

Committee for Risk Assessment (RAC)
Committee for Socio-economic Analysis (SEAC)

Opinion

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

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

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

11 June 2020

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11 June 2020

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

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

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

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

Chemical name(s): intentionally-added microplastics

EC No.: -

CAS No.: -

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

PROCESS FOR ADOPTION OF THE OPINIONS

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

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: Laure GEOFFROY

Co-rapporteur, appointed by RAC: Pietro PARIS

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

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

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

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: Karen THIELE

Co-rapporteur, appointed by SEAC: Simon COGEN

The draft opinion of SEAC

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

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

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

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

The opinion of SEAC

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

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

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

¹ Delete the unnecessary part(s)

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A. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter, after taking into account the comments received in the consultation, is:

Table 1 Proposed restriction by the Dossier Submitter

<p>Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)</p>	<ol style="list-style-type: none">1. Shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than 0.01% w/w.2. For the purposes of this entry:<ol style="list-style-type: none">a. 'microplastic' means particles containing solid polymer, to which additives or other substances may have been added, and where $\geq 1\%$ w/w of particles have (i) all dimensions $0.1\mu\text{m} \leq x \leq 5\text{mm}$, or (ii), for fibres, a length of $0.3\mu\text{m} \leq x \leq 15\text{mm}$ and length to diameter ratio of >3.b. 'microbead' means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.c. 'particle' is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface. Single molecules are not particles.d. 'particles containing solid polymer' means either (i) a particle of any composition with a continuous solid polymer surface coating of any thickness or (ii) particles of any composition with a solid polymer content of $\geq 1\%$ w/w.e. 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas.f. 'gas' means a substance which (i) at $50\text{ }^\circ\text{C}$ has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at $20\text{ }^\circ\text{C}$ at a standard pressure of 101.3 kPa.g. 'liquid' means a substance or mixture which (i) at $50\text{ }^\circ\text{C}$ has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at $20\text{ }^\circ\text{C}$ and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of $20\text{ }^\circ\text{C}$ 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:<ol style="list-style-type: none">a. Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)).
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	<ul style="list-style-type: none"> b. Polymers that are (bio)degradable, according to the criteria in Appendix X. c. Polymers with a solubility > 2 g/L, according to the criteria in Appendix Y. <p>4. Paragraph 1 shall not apply to the placing on the market of:</p> <ul style="list-style-type: none"> a. Substances or mixtures containing microplastics for use at industrial sites. b. Medicinal products for human or veterinary use as defined in EU Directives 2001/83/EC and 2001/82/EC. c. Substances or mixtures that are regulated in the EU under Regulation (EC) No 2019/1009 on Fertilising Products. d. Substances or mixtures containing food additives as defined in EU Regulation (EC) No. 1333/2008. e. <i>In vitro</i> diagnostic devices f. Sewage sludge (as defined in Directive XXX/XXX) and compost g. Food and feed h. <i>[OPTION A: granular infill used on synthetic sports surfaces where risk management measures are used to ensure that annual releases of microplastic do not exceed 7g/m²]</i> <p>5. Paragraph 1 shall not apply to the placing on the market of:</p> <ul style="list-style-type: none"> a. Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use. b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a). c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use. <p>6. Paragraph 1 shall apply from:</p> <ul style="list-style-type: none"> a. EIF for cosmetic products (as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009) and other substances or mixtures containing microbeads. 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).
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	<p>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.</p> <p>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).</p> <p>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.</p> <p>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.</p> <p>h. $EiF + 5$ years for other agricultural and horticultural uses including seed treatments.</p> <p>i. $EiF + 6$ years for 'leave-on' cosmetic products (as defined in regulation (EC) No 1223/2009).</p> <p>j. <i>[Either</i></p> <ul style="list-style-type: none"> o <i>$EiF + 3$ years for granular infill used on synthetic sports surfaces (if 4(h) retained – <u>OPTION A</u>) or,</i> o <i>$EiF + 6$ years for granular infill used on synthetic sports surfaces (if 4(h) not retained– <u>OPTION B</u>)</i> <p>7. From [$EiF + 24$ months] any supplier² of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b), 4(d), 4(e) or 5 shall ensure that, where applicable, either the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' provides, in addition to that required by other relevant legislation, any relevant instructions for use to avoid releases of microplastics to the environment, including at the waste life-cycle stage.</p> <p>The instructions shall be clearly visible, legible and indelible. Instructions may be in the form of pictograms</p> <p>Where written instructions are given, these shall be in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.</p> <p>In addition, any supplier of a substance or mixture containing a</p>
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² According to REACH definition in article 3(32), a supplier means "manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".

	<p>microplastic derogated from paragraph 1 on the basis of paragraph 4(a) shall identify, where applicable, either on the label and/or SDS and/or 'instructions for use' (IFU) and/or 'package leaflet' that (i) the substance or mixture is subject to the conditions of this restriction 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.</p> <p>8. From [EiF +36 months], any [industrial] downstream user using microplastic(s) derogated from paragraph 1 on the basis of paragraph 4(a) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year:</p> <ul style="list-style-type: none"> a) a description of the use(s) of microplastic in the previous calendar year, b) For each use, generic information on the identity of the polymer(s) used, c) For each use, an estimate of the quantity of microplastics released to the environment in the previous calendar year. <p>Any supplier placing a microplastic derogated from paragraph 1 on the market for the first time for 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:</p> <ul style="list-style-type: none"> d) a description of the intended end use(s) of microplastic placed on the market in the previous calendar year, e) For each intended end use, generic information on the identity of the polymer(s) placed on the market, f) For each intended end use, an estimate of the quantity of microplastics released to the environment in the previous calendar year. <p>ECHA shall publish a report summarising the information received by 30 June every year.</p>
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Note: In the event that the proposed restriction is added to Annex XVII of REACH Appendix X and Appendix Y will be an appendix to Annex XVII. The details of Appendix X and Appendix Y can currently be found in Table 22 and Table 23, respectively, in Section 2.2.1.6 of the Background Document.

A.1. THE OPINION OF RAC

See RAC opinion.

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 RAC and SEAC, as demonstrated in the justification supporting this opinion.

The conditions of the restriction proposed by SEAC are:

Taking into account RAC's conclusion on risk, SEAC considers that the definition of microplastics should not set a lower size limit. However, in order to ensure that the proposed restriction is implementable, enforceable and monitorable SEAC acknowledges the necessity to set a lower size limit for the conditions of the restriction as 0.1 µm.

B. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

B.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

B.1.1. Description of and justification for targeting of the information on hazard(s) and exposure/emissions (scope)

Summary of proposal:

See Background Document.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion:

See RAC opinion.

B.1.2. Description of the risk(s) addressed by the proposed restriction

B.1.2.1. Information on hazard(s)

Summary of proposal:

See Background Document.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

B.1.2.2. Information on emissions and exposures

Summary of proposal:

See Background Document.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

B.1.2.3. Characterisation of risk(s)

Summary of proposal:

See Background Document.

Table 2 Summary of microplastic use volumes and quantities released to the environment

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

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

B.1.2.4. Uncertainties in the risk characterisation

See RAC opinion.

B.1.3. Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

See Background Document

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion

B.1.4. Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See Background Document.

RAC conclusion(s):

See RAC opinion

Key elements underpinning the RAC conclusion(s):

See RAC opinion

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

Justification for the opinion of SEAC and RAC

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 primary 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.

SEAC and RAC conclusion(s):

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.

Key elements underpinning the SEAC and RAC conclusion(s):

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 in the environment), only a small

part to the overall environmental burden of microplastics³, 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 3 Microplastic use by sector (sectors marked in italics were analysed in depth in the Background Document)

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

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 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.

³ 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 EU-wide basis are currently considered by the EU Commission to address emissions from some sources of secondary microplastics (see EU Plastics Strategy). According to comments made by SCHEER (#2244) during the consultation, the percentage of primary microplastics in the environment are never higher than 10%, but that stock effects need to be taken into consideration (continuous emissions and persistence of the material).

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

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of 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 or to avoid double regulation. These are summarised in Table 4.

SEAC notes that the Dossier Submitter’s proposed was revised during opinion making based on responses to the consultation. The opinion reflects the revised proposal. All revisions to the proposal are described in the Background Document.

