ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): intentionally added microplastics
IUPAC NAME(S): n/a
EC NUMBER(S): n/a
CAS NUMBER(S): n/a

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About this report

The preparation of this restriction dossier on 'microplastics' was initiated on the basis of Article 69(1) of the REACH Regulation. The scope of this proposal is limited to intentional uses of microplastics as that was the scope set out in the request from the Commission.

The proposal has been prepared using version two of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of Annexes with more detailed information and analysis as well as details of the references used.

In the course of preparing this restriction, the Commission asked ECHA to explore the potential for co-operating during the preparation of the Annex XV report with Sweden. After preliminary discussions in May 2018, ECHA agreed that they would collaborate with KemI to prepare the Annex XV report, although Sweden will not be a formal Dossier Submitter. The Dossier Submitter would like to extend their thanks to KemI for their assistance.

ECHA (hereafter referred to as the Dossier Submitter) would like to thank the many stakeholders that made contributions to the call for evidence, the stakeholder workshop held in May 2018 and during bilateral discussions during the subsequent development of this report. The Dossier Submitter would also like to extend their thanks to the organisers and participants of the Micro2018 international microplastics conference, held in November 2018, who provided useful comments on an earlier draft of the risk assessment included in this report.

This report has been reviewed for confidential information.

Version 1.0 of this document was published on the ECHA website on 30 January 2019.

Version 1.1 of this document was published on 20 March 2019 to coincide with the beginning of the public consultation on the proposal and corrects a number of typographical errors present in version 1.0. A number of editorial revisions were also made to improve the readability of the document and improve the clarity of the proposal.

Version 1.2 of this document was published on 22 August 2019 to add a missing footnote to Table 44 in Annex D to the report.

Summary

The term 'microplastic' is not consistency defined, but is typically considered to refer to small, usually microscopic, solid particles made of a synthetic polymer[1]. They are associated with long-term persistence in the environment, if released, as they are very resistant to (bio)degradation.

Microplastics are manufactured and used (also termed intentionally added) in many mixtures placed on the market of the European Economic Area (EEA). It is these 'intentional' uses of microplastics which are the focus of the analysis and the proposed restriction reported here. The intent of the proposed restriction is not to regulate the use of polymers generally, but only where they meet the specific conditions that identify them as being microplastics and where their use will result in releases of microplastics to the environment.

Microplastics can also be formed in the environment as a result of the progressive (bio)degradation of larger synthetic polymer-based articles (e.g. plastic packaging, discarded or lost fishing gear), typically articles that are present in the environment as a consequence of inappropriate or ineffective disposal (e.g. littering). Much of the present focus on microplastics has arisen as a result of the growing awareness of the extent of anthropogenic litter in the marine environment, as well as its consequences. Microplastics formed in the environment are usually called 'secondary' microplastics and their risk management is outside the scope of this assessment.

The Dossier Submitter has identified that 'intentionally added' microplastics have diverse technical functions and are used in various consumer, professional, agricultural and industrial products, including in:

- agriculture and horticulture (in fertilisers and plant protection products);
- cosmetic products (both rinse-off and leave-on products);
- detergents and maintenance products (e.g. as fragrance encapsulation in laundry detergents and fabric softeners as well as in products for cleaning and polishing);
- paints, coatings and inks (in professional and consumer uses);
- chemicals used in the oil and gas sector;
- construction;
- medicinal products;
- medical devices; and
- food supplements and medical food.

Products containing microplastics have different (reasonably foreseeable) conditions of use, including how any wastes that arise during use are disposed. Therefore, releases of microplastics to the environment can occur through various pathways, principally via wastewater and/or municipal solid waste. Certain microplastics are deliberately released directly to the environment i.e. uses in agriculture and horticulture.

The availability of alternatives for the different uses also varies, as do the current market shares of these alternatives and the anticipated resources and time required to

[1] Polymers are substances within the scope of the EU REACH Regulation.

substitute the technical functions currently provided by microplastics in the event of a restriction.

The concern associated with microplastic particles stems from the potential environmental and human health risks posed by the presence of solid particles of synthetic polymer-based materials in the environment that:

- **are small** (typically microscopic) making them readily available for ingestion and potentially liable to transfer within food chains;
- **are very resistant to environmental (bio)degradation**, which will lead to them being present in the environment for a long time after their initial release;
- **(bio)degrade in the environment progressively via fragmentation** into smaller and smaller particles, theoretically via 'nanoplastic' particles;
- are **practically impossible to remove** from the environment after release.

Based on monitoring data that does not allow a distinction between secondary and 'intentionally added' microplastics, these properties are known to result in exposure to a wide range of organisms, including invertebrates, fish, marine reptiles, birds and cetaceans (either directly or via trophic transfer). Humans are known to be exposed to microplastics via their diet.

Based on the concerns, several EU Member States have banned products, or certain types of products that contain microplastics, typically 'microbeads' in wash-off cosmetic products.

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

Hazards have also been associated with environmental pollutants, such as Persistent Organic Pollutants (POPs) or metals that adsorb/absorb to microplastic particles in the environment and which may subsequently be released if microplastics are ingested, leading to enhanced bioaccumulation and/or adverse effects from the 'transferred' substances[2]. However, the current scientific consensus on this issue would suggest that ingestion of microplastics does not significantly enhance bioaccumulation of POPs relevant to other types of particulates present in the environment.

The Dossier Submitter has considered the risk assessment of microplastics using the threshold, non-threshold and 'case-by-case' approaches outlined in Annex I of REACH.

Releases to the environment occur principally via three pathways: (i) down-the-drain, (ii) municipal solid waste and (iii) direct release.

The different conditions of use associated with the different product groups/sectors result in large differences in the proportion of the microplastics in products that will be

[2] The microplastic in this sense can be considered as a vector facilitating exposure to another substance, rather than associated with adverse effects itself.

released. For example, almost all of the microplastics in a rinse-off cosmetic can be assumed to be released down-the-drain, whilst for different leave-on cosmetic products the quantity released down-the-drain varies from approximately 15 to 90% (average of approximately 50%), depending on the product category, on the basis of how the products are typically used (i.e. microplastic containing wastes are also disposed of in municipal solid waste). In comparison, 1.5% of the microplastics in consumer paints are assumed to be released down-the-drain at the point of use (with the remainder forming a film and ceasing to be microplastics).

A large proportion of microplastics that are disposed down the drain will subsequently be released to the environment. The down-the-drain pathway has an overall release factor of approximately 50%, with the release to agricultural soil via biosolids contributing 43 of the 50% (i.e. 86% of the releases to the environment from the down-the-drain pathway). This reflects the relatively large proportion of sewage sludge that is applied to agricultural soils or as compost in the EU (On average, 53% of sewage sludge in the EU is disposed to agricultural soils or as compost). The disposal of microplastics via municipal solid waste has an overall release factor of between 0.5 and 5%, depending on assumptions on the quantity of product packaging containing residual microplastics that is recycled.

Tentative 'effect' thresholds for microplastics have been recently proposed by various authors for the marine environment. However, the Dossier Submitter has concluded there is currently insufficient information to derive a robust predicted no effect concentrations (PNECs) for microplastics, that could be used to justify a conclusion that risks are adequately controlled, either based on current exposures in the environment or exposures that are forecast to occur in the future.

The lack of information for threshold-based risk assessment is particularly apparent for the terrestrial compartment (which is a key receptor for intentionally added microplastics either via direct application or the spreading of biosolids) and for any food chain-based route of exposure (i.e. the assessment risks arising through secondary poisoning). Equally, the bioaccumulation properties and hazard of nanoplastics, that are thought to be formed during the (bio)degradation of microplastics, are only currently poorly understood, which currently prevents an assessment of the risks posed by relevant breakdown/transformation products of microplastics in the environment. Theoretical considerations suggest that nanoplastics would be more readily taken up into cells than microplastics, which would lead to greater potential for adverse effects and bioaccumulation.

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

An important property of microplastics to also bear in mind when considering appropriate risk assessment is their 'extreme', arguably permanent, persistence in the environment. This property results in a situation where any releases contribute to a progressively increasing environmental stock, which would eventually result in exposures exceeding safe thresholds in the future, assuming that sufficient information becomes available to reliably derive them for different compartments. In this respect, the relevant risk

characterisation could be considered in terms of *when* will safe thresholds be exceeded, rather than *if* safe thresholds will be exceeded.

Based on these two considerations, the Dossier Submitter considers that microplastics should be treated as a non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment assumed to result in a risk. Therefore, the Dossier Submitter has concluded that the risks arising from intentional uses of microplastics that result in releases to the environment are not adequately controlled.

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

Nevertheless, despite these conclusions, the Dosser Submitter notes that provisional quantitative risk assessment for the marine environment reported in the scientific literature has indicated that the concentrations of microplastics currently occurring at some 'hot spot' locations in coastal regions could already exceed tentative effect thresholds. The concentrations of microplastics are forecast to increase in the environment over time. Therefore, the number of locations exceeding these tentative thresholds is likely to increase. The Dossier Submitter's conclusions do not contradict these.

For each of the sectors assessed, releases of microplastics per year to the environment were determined. In total, the quantity of microplastics that are eventually released into the environment under reasonably foreseeable conditions of use, is estimated to be close to 36 000 tonnes per year (with a range of approximately 10 000 - 60 000 tonnes per year).

To put this quantity of microplastic releases into perspective it is useful to estimate, in illustrative terms, how many tonnes of 'bulk' plastics would be necessary to release this quantity of microplastics per year. The Dossier Submitter has estimated that 36 000 tonnes of microplastics is comparable to an amount of 'bulk' waste plastic in the environment corresponding to approximately six times the present size of the 'Great Pacific Garbage Patch' or the releases of microplastics that could occur per year from about 10 billion plastic bottles.

A recent project for the European Commission[3] estimated of the scale of annual releases of microplastics emitted by (but not intentionally added to) products to EU surface waters. This study reports releases of 176 300 tonnes per year, with a lower and upper range of 71 800 to 280 600 tonnes per year. The greatest contributors to surface water were identified to be road tyre wear (94 000 tonnes per year) and losses of pre-production plastic pellets (41 000 tonnes per year), followed by road markings (15 000 tonnes per year) and the washing of clothes (13 000 tonnes per year). Therefore, although not of comparable size to total annual releases of microplastics from unintentional sources to surface waters, the quantities of intentionally added

[3] http://ec.europa.eu/environment/marine/good-environmental-status/descriptor-10/pdf/microplastics_final_report_v5_full.pdf

microplastics estimated to be released to the environment per year should not be considered to be insignificant, particularly when the 'stock' effects of microplastics are considered.

The Dossier Submitter concluded that the risks associated with EU manufactured or imported mixtures containing microplastics need to be addressed on a Union-wide basis for three reasons:

i. to ensure a harmonised high level of protection of the environment,

ii. some Member States have enacted national measures on microplastics, mainly in wash-off cosmetic products, but only Union-wide measures will curb microplastic emissions effectively, and

iii. to ensure the free movement of goods within the Union.

To justify proposing a Union-wide action, the Dossier Submitter has assessed the risk reduction potential and socio-economic impacts of several restriction options. As a result, the Dossier Submitter is proposing a restriction comprising three types of measures:

- a **restriction on the placing on the market** of microplastics on their own or in mixtures where their use will inevitably result in releases 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 Table 1.)

- a **labelling 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 they are not used or disposed of appropriately (See 2 for the uses this measure is applicable.).

- a **reporting requirement** to improve the quality of information available to assess the potential for risks in the future. (See 2.)

The proposed restriction is targeted at those mixtures that present a risk to the environment that is not adequately controlled and will reduce these risks progressively over the six years following the year of entry into force (approximately 2021). The detailed scope of the proposed restriction is presented in Table 3.

The proposed restriction is estimated to result in a cumulative emission reduction of approximately 400 thousand tonnes of microplastics over the 20 year period following its entry into force (a reduction of 85-95%[4] of the quantified emissions of intentionally added microplastics that would otherwise have occurred in the absence of the restriction taking effect) at a cost of approximately €9.4 billion (NPV). The average cost effectiveness of avoided emissions, for sectors where those have been quantified, is estimated to be €23/kg per year ranging from €1/kg to €820/kg per year (Table 1). The costs of the labelling requirements could not be quantified, but are considered to be negligible (Table 2).

The Dossier Submitter has assessed the effectiveness, practicality and monitorability of the proposed restriction.

[4] Range dependent on assumed effectiveness of labelling requirements and scenario assumptions. Annual emission reduction after all transitional periods have expired is calculated to be >90%.

Table 1 Summary of the impacts of the proposed restriction on placing microplastics on the market, 20-year analytical period

Sector	Emissions reduction (tonnes) (range)	Total costs (€ million, NPV) – central scenario (range) [1)]	Cost effectiveness (€/kg of emissions avoided) (range)	Reference in report
Controlled-release fertilisers and fertiliser additives	262 500 (67 500 - 442 500)	325 (70 – 1 263)	1.2 (0.2 - 18.7)	Table 23
Capsule suspension plant protection products (CSPs) and coated seeds	15 000 (5 250 – 25 500)	58 (29 – 317)	3.9 (1.1 - 60.3)	Table 23
Rinse-off cosmetic products containing microbeads[2)]	55 [2)]	Negligible	n/a	Table 25
Other rinse-off cosmetic products	50 200 (22 500 – 78 000)	1 080 (52 – 2 110)	22 (2 - 27)	Table 25
Leave-on cosmetic products	9 100 (4 200 – 13 900)	7 450 (1 600 – 14 400)	820 (380 – 1 040)	Table 25
Detergents and maintenance products containing microbeads [2)]	100 [2)]	Negligible	n/a	Table 26
Detergents and maintenance products containing encapsulated fragrance [3)]	1 140 (0 – 2 280)	115 (0 – 567)	101 (0 - 249)	Table 26
Other detergent and maintenance products	54 270 (8 685 – 99 850)	266 (10- 1 869)	5 (1 - 19)	Table 26
Waxes and polishes	11 025 (3 900 – 18 150)	92 (8 – 575)	8 (2 - 32)	Table 26
Totals	**403 245 (112 035 - 680 205)**	**9 373 (1 763 – 21 123)**	**23 [4)] (16 – 31)**	

Notes: [1)] Costs are rounded to the nearest million. [2)] 2017 data, use expected to be phased out by 2020. [3)] The low tonnage scenario for detergents and maintenance products is based on the definition of microplastics proposed by A.I.S.E. in the call for evidence. Since polymeric fragrance encapsulates are not in the scope of this definition, the lower range for this category is 0. When considering only the scenarios where fragrance

encapsulates are in scope, the lower value of the range is €25 million for total costs and €21 for cost-effectiveness. [4)] Average cost-effectiveness for the elements of the restriction where costs and emissions have been estimated quantitatively in Table 1.

Table 2: Summary of the impacts of labelling or reporting requirements from 2021 onwards

Sector	Emissions reduction (tonnes / year) (range)	Reference in report
Construction products (fibre-reinforcement of concrete and other adhesives)	No information	Table 24
Medical devices (MD) and *in vitro* diagnostic medical devices (IVD MD)	ca 0.27 tonnes p.a. (0.25–0.29)[a]	Table 27
Medicinal products (Diffusion controlled systems)	Not estimated (current emissions estimated to be 800 (300-1 300) tonnes p.a.)	Table 28
Medicinal products (Ion-exchange based controlled release)	Not estimated (current emissions estimated to be 300 (100-500) tonnes p.a.)	Table 28
Medicinal products (Osmotic systems)	Limited as the osmotic system is a niche market, and the osmotic system < 5mm represent a small proportion of this use	Table 28
Food supplements and medical food	No information	Table 29
Paints and coatings	Not estimated (current emissions estimated to be 2 700 tonnes p.a., 49 000 tonnes over 20 year analytical period)	Table 30
3D printing	No information	Table 31
Printing ink	No information	Table 32
Oil & gas	270 tonnes p.a. (~0 to 550 tonnes p.a.)	Table 33

Note: [a]: the release reduction is associated with the combined proposed measures for medical devices: the implementation of technical means to contain microplastics during the entire life-cycle of the medical devices and *in-vitro* diagnostic medical device + associated labelling

The proposed restriction is considered to be proportionate to the risk. Its cost-effectiveness is similar to REACH restrictions that have been decided previously. Furthermore, the proposed restriction is considered affordable for the impacted supply chains.

