microplastics in fragrance encapsulation would be 8.5 years and that, when passing the OECD biodegradation screening tests (which is considered unlikely by industry), the shortest timing could be five years. In contrast to this information received in the consultation, SEAC notes that some companies seem to be able to replace microplastics in the short-term[101]. Furthermore, there are indications of ongoing research into the development of biodegradable microcapsules[102]. Taking all available information into account, it is not currently possible for SEAC to draw a robust conclusion on the time needed to develop alternatives and hence on the most appropriate transition period. An option to ensure a

[101] https://www.henkel.com/sustainability/positions/microplastics

[102] https://www.iap.fraunhofer.de/en/press_releases/2020/biodegradability-of-microcapsules.html

smooth transition to alternatives and timely reduction of releases would be a review of the availability of alternatives in due time before the end of the transition period, e.g. four years after the entry into force of the restriction.

Agriculture

Based on the information received on the length of the re-authorisation process of plant protection products, the Dossier Submitter considered that a transitional period of eight years after entry into force for the use of microplastics in capsule suspension plant protection product formulations would be appropriate.

SEAC concludes that an eight year transition period for capsule suspension plant protection products is likely to improve proportionality of the restriction taking into account that this use contributes to a more efficient use of resources (active substances) and consequently a potentially lower environmental impact as well as operator exposure of the plant protection products concerned.

In the consultation on the SEAC draft opinion, stakeholders stated that a longer transition period would also be needed to substitute microplastics in coated seeds that are not plant protection products. SEAC considers that a longer transition period is not justified in this use by the evidence provided because (i) seed coatings will not have to be authorised as plant protection products, (ii) there is no information that would suggest seed coatings cannot be replaced independently from plant protection products containing microplastics , and (iii) microplastic-free coatings for seeds are already available on the market for some crops.

Infill on artificial sports pitches

Since the costs and benefits are uncertain, SEAC considers that a clear and unambiguous cost-effectiveness figure cannot be derived for either RO1 or RO2. SEAC therefore performed an indicative 'break-even' analysis, i.e. back-calculating the cost to society using several of the cost-effectiveness figures for other sectors (see Table 20). As such, SEAC can compare the societal costs associated with a specific cost-effectiveness figure to the approximate costs discussed in the cost section (see section B.3.7.1.3). In other words, if the back-calculated costs are greater than the costs in section B.3.7.1.3, then this is a potential indication that RO1 or RO2 could be considered proportionate.

SEAC notes that this analysis is intended for **illustrative purposes only** and should be read in conjunction with the cost section. It cannot and should not be construed as a quantitative assessment. **SEAC reiterates that *a clear cut choice for one of the scenarios can, in this case, only be taken based on policy priorities*.** RAC, from their point of view, has expressed a preference for RO2 (over RO4).

SEAC decided not to use cost-effectiveness figures from past restrictions since a one-to-one comparison is not completely possible between PBT-like substances (microplastics) and PBT substances (e.g. lead and mercury compounds).

SEAC decided to use three cost-effectiveness ratios from Table 20 on order to have a range of cost estimates: 133 €/kg (high costs scenario overall), 337 €/kg (high costs scenario for detergents containing fragrance encapsulates) and 870 €/kg (central costs scenario for leave-on cosmetic products).

Table 23 Indicative 'break even' analysis for infill restriction options.

Restriction option	**Low C-E:** **133 €/kg**	**Medium C-E:** **337 €/kg**	**High C-E:** **870 €/kg**	Costs according to section B.3.7.1.3)
RO1 (Full ban)[a]	€2.1 billion	€5.4 billion	€13.9 billion	€370 million - €430 million[b]
				€740 million - €860 million[c]
RO2 (Full ban, EiF+6 years)[d]	Significantly less than €2.1 billion	Significantly less than €5.4 billion	Significantly less than €13.9 billion	Significantly less than €370 million - €430 million[e]

Notes: societal cost are expressed in annual terms. [a] Avoided emissions: 16 000 tonnes/year. Does not take into account potential lost environmental benefits. [b] Market impacts to society. Does not include potential lost environmental benefits and social return on investment (SROI). [c] Does not include potential lost environmental benefits. Assumes SROI equal to market impacts to society. [d] Since the SROI is highly uncertain, but significantly lower than under RO1 (or even non-existent) due to the transition period, only the market impacts to society have been taken into account. These are mitigated by the transition period, but it is unknown to what extent. [e] Market impacts to society. Does not include potential lost environmental benefits.