Table 4 Proposed derogations by the Dossier Submitter

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

Para.	Derogation	Explanation
		<p>substitution of microplastics or implementation of containment measures can be sought and encouraged without disrupting the access to IVDs. This could be made via 'voluntary' actions from the sector. In the event, the information gathered via the reporting would reveal that the voluntary measures put in place by the sector do not lead to progressive reduction of release of microplastics into the environment, further regulatory action could be initiated by the EU Commission.</p> <p>In addition, products shall be required to communicate appropriate use and disposal instructions to minimise releases to the environment (paragraph 7).</p> <p>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 <i>in vitro</i> diagnostics undertaken under any specific regulation.</p> <p><i>In vitro</i> diagnostic devices could also be defined as "reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, whether used alone or in combination, intended by the manufacturer to be used <i>in vitro</i> for the examination of specimens, including blood and tissue donations, derived from living organisms".</p>
4.f	Sludge and compost.	<p>Complete derogation from the scope of the restriction as this was not intended to be part of the scope.</p> <p>Microplastics are indeed not intentionally added into sludge and composts. However, they might be present in industrial sludge and compost supplied or sold to professionals (e.g. farmers) or consumers as a result of water treatment (where microplastics will be removed from the water effluents and partition in sludge) or composting process (where secondary microplastics might be present due to the non-degradability of some composting inputs e.g. partially degradable plastics). These microplastics will be present unintentionally and it is not the intention of this restriction to prevent the placing on the market of these products.</p>
4.g	Food and feed.	<p>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.</p>
[4.h]	Infill used at pitches with RMMs to achieve minimal releases.	<p>Option A to address infill material.</p>
5.a	Substances, mixtures or articles containing microplastic where the microplastic is contained by technical means to prevent releases to the environment.	<p>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.</p> <p>Includes a requirement that appropriate OCs and RMMs are identified on product labelling, leaflet or instructions for use (IFU).</p> <p>This derogation is generic but is primarily intended to cover uses of microplastics in non-industrial professional or consumer settings, including <i>in vitro</i> medical diagnostic uses at clinical laboratories (e.g. at healthcare centres or hospitals), or water purification applications.</p> <p>Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the Agency (paragraph 8).</p>
5.b	Substances or mixtures containing microplastics where the physical properties of the microplastic are permanently modified when the mixture is used such that the polymers no longer fulfil the meaning of a microplastic	<p>Generic derogation from the restriction for uses of microplastics as a substance or in a mixture where the microplastics are 'consumed' or otherwise permanently cease to exist at the point of end use; this principally corresponds to the loss of the particulate nature of the microplastic through various physico-chemical processes or chemical reactions. The change must be permanent and irreversible.</p> <p>This would derogate film-forming functions of microplastics in all sectors, including those in cosmetic products, detergents and maintenance products and in paints/coatings; as well as any products where the microplastic particles cease to exist at the point of end use, such as in instances where they 'dissolve' (e.g. polyelectrolytes or certain detergents).</p> <p>However, as there could be some releases of 'unconsumed' microplastics under reasonably foreseeable conditions of use, these releases should be minimised.</p> <p>Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7)</p>

Para.	Derogation	Explanation
	given in paragraph 2(a).	and report the quantities used and released to the market to the Agency (paragraph 8).
5.c	Substances or mixtures containing microplastics where the microplastic are permanently incorporated into a solid matrix when used.	<p>Generic derogation from the restriction for uses of microplastics as substances or mixtures where the microplastics are permanently 'contained' at the point of use. Permanence is intended to relate to the useful (service) life of the solid matrix, not the waste life-cycle stage.</p> <p>This would derogate certain applications of microplastics in paints/coatings and in materials used in construction (concrete and adhesive). It is not considered to apply to any use that could be considered as temporary, such as use in cosmetic products. Any necessary preceding steps (e.g. mixing before the matrix becomes solid) should also be derogated from paragraph 1.</p> <p>However, as there could be some releases of 'uncontained' microplastics under reasonably foreseeable conditions of use (e.g. during the preparation, application and curing/setting of a solid matrix), these releases should be minimised. Therefore, uses benefiting from this derogation shall be required to communicate appropriate use instructions to minimise releases to the environment (paragraph 7) and report the quantities used and released to the market to the Agency (paragraph 8). Appropriate use instructions could include advice to avoid disposal of unused material to drains and watercourses and to clean up areas thoroughly after use. Releases that would occur at the end of the service life of the solid matrix (e.g. when it becomes waste at some undefined point in the future) shall be considered as part of the paragraph 8 reporting obligation.</p>

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

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

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

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

The Dossier Submitter also proposes that all suppliers placing on the market mixtures

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

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

- Editorial changes to use names to improve clarity;
- Lower size limit of the microplastics in the scope of the restriction increased from 1nm to 100nm;
- Term 'particle-containing polymer' replaced with the term 'polymer-containing solid polymer';
- Clarification added that single molecules are not particles;
- Term 'naturally-occurring polymer' replaced with the term 'natural polymer';
- Additional derogation for polymers with solubility >2 g/L added as paragraph 3(c);
- Additional derogations added to paragraph 4 for food additives (4.d), *in vitro* diagnostics (4.e), sludge and compost (4.f), food and feed (4.g) and infill material (4.f);
- 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.

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion

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 definition⁴ proposed by the Dossier Submitter is clear, based on a critical assessment of all information available, and taking 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 definition⁵ 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 disposal⁶ '**instructions for use and disposal requirements**⁷ 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.

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 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 Annex XV 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, 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 (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 minimising releases, are also derogated. Other derogations are

⁴ Including sub-definitions for microbead, particle, particle containing solid polymer, solid, gas, liquid, (bio)degradable polymers, natural polymers etc.

⁵ See 'Key Elements' section.

⁶ In other words, when releases of microplastics are not considered to be inevitable.

⁷ Includes instructions for proper use in the SDS (as an example) and labelling requirements.

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 and sludge).

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) might be warranted. SEAC finds this to be justified⁸.

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 most of 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 the costs to society. SEAC also took into consideration comments received during the consultation 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 proportional⁹ and/or 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

⁸ See the key elements and costs section for SEAC's analysis

⁹ Both in terms of cost vs benefits as well as in regard to technical feasibility.

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 measures¹⁰ 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 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 $1\text{nm} \leq x \leq 5\text{mm}$, or (ii), for fibres, a length of $3\text{nm} \leq$

¹⁰ Such as authorisation and article 68 §2 restrictions.

$x \leq 15\text{mm}$ and length to diameter ratio of >3 .

The Dossier Submitter notes that various other definitions have already 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 performed a screening of existing national and international legislation, as well as activities by academic and research organisations.

A first important thing 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 does however wish to emphasise that using the polymer definition under REACH creates a harmonised understanding, which is not the case in current legislation or research, even within the EU¹¹. During the consultation, 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 microplastics 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 (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'.

- 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 the 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 definition for their definition of microplastics. SEAC notes that this creates a harmonised understanding of the term. RAC, and the Dossier Submitter, has acknowledged that the CLP definition is however not fully fit-for-purpose when it comes to polymers without a melting point and has

¹¹ Although it should be noted that the recent Single Use Plastics Directive does use the REACH Polymer definition.

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 this¹². The Dossier Submitter has not done so in the current proposal since from a practical and empirical perspective *"it is open to interpretation and is not as straightforward as would be initially thought"*¹³. 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 has 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' has replaced the need to consider solubility in the definition itself.

- The Dossier Submitter discusses at length the particle size and morphology. Several elements are important to discuss according to SEAC.
 - o The Dossier Submitter states that there is a large consensus on the **upper size limit** (5 mm) for particles to be considered a 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).
 - o 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 many stakeholders indicated that a limit lower than 100 nm would cause considerable technical problems from an analytical standpoint, indicating, for example, that the presence of '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. FORUM echoed these comments. The Dossier Submitter acknowledged the practical difficulties associated with the 1nm limit, and therefore proposed to increase the lower limit in the conditions of the restriction to 100 nm to address the practical difficulties associated with the 1nm limit. However, RAC did not consider it necessary to set a lower size limit at all. 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 proposal to not set a lower size limit justified.
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

¹² This was reiterated by multiple stakeholders during the consultation on the restriction dossier.

¹³ 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.

for any Annex XVII entry resulting from this proposal, but rather the physical and chemical criteria themselves.