An EU-wide restriction limited to the use of microbeads only (microplastics used as an abrasive), as has been proposed by some industry stakeholders as a proportionate measure, would not result in any significant risk reduction as voluntary measures by industry have already largely resulted in substitution to alternative materials.

The Dossier Submitter considers that the proposed restriction is also justified for the following reasons:

- Microplastics are extremely persistent in the environment, are difficult to remove once they are there (irreversibility) and are continuing to be added to the environment (stock effects);

- Transition periods and derogations for certain sectors have been proposed with aim to minimise costs to society, without unnecessary delay in emissions reduction. In this manner industry will have enough time to develop and transition to suitable alternatives, including biodegradable polymers where this is appropriate;
- Labelling requirements have been proposed for uses where risks can be minimised by appropriate conditions of use and disposal. This provision will also enable information exchange along the supply chain;
- Reporting requirements have been proposed to improve the evidence base on the remaining uses of microplastics. This is considered a cost-effective way to enable the Commission and Member States to consider if and to what extent additional action could be needed in 5-10 years;
- While the risks posed by microplastics in the environment (and humans) are currently considered as uncertain the Dossier Submitter expects that the understanding of risks will increase significantly over the next 10 years as microplastics, nanoplastics, and their impacts continue to be further studied. As microplastics are extremely persistent and are practically impossible to remove from the environment once there, based on the option value theory of resource economics, it is appropriate to take cost-effective action now, despite these uncertainties.

For the sectors where specific transitional arrangement are proposed, the measure is justified in the following manner:

- Cosmetic products: The measure is justified for 'microbeads' contained in rinse-off products (i.e. microplastic with an exfoliating or cleansing function) with no transitional arrangements as industry is expected to have voluntarily phased out their use by 2020. The measure is also justified for other rinse-off and leave-on cosmetic products, with respectively four- and six-year transitional periods, based on the similarity to the cost-effectiveness of previous restrictions for substances with similar concerns and affordability for supply-chains.
- Controlled-release fertilisers: a relatively long (5-10 year) transitional period is justified to allow manufacturers to reformulate their products so that they achieve appropriate (bio)degradability in the environment (and that the benefits of the encapsulation technology can be retained in the interim period). Products typically require a minimum level of persistence in the environment to achieve their intended function (12-18 months). Fertiliser additives (e.g. anti-caking agents) could be restricted with a shorter transitional period. These transitional arrangements is intended to be synchronised with those for (bio)degradable polymers foreseen in the recent recast of the EU Fertilising Products Regulation.
- Detergents and maintenance products using 'microbeads': the measure is justified with no transitional arrangements as industry is expected to be able to phase out the use of microbeads as an abrasive by 2020.
- Detergents, waxes and polishes containing microplastics other than microbeads: a transitional arrangement of five years is considered appropriate to give industry sufficient time to substitute microplastics (and that the benefits of the encapsulation technology can be retained in the interim period).

- Capsule suspension plant protection products and biocides: The measure is justified with reference to the cost-effectiveness of previous restrictions for substances with similar concerns. A transitional arrangement of five years is considered appropriate to give industry sufficient time to substitute microplastics (and that the benefits of the encapsulation technology can be retained in the interim period).
- Medical devices and *in vitro* diagnostic medical devices[5]: The measure is justified with reference to the cost effectiveness of previous restrictions for substances with similar concerns. Continued use of existing medical devices and *in vitro* diagnostic medical devices is foreseen with improvements to risk management measures implemented to prevent release of microplastics throughout the product life-cycle.

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 to progress beyond the 'interim' criteria proposed here.

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

The restriction is designed so that enforcement authorities can set up efficient supervision mechanisms to monitor compliance with the proposed restriction and is practically implementable for companies. The Dossier Submitter considers that it is possible to determine if a product includes polymer-containing particles with all dimensions less than 5mm, or 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.

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.

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

[5] as defined in regulations (EC) 2017/745 and (EC) 2017/746

can be reported in the RAPEX system.

The Dossier Submitter believes that the derivation of test methods and criteria for establishing (bio)degradable microplastics will be important to ensure that the proposed restriction does not prevent innovation e.g. the further development of polymer encapsulation technologies. The Dossier Submitter considers that it is important to ensure that the benefits of polymer encapsulation, and similar innovative technologies can remain on the market, as long as their environmental sustainability is assured.

The restriction proposal is based on current scientific knowledge and available information on the intentional uses and risks of microplastics. As scientific understanding will continue to evolve, the proposal also requires that further information is collected on certain uses of microplastics after the entry into force of the restriction. This way, if additional measures are needed in the future, they would be based on the best possible information.

For the above reasons the Dossier Submitter recommends that the restriction is reviewed [5] years after entry into force to see how the market has adapted to the restriction, how well biodegradable polymers perform for the relevant uses and what additional information is available on the risks of microplastics to the environment and human health.

Proposed restriction

Table 3 Brief title: restriction on the intentional use of 'microplastics'

Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	1. Shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than [0.01]% w/w. 2. For the purposes of this entry: a. 'microplastic' means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ *x* ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ *x* ≤ 15mm and length to diameter ratio of >3. 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. d. 'polymer-containing particle' means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w. e. 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas. f. 'gas' means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa.

	g. 'liquid' means a substance or mixture which (i) at 50 °C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. 3. Paragraph 2a and 2b shall not apply to: a. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis). b. Polymers that are (bio)degradable, as set out in the criteria in Appendix X. 4. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastics for use at industrial sites. b. Medicinal products for human or veterinary use. c. Substances or mixtures that are regulated in the EU under Regulation (EC) No xxx/xxxx on Fertilising Products[6] 5. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastic where the microplastic is both (i) contained by technical means throughout the whole lifecycle to prevent releases to the environment and (ii) any microplastic containing wastes arising are incinerated or disposed of as hazardous waste. b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a). c. Substances or mixtures containing microplastic where the microplastic is permanently incorporated into a solid matrix when used. 6. Paragraph 1 shall apply from: a. EiF for cosmetic products (as defined in Article 2(1)(a) of regulation (EC) No 1223/2009) and other mixtures containing microbeads. b. EiF + 2 years for medical devices as defined in regulation (EC) 2017/745 and *in vitro* diagnostic medical devices as defined in regulation (EC) 2017/746.

[6] Regulation under development.

	c. EiF + 4 years for 'rinse-off' cosmetic products (as defined in regulation (EC) No 1223/2009) not already included in paragraph 6(a). d. EiF + 5 years for detergents (as defined in regulation (EC) No 648/2004) and maintenance products. e. EiF + 5 years for fertilising products not regulated in the EU as fertilising products under Regulation (EC) No xxx/xxxx on Fertilising Products that do not meet the requirements for biodegradability contained in that Regulation. f. EiF + 5 years for other agricultural and horticultural uses including seed treatment, plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012. g. EiF + 6 years for 'leave-on' cosmetic products (as defined in regulation (EC) No 1223/2009). 7. From [EIF + 18 months] any manufacturer, importer or downstream user responsible for the placing on the market of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b) or 5 shall ensure that the label and/or SDS, where applicable, '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 lifecycle stage. The instructions shall be clearly visible, legible and indelible. The label shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information labelling shall be included on the instructions for use. 8. From [EiF +12 months], any downstream user using a microplastic derogated from paragraph 1 on the basis of paragraph 4(a) or any importer or downstream user placing a microplastic derogated from paragraph 1 on the market on the basis of paragraphs, 4(b), 5(b) or 5(c) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: a) the identity of the polymer(s) used in the previous year, b) a description of the use of the microplastic, c) the quantity of microplastics used in the previous year, and d) the quantity of microplastics released to the environment, either estimated or measured in the previous year. ECHA shall publish a report summarising the information received by 31 March every year.

Note: Appendix X can be found in Table 21 in Section 2.2.1.6.

Report

1 Problem analysis

1.1 Background

1.1.1 'Microplastic' concern

The concern associated with 'microplastic' particles stems, in straightforward terms, from the potential environmental and human health risks that could be posed by the presence of solid particles of polymer-based materials in the environment that:

- Are small (typically microscopic) making them readily available for ingestion and potentially liable to transfer within food chains.
- Are very resistant to environmental (bio)degradation, which will lead to them being present in the environment for a long time after their initial release and significantly exceeding the very persistent (vP) criteria for substances included in Annex XIII of REACH.
- (bio)degrade in the environment progressively via fragmentation into smaller and smaller particles, theoretically via 'nanoplastic' particles.
- Practically impossible to remove from the environment after release.

These properties are known to result in exposure to a wide range of organisms including invertebrates, fish, marine reptiles, birds and cetaceans (either directly or via trophic transfer) and may also result in exposure to humans via food or water.

Microplastics have been documented to occur in almost all environments investigated, including seawater, sea ice and sediments in polar regions (Obbard, 2018) and the deepest ocean trenches (Peng et al., 2018); they can truly be considered as globally pervasive pollutants. Based on the increasing use of plastics, concentrations of microplastics in the environment are forecast to progressively increase as they are almost impossible to remove once dispersed within the environment and persist almost indefinitely (Jambeck et al., 2015, Geyer et al., 2017a). Many of the reviews conclude with the observation that contamination will continue to increase into the foreseeable future with the result that exposure of organisms is therefore largely unavoidable and likely to increase in magnitude in the future.

Various hazards have been associated with microplastic particles, including both physical/mechanical hazards e.g. obstructing or interfering with the normal functioning of feeding apparatus (potentially after being mistaken for food) or gills, as well as (eco)toxicological hazards introduced by the polymers themselves, or via the presence of residual monomers or polymer additives within the polymer matrix (e.g. stabilisers, plasticisers, flame-retardants, clarifying agents, anti-static agents, etc.).

Hazards have also been associated with environmental pollutants (e.g. POPs) that adsorb to microplastic particles in the environment and which may subsequently be released if microplastics are ingested (the microplastic in this sense can be considered as a vector for exposure).

Incomplete information on the risks arising from exposure to these materials is currently

available, although there is emerging evidence that exposure at current levels in the marine environment is already sufficient to exceed tentative 'no effect concentrations' for adverse effects (Everaert et al., 2018, Besseling et al., 2018). In addition, as concentrations of microplastics in the environment are predicted to increase over time (Geyer et al., 2017a), a larger number of sites are predicted to have microplastic concentrations that exceed no effect concentrations in the future (Everaert et al., 2018, Besseling et al., 2018).

Overall, the available literature describes an emerging understanding of the potential effects of microplastics, including intentionally-added microplastics, but only limited evidence that risks are likely to be occurring in the environment; despite ingestion and transfer to higher trophic levels being clearly observed. The extent of the scientific understanding of the hazards and risks posed by microplastics are summarised in subsequent sections of this report and in Annex C.

This restriction investigation is focussed on microplastics that are released to the environment as a consequence of the use[7] of products that intentionally contain or release them, although we have identified that the former is more common[8].

Work being done by others is focussed on legislation addressing microplastics released to the environment through the degradation of larger pieces of plastic (typically termed secondary microplastics[9] e.g. particles from the road wear of tyres) or through the littering of certain 'single-use plastics' e.g. cigarette butts.

Important elements of our assessment were to consider:

a) How microplastics should be appropriately identified (definition), and;

b) How and to what extent microplastics that are intentionally added to products are released to the environment and contribute to the microplastics concern.

The former is often referred to as the 'microplastic' definition. At the outset of this investigation one of the key questions related to whether the microplastic concern ought to be limited to common polymer-based synthetic 'plastics', such as polypropylene or polyethylene, or if other synthetic polymer-based materials that may also be extremely persistent in the environment as particles should be considered to contribute to the concern (e.g. elastomeric materials from the degradation of vehicle tyres or rubber infill in sports pitches).

Similarly, this concern is not limited to the marine environment, although the occurrence of plastic litter in the marine environment has raised awareness of the potential impacts of these materials, both for scientists and policy makers. In addition to the extensive literature of the occurrence of microplastics in the marine environment, microplastic particles have been reported to have been found in treated and untreated sewage

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[7] Considered to comprise the releases to the environment arising from 'reasonably foreseeable conditions of use'

[8] It is assumed that all microplastic particles are added to, or incorporated in, products to provide a technical function. Therefore, any deliberate addition of a microplastic to a product, irrespective of the specific function, is per se considered to be an intentional use.

[9] Note that there is some inconsistency in the use of the terms primary and secondary microplastics, with some authors including all releases of 'microplastics' from freshwater systems as primary microplastics, even where these have been formed from the degradation of larger articles, such as tyres or rubber granules (from synthetic sports surfaces), that are more typically considered to be secondary microplastics.

effluent (wastewater), sewage sludge (that is often applied to agricultural land as biosolids), freshwater and in the terrestrial environment. In addition to species of marine fish and shellfish, which is well documented (Lusher et al., 2017), microplastics have also been found in various foods and drinking water (Iiguez et al., 2017, Karami et al., 2017b, Karami et al., 2017a, Liebezeit and Liebezeit, 2014, Liebezeit and Liebezeit, 2013, Liebezeit and Liebezeit, 2015, Kosuth et al., 2018).

As a general observation, the use of the term 'microplastic', although now pervasive, may not appropriately characterise the diversity of synthetic polymeric materials associated with the concerns identified above.

We acknowledge that 'plastics' are typically understood to be solid materials comprised of 'mixtures' of certain organic polymers together with additives and that, therefore, not all polymers are strictly 'plastic'. However, for the purposes of this assessment, we propose that any synthetic polymer (with or without additives) that has the potential to exist as a small (typically microscopic) solid particle in the environment, and which is resistant to (bio)degradation, should be considered to be consistent with the concerns associated with the term 'microplastic'.

However, it is apparent that many stakeholders maintain a strictly semantic interpretation of the term 'microplastic', rather than acknowledge that the term could equally be used as a 'catch-all' term for synthetic polymer particles that demonstrate extreme persistence in the environment should they be released.

1.1.2 Request to develop an Annex XV restriction proposal

The request from the Commission was received by ECHA on 9 November 2017[10] and can be summarised, as follows:

- Prepare an Annex XV dossier in view of a possible restriction of *synthetic water-insoluble polymers of 5mm or less in any dimension (i.e. microplastic particles)*
- Microplastic particles, intentionally added to, or used in, certain products may pose a threat to the aquatic environment; including as a possible vector for POPs to enter the [human] food chain.
- Member States are already taking measures to prohibit use in some products, despite uncertainties in terms of risks/impacts (i.e. scientific research is ongoing); restriction process under REACH must be triggered.
- Commission is of the opinion that a potential risk to the environment may arise from the presence of microplastic particles used in the production of products for consumer and professional use that get into the aquatic environment, and that this risk needs to be addressed on a Union-wide basis
- Commission requests ECHA to develop an Annex XV report concerning the use of intentionally added microplastic particles to consumer or professional use products of any kind.

[10] Entered into the ROI on 17 January 2018; expected date of submission 11 January 2019

- ECHA should assess the need to include additional criteria in the definition of microplastic particles (e.g. biodegradability, solid state in the aquatic environment).

ECHA subsequently clarified with the Commission that the call for evidence, and any subsequent Annex XV report, should also consider industrial uses of microplastics, in addition to consumer[11] and professional[12] use products. This was necessary because the study undertaken by AMEC preceding the request from the Commission had identified uses of microplastics as abrasive blasting media[13] and in the oil and gas sectors (AMEC, 2017).

The Commission's description of 'microplastic particle' in their request does not include the term 'plastic', but rather refers to synthetic polymers. The description includes the term 'insoluble' to further qualify the types of synthetic polymers that should be investigated, but the physical state or relevant morphology of the material, e.g. solid, is not further qualified. This can be considered as a rather broad starting point.