For RO3 it is not possible to do this type of "break-even" analysis. Since it is impossible to estimate the emissions avoided and the costs, no cost-effectiveness ratio could be calculated and therefore no conclusion can be reached on proportionality. It is however clear that costs will be lower than RO1,2 and RO4, which indicates that this measure is affordable. It is also clear that the reduction in emissions will be very low or even non-existent.

For RO4 more robust cost estimates are available and therefore SEAC can provide cost-effectiveness figures with a higher degree of certainty.

To arrive at a cost-effectiveness range, the Dossier Submitter and SEAC made several assumptions. Of the 39 000 existing full-size pitch equivalents approximately 32 000 use polymeric infill material and have no measures in place to limit emissions to the environment. It was therefore assumed that about 32 000 pitches would require additional measures (costing €20 000 per pitch). SEAC finds these assumptions plausible, but found a higher average cost (€30 000 per pitch) to be more realistic based on the comments received in the consultation on the Annex XV report and the SEAC draft opinion.

The Dossier Submitter then assumed that an average full-sized pitch loses around 500 kg/year and this could at least reduced to 50 kg/year (approximately 10% of total emissions) which means that annually approximately 16 000 tonnes of infill emissions are avoided. Strictly following the RMMs in CEN TR 17519 these emissions could be reduced even further to 15 kg/year (approximately 3% of total emissions). **However, this would need to be confirmed by a full evaluation by RAC.**

Using these assumptions, SEAC arrives at a cost-effectiveness range of 40 – 60 €/kg. This indicates that RO4 might be proportionate. The European Synthetic Turf Council (ESTC) indicates that costs for mitigating emissions using risk management measures are not prohibitive and less than the cost of switching to alternatives. During opinion development UEFA stated that investments in pitches (i.e. incorporating RMMs) are already being made now which indicates that the cost-effectiveness range calculated should be seen as an upper bound.

As was the case for RO3, it is not possible to do a "break-even" analysis for RO5. Even though the costs will be identical to those of RO4 and the restriction option can therefore be considered affordable, the fact that it is impossible to estimate the emissions avoided and the costs, no cost-effectiveness ratio could be calculated and therefore no definite conclusion can be reached on proportionality.

SEAC notes that both of the Dossier Submitter's proposed restriction options for infill prohibit the "*placing on the market*" of microplastic infill material rather than its use. The Dossier Submitter confirmed that when developing Option A (RO4 – mandatory use of RMMs) the working assumption was that maintenance activities (i.e. regular "top-up" of infill) would continue as normal on all existing pitches after the end of the transitional period; necessitating the implementation of RMMs at all existing pitches in order to obtain infill from the market. However, SEAC notes that as the wording of the proposed restriction does not prohibit the use (or presence) of microplastic infill on sports surfaces, pitch owners/operators could stockpile microplastic infill material before the end of the transitional period for use in maintenance activities after the end of the transitional period without being legally obligated to implement RMMs. Similarly, existing pitches could avoid implementing RMMs after entry into force if they did not undertake any further maintenance activities with synthetic infill (although the performance of the pitch would eventually be compromised).

Medical devices

As pointed out in the section on costs, there is insufficient information on the impacts of the ban of the proposed restriction on medical devices to conclude on proportionality. As data is scarce, neither costs nor releases were estimated by the Dossier Submitter. Also, the volumes of microplastics used in substance-based medical devices that would be affected by the ban is unknown. Some industry representatives indicated during the consultation on the SEAC draft opinion that the proposed restriction would be disproportionate and requested a derogation (e.g. #715), but these requests were not substantiated with supporting information, neither emission estimates, nor costs estimation of the proposed restriction, required to justify a derogation.