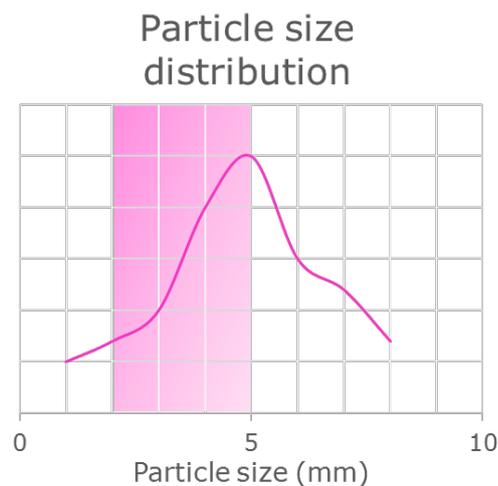
- The size limit should be assessed for **all dimensions of the material** since, as an example, plastic bags and films with a large surface area could otherwise also be covered by the restriction. SEAC agrees with the Dossier Submitter that these types of material should not be considered as intentionally added microplastics.
- Some stakeholders have expressed concerns regarding the size cut-offs for **fibres**. 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. Based on the information received during the consultation, the Dossier Submitter proposed then to set the lower limit to 300 nm for fibres. To be consistent with RAC's updated lower size limit (cf. above), no lower size length cut-off for fibres is proposed. SEAC finds this update by RAC justified. 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 needed to consider 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 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.
- 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 regards 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 fit the term:
 - A particle of any composition with a solid polymer content of $\geq 1\%$ 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 bigger 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 the opinion development it became clear that there are still technological barriers in identifying microplastics <100 nm. In certain cases, it might be possible that raw material suppliers can characterise materials <100nm and that formulators can avoid the use of microplastics <100nm even if they cannot be resolved analytically in final products. However, this does not necessarily ease enforceability 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 recommends to include a **temporary** lower size limit of 100 nm. This will help both compliance by industry and enforcement by the competent authorities. SEAC notes that flanking measures are needed to remove the aforementioned technological barriers in analysing the size of microplastics (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).

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. Ban – instruct¹⁴ – report

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 solid 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 consequent risks to the 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 impact¹⁵ 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

¹⁴ Includes instructions for proper use in the SDS (as an example).

¹⁵ See section on costs, benefits.

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 base¹⁶. 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 for the first time 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;
 - 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 for the first time (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

¹⁶ Which not only includes releases to the environment, but also unidentified specific uses and tonnages.

during the Consultation, the Dossier Submitter clarified and updated the wording of the background document to address the issues raised by stakeholders (e.g. double counting of emissions, disclosure of CBI).

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. Derogations from the restriction

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:

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

The Dossier Submitter indicates that the identified concerns regarding microplastics are, in general, related to synthetic polymers. The justification for excluding natural polymers that have not been chemically modified is stated to be that these are inherently biodegradable. SEAC notes that this is not always the case. 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 point 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 polymers¹⁷) that have not been chemically modified (as defined in article 3 point 40). SEAC finds it justified to include a derogation for “natural polymers”, 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

¹⁷ “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.”

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 persistent and accumulative 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. It is outside the remit of SEAC to assess the appropriateness of the proposed criteria.

- 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 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, even if in particle form during certain stages of the supply chain. Test methodology was proposed by the Dossier Submitter and evaluated by RAC. It is outside of the remit of SEAC to comment on the appropriateness of the test methodology. RAC finds the addition of this derogation justified under the proposed condition.

Products that do contain unintentionally-added microplastics 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 these 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 consultation industry has 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 (see Table 2).

For other uses a derogation from the ban might be justified based on proportionality considerations:

- Infill material

The Dossier Submitter performed an analysis of the information submitted during the 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. Full ban without transition period
2. Full ban with transition period (6 years)
3. Derogation from ban, but instructions for use and reporting requirements
4. Derogation conditional on technical risk management measures being implemented (with transition period)

Costs and benefits are assessed further on in the relevant sections. SEAC's main conclusion is that all scenarios might be proportional 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 of 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 seems significantly less effective compared to the other 3 scenarios.

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 (RO 4), 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 an emission reduction, implementability and enforceability viewpoint. 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/m²) 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. During the Consultation valuable information was provided by a diverse range of stakeholders (pitch owners, users and manufacturers) which is considered to provide a good basis for this guidance. 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 only 3 years after entry into force would be needed to strike a balance between the minimisation of socio-economic impacts and a timely and the most efficient reduction in emissions. Both the guidance and the transition

period will mitigate associated costs and improve the implementability and enforceability of the derogation.

- *In vitro* diagnostics (IVD)

Initially, the Dossier Submitter intended to derogate IVD products on the condition that 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 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 to incineration of microplastic containing solid waste
3. Derogation conditional to 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 environment¹⁸
5. 'instructions for use and disposal' and an annual reporting requirement

Given that releases of microplastics from IVD products are very low (estimated to 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.

iv. 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 5 Proposed transitional periods

Sector or product group	DS proposed Transitional period	DS summary justification	SEAC conclusions
<i>Mixtures containing microbeads (e.g. cosmetics and detergents)</i>	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.
<i>medical devices (where microplastics cannot be contained during end use)</i>	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	In principal, SEAC finds this justified considering the complexity of the product development of these products (including certification). However, as the information on the potential impact on substance-based medical devices is very limited. SEAC considers that the

¹⁸ either by substitution or containment of microplastics in the product

Sector or product group	DS proposed Transitional period	DS summary justification	SEAC conclusions
		for sufficient time to reformulate and transition to alternatives.	similarities to cosmetics per se does not provide sufficient justification for the TP. More specific information on the substitution process in substance-based medical devices would be needed to substantiate that 6 years TP is appropriate. Based on available information, SEAC cannot draw a final conclusion on the appropriateness of the transition period.
<i>Other rinse-off cosmetic products</i>	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.
<i>Detergents and other maintenance products without microbeads</i>	5 years for microplastics used in detergents other than polymeric fragrance encapsulates ¹⁹ , as well as for maintenance products 5 or 8 years for polymeric fragrance encapsulates	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 prefer 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. During the 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 therefore undertook the impact assessment considering both a 5- and an 8-year	SEAC finds 5 years justified since the proposed transitional period strikes a balance between the minimisation of socio-economic impacts and a timely reduction in emissions. 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, there is not sufficient information available for SEAC to conclude if a longer transition period (i.e. 8 years) would be necessary considering the work already being done by industry. If no alternative encapsulates would be available, an increased amount of perfume would have to be added to the products concerned in order to achieve a similar performance to using fragrance encapsulation. This would lead to increased costs for fragrance oils. Also, it might result in environmental impacts due to higher emissions of perfume as

¹⁹ While the majority of fragrance encapsulates is used in the detergents sector, a small part is also applied 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	DS summary justification	SEAC conclusions
		transition period for fragrance encapsulates.	well as to potentially increased detergent, energy and water use due to more frequent washing of textiles.
<i>Agricultural & horticultural uses: Controlled release fertilisers (CRF) & fertiliser additives</i>	5 years, to be aligned with the Fertilising Products Regulation (FPR)	Time is required for the development of biodegradable polymers. The transitional period is also 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).
<i>Agricultural & horticultural uses: Capsule suspension PPPs (CSPs) & coated seeds</i>	CSPs: 8 years (justified by information received in the consultation) Coated seeds: 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 transition period longer than 5 years is not justified.	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 agricultural 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.
<i>Leave-on cosmetic products</i>	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	SEAC finds a longer transitional period than for rinse-off cosmetic products justified due to the complexity of the formulations. The specific choice of the DS to propose 6 years is however not fully justified by evidence. SEAC can therefore not assess the

Sector or product group	DS proposed Transitional period	DS summary justification	SEAC conclusions
		<p>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.</p>	<p>appropriateness of a specific transition period.</p> <p>SEAC points out 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 other options would be more appropriate than a ban (see text under proportionality).</p>
<i>Instructions for use and disposal</i>	24 months	<p>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 process of labels or safety data sheets.</p>	<p>SEAC agrees with the proposed transition period (see text under proportionality)</p>
<i>reporting</i>	36 months	<p>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.</p>	<p>SEAC agrees with the proposed transition period (see text under proportionality)</p>
Other uses (not mentioned in this table)	No transitional period	<p>Prevent new uses of intentionally added microplastics.</p>	<p>SEAC finds this justified in light of the request of the Commission and the overarching goal of the restriction, to wit minimising microplastics emissions.</p>

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 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 $1 \mu\text{m} \leq x \leq 1 \text{mm}$;
- vi. **Thermoform and thermoset plastics** – restriction on thermoform and thermoset organic polymer ‘plastics’ only ($> 0.01\%$ w/w);

Table 6 gives an overview of different RMOs and includes a summary of the Dossier Submitter’s assessment and SEAC’s conclusions.