Emphasis of the request is on the releases to the aquatic environment leading to risks to the environment. As effects via the food chain are mentioned this also implies that risks to human health could also be considered if they are relevant. However, risks to humans via food are not explicitly mentioned in the request.

1.1.3 EU Member State legislation on intentionally added microplastics

Several EU MS have banned products, or certain types of products, that contain microplastics, typically 'microbeads' in rinse-off cosmetic products with an exfoliating or cleaning function. Relevant details are summarised in Table 4 below. The table illustrates that most of the EU countries have not yet taken action with regard to the microplastics concern through their national regulations.

Table 4: Overview of European regulatory action on intentionally added microplastics

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
Belgium			Plan to ban plastic particles (microbeads) in all rinse-off cosmetic products and toothpastes by 2019.
France		**X**	Ban the placing on the market of rinse-off cosmetic products for exfoliation or cleaning that contain solid plastic particles (define as microbeads smaller than 5 mm made of plastic in whole or in part, obtained by a hot-shaping process). Exemption for particles of natural origins (i) not persisting in the environment, (ii) not releasing active or biologic substance, (iii) not affecting animal food chain Entry into force: 1 January 2018

[11] According to the ECHA Guidance R.15, a "consumer product" is defined as a substance, mixture or article that can be purchased from retail outlets by members of the general public.

[12] ECHA Downstream User Guidance defines "professional users" as users who apply substances in a professional capacity which is not regarded as an industrial use. This includes craftsmen, and service providers that may or may not have a fixed workplace or workshop. This life-cycle stage covers all activities of a substance carried out by professional workers. These activities do not take place at industrial sites, and hence the nature of exposure stemming from them is different. The potential group of users is large, and the amount used by a single user is typically low compared to industrial use. This life-cycle stage covers the activities of craftsmen, cleaners, employees in public administration and the self-employed.

[13] https://compomat.com/plastic-blasting-media/

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
Ireland	**X**	**X**	Plan to prohibit the manufacture and use of certain products containing plastic microbeads (rinse-off cosmetic products and household cleaning products). Public consultation in 2018. Not yet in force.
Italy		**X**	Ban the marketing of exfoliating rinse-off cosmetic products or detergents containing microplastics No exemption Entry into force: 1 July 2020
Sweden		**X**	Ban the placing on the market of cosmetic products that are intended to be rinsed off or spat out and contain microplastics (defined as 'solid plastic particles that are smaller than 5 mm in any dimension and insoluble in water') which have been added to cleanse, exfoliate or polish. Exemption might be given to microplastics that have been manufactured using naturally occurring polymers as a raw material, are quickly broken down into monomers in the aquatic environment, and do not pose any risk to aquatic organisms Entry into force: July 2018
United Kingdom	**X**	**X**	Ban the use of microbeads (defined as 'any water-insoluble solid plastic particle of less than or equal to 5mm in any dimension') as an ingredient in the manufacture of rinse-off personal care products and the sale of any such products containing microbeads. Entry into force: January 2018 (manufacturing), and June 2018 (sales)

Source: SAM (2018), internet searches

1.1.4 Legislation on intentionally added microplastics outside of the European Union

Very few countries outside of the EU have already introduced bans on intentional use of microplastics, or one kind or another, or have drawn up voluntary agreements with industry for their phase out.

Table 5 below gives a sample of countries outside Europe that have put in place legislative measures that clearly refers to microplastics. The table provides only an illustration of worldwide action and is not intended to list all and every piece of legislation currently addressing the microplastics concern.

Table 5: Overview of non-EU regulatory action on intentionally added microplastics

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
Australia			Voluntary actions from industry on-going
Brazil			Intention to ban the manufacturing and placing of the market of personal care products containing microbeads.
Canada	**X**	**X**	Ban on the manufacturing, import, and placing on the market of any toiletries (including natural health product and non-prescription drug) for cleansing or hygiene that contain microbeads. Entry into Force: 1 July 2018
India			Intention to ban the use of microbeads as ingredients in cosmetics, household laundry detergent bars, synthetic detergents for washing woollen and silk fabrics, synthetic detergents for industrial purposes, and household laundry detergent powders.

Country	Ban on manufacture	Ban on placing on the market	Regulatory action overview
New-Zealand	**X**	**X**	Ban on the manufacturing and placing of the market of wash-off products containing microplastics with the purposes of exfoliation, cleaning, abrasive cleaning or visual appearance of the product (e.g. . exfoliating and cleaning cosmetics, abrasive cleaning products, car and industrial cleaning products). Exemption: medical devices and medicines Entry into Force: 7 June 2018
Republic of Korea	**X**	**X**	Ban on the manufacturing and placing of the market of cosmetics and sanitary aids (gargle, toothpaste and teeth whitening) containing microplastics. Entry into Force: 19 May 2017 (sanitary aids) and 1 July 2017 (cosmetics)
United States of America	**X**	**X**	Ban on the manufacturing and placing of the market of rinse-off products with exfoliating or cleansing function on the human body or any part thereof. Exemption: drugs that are not also cosmetics Entry into Force for rinse-off cosmetics: 1 July 2017 (manufacturing), and 1 July 2018 (sales) Entry into Force for rinse-off cosmetics that are also non-prescription drugs: 1 July 2018 (manufacturing), and 1 July 2019 (sales)

Source: United Nations Environment Program (2018), internet searches

1.1.5 Other relevant EU activities

1.1.5.1 EU council and parliament

On the 13th of September 2018 the European Parliament adopted a resolution on European Strategy for plastics in a circular economy (2018/2035(INI)) where it calls on the Commission to introduce a ban on microplastics in cosmetics, personal care products, detergents and cleaning products by 2020 and, furthermore, calls on ECHA to assess and prepare, if appropriate, a ban on microplastics which are intentionally added to other products, taking into account whether viable alternatives are available[14].

On 19 December 2018, the European Parliament and the Council of the European Union reached a provisional political agreement on the ambitious new measures proposed by the Commission to tackle marine litter at its source, targeting the 10 plastic products most often found on our beaches as well as abandoned fishing gear.

It envisages different measures to apply to different product categories. Where alternatives are easily available and affordable, single-use plastic products will be banned from the market, such as plastic cotton buds, cutlery, plates, straws, drink stirrers, sticks for balloons, products made of oxo-degradable plastic and food and beverage containers made of expanded polystyrene. For other products, the focus is on limiting their use through a national reduction in consumption; on design and labelling requirements; and waste management/clean-up obligations for producers.

[14] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2018-0352+0+DOC+PDF+V0//EN

1.1.5.2 Scientific Advice Mechanism (SAM)

The EU Commission's Group of Chief Scientific Advisors[15] decided at its 12th meeting (27 April 2018) to launch work leading to scientific advice on microplastic pollution based on a review of scientific evidence by SAPEA. The Group of Chief Scientific Advisors adopted an Initial Statement on the subject on 9th July during its plenary meeting in Toulouse[16]. The Scientific Advisors intend to deliver to the Commission an Explanatory Note before the end of 2018 based on a SAPEA scientific evidence review report, and a Scientific Opinion in 2019.

The Dossier Submitter has co-operated with the EU SAM through the process of developing this report.

1.1.5.3 EU funded scientific research projects

Significant research efforts are being expended to further under the microplastics issue. As well as countless individual research projects, the EU has funded several large research projects relevant to microplastics, which are briefly described below.

As part of the Oceans Joint Programming Initiative (JPI Oceans)[17], four research projects with overall funding of € 7.7 million were launched in January 2016 to investigate ecological aspects of microplastics as a three-year pilot (these projects are therefore scheduled to finish during 2019)[18]:

- BASEMAN focuses on overcoming standardisation and comparability deficiencies in the measurement and monitoring of environmental microplastics;
- EPHEMARE is examining the ecotoxicological effects of marine microplastics;
- PLASTOX is investigating the ingestion, food-web transfer, and ecotoxicological impact of microplastics, together with persistent organic pollutants (POPs), metals and plastic additive chemicals associated with them, on marine species and ecosystems; and
- WEATHER-MIC investigated the weathering processes of microplastics and the distribution and toxic impacts of the resultant particles and the implications for risk assessment.

The coordination and support action Seas, Oceans and Public Health in Europe (SOPHIE) which runs from 2017 to 2020 exploring the interplay between the health of the marine environment and that of humans will include work on microplastics. It aims to build a network of researchers and practitioners from two traditionally distinct groups; marine and maritime specialists; and the medical and public health community.

TOPIOS (Tracking Of Plastic In Our Seas) is a 5-year (2017-2022) research project, funded through a European Research Council Starting Grant. Its goal is to improve understanding of the way plastic litter moves through our ocean by developing a comprehensive model for tracking marine plastic through our ocean.

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

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

[17] http://www.jpi-oceans.eu/

[18] http://www.jpi-oceans.eu/ecological-aspects-microplastics

In addition to these completed projects, relevant finished projects include: CLEANSEA (2013-15) addressing the monitoring and management of marine litter; NANOPLAST (2013-16) consisting of a computational modelling approach to the interaction of nanoplastics with biological membranes; and FreshwaterMPs (2015-17) investigating the degradation and fate of plastics in freshwater systems and the toxicity of microplastics to freshwater biota.

In general, it can be readily appreciated that large quantities of information relevant to the microplastics issue has become available over recent years and that significantly more information will become available in the next five to ten years that will enhance current understanding.

Where ongoing and completed projects have published research in the scientific literature they have been considered as part of the literature screening and review undertaken for this Annex XV report.

1.2 Regulatory definition of 'microplastic'

Considerations on the identification of 'microplastics' under REACH was communicated to stakeholders in the note on substance identification and the potential scope of a restriction on uses of 'microplastics', published by ECHA in July 2018[19]. This section summarises relevant considerations and presents a proposal for a regulatory definition of microplastics. Further details are presented in Annex B.

1.2.1 General considerations

The term "microplastic" was first used to describe minute pieces of marine litter by Richard Thompson and co-authors in their seminal publication in the journal Science: 'Lost at sea: where is all the plastic?' (Thompson et al., 2004). The term has since become widely used not only in scientific publications but also across the mainstream news and media.

However, whilst many different definitions have been proposed, there is no standardised understanding of what substances, and in what physical form, the term actually refers to. This has resulted in inconsistencies in different scientific investigations as well as between regulations implemented (or proposed) in different countries (or jurisdictions within countries) to address the microplastic concern.

Examples of regulatory approaches for microplastics' implemented in different countries, as well as academic and research organisations), typically use 'microplastic' as an umbrella term and then define the meaning in relation to the context in question more precisely (for examples see Annex A). Some approaches have used the terms 'microbead' and 'microplastic' as synonyms; most significantly the US microbead-free waters act 2015 and The Environmental Protection (Microbeads) (England) Regulations 2017. In many cases the term microbead is associated with a synthetic polymer-based particle used for exfoliating, scrubbing or polishing although it is noteworthy that the

[19] https://echa.europa.eu/documents/10162/13641/note_on_substance_identification_potential_scope_en.pdf

English regulations use the term microbead without specifying its function[20].

The term 'plastic', whilst often understood on an intuitive level, is often interpreted differently on a technical level. This ambiguity is highlighted in a European Committee for Standardisation (CEN) technical report on vocabulary in the field of degradable and biodegradable polymers and plastic items (CEN, 2006). The report notes that:

"The terms plastic or plastics do not have a precise meaning because they reflect rather complex formulated systems whose exact composition is generally unknown."

The International Standards Organisation (ISO) technical report on plastics vocabulary (CEN, 2013) define 'plastic' (as a noun) as:

"material which contains as an essential ingredient a high polymer and which, at some stage in its processing into finished products, can be shaped by flow

Note 1 to entry: Elastomeric materials, which are also shaped by flow, are not considered to be plastics."

In the ISO definition 'plastic' is a state of a 'material' that contains a 'high polymer' that can be "shaped by flow". These terms, in turn, require definition. It is clear that the definition of "plastic" is, similar to microplastic, not subject to universally accepted standardisation.

Looking at the 'microplastic' definitions used to date in different regulatory jurisdictions (Annex A), the term 'plastic' is usually defined in the EU with reference to the term 'polymer' although the definition of 'polymer' is not consistent. Some use the REACH Regulation definition (as proposed or with variations) whilst others list specific polymers (e.g. polyethylene). It is worthwhile to note that the REACH definition of polymer covers both naturally occurring and synthetic polymers, but that the microplastic concern is, in general, associated with synthetic polymers. This will be discussed in later sections of this report.

Many authors that have reflected on how to appropriately define the term 'microplastic' resulting in a range of different definitions (Hartmann et al., 2019). Some definitions are specific to 'synthetic polymers', and/or to specific polymer classes (e.g. thermosets) and/or some to certain polymer characteristics (e.g. those that retain their shape during use). However, certain of the other aspects of microplastic definitions appear almost universally, for example: 'particle', 'solid' and 'dimensions of 5 mm or less'. Many definitions have additionally included considerations with regard to aspects such as 'solubility' and '(bio)degradability'.

In terms of relevant dimensions, different definitions have included a size criterion of < 5 mm in one dimension, in all dimensions or not specified a dimension. The upper limit of 5mm appears to be universally accepted, but the Dossier Submitter notes that this is acknowledged to be a pragmatic solution that reflects 'operational considerations' (based on the classification of different types of marine litter during monitoring) as much as (eco)toxicological hazard or risk. Hartmann et al. (2019) note that it is not yet possible to set appropriate size criteria for microplastics and other types of plastic litter based

[20] Whilst the Environmental Protection (Microbeads) (England) Regulations 2017 do not specify the function of the microplastic within the scope of the regulation the legislation it is, as many others, limited in scope to 'wash-off' cosmetic products (also termed 'rinse-off' cosmetics, such as face washes, scrubs, toothpastes and shower gels). These types of products typically utilise microplastics for their exfoliating/abrasive functions, although microplastics are known to have other functions in wash-off cosmetics e.g. as opacifying agents.

solely on (eco)toxicological considerations. Nevertheless, a size limit of 5mm or less is associated with particles that could be readily ingested by organisms (or would generate smaller particles over time if released to the environment). Ingestion of larger items of plastic waste (e.g. plastic bags) are more typically associated with physical hazards for macrofauna or megafauna, such as physical blockage of the digestive tract after accidental or mistaken ingestion (e.g. marine reptiles, birds and whales).

Regulatory oversight and action in the EU and elsewhere, to date, has focused on uses of microplastics/microbeads in cosmetic and personal care products, particularly wash-off/rinse-off consumer products (e.g. facial scrubs). However, polymeric materials with physical properties that are broadly equivalent to the microplastics used in wash-off/rinse-off cosmetics are used in a multitude of other applications across other sectors where they could also inevitably result in releases to the environment under reasonably foreseeable conditions of use. Therefore, any 'fit for purpose' regulatory definition should be applicable across different product categories and sectors.

1.2.2 Identity of the substance(s), and physical and chemical properties

1.2.2.1 Proposal for a regulatory definition of a microplastic under REACH

The study undertaken by the Commission preceding the request to ECHA for a restriction proposal (AMEC, 2017) had also noted that a range of different definitions could be considered for microplastics. The request from the European Commission to develop a restriction proposal on intentionally added microplastics included a further definition, referring to microplastic particles as *'synthetic water-insoluble polymers of 5mm or less in any dimension'* (COM, 2017).

ECHA, with the agreement of the Commission, subsequently adopted a 'working definition' for microplastic particles for its call for evidence launched in March 2018 at the beginning of its analysis as *'any polymer , or polymer-containing, solid or semi-solid particle having a size of 5mm or less in at least one external dimension*. In this case 'polymer' referred to the REACH definition for polymers.

The call for evidence requested stakeholder input on the definition and where this was received it was into account.

After considering the advantages and disadvantages of the various definitions for microplastic, the Dossier Submitter proposes the following definition for the purposes of this restriction. Further details are outlined in Section 2.2.1.1 and in Annex B.