Nevertheless, the similarity of the use to cosmetic products, in terms of technical function, suggest that the proposed restriction could be proportionate. However, further information would be needed to underpin this conclusion. SEAC notes that a review of the substitution of microplastics prior to the end of the proposed transitional period, e.g. 4 years after entry into force, could provide useful information .

***In vitro* diagnostics**

Information received in the consultation on the Annex XV report indicated that the implementation of technical means of containment (as required under the initially proposed conditions of derogation 5a) would entail substantial costs (see cost section). In response to these comments, the Dossier Submitter estimated the costs of the implementation of technical means to prevent microplastic emissions (incineration of solid and liquid waste – RO3) as well as a ban with a transition period ranging between 8 and 15 years (RO 4). Given that the releases of microplastics from IVD products are very low (estimated to be 270 kg per year), the Dossier Submitter concluded that that both RO 3 and RO 4 would be disproportionate. This conclusion is underpinned by the very low cost-effectiveness of these options (cost per kg emission reduced ranged between €0.3 million and 10 million) as the annual costs of release prevention (RO 3) as well as substitution (RO 4) were estimated to be more than €100 million (see section on costs). Therefore, the Dossier Submitter proposed to

manage microplastic emissions from IVD products by mandatory instructions for use and reporting requirements (RO 5) instead.

SEAC concurs with this conclusion. In addition to (i) the low releases from this use of microplastics and (ii) the low cost-effectiveness indicating much higher costs than the level that was accepted in former restrictions on PBT/vPvB substances[103], SEAC points out that another argument in favour of the Dossier Submitter's proposal (RO 5) is the fact that (iii) IVD products are important for the functioning of healthcare and there are currently no alternatives available.

The reporting requirement will provide a better evidence base to assess if there is further need to regulate microplastic emissions from IVD products. Also, over the longer term the substitution of microplastics (or their containment) may become less costly, because alternative materials will be developed. Therefore, SEAC considers that the derogation of IVD products should be re-evaluated during the review of the proposed restriction envisaged by the Dossier Submitter.

Sectors affected by 'instructions for use and disposal' (IFUD) and reporting requirement

The clarifications made by the Dossier Submitter during the opinion-making process on the requirements to provide 'instructions for use and disposal' as well as to provide annual reports on releases underline that even if the economic impact is significant it is likely not to be as substantial as indicated by the numerous comments received during the consultation. However, in the consultation of the SEAC draft opinion, stakeholders indicated that the costs to companies resulting from the reporting requirement could still be substantial (see discussion on costs).

SEAC agrees that these two requirements will facilitate to (i) minimise emissions from uses where a ban was considered to be disproportionate or not sufficiently substantiated and (ii) create a better evidence base on uses and releases of primary microplastics, for authorities as well as for actors along the supply chains involved. Based on the information available the costs of these two requirements seem largely affordable and the Dossier Submitter provided for sufficient flexibility for actors to choose cost-efficient approaches to comply with the requirements.

With regard to the **instructions for use and disposal**, SEAC considers that the effort to implement the requirement is likely to be moderate. This conclusion is supported by statements received from industry stakeholders indicating that IFUD was proportionate. Still, there were requests to derogate the following specific uses from the instructions for use and disposal requirement in the consultation on the SEAC draft opinion:

- bioresorbable polymers which will degrade under the conditions of use as it was argued that the requirement could be misunderstood in the market and therefore lead to negative effect on the business (#669)
- polymeric resins, such as tackifying resins, as it was argued that customers of resins already convert the resins into a form that is not microplastics or contains any microplastics and there would therefore be no additional gain in safe handling (#744).

[103] Oosterhuis et al., 2017. (see Background Document)

- toners, since it was argued that there is no environmental emission of microplastics under the normal use condition of machines and there is already a mechanism in which toner remaining in used cartridges is retrieved and properly processed (#799).
- ink-, toner- and 3D-printing since it was argued that they are not intended to release microplastics (#760).
- food additives, as it was argued that the requirement would be likely to create confusion with consumers, given that food additives are not toxic chemicals but authorised safe food ingredients (#758).
- medicinal products, since it was argued that the requirements laid down in Directive (EU) 2001/83 and the Product-information templates (e.g. QRD-template) is sufficient to avoid the release of synthetic polymers in the environment (#714).