Table 6 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)	
<i>All uses (no derogations)</i>	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.	<u>Costs:</u> Significant increase. Increased number of products in scope and lack of time to develop alternatives (no transitional periods). <u>Benefits:</u> Emission reduction higher than the proposed restriction. Additional uses in this RMO have significantly less emissions than the uses already	<u>Practicality:</u> Lower due to the lack of transitional periods and the increased scope. Industry and enforcement authorities cannot plan for the implementation of the restriction. <u>Monitorability:</u> More complicated due to the entry into effect of the requirements for several sectors at	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,

		<p>captured by the proposed restriction.</p> <p><u>Proportionality:</u> Not considered to be proportional. Costs are significantly higher than the proposed restriction and likely to outweigh additional benefits.</p>	<p>the same time, among others.</p>	<p>harmful impacts on industry (lack of transitional periods) and disadvantages to society (loss of critical functionality).</p>
<i>Instruction for use</i>	<p>Not all emissions can be minimised via instruction for use (e.g., detergents, agricultural uses, rinse-off and several leave-on cosmetics, etc.).</p>	<p><u>Costs:</u> 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).</p> <p><u>Benefits:</u> 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.</p> <p><u>Proportionality:</u> Lower because of high costs and low benefits.</p>	<p><u>Practicality:</u> 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.</p> <p><u>Monitorability:</u> More complicated.</p>	<p>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.</p> <p>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.</p>
<i>Specific uses</i>	<p>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.</p>	<p><u>Costs:</u> 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.</p> <p><u>Benefits:</u> Risk reduction would be similar or lower.</p> <p><u>Proportionality:</u></p>	<p><u>Practicality:</u> Similar to the proposed restriction.</p> <p><u>Monitorability:</u> Similar to the proposed restriction.</p>	<p>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.</p>

		Probably lower (due to possible decreased benefits).		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.
<i>Microbeads</i>	Limited effectiveness in reducing the identified risk.	<p><u>Costs:</u> Reduced costs since industry has already voluntarily phased out the majority of such uses.</p> <p><u>Benefits:</u> 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.</p> <p><u>Proportionality:</u> Proportional but not effective.</p>	<p><u>Practicality:</u> High, since industry is already implementing a voluntary agreement similar to this RMO.</p> <p><u>Monitorability:</u> High.</p>	SEAC agrees with the dossier Submitter's assessment and finds it justified to discard this option since it would not cover all uses linked to the identified risk.
<i>Smaller size characteristics</i>	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').	<p><u>Costs:</u> Would be similar, but there are potential savings from the reduced scope and less costly testing methods.</p> <p><u>Benefits:</u> Reduced risk reduction and therefore reduced benefits. Does not capture nanoparticles for which there is already a concern. Some microplastics</p>	<p><u>Practicality:</u> Higher since testing methods are more accessible.</p> <p><u>Monitorability:</u> Lower since there would be no additional information on nanoplastics.</p>	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.

		<p>would also not be covered.</p> <p><u>Proportionality:</u> Not clear if increase in proportionality.</p>		<p>SEAC does however not agree that monitorability would be lower. The Dossier Submitter presumes this based on the fact that they would not get information on nanoplastics. 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).</p>
<p><i>Thermoform and thermoset plastics</i></p>	<p>Several stakeholders proposed to only cover these types of organic polymers.</p>	<p><u>Costs:</u> Since less companies are effected costs would be reduced.</p> <p><u>Benefits:</u> Unlikely to have the same risk reduction effect and therefore benefits as less polymers are in scope.</p> <p><u>Proportionality:</u> Not clear if increase in proportionality.</p>	<p><u>Practicality:</u> Similar to the proposed restriction</p> <p><u>Monitorability:</u> Same as the proposed restriction.</p>	<p>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.</p>

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 dossier²⁰, 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 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

²⁰ 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.

most appropriate EU-wide measure.

B.3.2. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See Background Document

RAC conclusion(s):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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 assessment²¹ 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 on information gained during the consultation and changed 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

²¹ 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).

the environment (i.e. polymeric infill material) based on information received during the consultation.

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 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 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**²². 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 in agriculture and horticulture uses and fragrance encapsulation in detergents, 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, e.g. in case of plant protection products, authorised. Because of these uncertainties with regard to the availability and feasibility of alternatives (as well as other considerations, e.g., emissions reduction from the derogated uses), the Dossier Submitter recommends to review 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 are reformulation costs, whereas raw material costs are less important in comparison. Both are summarised for the different sectors affected in Table 7.

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.

Raw material costs

Alternatives to microplastics are assumed to be of higher costs, accordingly raw material costs

²² In addition, substitution costs were estimated for synthetic infill material as well as for *in vitro* diagnostics with the conclusion that a ban would not be the most appropriate EU-wide measure for the use of microplastics in these applications.

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 7).

Table 7 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)	15 – 53	36 - 2 000
Leave-on cosmetic products	2 100 (1 100 - 3 000)	5 - 13	1 600 – 13 000
Detergents and maintenance products			
Fragrance encapsulates ^c	400 (260 – 540)	0 – 183	293 – 554
Other detergents	15 200 (9 440– 20 960)	0 – 173	43 – 1 059
Waxes, polishes and air care products	1 300	0 – 11	0.5 – 8
Total		200 (20 – 430)	9 300 (2 100 – 18 000)

^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 8). These costs are estimated to be less than €2.1 billion (NPV).

Table 8 Profit losses estimated for the high scenario (worst case)

Cosmetics	Detergents and maintenance products		
Leave-on cosmetic products	Fragrance encapsulates	Other microplastics used in detergents	Waxes, polishes and air care products
€1.9 billion	€74 million	€98 million	€0.7 million

Cost of implementing technical means to reduce emissions (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. 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 (say 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 anyways and with a sufficiently long transitional period granted the cost of retrofitting can be expected to be succinctly lower.

Notwithstanding the hefty 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 loses around 500 kg per year. If that loss were to be reduced to, say, 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) and RO4 (technical RMMs) in detail with the premise that a transition period for RO4 should allow limiting 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 9. 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.

Table 9 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 may now be devised:

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

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

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 9, 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.

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 one 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 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' 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, quantity 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 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 ECHA²³ 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).

The Dossier Submitter points out that compliance can be ensured solely on the basis on

²³ 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).

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

SEAC notes that, as reported by the Dossier Submitter, for some product groups, e.g. 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 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' and reporting will be moderate, in particular as not all actors of the supply-chain will be affected, the extent of information required is limited and the transition periods give actors sufficient time to smoothly implement the requirements.

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. 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)²⁴. 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

²⁴ This is in line with SEAC opinions on other restrictions, e.g. D4, D5 in wash-off cosmetic products.

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 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. However, SEAC also observes that the functions of microplastics in different products are partly similar (e.g. encapsulation or opacifying)²⁵, 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. Therefore, spending on R&D to develop alternatives is difficult to quantify per product, because the number of products to be reformulated capitalising the R&D investment needs to be known. Furthermore, 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.

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

²⁵ 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.

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 material costs are estimated for the agriculture/horticulture product groups, the baseline price assumed for microplastics for detergents and cosmetics is respectively €1 100 and €1 300/tonne, with assumptions for both sectors of 50% price difference with the alternatives as per information from industry. It would have been desirable for the Dossier Submitter to provide further justification of the approach for different sectors. However, 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 under B. 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. In general, SEAC accepts this argument since it is unlikely that the costs to provide instructions for use and disposal (in terms of enhanced supply-chain communication) would significantly change the range of total costs estimated by the Dossier Submitter. The Dossier Submitters assessment and information received in the consultation are further discussed below under B.

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 or (ii) all polymers for which there was information that they can be used in cosmetics in the high scenario (520 polymers). SEAC considers that in particular the high scenario overestimates the number of products containing microplastics, because not all polymers used in cosmetics will actually 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)²⁶. Information received from industry in the consultation substantiate that the total number of formulations containing microplastics is likely to be lower than estimated in the high scenario. 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 to be reformulated in each specific product category depending on their share of the number of products on the market compared to the share of alternative (polymer-free)

²⁶ About 40% of all polymers used fall in the scope of the ban based on information from industry submitted during the consultation on the dossier, 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.

products²⁷. The assumptions made by the Dossier Submitter are underpinned by experiences from the phase out of microbeads in cosmetics²⁸ 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, on the whole information received by industry during the consultation (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 applied 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 cosmetics²⁹. The Dossier Submitter reflected this additional effort to develop alternatives and substitute microplastics by using a higher estimate for the cost per reformulation for leave-on cosmetics³⁰. The estimates used by the Dossier Submitter for the cost per reformulation were challenged by industry during the consultation indicating that the cost would be much higher for products where there are no alternative ingredients available yet (e.g. #2220, #2361, #2375, confidential submissions). SEAC considers that the estimate provided by industry is likely to be overestimated and may reflect the marginal, but not the average cost to reformulate.