- **'microplastic'** means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ *x* ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ *x* ≤ 15mm and length to diameter ratio of >3. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis) are excluded, as are polymers that are (bio)degradable.
- **'microbead'** means a microplastic used in a mixture as an abrasive i.e. to exfoliate, polish or clean.
- **'polymer'** means a substance within the meaning of Article 3(5) of Regulation (EC) No 1907/2006 (REACH).
- **'particle'** is a minute piece of matter with defined physical boundaries; a defined physical boundary is an interface.

- **'polymer-containing particle'** means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w.
- **'solid'** means a substance or a mixture which does not meet the definitions of liquid or gas.
- **'gas'** means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa.
- **'liquid'** means a substance or mixture which (i) at 50 °C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa.

The Dossier Submitter has not interpreted the term 'microplastic' in a strictly semantic sense, but rather considers that the term is representative of small, typically microscopic, synthetic polymer particles that resist (bio)degradation.

The intent of the definition is not to regulate the use of polymers generally, but only where they meet the specific conditions that identify them as being 'microplastics'.

Hartmann et al. (2019) recently published recommendations for a standardised definition and categorisation framework for plastic debris, including for microplastics. Whilst there are some differences between the regulatory definition of a microplastic developed for the purposes of this restriction and that presented by Hartmann et al. (2019), the approaches are similar in most respects. This is particularly notable in relation to the diversity of synthetic polymer types that are recommended to be included as well as the exclusion of naturally occurring polymers and polymer gels.

1.2.2.2 Justification for grouping

The substance identification currently proposed for the restriction is 'polymers', as defined in REACH Article 3(5), supplemented with criteria on relevant particle morphology, physico-chemical properties and persistence in the environment.

The justification for grouping is underpinned on the basis of the similarity of physical-chemical properties, morphology and persistence in the environment and the link between these properties and the 'microplastic concern' introduced in Section 1.1.1. All substances with these properties are 'microplastics', irrespective of the identity of the particular polymer.

1.3 Manufacture and uses

This section summaries the uses of 'intentionally added' microplastics in consumer and professional products in the EEA. Additional information is included in Annex D. Some indicative information on the manufacture of microplastics, in terms of the mixtures placed on the market for downstream users, is provided in Annex A.

1.3.1 Summary of uses

The Dossier Submitter identified various intentional uses of microplastics in consumer and professional products, either from the call for evidence or literature searches. These

uses are summarised in Table 6. Not all of these uses of microplastics result in releases to the environment, which will determine if and how they would be affected by the proposed restriction. In addition, different uses often have a different 'substitution profile' and there would also be different consequences for society for a restriction on use. These are described in the 'Impact Assessment' outlined in Section 2 of the report with supporting information and analysis presented in Annex D.

Table 6 Summary of uses and technical functions of microplastics in consumer and professional products

Product group	Brief details of use and technical function(s)
Cosmetic products	Microplastics are used in cosmetic products to provide variety of functions, e.g., exfoliating/cleansing functions, opacity control, smooth and silky feeling in products and an illuminating effect on the skin. They can be used in lipstick, loose or pressed powders and liquid or thick emulsions with powdery feel. Microplastics may also be used as a carrier for other ingredients.
Detergents and maintenance products	Microplastics are used in detergents and maintenance products to provide a range of functions, including as abrasives, fragrance encapsulations, opacifying agents and anti-foam agents. They can be used in surface cleaning products, fabric softeners, dishwashing liquids, waxes and polishes.
Agricultural and horticulture	Microplastics are used in controlled-release formulations (CRF) for fertilisers and plant protection products (typically as microencapsulation), as fertiliser additives (e.g. anti-caking agents) and as soil conditioners. Similar to microencapsulation, seed coating involves the deposition of polymeric material on seeds such that coated seeds may be considered microplastic particles as they fall below the upper size limit of 5 mm.
Medical devices and *in vitro* diagnostic medical devices	Microplastics have various functions in medical devices (MD) and *in vitro* diagnostic medical devices (IVD MD). Microplastics in medical devices are used as polymeric filters, adsorber and absorber granulates and in ultrasound devices. Microplastics, often with inorganic (e.g. iron oxide) cores and chemically functionalised surfaces, are ubiquitous as reagents in IVD medical devices and are essential in all automated IVD tests conducted worldwide. Microplastics are also frequently used in the manufacturing of IVD reagents and devices (e.g. chromatography columns used to purify antibodies).
Medicinal products for human and veterinary use	In medicinal products, microplastics are the backbone of many 'controlled-release' medicines: in contrast to immediate release, these formulations can deliver drugs with a delay after its administration (delayed release), or for a prolonged period of time (extended release), or to a specific target organ in the body (targeted release dosage). Controlled-release mechanisms allow to protect the active substance from the physiological environment (e.g. enzymes, pH), to control its release at a specific predetermined rate in specific location/organ. In addition, microplastics can be used for their taste masking function. In medicinal products, microplastics are often classified as excipients, but they can also be authorised as an active pharmaceutical ingredient (API).
Food complement and medical food	Similarly to the medicinal products use, microplastics are used in the formulation of food complements (e.g. vitamins) as 'controlled-release' agent, and to hide unpleasant taste.
Paints, inks and other coatings	Microplastics are an integral part of polymer dispersion binders in water-based paints and coatings, where they are present to coalescence into films (film-forming function). Microplastics are also used as speciality additives in architectural and industrial coatings (wood, plastic, metal). Microplastic additives enhance properties like matting, abrasion resistance, scratch resistance, mark resistance and side sheen control. In addition, they are used to add texture and structure to surfaces. Microplastics are also used in combination with metallic pigments to achieve a sparkle effect by controlling pigment orientation.
Oil and gas	Microplastics are used as additives in drilling and production chemicals (lubricants, friction reducing agents, antifoam agents, demulsifiers).
Plastics	Microplastics are used as speciality additives in thermoplastic masterbatches and engineered materials as light diffusion agents, anti 'blocking' agents and to introduce surface structure. Pre-production plastic (resin) pellets (also called

Product group	Brief details of use and technical function(s)
	'nurdles') that are used as raw materials in extrusion / moulding processes in article production, by nature of their size, are also microplastics.
Technical ceramics	Microplastics are used as a pore forming additive to achieve the correct size and amount of pores in porous ceramics. According to industry stakeholders these materials are combusted as part of the production process.
Media for abrasive blasting	Plastic granules are used to remove difficult contaminants e.g. paint, plastics, rubber and adhesive from plastic tools and dies etc. The underlying surface is normally not affected by the blasting as the different plastic materials are somewhat softer than those made of minerals or metal. The material of the granules varies depending on the wanted features; they may consist of poly methyl metacrylic polymer, melamine, urea formaldehyde, urea amino polymers or poly amino nylon type. The granulate size ranges from 0.15-2.5 mm and the relative density is > 1000 kg/m3, indicating they will not float.
Adhesives	The intentionally added microplastics can be used as a spacer in adhesives and metallic plated microplastic particles can be used in conductive adhesives in electronics.
3D printing	Polymeric materials are used in Fused Deposition Modelling (FDM) printers for consumers. These printers are smaller than industrial ones and can be bought by private consumers to print smaller objects.
Printing inks	The toner in laser printing is mostly made of granulated plastic to make the powder electrostatic.

Notes: See Annex D for additional information.

1.4 Risk assessment

1.4.1 Approach to risk assessment

The section will summarise the available information on the hazard and risk of 'microplastics' principally from an environmental perspective, although relevant information for human health risks will be briefly discussed (indirect exposure via food). Hazard and risks will be explored from three complementary perspectives and overall conclusions will be presented in form of a 'weight of evidence'. The assessment has been informed by a comprehensive structured literature screening and mapping.

Numerous comprehensive assessments of the (eco)toxicity of microplastics have been published in recent years, such as those reported by Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP, 2016, GESAMP, 2015, GESAMP, 2010) and the Food and Agriculture organisation of the United Nations, FAO (Lusher et al., 2017). The European Food Safety Authority has also published a note on the risks of microplastics in food (EFSA, 2016). The assessment in this report aims to build upon these, and other, previous assessments. Where relevant, recent research that had not been considered in previous assessments will be highlighted.

It should also be noted that SAPEA[21] are due to publish an 'evidence review report' on microplastics in nature and society in January 2019 as part of the European Commission Group of Chief Scientific Advisors work on microplastics[22]. This review has been conducted independently from the assessment presented in this report and should be considered as complementary to it.

Increasingly, studies focussing specifically on the risk assessment of microplastics have been published (Koelmans et al., 2017a, Burns and Boxall, 2018, Everaert et al., 2018,

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

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

Besseling et al., 2018). Therefore, particular attention has been paid to these studies.

Risk assessment of chemicals under REACH can be performed in several ways, depending on the hazard properties of the substance. As the hazard properties of microplastics are complex and in many instances uncertain (e.g. issues surrounding particle size, persistence, degradation) a range of risk assessment paradigms will be considered in this report, specifically:

1. 'Conventional' (eco)toxicological risk assessment based on the derivation of an effects threshold (PNEC) and quantitative risk characterisation (PEC/PNEC or RCR approach),

2. PBT/vPvB perspective, and

3. Case-by-case assessment according to para 0.10 of Annex I of REACH.

A 'case-by-case'[23] approach to hazard and risk assessment of microplastics is investigated, underpinned by what can be referred to as their 'extreme' persistence in the environment and the potential for this to result in a non-reversible pollution stock associated with potential for environmental and/or human health risks.

The risk assessment has been supported by an assessment of the releases arising from the intentional uses of microplastics

A summary of the available information on reported exposures and the environmental fate of microplastics is also provided, although these studies are of limited usefulness as they do not distinguish intentionally added and 'secondary' microplastics in the environment.

The information in this section of the report is presented as follows:

- Releases to the environment
- Environmental fate
- Environmental and human health hazard
- Risk characterisation

1.4.1.1 Literature screening

The risk assessment has been underpinned by a structured search and screening of the scientific and grey literature using Scopus[24], which resulted in the identification of around 900 articles relevant in some respect to the risk assessment of microplastics (e.g.

[23] According to Annex I para 0.10 of REACH. There is no specific guidance produced on this type of risk assessment. However, the CSA-IR guidance states 'in relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and summarised in the safety data sheet.' In the CSRIR guidance, chapter E it states 'Risk characterisation of particular effects not covered by the other protection targets, e.g. ozone depletion, photochemical ozone creation potential (c.f. Annex 1 (0.10)), shall be done on a case-by-case basis and this should be documented and justified in the CSR.' In previous risk assessments carried out under ESR this type of assessment was used for MBTE which gives a strong taste to drinking water.

[24] Scopus is an abstract and citation database of peer-reviewed literature: scientific journals, books and conference proceedings collated by Elsevier. Available at www.scopus.com

studies on their use, release, fate, occurrence, exposure and effects). Key metadata from these articles were extracted and summarised to allow studies relevant to different aspects of microplastic risk assessment to be readily categorised and summarised. Discussions with stakeholders during the development of this report, including scientific experts, have also identified relevant studies that were not highlighted in the literature screening, particularly recently published studies. These studies have been included in the assessment.

On the basis of the screening it can be readily appreciated that the scientific literature relevant to the hazard and risk assessment of microplastics has grown rapidly over the last 10 years from a small number of publications to a large and diverse literature describing the detection (i.e. analytical methods), occurrence, sources, exposure and (eco)toxicity of microplastics.

From the available literature, it is clear that research has been focussed primarily on the marine environment, but that recently there is a greater focus on the freshwater aquatic and terrestrial compartments. There is also an emerging literature on analytical methods for detecting microplastics, particularly in complex environmental samples. In general, although considered likely to occur in the environment, there is an absence of information on nanoplastics, which is a significant knowledge gap.

1.4.2 Releases to the environment

1.4.2.1 Principal pathways into the environment

Releases of intentionally added microplastics to the environment from the specific uses (product groups) identified are each associated with one or more of the following three principal release pathways of microplastics to the environment:

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

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

For example, 'rinse-off' cosmetic products are disposed of predominantly down the drain with wastewater whilst some 'leave-on' cosmetic products are more likely to be disposed of in municipal solid waste (although they may also be washed-off and disposed of via wastewater). In contrast, microplastics used in fertilising products are dispersed directly into the environment on application of the fertilising product, without a preceding waste life-cycle stage.

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

Release estimates are based on the quantity of microplastics used that are disposed of

via each of the three pathways. The three pathways are, on the whole, independent, but in some specific circumstances are linked, e.g. where product packaging disposed of in municipal solid waste leads to wastewater releases through the washing of shredded material during recycling. The proportion of microplastics disposal via each of the principal pathways in each of the specific uses assessed are given in Table 7. Further details of the approach to estimate the quantities releases via the different pathways for each of individual uses are given in Annex G.

The following sections outline the methodology, assumptions and underlying data used to derive an EU level estimate of the microplastics released to the environment after a product containing intentionally added microplastics is used and subsequently disposed of via one of the three principal pathways.

The methodology essentially comprises an EU level assessment of the fate and behaviour of microplastics within the applicable waste treatment / management processes that they will likely to be subject to after their initial use and subsequent disposal (e.g. wastewater treatment or municipal solid waste).

Where data allows, releases to the environment have been estimated for each of the specific uses quantitatively. Where a quantitative assessment has not been possible a semi-quantitative or qualitative approach will be presented. Release factors are based, where possible, on empirical data on the fate and behaviour of microplastics during waste treatment identified from the literature. Where such data is not available default values from ECHA Guidance or other relevant sources have been applied. In both cases, sources are clearly identified in the summary tables below.

The methodology allows a large part of the releases to different environmental compartments to be quantified and for 'release factors' for specific uses to be calculated (i.e. the proportion of the quantity used in products that will eventually be released to the environment). The methodology facilitates an understanding of the 'mass flows' of microplastics through different pathways into the environment and allows the most significant pathways into the environment to be identified. The methodology also enables the 'effectiveness' of certain consumer behaviours and waste management practises to prevent or minimising releases of intentionally added microplastics to the environment to be evaluated.

The estimated release from the different specific uses (product groups) are reported in Section 1.6 of the report and is termed the 'baseline'. The impact on the baseline of the proposed restriction is described in the impact assessment, reported in Section 2.

The range of conceptual source, pathway, receptor relationships for microplastics modelled as part of this assessment are summarised in Figure 1 and are described in further detail in the sections below.