SEAC considers that none of them was sufficiently substantiated in order to conclude that an inclusion in IFUD was disproportionate.

As the **reporting** requirement is likely to result in significant costs to the companies concerned, SEAC points out that it is important to balance information needs for better risk management against the costs to collect this information in order to make reporting as efficient as possible. The Dossier Submitter as well as industry stakeholders proposed different options to reduce the costs of reporting, e.g. by setting a threshold for the volumes of microplastics used or released to be reported or by limiting the reporting requirement to certain actors in the supply chain (see discussion in B 3.3.1). SEAC notes that information on the proportion of companies or supply chains that would be affected by a particular threshold would have to be known in order to assess the impact of different reporting thresholds. However, this information was not available. With regard to the option to limit reporting to certain actors in the supply-chain, SEAC considers that the reporting could be difficult to manage for small and micro-sized companies, which constitute a large share of actors for some of the supply chains covered by the requirement[104]. It could be an option to exclude these from the obligation to make the restriction proposal more cost-effective. However, SEAC cannot assess if and to what extent this option would reduce the value of information obtained and hence its usefulness for future risk management. Overall, SEAC therefore cannot draw a firm conclusion on how the different options to reduce costs would compromise the benefits of reporting in terms of facilitating better risk management.

The overall cost of the reporting requirement can also be reduced by cost-effective implementation, for instance by taking into account existing reporting schemes (e.g. OSPAR) or by setting a favourable reporting deadline.

SEAC considers that annual reports may not be needed to achieve the objectives of the reporting obligation. A longer interval such as every two years may also generate sufficient data to reveal if further regulatory action is needed and would be less resource-intensive. A longer reporting interval was also raised by some industry stakeholders in the consultation of the SEAC draft opinion. However, others actually preferred annual reporting stating that the main effort would be the collection of the data, not the preparation of the actual report to ECHA.

[104] SEAC assessed randomly the industry structure of the different sectors to be covered by the reporting requirement based on Eurostat enterprise statistics.

In terms of the transition period of 36 months, SEAC notes that information received in the consultation of the SEAC draft opinion indicates that certain actors in the supply chains, e.g. manufacturers of microplastics, are likely to be already able to report earlier, e.g. due to efforts spent to implement voluntary industry initiatives. SEAC considers that for these actors a shorter transition period, i.e. 12 months seems to be justified.

B.3.3.5. Uncertainties in the proportionality section

The uncertainties identified for restriction costs and benefits described in the corresponding sections of the opinion also apply here. Overall the uncertainties related to costs and benefits of the proposed measures for infill material are not substantial enough to have a significant impact on the conclusions reached in this opinion.

B.3.4. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of 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 polymers which do not fall under the microplastic definition or are exempted based on their biodegradability 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 the method applied for determining the amount of polymer will need to be decided on a case-by-case basis, but that suitable methods are available.

RAC and SEAC conclusion(s):

Taking into account, among other elements, information in the Background Document, the consultations on the Annex XV report and the SEAC draft opinion 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 supporting measures to facilitate implementation will be necessary.

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.

1. Wording of the restriction

While the Committees have concluded that the wording and scope of the restriction is sufficiently 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 consultations (ANNEX XV and SEAC DO consultations), the following terms required further clarification. In some cases the Dossier Submitter was already able to provide clarifications during opinion-making by means of the Background Document (noted below):

- "industrial sites" in paragraph 4a: insufficient information on how this should be interpreted. During the consultation on the Annex XV report 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 based on the definition from the CLP Regulation (see section B.3.5).
- "*in vitro* diagnostic devices" in paragraph 4e: based on comment received during the SEAC DO consultation (#802), this term could 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 *in vitro* for the examination of specimens, e.g. body fluids and tissue donations from organisms".
- "other mixtures" in paragraph 6a: it should be explained if this only refers to other cosmetic mixtures or to all mixtures containing microbeads. The Dossier Submitter clarified that the intention is that this paragraph refers to all mixtures containing microbeads.
- In paragraph 6b: the reference to the classification rule 21 in the MDR is removed based on feedback from DG Sante.
- For readability purpose, and to clarify the IFUD requirement for the different actors in the supply chain (i.e. suppliers to industrial use, vs suppliers to non industrial use), the paragraph 7 is split up in two distinct paragraphs.