This conclusion is supported by the fact that alternatives are on the market already for most functions of microplastics (see Bertling et al. (2018), summarised in BD, Annex D5, pp 206). For some functions the availability of alternatives seems limited such as film-forming (which is excluded from a ban based on derogation 5b) and skin conditioning. However, information received from industry in the consultation indicates that also for these functions some alternatives seem to exist (confidential submission). Therefore, the number of reformulations that will require extensive initial R&D to develop alternatives is likely to be limited. Therefore, not all reformulations can be expected to be equally resource-intensive.

This conclusion is confirmed by information provided by industry indicating that usually

²⁷ 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).

²⁸ Only about 50 % of all products containing microbeads were reformulated.

²⁹ 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 Cosmetics 2018).

³⁰ The Dossier Submitter estimated €365 000 (€42 000 for SMEs) for rinse off and €50 000 (€63 000 for SMEs) for leave-on based on information available from the restriction on D4 and D5 in wash-off products (reference RTI study).

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 usually 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. Also, 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. In line with these arguments, also conflicting information was submitted by industry during the consultation suggesting that the cost per reformulation would actually be much lower than estimated by the Dossier Submitter (confidential submissions).

Therefore, SEAC considers the estimates used by the Dossier Submitter to be overall appropriate to reflect the average reformulation costs to be expected.

In the consultation, 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 impact to occur very much depends on the number of reformulations and the performance of reformulated products compared to products containing microplastics.

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 market share of polymer-free products 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 higher number of different microplastic ingredients (to achieve different functions). Also, comments received in the consultation indicated that the substitution process could be more costly, e.g. in terms of additional testing (#2360, confidential submissions). SEAC considers that that the costs to substitute microplastics in make-up, lip and nail products are critical for assessing the proportionality of the restriction proposal. (discussed in the section on proportionality). There are 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 products³¹ characterised by small differences, e.g. on the basis of colour, within the same brand name and product series³².

³¹ 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.

³² 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

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. This is due to a share of the products (mainly leave-on cosmetics) that contain D4, D5 and D6 as well as microplastics, 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

Also for detergents and maintenance³³ products a considerable number of products can be expected to be reformulated in response to the proposed restriction (see Annex D6 to BD 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. 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. Furthermore, the range of costs per reformulation estimated by the Dossier Submitter was generally confirmed by information received in the consultation, although there were comments stating that more complex reformulations would cost significantly more. Therefore, the Dossier Submitter updated the upper values of reformulation costs used in the cost assessment based on the information received in the consultation. Where more specific information was submitted in the consultation, the Dossier Submitter took this information into account when updating the assumptions made, e.g. a higher number of reformulations for polymeric fragrance encapsulates as it was indicated in the consultation 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 BD). 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 the cost to reformulate can be expected to be substantially higher than the cost to provide instructions for use and reporting.

For one application of microplastics, the **encapsulation** of active ingredients (e.g. to apply fragrances in detergents and also cosmetics), substitution seems to be more difficult and no alternatives are available yet according to information received in the consultation. 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. Furthermore, the Dossier Submitter estimated the costs of using higher amounts of perfume in case alternative materials for encapsulation would not be available yet at the end of the transition

alternative for all these separate reformulations.

³³ 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).

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). Industry stated in the consultation that reformulation costs, in particular R&D costs to develop alternatives, would be even higher. The Dossier Submitter updated the upper values used in the cost assessment taking into account the information received in the consultation.

Agriculture and horticulture products

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

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 assumed (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.

For plant protection products, industry provided further information during the consultation 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.

Synthetic infill material

SEAC has assessed, where possible (semi-)quantitatively, the costs for several possible Risk Management Options in order to give an overview of possible impacts to society. This analysis reflects all of the information available to SEAC. 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 this restriction proposal, but is also an important factor in the decision-making process.

1. RO1: Full ban of infill material covered by the Microplastics definition (from entry into force)

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 playgrounds³⁴).

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 opinion for the 'PAHs granules restriction'. Several important differences however need to be borne in mind:

³⁴ Which is the scope of the "PAH granules restriction".

- Although the 'PAHs granules restriction' also covers virgin infill material, the end-of-market scenario only impacted End-of-Life Tyre (ELT) infill since, according to available information, virgin infill (TPE, EPDM, etc.) would not contain PAHs. Under the microplastics restriction virgin infill would also be impacted.
- The microplastics restriction identifies a risk to the environment while the 'PAH granules restriction' dealt with a human health risk.

From a cost perspective these differences show that the impacts for the infill industry would be higher than under the 'PAH granules restriction'.

Since the market share of ELT-derived rubber infill is 90-95%, the cost estimates linked to the end-of-market scenario in the 'PAHs granules restriction' are considered to be a realistic low-end approximation of the actual impact to the infill industry³⁵. The overall societal costs of a full ban on infill material can therefore be estimated to be around €3 000 million - €3 500 million over a 10-year period³⁶ (market impacts to society). For further information, we refer to the "PAH granules restriction" dossier and SEAC's analysis of it.

Further to these costs, SEAC acknowledges that there are certain small environmental benefits³⁷ associated with the re-use of end-of-life tyres as infill material (100 000 tonnes/year). Landfilling is not an option due to EU legislation and there is limited capacity in energy recovery (i.e. incineration³⁸). 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 pyrolysis and black carbon manufacture. It is therefore unknown if and to what extent these lost benefits are a significant factor from a cost perspective. SEAC reiterates this is only part of a larger policy and environmental discussion (e.g. end-of-life) surrounding artificial pitches which falls outside of the committee's remit. In any case, potential lost benefits should be considered as costs additional to the already mentioned costs due to market impacts. These lost benefits could not be monetized.

During the Consultation various national football associations have submitted estimates for the "social return on investment" (SROI) from football participation (both on natural and artificial pitches), essentially trying to monetise the benefits for public health and wellbeing, the economy and society at large. These associations used a model developed by UEFA to assess these social opportunity costs. While SEAC was not able to assess the methodological underpinnings of the SROI model, SEAC acknowledges that this restriction option will engender significant social opportunity costs. However, these will certainly not reach the figures mentioned in the comments (i.e. several billion euros). A full ban on infill material covered by the microplastics definition will 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

³⁵ 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 let on.

³⁶ Time period used in the "PAH granules restriction" which corresponds to the lifetime of an artificial pitch.

³⁷ Resource efficiency: reuse of tyres as a secondary raw material and reduced energy need compared to manufacture of virgin material.

³⁸ Incineration can only take place in cement mills due to the high energy content of the granules.

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 equal to or higher than the societal costs due to market impacts (see earlier).

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

During the Consultation multiple German respondents indicated that a 6-year transitional period would allow for a gradual move towards artificial turf systems that either use natural infill material or are infill-free. This claim was also echoed by UEFA. On the other hand, many other respondents have stated that some alternatives will not be suitable under certain circumstances (climate, professional or amateur play, etc) and also called into question 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 since time is given to industry to find/implement suitable alternative infill material and turf systems and raise their availability.

The Dossier Submitter provided a rough quantitative cost assessment. SEAC notes that there does 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 replacement cost for all existing pitches (32 000 full size pitch equivalents). This is in contradiction with the statement that because of the transition period only a limited number of pitches (10-20%) would need to be prematurely replaced. Costs associated with the replacement of pitches that reach the end of their lifetime during the transition period, would be incurred regardless and can therefore not be part of the overall impacts of RO2.

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 according to the Dossier Submitter. 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 rise. While some of these alternatives are at the moment more expensive, it is in principle to be expected that prices would drop because of higher availability.

As was the case under the previous RMO (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, 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 these 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 RO.

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).

Considering the wording of the restriction 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 RO will be significantly lower compared to RO1-2 and RO4.

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

During the Consultation 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.