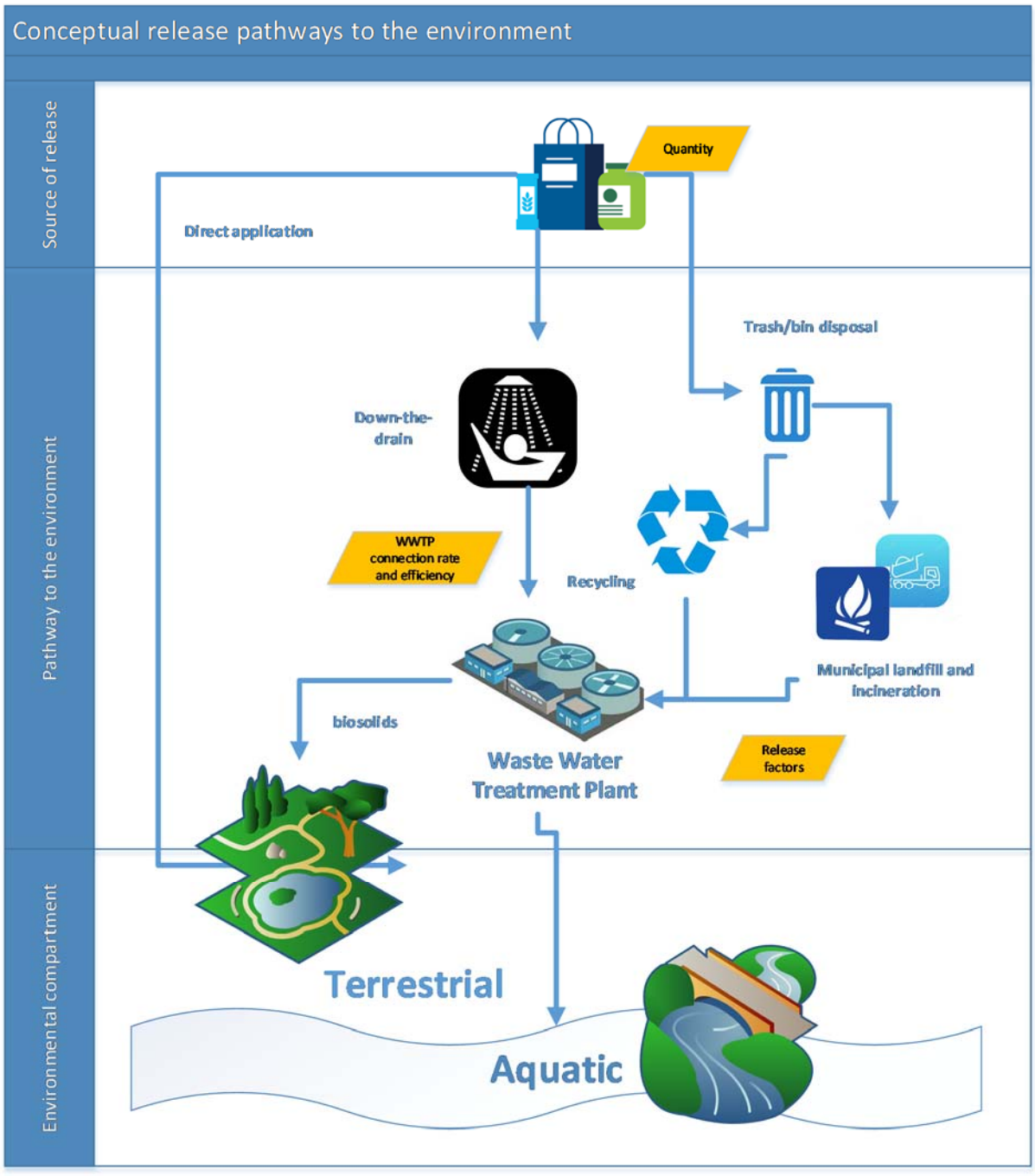


Figure 1 Conceptual source, pathway, receptor relationships for microplastics used in consumer and professional products.

Table 7 Microplastic releases via each of the three principal pathways to the environment.

Sector / Product group	Percentage of overall release to each pathway		
	DTD[a]	MSW[b]	DRE[c]
Cosmetic Products	-	-	-
- Exfoliators/cleansers	95%	5%	-
- Other uses in rinse-off	95%	5%	-
- Leave-on	50%[i]	50%	-
Detergents and maintenance	-	-	-
- Detergents containing fragrance encapsulates	100%	-	-
- Other detergents	100%	-	-
- Waxes and polishes[d]	77%	-	33%
Agriculture and horticulture	-	-	-
- Controlled release fertilisers	-	-	100
- Fertiliser additives	-	-	100
- Treated seeds	-	-	100
- Capsule suspension PPPs/biocides	-	-	100
Oil and gas	-	-	100%[f]
Paints and coatings[e]	-	-	-
- Consumer uses	100	0	0
- Professional uses	100	0	0
Medicinal products	-	-	-
- Ion exchange resins - Matrix or polymer film for controlled release	95%[g]	5%	0%
Medical devices / *in vitro* diagnostic medical devices[h] Ca. 100 (used) Ca. 0.29 (loss)	50%	50%	0%

Notes:
a: down the drain
b: municipal solid waste
c: direct release to the environment
d: 15% to air and 30% to water in accordance with Environmental Release Category (ERC) 8C
e: 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, based on relevant OECD emission scenario documents. Service life release would be directly to the environment or to wastewater.
f: direct release primarily to marine environment of approximately 270 tonnes per annum.
g: microplastics are fully excreted by the body after ingestion. It is also assumed that 5% of the medicines in Europe are unused and discarded by the consumers with their household waste.
h: during use, microplastics are essentially contained in equipment or cartridge and treated as hazardous waste/incinerated at their end of life. See Annex D for further information.
i: Average assumption for leave-on cosmetic products. A survey of consumer habits revealed that consumers washed off (or used cotton wool/pads that were later disposed of in toilet) the following leave on products, as follows: skin care – 76%, sun/tanning products - 87%, make-up – 28%, deodorant/antiperspirant products – 90%, nail varnish/remover – 18%, hair styling & other – 91%. In addition, it was assumed the 5% of cosmetic products was disposed in MSW without use.

1.4.2.2 Releases to wastewater (down-the-drain release pathway)

Releases of microplastics to the environment via the **'down-the-drain'** pathway have been identified in the literature from several of the intentional uses, specifically releases of 'microbeads' used in cosmetic and household care products (Kalčíková et al., 2017, Mason et al., 2016, Talvitie et al., 2017a, Carr et al., 2016, Duis and Coors, 2016). Wastewater effluents are considered as a significant point source of microplastics to the environment (McCormick et al., 2016, AMEC, 2017, Eunomia, 2018).

Siegfried et al. (2017), reported the development of a modelling approach to estimate the composition and quantity of point-source microplastic fluxes from large European rivers to the sea. In this study, the majority of microplastic inputs were secondary microplastic materials derived from tyre and road wear particles (42%) and fibres from synthetic textiles (29%). However, microbeads from personal care products were estimated to comprise 10% of microplastic releases (based on a release estimate of 0.0071 kg capita/year). The study was able to discern regional differences in releases of microplastics based primarily on the type of wastewater treatment technology implemented (including no treatment; with two-thirds of microplastic releases occurring to the Mediterranean and Black Sea where wastewater treatment was less effective than in river basins draining to the North Sea, Baltic and Atlantic Ocean). Based on this study it would seem that the type of treatment technology in place can have a significant impact on releases. van Wezel et al. (2016) modelled the release of primary microplastics from consumer products via wastewater in the Netherlands, including cosmetic products, cleaning agents and paints and coatings and concluded that all product categories contribute relevantly to overall releases.

The fate and behaviour of primary and secondary microplastics during wastewater treatment has been reported in the literature by numerous authors. Wastewater treatment is generally considered to be effective in preventing the release of microplastics to surface waters, although the type of treatment used affects the observed 'retention efficiency' (Dris et al., 2015, Talvitie et al., 2015, Carr et al., 2016, Mason et al., 2016, McCormick et al., 2016, Michielssen et al., 2016, Murphy et al., 2016, Danish Environmental Protection Agency, 2017, Kalčíková et al., 2017, Leslie et al., 2017, Mintenig et al., 2017, Talvitie et al., 2017a, Talvitie et al., 2017b, Ziajahromi et al., 2017, Lares et al., 2018, Prata, 2018b).

Secondary treatment would appear to result in at least 95% retention of microplastic particles (by number) in solid phases (Table 9). It is noteworthy that that grit and grease removal treatment stages that are typically present as part of preliminary effluent treatment in wastewater treatment facilities are reported by some authors to be particularly effective at removing microplastics from the aqueous phase of wastewater, either by simple settlement or via the skimming of floating particles trapped within the buoyant grease fraction (Carr et al., 2016, Murphy et al., 2016, Talvitie et al., 2017b). However, this stage of wastewater treatment is relatively less well characterised than other elements as it is not always specifically investigated in studies on the fate and behaviour of microplastics during wastewater treatment, which means that this is not always information reported on the removal efficiency of these types of treatment.

In contrast, tertiary treatment technologies, such as membrane bioreactors or sand filters, are typically only reported to be marginally more effective at retaining microplastics than secondary treatment alone (Mintenig et al., 2017, Michielssen et al., 2016, Carr et al., 2016, Lares et al., 2018, Talvitie et al., 2017a, Talvitie et al., 2017b).

Overall, this is perhaps not unexpected as wastewater treatment processes have typically been engineered to remove particulates from wastewater (usually termed as suspended solids), whilst tertiary treatment technologies are usually focussed on 'polishing' effluent quality in terms of specific parameters, such as nitrogen or phosphorus content; these are specific technologies that could be considered unlikely to affect the removal of microplastics.

In all cases, the 'removal' of microplastics that is observed during wastewater treatment refers to the partitioning (through settlement) of microplastics from the aqueous phase to a solid phase, principally sludge or the 'grit' fraction. No loss to air is expected. (Bio)degradation of microplastic particles has not been observed during wastewater treatment, although fragmentation of larger particles during wastewater treatment has been hypothesised (Danish Environmental Protection Agency, 2017) and Mahon et al. (2017) reported changes to the morphology of microplastics in sewage sludge after various sludge treatment processes, including thermal treatment, anaerobic digestion and lime stabilisation. Many studies report the presence of microplastics in sewage sludge, typically at high concentrations. For example, the Danish Environmental Protection Agency (2017) report a median concentration of microplastics in dewatered sludge sampled from five WWTWs of 4.5 mg/g, which corresponds with microplastics comprising 0.7% of the dewatered sludge.

Recognising this, no (bio)degradation of microplastics was assumed to occur during wastewater treatment when estimating releases to the environment via the down-the-drain pathway. This is consistent with other studies on the transfer of plastics in the environment (Geyer et al., 2017a, Siegfried et al., 2017, Jambeck et al., 2015, AMEC, 2017).

Therefore, the eventual form of sludge disposal that occurs (e.g. incineration, landfill or spreading of bio solids onto agricultural land) is a critically important element to consider when assessing microplastic inputs to the environment from the down-the-drain pathway. When treated wastewater sludge is spread onto agricultural soils then the microplastics contained within them are released to the environment.

It should be noted that the methods and approaches reported in the literature for sampling and quantifying microplastics in treated and untreated wastewater and sewage sludge are not currently subject to standardisation and, on the basis of the range of sampling and identification methods reported in the literature, there is likely to be a significant potential for variability in reported retention rates solely on the basis of differences between the methods used in individual studies.

However, it is possible to discriminate between studies using simple criteria e.g. on the basis of whether details of sampling protocols were reported and whether microplastics in samples were subject to identification using both visual and confirmatory spectroscopic methodologies (such as FTIR[25]) to avoid the incidence of false positives. Sufficient details of the prevailing wastewater treatment are also considered necessary. All of the studies used to unpin the estimates of retention efficiency used in this assessment report are based on well reported studies that used FTIR, or equivalent methods, to confirm the identification of microplastics in samples.

In addition, differences in how the occurrence and frequency of microplastics are

[25] FTIR: Fourier-transform infrared spectroscopy – is a techniques used to obtain an infrared spectrum of a material to facilitate its identification.

expressed (e.g. on a particle number or particle mass basis) can also influence the reported effectiveness of treatment, with estimates based on particle mass generally preferred over particle number-based methodologies (Danish Environmental Protection Agency, 2017) as microplastics could fragment during wastewater treatment. However, as only relatively few studies currently report wastewater effectiveness on a particle mass basis, effectiveness values based on reduction of particle number were considered for this assessment.

Approach to estimating releases

As the modelling study reported by Siegfried et al. (2017) highlighted the importance of different levels of wastewater treatment on releases, it was considered appropriate to incorporate the range of retention efficiencies for microplastics observed in different wastewater treatment types in the estimates of releases made for this Annex XV report.

Although such a distinction is not typically necessary in chemical risk assessments undertaken according to ECHA Guidance, it was also noted that an approach distinguishing between microplastic fate and behaviour during primary, secondary and tertiary treatment wastewater treatment was also utilised in the recent studies on the sources and releases of microplastics to the environment for the European Commission reported by Eunomia (2018) and AMEC (2017), respectively.

The down-the-drain release pathway can be relatively well characterised using the available information on the fate and behaviour of microplastics in different types of wastewater treatment in combination with the existing good quality information on the type of wastewater treatment applied on an EU level and information on the disposal of the sludge arising from wastewater treatment.

Therefore, estimates of releases via the down-the-drain pathway for the purposes of this assessment comprise the following elements:

1. Whether and to what extent wastewater is treated in a wastewater treatment facility prior to release (or released without any treatment); e.g. primary, secondary or tertiary treatment.
2. The efficiency of wastewater treatment to either (i) degrade microplastics or (ii) to remove (partition) microplastics from the aqueous phase to the sludge during treatment (after treatment sludge can be referred to as biosolids).
3. The subsequent disposal route of biosolids e.g. landfill, incineration, agricultural land

In terms of elements one and two above, Eunomia (2018), identified eight empirical studies reporting the retention of microplastics in wastewater treatment. From these studies Eunomia (2018) derived maximum and minimum retention rates for microplastics in primary, secondary and tertiary level wastewater treatment in the EU; with the mean of the minimum and maximum values used for the release assessment (Table 8). From these data minimum and maximum removal efficiency estimates for individual EU Member States were derived, ranging from 22% to 94%, which took into account the population served by wastewater treatment and the level of treatment achieved. Eunomia (2018) did not consider the disposal route of microplastic containing sludge.

AMEC (2017), in their assessment of releases and exposure arising for various 'intentional added' use of microplastics, applied the EU average minimum and maximum

removal efficiency derived by Eunomia of 53% and 85%, respectively, but supplemented these factors with a default retention efficiency value of 92% (8% to effluent) derived using EUSES (version 2.1.2).

Table 8 Maximum and minimum microplastic retention rates in wastewater treated applied by Eunomia (2018)

	Retention rate (%)				
	Primary	**Secondary**	**Tertiary**	**Other[a]**	**Unknown[f]**
Max	78[b]	98[b]	99.7[c]	50	0
Min	17[d]	29[d]	72[e]	50	0
Mean	47.5	63.5	85.9	50	0

Notes:
a: Other types of treatment reported by EuroStat include 'not specified', independent, and truck transport. A default value of 50% is used for treatment with no associated data. This accounts for 12% of the EU population.
b:Murphy et al. (2016)
c:Danish Environmental Protection Agency (2017)
d:Ziajahromi et al. (2017)
e:Leslie et al. (2017)
f: A default value of 0% was assumed for no treatment, which accounts for around 9% of the EU population

The literature review undertaken for the preparation of this Annex XV report identified several additional studies relevant to the assessment of retention of microplastics during wastewater treatment, which were reviewed alongside those originally utilised by Eunomia (2018) for the purposes of deriving retention efficiency values for use in this assessment.

Three of the studies used by Eunomia (2018) to identify upper or lower bounds for removal efficiency were excluded from this assessment, as follows:

Leslie et al. (2017), was cited by Eunomia (2018) as reporting a mean microplastic retention of 72% for tertiary treatment based on samples from seven WWTWs in the Netherlands. Review of the study identified that the cited mean removal efficiency of 72% related to concurrent influent/effluent sampling from four WWTWs, rather than seven and that there was no accompanying information on the level of treatment in place at these works. On this basis the value cannot be reliably used to establish a removal efficiency of 72% for tertiary treatment. In addition, The Dossier Submitter notes that the authors of the study themselves state that the results were *'not suitable for assigning treatment efficiency'*.

A study by the Danish Environmental Protection Agency (2017) was cited by Eunomia (2018) are reporting a retention rate of 99.7% for tertiary treatment. Although an exceptionally well conducted and reported study, the Dossier Submitter notes that the authors present the results as indicative of 'average Danish WWTWs', which cannot therefore be attributable to certain class of wastewater treatment. The authors report retention efficiency from 10 WWTWs in DK of 99.6 to 99.7% (25^{th} to 75^{th} percentile) based on mass and 93.7 to 93.8% based on number of particles. The greater efficiency observed based on mass could be as larger particles are more efficiently removed during primary settling. In general, smaller particles observed in treated effluent than in influent, which was proposed to be either as a consequence of differential removal or the 'degradation' of larger particles during treatment. The authors report that the removal efficiency of different polymers was similar.