- "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: the term should be clarified according to Forum.
- "downstream user" in paragraph 8: to reflect the intention of the Dossier Submitter, and following a comment (#735) highlighting the inconsistency between the Background Document explanation in section 2.2.1.5 and the wording in the restriction proposal, it is proposed to replace "downstream user" by "actor in the supply chain, as defined in REACH article 3(17)" so to clarify that manufacturers of microplastics also have to fulfil this requirement.

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.

2. Implementing the restriction

The Dossier Submitter indicates that the implementation of the restriction should prove to be rather straightforward. However, the Background Document is very brief when it comes to providing justifications for this. In the Committees' view the Background Document does not identify all of the 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 account[105].

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 approach[106] 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 a list of 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.

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. RAC and SEAC note that these decision trees are now included as part of the Background Document (developed by the Dossier Submitter during opinion development), but should be available 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

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

[106] 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?

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.

Forum also indicates that the measurement of nanoplastics (<100nm) will be problematic (impossible or at extremely high testing cost). This is echoed by several comments made during the consultations on the Annex XV report and the SEAC draft opinion. 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 until the aforementioned technological barriers have been resolved. 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 required for enforcement may not be straight-forward until reaching sizes of 1 µm or even larger (especially if present in complex mixtures). Thus, from an enforcement perspective, lower size limits of 1 nm, 50 nm 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 currently be analytically 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 size 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. Lower size limits of 50 or 100nm would probably be equally efficient as it is sufficient that 1% of the particles (w/w) exceed the size limit (if at all possible to measure in products) for the restriction to apply. For reasons stated earlier in the opinion, SEAC would advise to have a 1 nm lower size limit in the definition to make it fully fit for purpose. This also provides clarity for enforcement.

In theory, there are analytical methods that are appropriate for microplastics >100 nm. However, currently available analytical methods are probably equally unreliable 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 ("document-based" enforcement vs analytical-based enforcement). This statement does however not imply that internal procedural and organisational changes will not be necessary. Forum has indicated that document-based enforcement can only build upon obligatory documentation, however the restriction proposal does not detail which documentation is obligatory.

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 to be 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, supporting measures (e.g. guidance documents) to support the implementation are necessary.

B.3.5. Monitorability

Justification for the opinion of RAC and SEAC

Summary of 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 relatively 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 'Safety Gate' (RAPEX) system.

RAC and SEAC conclusion(s):

Based on the information in the Background Document and the Forum advice, RAC and SEAC

conclude that the proposed restriction is monitorable with the 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.

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 all aspects 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

Summary of 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 of the Background Document.) 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 transitional arrangements (i.e. before the biodegradability 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.

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.4.1. 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 though 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.

SEAC conclusion(s):

Please see relevant sections on costs, benefits and proportionality for justification.

Overall, the uncertainties related to costs, benefits and proportionality of the proposed measures for infill material are not substantial enough to have a significant impact on the conclusions reached in this opinion.

Key elements underpinning the SEAC conclusion(s):

Please see relevant sections on costs, benefits and proportionality for justification.

B.5. REFERENCES

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Appendix I: Overview on the opinion-making process in SEAC for different uses of microplastics