Very disparate information was also submitted on costs for putting into effect these technical measures. 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 DS: €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 RO of €640 million (PV). Using an average cost of €30 000 per pitch this overall cost estimate goes up to €960 million (PV). A transition period of 6 years would mitigate most of these costs since 80-90 % of the pitches can be refurbished/replaced at the end of their foreseen lifespan according to the Dossier Submitter. Considering the fact that the average lifespan of an artificial pitch is 10 years SEAC finds this plausible.

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.

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 material³⁹ 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.

Medical devices

Microplastics are used in a multitude of products used for medical purposes such as equipment like adsorbers for blood treatment or ions exchange resins but also mixtures like dental filling material or sunscreen (so called substance-based medical devices). During the preparation of the Annex XV proposal the Dossier Submitter was not fully aware of these substance-based medical devices 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 reporting requirements).

Information received during the consultation 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 cosmetics (e.g. cream to apply on the skin or toothpaste) and microplastics have the same functions as in cosmetics. Therefore, the Dossier Submitter proposed the same transition period as for leave-on cosmetics, i.e. 6 years, referring to the similarities to cosmetics. 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 would be desirable. Even though SEAC agrees that there are a lot of similarities to cosmetics, there may also be differences in terms of reformulation process and testing required as well as regulatory requirements. Comments received during the consultation indicate that the cost per reformulation could be higher than for cosmetics. In this respect, SEAC refers to the consultation of the SEAC draft opinion as a possibility to obtain additional information on substance-based medical devices.

in vitro diagnostic devices (IVD)

Initially, the Dossier Submitter intended a derogation for IVD devices conditional to the containment of microplastics throughout the lifecycle of these products (derogation 5a). During the consultation 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 BD D 7). According to this assessment, the economic impact would be in the order of magnitude of billions of Euros over a 20-year 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 to €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).

³⁹ Which might or might not be the case in member states other than the Netherlands.

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 AfAs 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 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 (entry paragraph 7). Furthermore, the Dossier Submitter proposed an obligation for industrial users and suppliers⁴⁰ of the products concerned to provide **annual reports on identity, uses and releases** of microplastics used (entry paragraph 8). Sectors covered by these requirements are:

- *in vitro* diagnostic devices (IVD)
- other medical devices (if not covered by ban)
- cosmetics (if not covered by ban)
- detergents (if not covered by ban)
- medicinal products
- food additives
- paints and coatings
- construction products
- toners and printing inks
- 3D printing
- industrial uses, e.g. oil and gas

During the consultation 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 to clarify what actually is required from the actors involved along the supply chain.

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 BD 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. 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. The Dossier Submitter highlights that the obligation leaves flexibility to the actors involved with regard to the means that is chosen to provide 'instructions for use and disposal', for instance cost-effective solutions can

⁴⁰ placing a microplastic on the market for the first time

be used such as pictograms.

SEAC considers that the analysis carried out by the Dossier Submitter illustrates the range of costs to be expected to comply with the requirement on a 'per label' basis. 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 products covered is unknown. SEAC notes that products are relabelled on a regular basis and that the longer transition period of 24 months as it is proposed now 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.

With regard to the **reporting requirement**, many comments were received during the consultation of the proposal 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 BD 2.2.1.5). 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 the first time would have to report annually the use, the identity and the estimated releases of microplastics. Furthermore, the Dossier Submitter focussed the reporting required onto key information (use and 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 users⁴¹ as well as consumers are not covered by the requirement so that a limited number of actors will be affected by the reporting obligation. When it comes to 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.

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 has adopted a similar approach for assessing the benefits of the proposal as the one SEAC recommends for evaluating PBT/vPvB (-like) substances⁴². 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%⁴³ of cumulative emissions (over 20

⁴¹ 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.

⁴² https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpVB_substances_seac_en.pdf

⁴³ Range dependent on assumed effectiveness of 'instructions for use and disposal' requirements and scenario assumptions.

years) or more than 90 % of annual emissions (once all transition periods have passed) 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 expected entry into force of the proposed restriction.

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 building upon microplastics as stock pollutants that are characterised by their **extreme persistence in the environment** and by a fundamental lack of 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 homogeneously like other stock pollutant such as greenhouse gases in the environment. Therefore, the reduced emissions resulting from the proposed restriction would predominantly affect the environmental stock of microplastics in 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 major emission sources known. While the impact of this emission reduction is unknown, SEAC notes that RAC has confirmed that – comparable 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.

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 values. 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.

When considering the overall benefits of the proposed restriction, SEAC finds 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 (low hanging fruit). This conclusion is supported by comments received from the water sector in the consultation indicating that microplastics already now are 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 in the long-run. However, this does not affect the benefits of the proposed restriction because, (i) as this long-range transport potential of microplastics is acknowledged to be limited, the proposed restriction will effectively reduce 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 has to be considered a benefit, even though other emission sources may remain.

Infill

Based on a thorough assessment of Consultation comments 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 this restriction proposal, but is an important factor in the decision-making process, especially when it comes to the benefits of the discussed ROs.

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. Especially the very high concentration of zinc oxide contained in the rubber particles is a 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 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 sent for incineration. 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 pyrolysis and black carbon manufacture. It is therefore unknown 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 ROs). 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 Consultation. 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 RO would still allow average annual EU emissions of 1600 tonnes (10% of the original emissions).

This analysis reflects all of the information available to SEAC.

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 is quantified for leave-on cosmetics, i.e. for the share of reformulations where delays have been assumed under the High scenario. The Dossier Submitter estimated that these would not exceed €70 million over the study period of 20 years.

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 do not require substantial resources. (See also Section B.3.7.1.3) The requirements that would likely incur the largest costs to industry relate to the proposed restriction on the placing on the

market of microplastic-containing products (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-free and – containing products (and sometimes both at the same time) 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 mixtures. Therefore, while it is possible that in the worst-case scenario these impacts may materialise for microplastic-containing products, it is also likely that value-added and exports of microplastic-free products may 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, stakeholders raised concerns about the impact of the proposal on SMEs, exports and employment (in particular in 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 producer of alternative products also often are SMEs, which in turn may benefit from the restriction. Hence, the impact on SMEs could be more a distributional 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 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 SEAC⁴⁴.

For sectors with restrictions on the placing on the market of microplastics, the Dossier Submitter calculated cost-effectiveness ratios based on cost and release estimates separately for each of the sectors and product groups assessed. The original figures were revised taking into account changes of cost and release estimates based on information received during the consultation (see Table 10).

Table 10 Summary of cost-effectiveness of proposed restriction on placing on the market

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
<i>only make-up, lip and nail products</i>	800	2 200	3 300
<i>Other LO (excluding make-up/lip/nail products)</i>	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
Overall cost-effectiveness (€/kg)	2	19	133

The cost-effectiveness of the proposed restriction on the placing on the market shows that these 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.

The ranges of the figures reflect the considerable uncertainty associated with the tonnages of microplastics covered by the ban of the proposed restriction (see section on emissions) and the costs that can be expected to be induced (see section on costs).

The cost-effectiveness estimates of the restriction proposal on microplastics are within the range of other adopted restriction measures on environmental pollutants, e.g. PBT/vPvB(-like) substances. This is supported by Oosterhuis et al. (2017). The study concludes that, although cost estimates of previously adopted actions do not allow deriving a value for society's willingness to pay to reduce PBT presence, use, and emissions, the available

⁴⁴ https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpVB_substances_seac_en.pdf

evidence suggested that measures costing less than €1 000 per kilogram of emission reduction would usually not be rejected for reasons of disproportionate costs, whereas for measures with costs above €50 000 per kilogram PBT such a rejection is likely (Oosterhuis et al., 2017). Therefore, the Dossier Submitter concludes 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 (micro-) plastics 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 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 fact to be taken into account when assessing the proportionality of the proposed restriction.

The Dossier Submitter concludes 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) alternatives already exist or there is information that they can be developed within 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.

Even though a clear conclusion on proportionality is not possible recognising the uncertainties of the impacts of the restriction, SEAC considers that the **irreversibility of microplastic emissions** is a key argument in favour of 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. SEAC underlines that such situations, proportionality ultimately depends on policy priorities and cannot be demonstrated by evaluating the costs and benefits of the proposal.

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 underpinning that microplastics can be substituted within the proposed transitional periods.

For **capsule suspension plant protection products** SEAC considers that an extension of the transition period in order to account for the time needed for re-authorisation could improve the proportionality of the restriction, also taking into account the potential positive environmental impact of these uses and that it seems to take more time to develop alternatives.