Ziajahromi et al. (2017), was cited by Eunomia (2018) as the basis for removal efficiencies for microplastics of 17%, 29% and >90% for primary, secondary and tertiary treatment, respectively. The removal efficiency of 17% was used as the basis for the lower bound removal efficiency for primary treatment. Review of this study by the Dossier Submitter identified that Ziajahromi et al. (2017) did not report influent concentrations (either in the study or the accompanying supplementary information) and that, therefore, the efficiencies derived by Eunomia (2018) were not reliable removal efficiency estimates, but rather indicative of the relative removal efficiency between different stages of treatment. As such, they cannot be used to underpin overall removal efficiency estimates.

In total, eight studies reporting retention factors were considered sufficiently reliable for deriving mean retention factors for this assessment and are reported in Table 9. The mean retention factors for wastewater treatment used for this assessment are significantly greater than the retention factors used by Eunomia (2018).

Table 9 Microplastic wastewater treatment retention factors used in the down-the-drain release pathway assessment

Treatment type	Microplastic retention (%)	Reference and notes (size of particles)
Primary	83	Dris et al. (2015)
	78	Murphy et al. (2016)
	Mean 80.5	
Secondary	95	Dris et al. (2015)
	98.4	Murphy et al. (2016)
	98.3	Lares et al. (2018)
	99.6	Talvitie et al. (2017b)
	96	Michielssen et al. (2016)
	99	Magnusson and Noren (2014) cited by Talvitie et al. (2015)
	Mean 97.5	
Tertiary	99.9	Magnusson and Noren (2014) cited by Talvitie et al. (2015)
	99.9	Carr et al. (2016)
	97	Mintenig et al. (2017)
	99.4	Lares et al. (2018)
	99.7	Michielssen et al. (2016)
	Mean 99.2	

Based on the available information it has not been possible to estimate differential removal efficiency for different sizes of microplastic particles, as proposed by Duis and Coors (2016). Further information on this aspect of the fate and behaviour of microplastics during wastewater treatment may become available in the future.

However, preliminary findings on the fate of nanoplastics during wastewater treatment were recently reported by Frehland et al. (2018) at the Micro2018 conference in Lanzarote. The Frehland et al. (2018) study employed polystyrene nanoplastics (with a diameter of 160 nm) 'tagged' to contain palladium (Pd), which allowed their fate within a pilot-scale conventional activated sludge process (600 hours operation) to be tracked

using analytical techniques for metal analysis (i.e. ICP-MS and TEM/EDX). The authors report that over 98% of nanoplastics were associated with sludge after batch experiments. Although preliminary, the level of retention reported for nanoplastics is clearly within the range of retention factors in the literature for larger microplastic particles in conventional activated sludge wastewater treatment. The authors also report that the concentration of nanoplastics in the effluent correlate well with the level of total suspended solids (TSS) in the effluent.

Information on the distribution of wastewater treatment levels and the disposal routes of sewage sludge within individual EU Member States in was obtained from EuroStat[26].

Overall, after assessing all the relevant routes to the environment associated with the pathway, the down-the-drain pathway has a release factor of approximately 50%, with the release to agricultural soil via biosolids contributing 43 of the 50% (i.e. 86% of the releases to the environment from the down-the-drain pathway). This is the result of the relatively large proportion of sewage sludge that is applied (after treatment) to agricultural soils or as compost in certain Member States (based on the latest available data from EuroStat, 53% of sewage sludge in the EU is disposed to agricultural soils or as compost, with a range of between 0 and 90% for individual Member States). The remaining releases (7% of the 50% - 14% of releases to the environment via this pathway) predominantly arise via treated municipal wastewater. All of the other routes to the environment (e.g. via the incineration or landfilling of sewage sludge) comprise less than 1% of overall releases, and can be considered as minor sources of microplastic to the environment, even when releases are based on conservative default values from ECHA R.18 Guidance.

The down the drain release pathway is summarised in Figure 2 and Table 10.

[26] https://ec.europa.eu/eurostat/data/database?node_code=env_ww_spd#

Table 10 Data and assumptions used to describe the down-the-drain release pathway.

Element	Details
Influent load per MS	
Estimate of the quantity of microplastics released to wastewater per year in Member States	EU level tonnage data for each product group expressed on a *per capita* basis. MS specific influent load (T/yr) calculated based on MS resident population. Population data obtained from EuroStat[1].
Releases without treatment	
Storm water discharges	Releases to surface waters as stormwater from combined sewer systems was estimated as per Eunomia (2018): 5% loss from each CSO, with 50% of wastewater systems assumed to be combined. Overall release to surface water estimated as 2.5% of influent load.
Population not connected to urban and other wastewater treatment plants	MS specific data obtained from the latest year reported in EuroStat[2]. 100% release to surface water for the unconnected population. Average connection rate of 90.2%, range from 52.2% (RO) to 100% (AT, DE, DK, FR, LV, MT, NL, SE)
Releases with wastewater treatment	
Population connection to urban and other wastewater treatment	MS specific data obtained from the latest year reported in EuroStat[2].
Proportion of connection population with different levels of treatment.	MS specific data obtained from the latest year reported in Eurostat[2]: Primary, Secondary, Tertiary, not specified, independent, tanker transport.
Microplastic retention during wastewater treatment.	Retention efficiency (partitioning to sludge/grit) as reported in Table 9: primary 80.5%, secondary 97.5, tertiary 99.2%. Average removal efficiency for each MS calculated as per Eunomia (2018) based on the relative proportion of the different treatment levels in an MS; approach modified to assume that retention of microplastics during 'independent' and 'tanker' treatment was equivalent to average MS removal and retention during 'unknown' treatment equivalent to primary treatment. Microplastics not retained during wastewater treatment are assumed to be releases to surface water.
Retention of microplastics in the grit fraction and subsequent disposal.	22.5% of microplastics assumed to be retained in the grit fraction after Murphy et al. (2016). At 50% of sites grit is assumed to be disposed to landfill (see release from landfill below); At 50% of sites grit is disposed alongside sewage sludge.
Disposal route of sludge	MS specific data from EuroStat[3] on the proportion of sludge disposed of via different routes: agriculture/horticulture, landfill, incineration, other.
Release from sludge disposal	
Agricultural and compost (biosolids)	**100%** release to environment; predominantly to soil, but transport to other compartments via dusts/run-off could occur.
Landfill	Release to air (via dust): **10%** - ECHA R.18 Guidance default (Table 6) '*plastic material has low weight and dust is likely to occur*' Release to water (via leachate): **0.6% -** ECHA R.18 Guidance default (3.2% * primary treatment efficiency) Release to soil (via permeation): **0.16%** ECHA R.18 Guidance default
Incineration	Release to air: **0.01%** - ECHA R.18 Guidance default Release to water: **0.01%** - ECHA R.18 Guidance default Release to soil: n/a
Other	Insufficient information on disposal to assess releases, corresponds to approximately 8% of sludge disposed in EU.
Overall release factor of 50%. 43% to agricultural soil via application of biosolids, 7% to surface water from treated WWTW effluent; all other sub-routes combined contribute <1% to total releases.	
Notes: 1:http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=demo_pjan&lang=en 2:http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=env_ww_plt&lang=en 3:http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=env_ww_spd&lang=en	

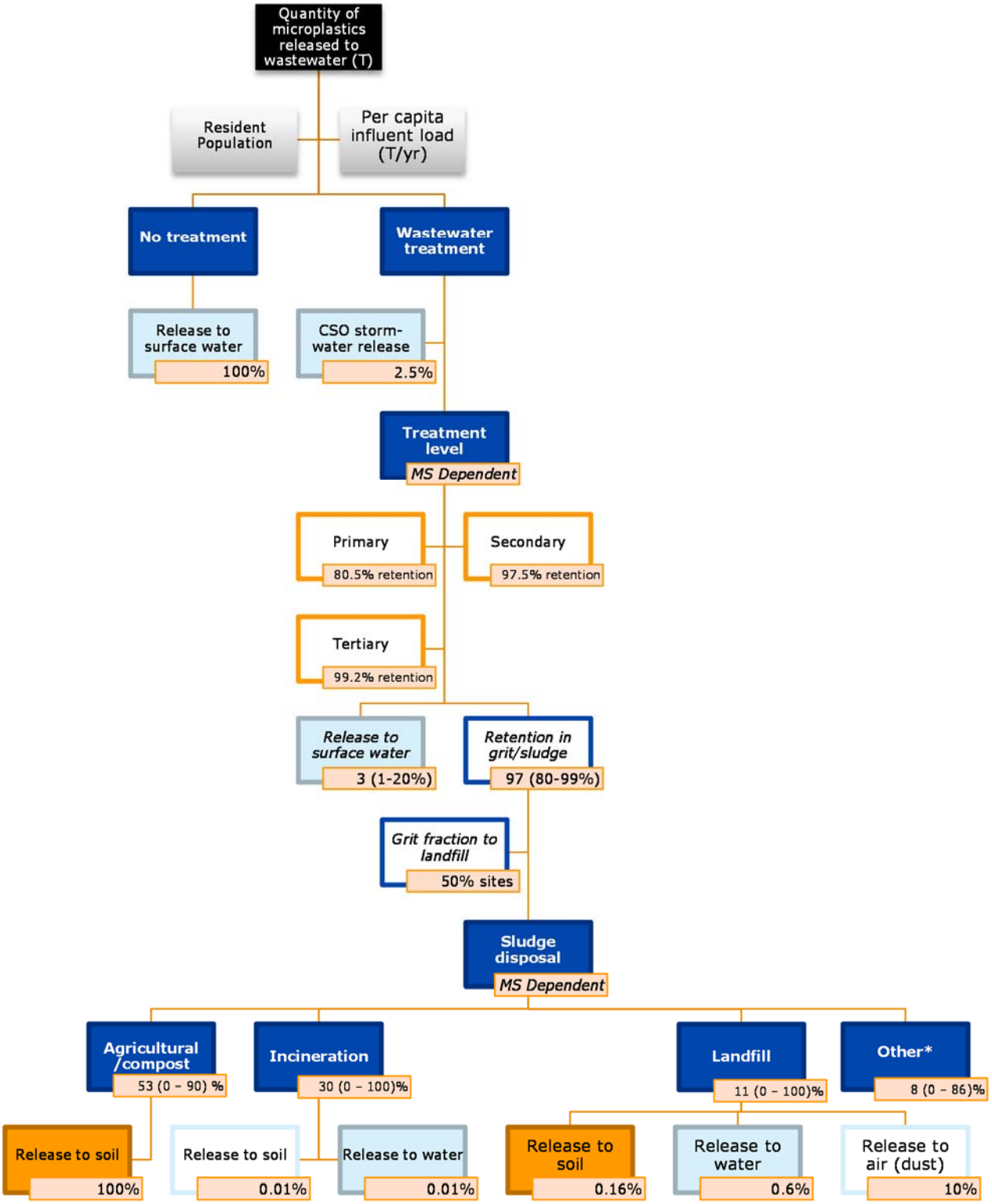


Figure 2 Summary of the down-the-drain release pathway

1.4.2.3 Releases to municipal solid waste (bin/trash)

Releases of microplastics to the environment can also occur through the disposal of municipal solid waste, the so-called **'trash or bin'** disposal pathway. For example, this pathway is relevant for microplastics in cosmetic products or paints that are present on used tissues or wipes.

No information on releases via this pathway was identified in the literature, which is currently focussed on releases via wastewater. Therefore, releases from municipal waste are characterised based, predominantly, on default release factors from ECHA R.18 Guidance supplemented with data from EuroStat on the relative proportion of municipal waste disposed of via different routes, e.g. incineration (including energy recovery) and landfill (including backfilling). No recycling of the microplastics in waste is assumed.

In addition to releases to air, water and soil from landfill and incineration the pathway assumes that some releases will occur via the recycling of cosmetic product packaging that is disposed containing residual product (5% of total product volume is assumed to be disposal of unused in packaging). Releases are assumed to occur via the shredding and washing processes common to plastics recycling operations. Releases to the environment though this 'sub-pathway' are characterised as per the wastewater release pathway. Release estimates assume that 10% of product packaging disposed to municipal solid waste is recycled. This level could be expected to increase considerably in the future as greater amounts of plastic product packaging are recycled, particularly cosmetic product packaging which is currently considered as relatively difficult to recycle (on this basis that packaging often contains mixed materials e.g. pump mechanisms). A similar sub-scenario was incorporated into the recent ECHA Annex XV restriction proposal (published January 2019) on D4, D5 and D6, which also assessed releases from cosmetic products.

Overall, after assessing all the relevant routes to the environment associated with the pathway, the municipal solid waste pathway has a release factor of approximately 0.5%, which is significantly smaller than the overall release factor of 50% for the down-the-drain pathway. However, the specific scenario for the disposal of cosmetic product packaging containing residual product has a release factor of 5%, based on a relatively low recycling rate of 10%. Whilst also having a much smaller potential for release than the down-the-drain pathway, higher rates of recycling in the future could significantly increase releases via this route. This pathway is further elaborated in Table 11 and Figure 3.

Table 11 Data and assumptions used to describe the municipal solid waste release pathway

<table>
<tr><th>Element</th><th>Details</th></tr>
<tr><td colspan="2">Proportion of municipal solid waste disposed via different routes</td></tr>
<tr><td>Estimate of the relative proportion of municipal solid waste disposed of via landfill, incineration and other routes. Microplastics present in tissues/wipes are assumed to be disposed of in equivalent proportions.</td><td>EU level data (latest year available: 2014) on the quantity of municipal solid waste disposed of via incineration, energy recovery, landfill, backfilling, recycling and other from EuroStat[1]. Data adjusted to omit recycling, which is not considered to occur for microplastics. Incineration and energy recovery categories combined, as were landfill and backfill categories. The ‘other’ category was omitted from release estimates as this route comprised <1% of total waste disposed

<u>Quantity of waste in EU disposed by different routes in 2014</u>
<table>
<tr><th>Incineration (inc energy recovery</th><th>Landfill (inc backfill)</th><th>Other</th></tr>
<tr><td>139 million T/yr</td><td>208 million T/yr</td><td>13 million T/yr</td></tr>
<tr><td>40%</td><td>60%</td><td><1%</td></tr>
</table></td></tr>
<tr><td>Landfill (backfill)</td><td>Release to air (via dust): 0.05% - ECHA R.18 Guidance default (Table 23)
Release to water (via leachate): 0.6% - ECHA R.18 Guidance default (Table 23: 3.2% * primary treatment efficiency)
Release to soil (via permeation): 0.16% ECHA R.18 Guidance default (Table 23)</td></tr>
<tr><td>Incineration (energy recovery)</td><td>Release to air: 0.01% - ECHA R.18 Guidance default
Release to water: 0.01% - ECHA R.18 Guidance default
Release to soil: n/a</td></tr>
<tr><td colspan="2">Overall release factor of 0.5%. 0.4% from landfill leachate and 0.1% from landfill permeation; all other routes <<0.1%.</td></tr>
<tr><td colspan="2">Release from recycling of cosmetic product packaging</td></tr>
<tr><td>Estimate of the volume of material that could be released to the environment through the recycling of product packaging.</td><td>5% of product volume disposed unused in packaging. 10% of material assumed to be recycled with 100% of microplastics assumed to be released to wastewater during shredding/washing processes common to recycling. Release estimates based on down-the-drain pathways described in Section 1.4.2.2. Releases from remaining 90% of packaging as per assumptions for municipal solid waste above.</td></tr>
<tr><td colspan="2">Overall release factor of 6%. 4% to agricultural soils via biosolids addition, 1% to surface water through treated WWTW effluents; all other routes combined <1%.</td></tr>
<tr><td colspan="2">Notes:
1: http://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=env_wasoper&lang=en</td></tr>
</table>