Sector	Original proposal	Key consultation input	Changes of DS proposal	SEAC conclusion
Agriculture	Ban on fertiliser and plant protection products (PPP) with a TP of 5 years	Information on the length of the authorisation process for PPP	With 5 years TP substitution of microplastics in PPP and re-authorisation would not be feasible → longer TP (8 years) justified	SEAC agrees with changed proposal.
Cosmetics: rinse-off	Ban with 4 years TP	Longer TP requested based on the high number of reformulations	No change, because request was not sufficiently justified.	SEAC agrees with DS proposal.
Cosmetics: leave-on	Ban with 6 years TP	Derogation or longer TP requested based on high number of reformulations and time needed to develop alternatives	No change, because not sufficiently justified.	SEAC agrees. For product groups with relatively low releases other measures may also be proportionate (see opinion text).
Detergents and maintenance products	Ban with 5 years TP	Information on the impact to substitute microplastic fragrance encapsulates	No change, because not sufficiently justified.	SEAC agrees with DS proposal.
Fragrance encapsulates	Ban with 5 years TP	Information on the impact to substitute microplastic fragrance encapsulates	5 or 8 years for the encapsulation of fragrances	Uncertain if 8 year TP is justified. Review of TP recommended, e.g. 4 years after EiF.
Medical devices	Medical devices were considered to be permanently contained (paragraph 5a)	substance-based medical devices are not contained due to their similarity to cosmetics	Ban with 6 years TP	SEAC generally agrees, but considers that there is very limited evidence on the impact of a ban. Review recommended before end of TP recommended, e.g. 4 years after EiF.
Infill material	Not explicitly addressed in the assessment, but covered by ban	Derogation or ban with sufficiently long TP requested based on the socio-economic impacts of an immediate ban	DS proposes technical means to lower releases to 7 g/m^2 (option A) or a ban on placing on the market after 6 years (option B).	All options assessed by the DS could be considered proportionate (see opinion text).
***in vitro* diagnostic devices (IVD)**	Derogation conditional to permanent containment (paragraph 5a)	Information on the impacts of substitution and containment of microplastics	Derogation from ban Instruction for use and reporting required instead	SEAC agrees with changed proposal.

Instructions for use and disposal and reporting e.g. uses on industrial sites (4a), medicinal products (4b), food additives (4d) paints & coatings, construction products (5)	Instructions for use and disposal: 18 months TP Reporting: 12 months TP, annual reports	Information on the impacts of substitution and containment of microplastics	Clarified which actors of the supply-chain will be affected Instructions for use and disposal: 24 months TP Reporting: 36 months TP, annual reports	SEAC agrees with changed proposal. For reporting, TP for manufacturers of microplastics could be reduced to 12 months. Small or micro-sized companies could be excluded (see opinion text).
Sewage sludge and compost	not addressed	microplastics occur unintentionally	derogation from the restriction	SEAC agrees with proposal
Food and feed.	not addressed	microplastics occur unintentionally	derogation from the restriction	SEAC agrees with proposal
Notes: Proposed Action (current proposal): dark grey = ban; medium grey = technical means to reduce releases; light grey = instruction for use and reporting requirements white = complete derogation				

Appendix II: Summary of impacts of the proposed restriction

Summary of costs

As documented in the BD (Section 2.5),

Table 24 Summary of quantified economic impacts of the proposed restriction.

Impacts\Scenarios	Low [€m]	Central [€m]	High [€m]
Economic impacts			
Material	20	197	433
Reformulation	2 088	9 307	18 000
Enforcement	3	3	3
Other economic impacts	n/a	n/a	2 073
Wider economic impacts			
Employment	n/a	n/a	70
Trade			230
Total Restriction Costs *	**2 100**	**9 500**	**20 800**

Notes: * NPV in €2017 million, figures rounded; total restriction costs exclude polymeric infill material since restriction options vary in terms of their costs. Moreover, the impacts in the table are based on a 5-year transitional period for fragrance encapsulates. With an 8-year transitional period for fragrance encapsulates, the total restriction costs would be €9.3bn (€2.1bn to €20.6bn).

Costs per sector

In addition to the economic impacts analysed in detail in Annex D to the BD, Tables 25 to 37 in the Background Document summarise the cost per sector. Table 25 presents a breakdown of the expected restriction costs into categories for those sectors for which the available information permitted a cost analysis.

Table 25 Breakdown of the expected restriction costs into categories per sector.