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 (> 6 years) could also be considered proportionate taking into account the low contribution to overall emissions as well as the possible impact on SMEs of a ban of microplastics in these products.

With regard to polymeric **fragrance encapsulation**, further information on the availability of alternatives and on the substitution process would be needed to draw a final conclusion on the most appropriate transition period in terms of proportionality.

For **infill material**, all options assessed by the Dossier Submitter that effectively reduce releases could be considered proportionate.

In terms of the 'instructions for use and disposal' as well as the reporting requirement SEAC points out that the costs of their implementation are likely to be moderate and the benefits in terms of lower releases (along the supply chain) and a better evidence base to facilitate future action seem likely. With regard to reporting, SEAC considers that biennial reporting (compared to annual as proposed by the Dossier Submitter) may also be sufficient to achieve a sound evidence base within a reasonable time frame and will reduce the resources needed for industry as well as authorities to process the information generated.

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 lack of knowledge of their environmental effects, which hampers measuring the impacts of emission abatement. As a consequence, a quantitative comparison of costs and benefits of the restriction is not possible. Therefore, estimating the **cost-effectiveness** is a suitable approach to support the proportionality assessment of the proposed restriction. However, SEAC underlines that the cost-effectiveness analysis (CEA) per se does not allow for a final conclusion if regulatory action is proportionate or disproportionate. 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 (see Oosterhuis and Brouwer, 2015), 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, it cannot be established what level of costs would be acceptable to reduce microplastic emissions based on CEA.

Therefore, it is difficult for SEAC to draw a robust conclusion on the proportionality of the proposal, because 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. A key argument in favour 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.

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 means to reduce releases). In order to conclude if substitution of microplastics is proportionate or not, SEAC considers that the concept of 'essential use' could provide meaningful input to the decision-making process. The concept was applied to implement the Montreal Protocol on Substances that Deplete the Ozone Layer and recently has been further discussed and developed to support regulation on PFAS (Cousins et al. (2019)), which are of similar concern to microplastics in terms of their environmental persistence. Accordingly, an 'essential use' would be a use of a substance, which is necessary for (i) health and safety or is critical for the functioning of society and (ii) for which there are no available technically and economically feasible alternatives. Of course, this concept leaves room for interpretation and therefore cannot provide clear-cut conclusions, but it may support to identify uses, for which a derogation is likely to improve proportionality.

Concerning microplastics, available information indicates **alternatives** do already exist or are likely to be developed in the foreseeable future for the vast majority of uses. SEAC considers that the availability of alternatives is another important argument in favour of proportionality of the proposal. The transition periods proposed by the Dossier Submitter in general are appropriate to allow for the development of 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 these **costs** overall **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 consultation. Overall, the information available to assess affordability is limited meaning that there is not sufficient evidence for 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, 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 lesser extent to microplastic releases, i.e. make-up, lip and nail

products⁴⁵. Therefore, replacing microplastics in these products is by far not as cost-effective as 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 not covered by the ban (see cost section). In addition, there are indications that releases could be higher than estimated by the Dossier Submitter. This means that it actually could be more cost-effective to substitute microplastics also in those product groups with relatively low releases than indicated by the cost-effectiveness estimated by the Dossier Submitter (€ 800 - €3 300 per kg).

Taking into account that this level of costs still was considered proportionate in some restrictions on PBT(-like) substances (Oosterhuis et al. (2015)) and that there is no established proportionality benchmark for cost-effectiveness, SEAC considers that there is currently insufficient justification to exclude certain cosmetic products such as lip or nail products from the proposed ban on a cost-effectiveness basis.

Table 11 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 highlight the resources needed to replace microplastics in leave-on cosmetic products indicating that reformulation capacities would be exceeded, which could be particularly difficult for SMEs operating in the sector. SEAC agrees that the investments needed to develop and use alternatives instead of microplastics are likely to be substantial, but also notes that in principal there seem to be alternatives to replace microplastics in all cosmetic products categories. Given the uncertainties on the resources and investments the reformulation of products containing microplastics will actually require and considering that it is also likely that producers of alternative products may 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 on microplastic content and instructions for disposal is given to consumers ('instruction for use and disposal'). Furthermore, these uses should be covered by the reporting obligations in order to obtain better evidence on releases and take future further action (such as a ban on the placing on the market) in the event emissions do not sufficiently decline. Potential excessive costs as claimed by industry would be avoided with this option and at the same time some emission reduction may be attainable (starting from an earlier date: within 2 years of EiF for

⁴⁵ Make-up, lip and nail products they are predominantly (~ 70 %) removed from skin with tissues or wipes and disposed 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 BD.

instructions for use vs the proposed ban with a transitional period of 6 years). However, the overall effectiveness of this option is likely to be significantly lower than a ban.

- Ban with longer (> 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 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), also the Dossier Submitter acknowledged the possibility (in the high scenario) that not all reformulations would be finalised by the end of the 6-years-transition period proposed. SEAC highlights that there is not sufficient information to determine the optimal transition period. On the other hand, a longer transition period would mean more emissions of microplastics to the environment. In order to keep these additional emissions to a minimum, complementary 'instructions for use and disposal' could increase the effectiveness of this option.

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

Detergents and maintenance products

For most uses in detergents, substitution of microplastics is a very cost-effective measure to reduce emissions. However, for polymeric **fragrance encapsulates**⁴⁶ it is more costly to replace, because alternatives have not been finally developed yet. Therefore, uncertainty remains whether alternatives for polymeric fragrance encapsulates will become available within the transition period originally proposed by the Dossier Submitter (i.e. 5 years for polymeric fragrance encapsulation). Industry Stakeholders have commented during the consultation that the proposed transition period is too short to develop alternatives and that up to 10 years would be needed to switch to alternatives (#2160 #2239).

The additional costs to be incurred if alternatives would not be available, were estimated by the Dossier Submitter in the high cost scenario (additional perfume use, profit losses) and thus are reflected in the cost-effectiveness figures. SEAC notes that based on these figures it cannot be concluded that it would be disproportionate to phase out microplastics used as polymeric fragrance encapsulates after a 5 year transition period. A longer transition period for the use in polymeric fragrance encapsulates is likely to decrease the costs of the proposed restriction, because profit losses and the use of additional perfume oils due to delayed reformulations could be prevented. The Dossier Submitter assessed this impact by deriving additional cost estimates based on an 8 year transition period, indicating a ~30% reduction of the cost per kg microplastic emissions reduced (from €173 to €128 per kg). Again, SEAC points out that a longer transition period would involve higher emissions (~600 t) of microplastics in total and hence lower the effectiveness of the proposed restriction (see Annex D.6.7 in the BD).

⁴⁶ A minor percentage of polymeric fragrance encapsulates is also used in cosmetics (< 1% of production volumes).

Table 12 Fragrance encapsulates: Impacts of 5 and 8 years transition period.

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

The Dossier Submitter is not making any recommendations on which of these two transition periods is more appropriate for fragrance encapsulates. Noting these changes in both – costs and emission reduction – SEAC considers that both transition periods may be found to be proportionate. However, further information on the development of alternatives and on the substitution process would be needed to facilitate a final conclusion on the most appropriate transition period.

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 8 years after entry into force for the use of microplastics in capsule suspension uses would be warranted.

In addition, SEAC finds that the longer transition (i.e. 8 years) periods 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 of the plant protection products concerned.

Infill

Since the costs and benefits are uncertain, a clear and unambiguous cost-effectiveness figure cannot be derived for RO1-2. SEAC therefore decided to perform an indicative “break-even” analysis, i.e. back-calculating the cost to society using the several of the cost-effectiveness figures derived for other sectors (see Table 10). 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 higher than the costs in section B.3.7.1.3, then this is a potential indication that the measure might be proportional.

SEAC needs to stress that what follows is 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 however expressed a preference for RO2.

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 3 C-E ratios from Table 10 to have a range of cost estimates: 133 €/kg (high overall C-E), 337 €/kg (high C-E for detergents containing fragrance encapsulates) and 870 €/kg (central C-E for leave-on cosmetics).

Assumptions for break-even analysis	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 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 C-E range, the Dossier Submitter and SEAC have 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.

The Dossier Submitter then assumed that an average full-sized pitch loses around 500 kg/year and this could at least be reduced to 50 kg/year (approximately 10% of total emissions) which means that annually approximately 16 000 tonnes of infill emissions are avoided.