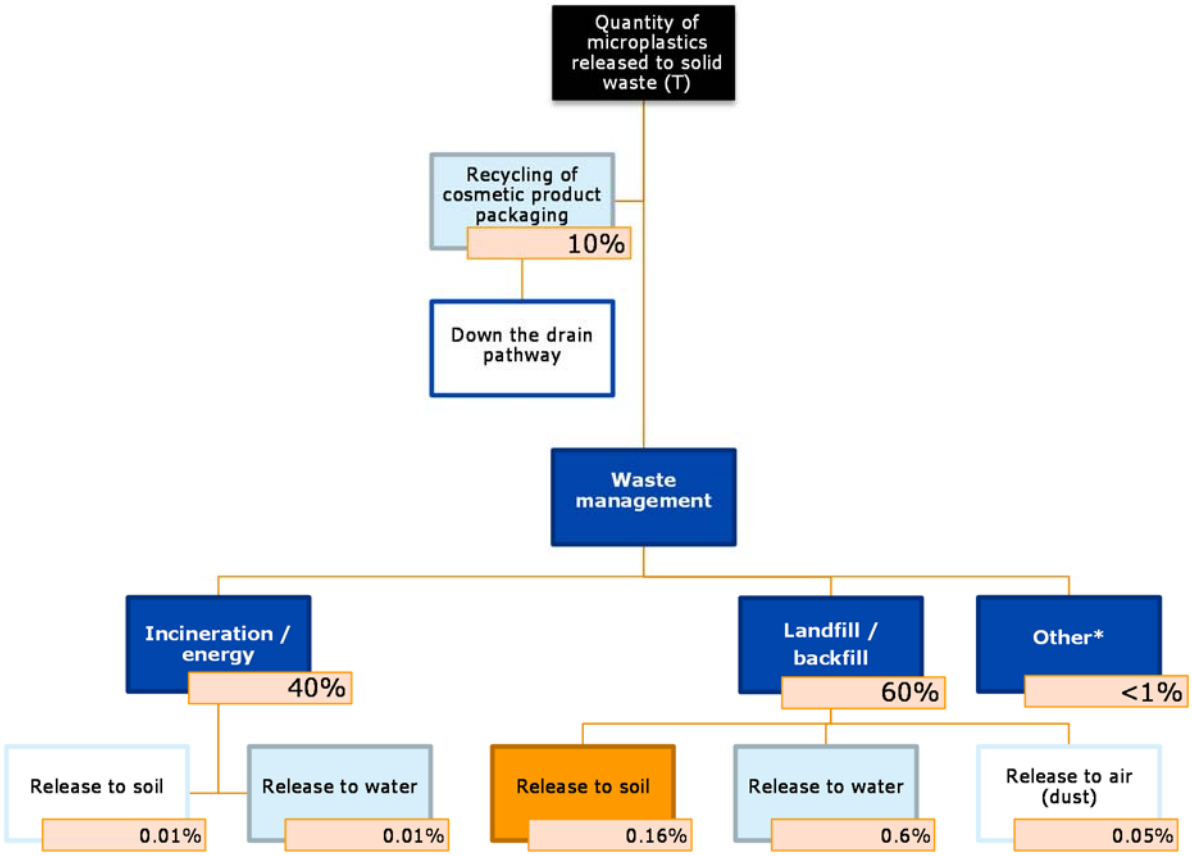


Figure 3 Summary of the municipal solid waste release pathway

1.4.2.4 Direct releases to the environment (agricultural soil)

Releases of microplastics are also known to occur through **'direct application to soils'**, i.e. agricultural and horticultural uses of microplastics in fertilising products or in capsule suspension formulations of plant protection products. In these instances, releases are relatively straightforward to quantify and are simply the quantities reported to be used per year in the EU. Overall the release factor can be considered to be 100%.

1.4.2.5 Mass flows

Despite the different pathways outlined above having very different intrinsic release factors, overall releases are dependent on the quantity of microplastics disposed via each of the pathways. For example a use that disposes a large quantity of releases to municipal solid waste could still lead to greater overall releases to the environment than a down-the-drain use, should the quantity of microplastics entering the pathway be sufficiently great.

Figure 4 summarises the mass flow of microplastics associated with uses of leave-on cosmetic products. The figure includes both down-the-drain and municipal solid waste pathways as leave on cosmetic products are disposed of to both pathways (refer to Table 7). The thickness of the arrow connecting the different elements of the figure denotes the quantity of microplastics flowing though the various routes to the environment.

Releases to solid waste lead to significantly smaller quantity of releases to the environment than down-the-drain releases, despite a similar quantity being disposed to each route (Table 7). Some waste management practises, specifically the incineration of

waste and sludge containing microplastics, can effectively prevent the release of microplastics to the environment. Landfilling of wastes may also be relatively effective risk management measure. Conversely, any down-the-drain release of microplastics has considerable potential for releases to the environment, at least based on current rates of sludge disposal to agricultural soil in the EU.

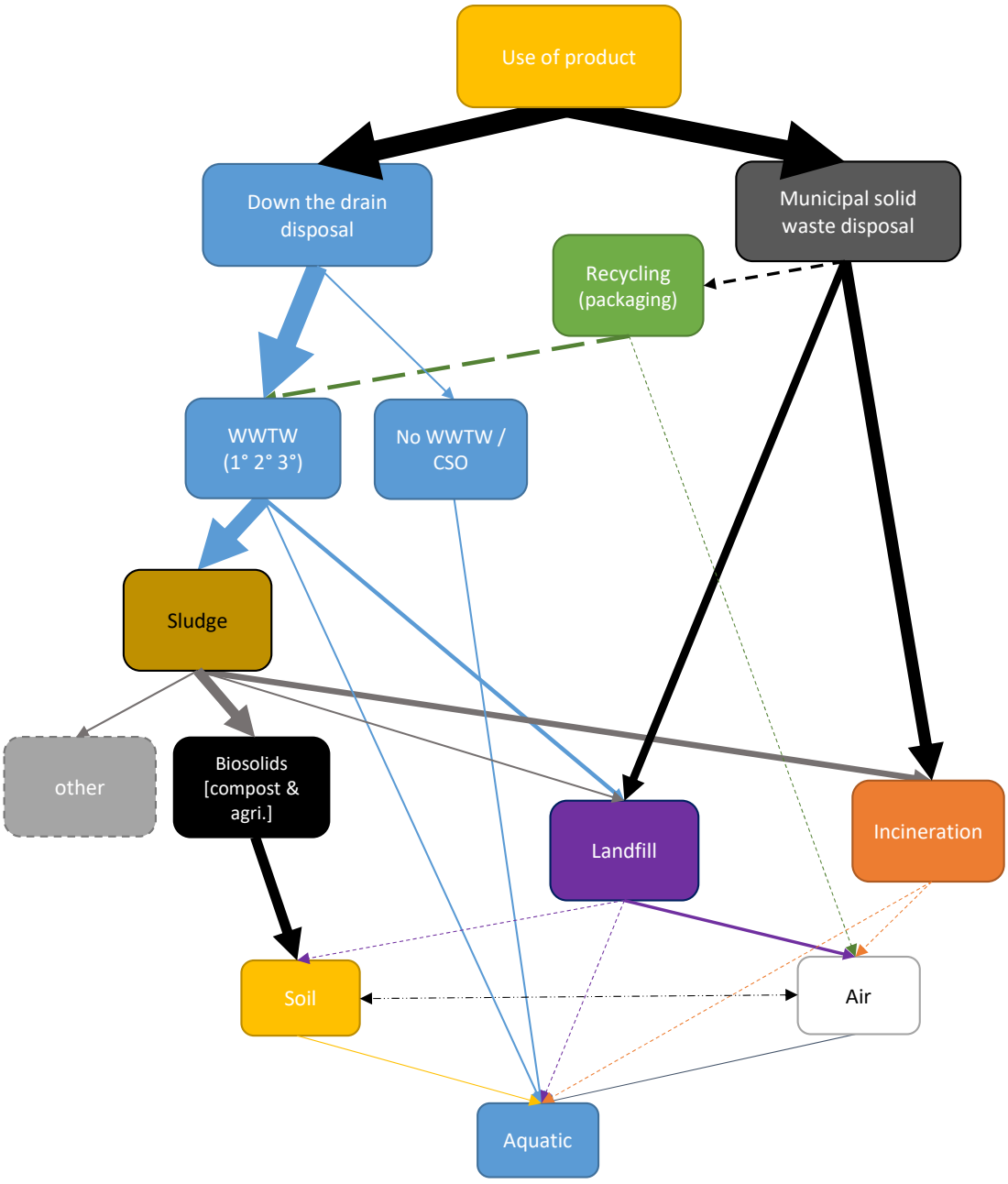


Figure 4 Mass flow of microplastics from leave on cosmetic products after disposal down-the-drain or in municipal solid waste.

1.4.3 Environmental fate

Once released to environmental compartments (air, soil, aquatic) microplastics will be subject to transport and degradation processes. In terms of (bio)degradation,

microplastics are themselves sources of secondary microplastics, comprising progressively smaller particles due to embrittlement, abrasion or degradation of primary microplastics, theoretically including nanoplastics (GESAMP, 2015, Koelmans et al., 2015, Koelmans et al., 2017b). The mechanisms and rate of (bio)degradation of microplastics in the environment are discussed further in Section 1.4.6, although this is not currently well understood.

Transport processes redistribute plastics between compartments and result in a net flow of materials from the terrestrial compartment (including run-off from agricultural soils amended with biosolids), via freshwater, to the marine compartment; including ocean sediments (Geyer et al., 2017b, Kooi, 2018, Rochman, 2018). Microplastics disposed to land could remain in the soil, run-off to water or be dispersed by wind (Duis and Coors, 2016).

The fate of microplastics and nanoplastics in rivers will depend on the size, density and shape of the materials, which in turn influence their sedimentation and aggregation behaviour; as would 'biofouling' (the growth of a biofilm on the particle)(Alimi et al., 2018). Microplastics can also be redistributed between compartments as a result of flooding (Hurley et al., 2018).

Models predicting the fate of micro and nanoplastics in freshwaters and river basins have been reported in the literature (Besseling et al., 2017b, Siegfried et al., 2017, Liedermann et al., 2018, Nizzetto et al., 2016, Unice et al., 2019a, Unice et al., 2019b). These studies did not specifically address intentionally added microplastics.

Despite these studies, there is currently insufficient knowledge to reliably model the fate and transport of microplastics across environmental compartments on a quantitative basis. Information on the fate of microplastics in soils and air are particular data gaps. Existing environmental fate models, such as SimpleBox (which underpins the EUSES fate model) could be modified to model the fate and behaviour of microplastics and nanoplastics (Koelmans et al., 2018).

1.4.4 Environmental and human health hazard assessment

1.4.4.1 Classification and labelling

Not applicable

1.4.4.2 Summary of scientific and grey literature

This section of the Annex XV report comprises a critical analysis of the (eco) toxicological effects of microplastics that have been documented in the literature. Although there is limited published literature specifically in relation to 'intentionally used' microplastics, the test materials used in (eco)toxicity studies are typically manufactured materials (either by researchers themselves, or purchased from suppliers) rather than obtained from the field (although there are exceptions to this). On this basis, journal articles and 'grey' literature reports purporting to both primary (intentionally added) and secondary microplastics are both considered to be relevant to the risk assessment of 'intentionally added' microplastics.

The analysis comprises a summary and critical analysis of (i) key review papers on the topic (both from the peer reviewed and grey literature) and (ii) the most influential

studies/articles published in the scientific literature to date.

Review articles provide an overview of trends in research and highlights areas of consensus on the (eco)toxicological effects of microplastics; gaps in current knowledge are often clearly articulated.

Individual studies often provide new insight into a specific aspect of adverse effects, fate or behaviour in the environment. The most influential (i.e. highly-cited) of these were identified using objective criteria and critically assessed in terms of their relevance and reliability, as per a conventional (eco)toxicity study used in a chemical risk assessment i.e. assessment against the criteria described by Klimisch et al. (1997). The Dossier Submitter acknowledges that many of the most influential studies on microplastics are 'non-standard' studies that were not specifically intended to be used in a risk assessment. Therefore, the standard approaches for assessing reliability are not always appropriate. Nevertheless, such an approach allows a consistent appreciation of the underlying scientific evidence base on the (eco)toxicity of microplastics.

1.4.4.3 Review articles

Eighty six review articles have been published in the area of microplastics since the emergence of this field in the early 2000s[27]. A large proportion of these review articles were published after 2014 (Figure 5). Figure 6 gives an indication of the most active researchers in this field, from the perspective of review articles.

Alongside this, a growing number of grey literature studies (defined here as reports derived from government organisations, charities, and professional bodies) have been completed. Several of the most relevant reviews have been included in the assessment.

Over time the field has developed from early findings that documented the occurrence and prevalence of microplastics in the environment to more refined studies on the physiological impacts and effects at the cellular level in exposed organisms. The growing concern around microplastics has arisen largely as a result of a combined set of characteristics that have drawn the attention of ecotoxicologists to their safety and toxicity, including their:

- Persistence i.e. resistance to (bio)degradation
- Increasing input to the environment – corresponding to the increased use of plastics worldwide
- Potential to cause harm to organisms via direct and indirect mechanisms
- The presence of chemical contaminants within and adsorbed to the plastics that are known to cause harmful effects
- Limited potential for removal (i.e. remediation) once in the environment

[27] Data from 'Scopus' bibliographic database accessed in October 2018 using the search term 'microplastic'.

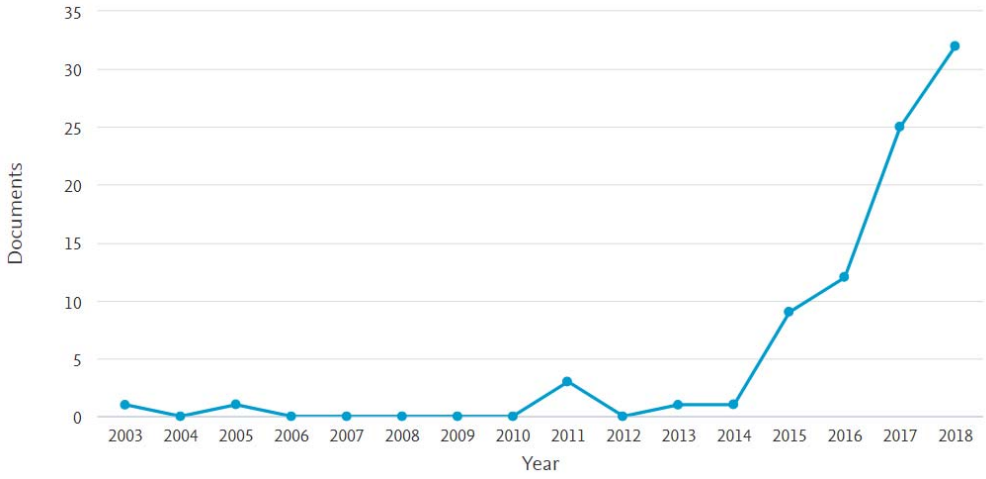


Figure 5. Number of review articles published since 2003, based on the search term 'microplastic' in Scopus in October 2018

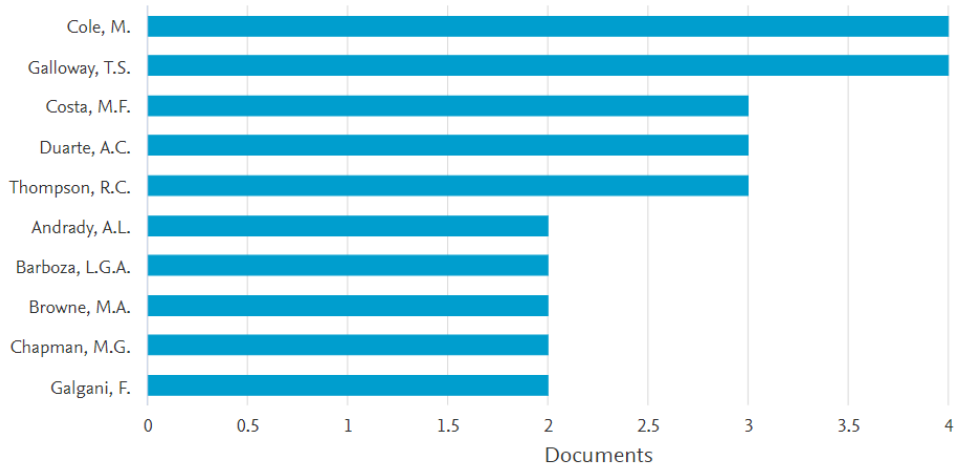


Figure 6. Top 10 authors publishing review articles in the area of microplastics

Twenty of the most relevant review articles on the (eco)toxicity of microplastics in biota and humans were selected from the wider list of literature identified in the literature screening and mapping[28].