Cost categories per sector\Scenarios	Low [€m]	Central [€m]	High [€m]
Material	*20.4*	*197.2*	*433.5*
CR fertilisers and fertiliser additives	n/a	n/a	n/a
Capsule suspension PPPs and coated seeds	n/a	n/a	n/a
Other rinse-off cosmetics	15.4	34.4	53.4
Leave-on cosmetics	5.0	9.0	13.0
Fragrance encapsulates	0.0	85.6	183.1
Other detergents	0.0	62.8	173.2
Waxes, polishes and air care	0.0	5.4	10.7
Reformulation/R&D	*2 088.1*	*9 307.4*	*1 8001.0*
CR fertilisers and fertiliser additives	11	31	63
Capsule suspension PPPs and coated seeds	60	233	545
Other rinse-off cosmetics	36.3	1 046.5	2 056.7
Leave-on cosmetics	1 600.0	7 300.0	13 300.0
Fragrance encapsulates	292.7	440.4	554.1
Other detergents	43.1	66.6	1 059.1
Waxes, polishes and air care	0.4	0.7	7.9
Enforcement	*2.9*	*2.9*	*2.9*
CR fertilisers and fertiliser additives	0.4	0.4	0.4
Capsule suspension PPPs and coated seeds	0.4	0.4	0.4
Other rinse-off cosmetics	0.5	0.5	0.5
Leave-on cosmetics	0.4	0.4	0.4
Fragrance encapsulates	0.4	0.4	0.4
Other detergents	0.4	0.4	0.4
Waxes, polishes and air care	0.4	0.4	0.4
Employment losses	*0.0*	*0.0*	*70.0*

CR fertilisers and fertiliser additives	n/a	n/a	n/a
Capsule suspension PPPs and coated seeds	n/a	n/a	n/a
Other rinse-off cosmetics	n/a	n/a	n/a
Leave-on cosmetics	0.0	0.0	70.0
Fragrance encapsulates	n/a	n/a	n/a
Other detergents	n/a	n/a	n/a
Waxes, polishes and air care	n/a	n/a	n/a
Impacts on trade	*0.0*	*0.0*	*230.0*
CR fertilisers and fertiliser additives	n/a	n/a	n/a
Capsule suspension PPPs and coated seeds	n/a	n/a	n/a
Other rinse-off cosmetics	n/a	n/a	n/a
Leave-on cosmetics	0.0	0.0	230.0
Fragrance encapsulates	n/a	n/a	n/a
Other detergents	n/a	n/a	n/a
Waxes, polishes and air care	n/a	n/a	n/a
Other economic impacts	*0.0*	*0.0*	*2 072.9*
CR fertilisers and fertiliser additives	n/a	n/a	n/a
Capsule suspension PPPs and coated seeds	n/a	n/a	n/a
Other rinse-off cosmetics	n/a	n/a	n/a
Leave-on cosmetics	0.0	0.0	1 900.0
Fragrance encapsulates	0.0	0.0	74.3
Other detergents	0.0	0.0	97.9
Waxes, polishes and air care	0.0	0.0	0.7
Restriction costs for polymeric infill (RO2)	*n/a*	*9 591.1*	*n/a*
Incremental replacement cost (RO2)	n/a	5 510.4	n/a
Incremental maintenance cost (RO2)	n/a	4 080.7	n/a
Incremental control cost (RO2)	n/a	0.0	n/a
Restriction costs for polymeric infill (RO4)	*n/a*	*1 282.0*	*n/a*
Incremental replacement cost (RO4)	n/a	0.0	n/a
Incremental maintenance cost (RO4)	n/a	0.0	n/a
Incremental control (RO4)	n/a	1 282.0	n/a
Total Restriction Costs *	***2 106.0***	***9 498.1***	***20 796.9***
CR fertilisers and fertiliser additives	16.0	47.0	93.5
Capsule suspension PPPs and coated seeds	100.4	407.1	930.4
Other rinse-off cosmetics	52.1	1 081.4	2 110.6
Leave-on cosmetics	1 600.0	7 300.0	15 500.0
Fragrance encapsulates	293.1	526.4	811.9
Other detergents	43.5	129.8	1 330.6
Waxes, polishes and air care	0.9	6.5	19.8

Notes: * NPV in €2017 million; total restriction costs exclude polymeric infill material since restriction options vary widely in terms of their costs. Moreover, the impacts in the table are based on a 5-year transitional period for fragrance encapsulates. With an 8-year transitional period for fragrance encapsulates, the total restriction costs would be €9.3bn (€2.1bn to €20.6bn).