Using these assumptions SEAC arrives at the following C-E range: 40 – 60 €/kg. This indicates that RO4 might be proportional. 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.

Medical devices

As pointed out in the section on costs, there is not sufficient information on the impacts of the ban of the proposed restriction on medical devices to draw a final conclusion 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.

Similarities to cosmetics suggest that the proposal could be proportionate. However, further information would be needed to underpin this conclusion.

***In vitro* diagnostics**

Information received in the consultation indicated that the implementation of technical means in order for IVD products to comply with the restriction (derogation 5a) would entail substantial costs (see cost section). Addressing the issues raised 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 releases of microplastics from IVD products are very low (estimated to 270 kg per year), the Dossier Submitter concluded that that 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 substances⁴⁷, 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 thus can be considered as an 'essential use' of microplastics as 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, in the long-run the substitution of microplastics may become less costly, because alternative materials will be further 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 (ref to BD).

Sectors affected by 'instructions for use and disposal' 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 uses, identity and releases of microplastics used in products that are derogated from the ban of the restriction proposal underline that even if the economic impact is significant it will not be as substantial as indicated by the numerous comments received during the consultation.

SEAC considers 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 affordable and the Dossier Submitter provided for sufficient flexibility for actors to choose cost-efficient approaches to comply with the requirements. 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

⁴⁷ Oosterhuis et al., 2015

resource-intensive.

SEAC points out that more information to assess the impacts of the 'instructions for use and disposal' and reporting requirements as specified by the Dossier Submitter is needed to facilitate a final conclusion on proportionality.

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 require additional research and development.

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

The restriction is designed so that enforcement authorities can set up efficient supervision mechanisms to monitor compliance with the proposed restriction and is practically implementable for companies. The Dossier Submitter considers that it is possible to determine if a product includes particles containing solid polymer with all dimensions less than 5mm, or fibres with length <15mm. For the cases where the particle is mainly non-polymer, there is also a need to determine the amount of polymer present in the particle. The Dossier Submitter considers that applied method for determining the amount of polymer will need to be decided on a case-by-case basis, but that suitable methods are available.

RAC and SEAC conclusion(s):

Taking into account, among other elements, information in the Background Document, the consultation and the advice given by Forum, SEAC and RAC are of the view that the proposed restriction options are practical and enforceable. This conclusion is reached in spite of the original proposal containing limited information regarding the practicality and enforceability of the proposed restriction.

However, the Committees as well as Forum stress that a prerequisite for the validity of this conclusion is that parts of the microplastics definition are clarified, derogations are further explained and extensive guidance for industry and national inspectors is provided. It is clear that for a well-thought-out, but broad and complex, restriction, flanking measures to support the implementation are necessary.

Key elements underpinning the RAC and SEAC conclusion(s):

The Committees agree with Forum that due to the broad scope and complexity of the restriction proposal the elaboration of dedicated guidance document 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 clear and fit-for-purpose, some clarifications are necessary. Several stakeholders provided comments to that effect during the consultation as well as Forum in its advice.

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

- "industrial sites" in paragraph 4a: insufficient information on how this should be interpreted. During the consultation several industry stakeholders indicated that this should be changed to "industrial installations" in order to be consistent with other restrictions.
- "medicinal products for human or veterinary use" (paragraph 4b): should refer directly to the corresponding Union legislation. This has already been taken into account by the Dossier Submitter during the opinion development (see section B.3.5).
- "permanently modified" in paragraph 5b: the consultation made clear that varied and broad practical interpretations exist among stakeholders. The Committees therefore suggest a harmonised interpretation be provided which is also an explicit demand from Forum. This has already been taken into account by the Dossier Submitter during the opinion development (see section B.3.5).
- "other mixtures" in paragraph 6a: it should be explained if this only refers to other cosmetic mixtures or to all mixtures containing microbeads.
- "maintenance products" in paragraph 6d: should be defined since the regulation on detergents does not seem to describe such products. This has already been taken into account by the Dossier Submitter during the opinion development (see section B.3.5)
- "legible" in paragraph 7: a precise definition should be provided since this seems to be an ongoing issue from a practical enforcement point of view.
- "relevant instructions" in paragraph 7: should be clarified according to Forum.

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. The Annex XV dossier is however very concise when it comes to providing justifications for this. In the Committees' view the restriction dossier does not

capture difficulties that may arise for both companies and national inspectors during the implementation phase of the proposed restriction. In certain instances possible barriers to compliance are not discussed and in other instances they are dismissed even though the characteristics of a sector, or of the way different Member States inspect compliance, are not taken into account⁴⁸.

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 approach⁴⁹ mentioned in the restriction dossier. This decision tree could provide a step-by-step guide in order to assess if a polymeric substance is covered by the **microplastics definition**. Including possible analytical methods in order to assess if a polymer fits the definition and exceeds the concentration limit of 0.01%, is also considered advisable. The Dossier Submitter has however indicated that these methods are available and should therefore be able to provide, at the very least, general information. It is acknowledged that it would be impossible to provide guidance for every situation that would arise for every sector or product group covered. Furthermore, it is also considered advisable to provide a decision tree on the **obligations for different actors in the supply chain**, address the links with other Community legislation (sectors, emissions and/or product groups) and further clarify the derogations. These decision trees are part of the background document, but should be presented to industry and inspectors in a dedicated and more accessible document.

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

Several specific issues that warrant further attention are analysed below.

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

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

RAC and SEAC acknowledge current technological barriers in identifying microplastics <100 nm. Discussions with a JRC expert have indicated that, at the moment, this size limit is the cut-off for performing reliable analyses. SEAC therefore proposes to limit

⁴⁸ As an example, in certain Member States joint REACH – Cosmetics/detergents/PPP inspections are carried out, in others not.

⁴⁹ 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?

the targeting of the restriction to microplastics >100nm until the aforementioned technological barriers have been resolved.

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

It remains clear that 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 discussed⁵⁰, 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 expert), the Committees consider that the currently proposed transitional periods should afford inspection services and industry enough time to prepare for future compliance checking.

A specific point that needs to be mentioned here is that 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 the proposed restriction cannot be considered implementable. Since the Committees cannot predict the future evolution of this technology a review of the state of play at or just before the end of the transitional period is warranted in this case.

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

B.3.5. Monitorability

Justification for the opinion of RAC and SEAC

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 fairly large). For uses derogated from the restriction on use, the proposed reporting requirement will allow information on them to be gathered and, where necessary, future additions to the restriction could be considered. For imported mixtures, the compliance control can be accomplished by border authorities and notifications of any violation of the restriction can be reported in the RAPEX system.

RAC and SEAC conclusion(s):

Based on the information in the background document and the Forum advice on this aspect

⁵⁰ See the section "*Justification whether the suggested restriction is the most appropriate EU wide measure – Scope including derogations*".

SEAC concludes that the proposed restriction option for intentionally added microplastics is monitorable with following caveats:

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

Key elements underpinning the RAC and SEAC conclusion(s):

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

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

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

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

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.) As summarised in the preceding sections, the conclusions on the proportionality of the proposed restriction hold also when worst-case values for key assumptions are applied.

However, for some sectors (e.g., agriculture and horticulture, detergents with encapsulation technology), the conclusion on proportionality is conditional on biodegradable alternatives with the same or similar functionality becoming available in the medium term. If this were

not the case, then this would cast doubt on the proportionality of the proposed restriction, as the benefits of non-degradable polymers used in some sectors (e.g., agriculture and horticulture) can be substantial.

When considering the optimal length of transition before the 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):

See RAC opinion.

Key elements underpinning the RAC conclusion(s):

See RAC opinion.

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

Cousins, I.T., Goldenman, G., Herzke, D., Lohmann, R., Miller, M., Ng, C.A., Patton, S., Scheringer, M., Trier, X., Vierke, L. and Wang, Z., 2019. The concept of essential use for determining when uses of PFASs can be phased out. *Environmental Science: Processes & Impacts*, 21(11), pp.1803-1815.

Appendix: Overview on the opinion-making process

Sector	Original proposal	Key PC 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.
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	5 or 8 years for the encapsulation of fragrances	SEAC considers a 8 year TP would require further substantiation.
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
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	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.
Sectors covered by instructions for use and disposal and reporting (e.g. uses on industrial sites, medicinal products, paints & coatings, construction products, inks, food additives)	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. Reporting period might be extended (see opinion text).
Notes: Proposed Action (current proposal): dark grey = ban; light grey = technical means to reduce releases; white = instruction for use and reporting requirements				