This approach effectively captured the changing state of the literature over time and allowed any emerging general consensus that developed on the hazard or risk posed by microplastics to biota to be identified. The list of articles and grey literature selected for

[28] The starting point was the approximately 900 articles prioritised in the literature screening (from the 76 000 potentially relevant articles identified for the literature searches). Review articles were identified from this list if they were already categorised as 'review' articles by Scopus (the citation database used for the literature review and screening) or where the word 'review' or 'summary' was present in the abstract. All environmental compartments and species were included. Relevant 'grey' literature studies (e.g. FAO and GESAMP) were included in the list and given equal weighting to those from peer reviewed publications. Following this, review articles were sorted chronologically (from oldest to newest) and ordered by the total number of citations (statistics from August 2018). The 55 review articles identified were then screened to exclude those that were focussed on other aspects of microplastics, such as analytical methods, and to identify those reviews that specifically examined the (eco)toxicological effects of microplastic. Twenty review articles were selected for detailed review and included both influential (i.e. highly cited) as well as more recent review studies.

summary and review can be found in Table 12. Summaries of individual studies are presented in Annex C.

Table 12 List of articles and grey literature included in the summary of review articles

Author/s	Title
Scientific literature (presented chronologically)	
Andrady (2011)	Microplastics in the marine environment
Cole et al. (2011)	Microplastics as contaminants in the marine environment: A review
Wright et al. (2013b)	The physical impacts of microplastics on marine organisms: A review
Ivar Do Sul and Costa (2014)	The present and future of microplastic pollution in the marine environment
Eerkes-Medrano et al. (2015)	Microplastics in freshwater systems: A review of the emerging threats, identification of knowledge gaps and prioritisation of research needs
Galloway (2015)	Micro- and nano-plastics and human health
Duis and Coors (2016)	Microplastics in the aquatic and terrestrial environment: sources (with a specific focus on personal care products), fate and effects
Koelmans et al. (2016)	Microplastic as a Vector for Chemicals in the Aquatic Environment: Critical Review and Model-Supported Reinterpretation of Empirical Studies
Phuong et al. (2016)	Is there any consistency between the microplastics found in the field and those used in laboratory experiments?
Auta et al. (2017)	Distribution and importance of microplastics in the marine environment: A review of the sources, fate, effects, and potential solutions
Connors et al. (2017)	Advancing the quality of environmental microplastic research
Horton et al. (2017)	Microplastics in freshwater and terrestrial environments: Evaluating the current understanding to identify the knowledge gaps and future research priorities
Burns and Boxall (2018)	Microplastics in the aquatic environment: Evidence for or against adverse impacts and major knowledge gaps
Anbumani and Kakkar (2018)	Ecotoxicological effects of microplastics on biota: a review
Foley et al. (2018)	A meta-analysis of the effects of exposure to microplastics on fish and aquatic invertebrates
Scherer et al. (2018)	Interactions of microplastics with freshwater biota
Grey literature (presented chronologically)	
Lassen et al. (2015)	Microplastics: Occurrence, effects and sources of releases to the environment in Denmark
EFSA (2016)	Statement on the presence of microplastics and nanoplastics in food, with particular focus on seafood
GESAMP (2016)	Sources, fate and effects of microplastics in the marine environment: part two of a global assessment
Lusher et al. (2017)	Microplastics in fisheries and aquaculture: status of knowledge on their occurrence and implications for aquatic organisms and food safety (UN FAO)

The body of literature is largely focussed on the marine environment, with fewer studies in freshwater environments and very few on terrestrial organisms, despite the potential for exposure via sewage sludge applied to land and aerial deposition of microplastics (refer to Section 1.4.2). The prioritised articles tend to focus on common themes, particularly:

- How to define microplastics – stressing the importance of adopting a common working definition.

- The lack of standard analytical methods and comparable approaches for reporting concentrations / effects across studies.
- Effects in biota seen in either the laboratory or the field. These are often subdivided into physical/mechanical effects of microplastic exposure (e.g. blocking of feeding appendages or the gastrointestinal tract of animals) and effects associated with the leaching of constituents (e.g. additives) or impurities from the microplastic manufacturing process from the polymer matrix.
- The potential for microplastics to transport and facilitate the bioaccumulation of hydrophobic organic contaminants – HOCs, e.g. POPs; 'carrier' or 'vector' effects.
- Possible extrapolation to humans through the consumption/trophic transfer of microplastics through the food chain.

The body of literature on microplastics is growing rapidly with articles being published in the scientific literature on an almost daily basis[29]. Many of these studies are concerned with the reporting the occurrence, concentration and characterisation (e.g. composition / morphology / properties) of microplastics in different environmental compartments or locations with, until more recently, relatively fewer reporting the results of studies investigating the hazard and risk posed by different types of microplastics to the environment or to human health.

Microplastics have been documented to occur in almost all environments investigated, including seawater, sea ice and sediments in polar regions (Obbard, 2018) and the deepest ocean trenches (Peng et al., 2018); they can truly be considered as globally pervasive pollutants. Based on the increasing use of plastics, concentrations of microplastics in the environment are forecast to progressively increase as they are almost impossible to remove once dispersed within the environment and persist almost indefinitely (Jambeck et al., 2015, Geyer et al., 2017a). Many of the reviews conclude with the observation that contamination will continue to increase into the foreseeable future with the result that exposure of organisms is therefore largely unavoidable and likely to increase in magnitude in the future.

Early reviews by Andrady (2011), Cole et al. (2011) and Wright et al. (2013b) focus on the scale of the plastics problem, the physical attributes and weathering of polymer types and the evidence that organisms are able to ingest microplastics.

Ecotoxicity studies were relatively scarce in earlier years and those that did take place typically focussed on the ability of organisms to ingest microplastics and their occurrence in the gut, rather than exploring adverse effects on organisms. Ingestion in laboratory studies has since been linked to a diverse range of sub-lethal endpoints, including reduced food intake, false satiation and reduced energy reserves, as well as mortality and sub-lethal 'apical effects', such as on growth rates or reproduction (Besseling et al., 2018). Translocation of microplastics from the gut to other secondary tissues after ingestion has also been reported in some species, although in some cases translocation

[29] Using the search term 'microplastic' in Web of Science, 359 articles were published in the scientific literature between 09/02/2018 and 08/01/2019.

observed on histological sections is thought to be an artefact of sample preparation rather than true translocation (Duis and Coors, 2016, Besseling et al., 2017a).

1.4.4.4 Influential articles

The top 25 'influential articles' on the (eco)toxicity of microplastics were identified from the literature[30]. These are listed in Table 13 and are summarised in greater detail in Annex C and discussed, where applicable, in the sections below that summarise key aspects of microplastics (eco)toxicity. The approach to identify influential articles based on citations is acknowledged to preferentially identify older articles (as these are more likely to be cited than newer ones). However, more recent studies are typically identified in the review articles considered above, as well as in discussions that the Dossier Submitter has held with experts.

Table 13 List of the 25 most influential articles on the (eco)toxicity of microplastics from the scientific literature (ordered based on citations)

Author/s	Title	No. citations
Browne et al. (2008)	Ingested microscopic plastic translocates to the circulatory system of the mussel, *Mytilus edulis*.	374
Cole et al. (2013)	Microplastic ingestion by zooplankton	316
Rochman et al. (2013)	Ingested plastic transfers hazardous chemicals to fish and induces hepatic stress	260
Von Moos et al. (2012)	Uptake and effects of microplastics on cells and tissue of the blue mussel *Mytilus edulis* L. after an experimental exposure	202
Besseling et al. (2013)	Effects of microplastic on fitness and PCB bioaccumulation by the lugworm *Arenicola marina* (L.	184
Browne et al. (2013)	Microplastic moves pollutants and additives to worms, reducing functions linked to health and biodiversity	178
Wright et al. (2013a)	Microplastic ingestion decreases energy reserves in marine worms	157
Van Cauwenberghe et al. (2015)	Microplastics are taken up by mussels (*Mytilus edulis*) and lugworms (*Arenicola marina*) living in natural habitats	130
Cole et al. (2015)	The impact of polystyrene microplastics on feeding, function and fecundity in the marine copepod *Calanus helgolandicus*	124
Avio et al. (2015)	Pollutants bioavailability and toxicological risk from microplastics to marine mussels	117
Besseling et al. (2014b), Besseling et al. (2014a)	Nanoplastic affects growth of *S. obliquus* and reproduction of *D. magna*	103
Sussarellu et al. (2016)	Oyster reproduction is affected by exposure to polystyrene microplastics	91
Oliveira et al. (2013)	Single and combined effects of microplastics and pyrene on juveniles (0+ group) of the common goby *Pomatoschistus microps* (Teleostei, Gobiidae)	90
Lee et al. (2013)	Size-Dependent Effects of Micro Polystyrene Particles in the Marine Copepod *Tigriopus japonicas*.	76

[30] 25 articles were identified as 'most influential' from the approximately 900 articles prioritised in the literature screening. Articles were selected on the basis that they (i) reported (eco)toxicological effects in organisms after exposure to microplastics (ii) were highly cited in Scopus (as of July 2018) and (iii) consistently identified in review articles. The reliability of each study was scored using the criteria proposed by Klimisch et al. (1997). Further details in Annex C.

Author/s	Title	No. citations
Lu et al. (2016)	Uptake and Accumulation of Polystyrene Microplastics in Zebrafish (*Danio rerio*) and Toxic Effects in Liver	71
Lithner (2009)	Leachates from plastic consumer products - Screening for toxicity with *Daphnia magna*	62
Hämer et al. (2014)	Fate of Microplastics in the Marine Isopod *Idotea emarginata*	55
Kaposi (2014)	Ingestion of microplastics has limited impact on a marine larva	55
Watts et al. (2015)	Ingestion of Plastic Microfibers by the Crab *Carcinus maenas* and Its Effect on Food Consumption and Energy Balance	48
Huerta Lwanga et al. (2016)	Microplastics in the Terrestrial Ecosystem: Implications for *Lumbricus terrestris* (Oligochaeta, Lumbricidae)	46
Wardrop et al. (2016)	Chemical Pollutants Sorbed to Ingested Microbeads from Personal Care Products Accumulate in Fish	41
Au et al. (2015)	Responses of *Hyalella azteca* to acute and chronic microplastic exposures	41
Pedà et al. (2016)	Intestinal alterations in European sea bass *Dicentrarchus labrax* (Linnaeus, 1758) exposed to microplastics: Preliminary results	39
Rehse et al. (2016)	Short-term exposure with high concentrations of pristine microplastic particles leads to immobilisation of *Daphnia magna*	39
Batel et al. (2016)	Transfer of benzo[a]pyrene from microplastics to *Artemia nauplii* and further to zebrafish via a trophic food web experiment: CYP1A induction and visual tracking of persistent organic pollutants	39

Notes: The number of citations obtained from Scopus. Correct as July 2018

1.4.4.5 Exposure and ingestion

There is extensive experimental and environmental monitoring data demonstrating that microplastics can be ingested by a diverse set of species representing different taxonomic groups and occupying various ecological niches and positions along food chains; ingestion has currently been documented in around 220 species (GESAMP, 2015, GESAMP, 2016, Lusher et al., 2017).

Field studies typically confirm that the incidence of microplastic accumulation in wild fish is relatively low (1-2 items per individual). The prevalence of microplastics reported in invertebrate species, including shellfish, are typically greater. Egestion of microplastics after ingestion can occur rapidly in certain organisms (i.e. over a few days or hours) such as copepods, amphipods and bivalves (Duis and Coors, 2016, Batel et al., 2016).

1.4.4.6 Translocation

Translocation describes the movement of an 'accumulated' microplastic from one part of an organism to another, typically from the gut or respiratory organs to another secondary tissue. Translocation has been reported for microplastic particles in invertebrates, typically species of mussel, and fish. It is usually investigated using histopathological techniques.

Translocation of microplastics in mussels has been reported in numerous laboratory studies (Browne et al., 2008, Avio et al., 2015, Von Moos et al., 2012). The observation of translocation of microplastics in fish and other invertebrates has been reported (Lu et al., 2016), but is not considered by the scientific community to be definitively proven, and possibly an experimental artefact introduced during the preparation of histopathological sections (i.e. the drag over from one section to another during slicing).

The translocation of nanoplastics in whole organisms after realistic exposure has not yet been reported in any species due to the methodological challenges of visualising nanoparticles in cells.

Despite evidence of ingestion and the potential translocation of microplastics across tissues and trophic levels in laboratory studies, these same effects have not yet been demonstrated in the environment. To this end, Lusher et al. (2017) indicates that translocation or accumulation in host tissues, in principle, has the potential to affect a wide range of species. However, the current evidence that this occurs in the field in fish seems relatively weak (Ziccardi et al., 2016).

1.4.4.7 Trophic transfer

Given the confirmed presence of microplastics in a range of taxa, suggestions have been made regarding the possibility of trophic transfer of microplastics through food chains, including both aquatic and terrestrial food chains. Studies have demonstrated trophic transfer of microplastics in the laboratory (Murray, 2011, Farrell and Nelson, 2013, Setälä et al., 2014, Tosetto et al., 2017). However, these studies are difficult to interpret in relation to potential trophic transfer in the field (Burns and Boxall, 2018). A study by Güven et al. (2017), is cited by Burns and Boxall (2018) as evidence that microplastics have low biomagnification as a result of significant gut clearance in fish. In addition, any adverse effects arising from such transfer, such as secondary poisoning, particularly under environmental conditions are unknown. Nevertheless, as primary consumers readily ingest microplastics the potential for trophic transfer to predatory levels of food webs cannot be disputed.

1.4.4.8 Observed effects

Ecotoxicity testing with microplastics has been conducted on a range of species from across different environmental compartments, including, annelids, zooplankton, crustaceans, algae, mussels and fish (Connors et al., 2017, Besseling et al., 2018, Lusher, 2015). The majority of studies have reported effects on marine species and / after short-term (acute) exposures. Some have reported an absence of effects after short-term exposures (Beiras et al., 2018, Kaposi, 2014). There is relatively limited data on effects of exposure to microplastics over long-term (chronic) exposure durations.

Besseling et al. (2018) present an overview of 168 effect/no-effect concentrations (termed effect thresholds by the authors) for aquatic species obtained from 66 studies and the previous assessment of Lusher (2015) and Connors et al. (2017). Endpoint included were survival, feeding, growth, reproduction, moulting, malformation, behaviour, photosynthesis, oxidative stress, enzyme activity, inflammation, gene expression and nutrient cycling; all of which were considered by the authors to be relevant to population or community-level effects, given time. All exposure durations were included although studies investigating the effects of microplastics as a 'vector' facilitating the update/bioaccumulation of environmental contaminants were excluded.

Effect concentrations were converted to be expressed in mg/L for aqueous exposures and g/kg (dw) for exposures via sediment or food (Table 14). Effect concentrations are observed to range of over many orders of magnitude, some at very low concentrations (i.e. pg/L exposure concentrations). Effect concentrations for microplastics are reported, perhaps counterintuitively, to be typically lower (more sensitive) than those for nanoplastics. However, there is insufficient information reported on the comparability of the underlying test data to infer any conclusions from this observation.

Only two studies with fish have used environmentally relevant concentrations of microplastics. The first of these was Rochman et al. (2013) that report a chronic dietary exposure of Japanese medaka (*Oryzias latipes*) to low-density polyethylene (LDPE) microbeads of < 0.5 mm diameter for two months (virgin and marine-aged test materials were used). The authors report increased bioaccumulation of PAHs, PCBs and PBDEs in the marine-aged polyethylene treatment and increased hepatotoxic stress (characterised on the basis of histopathology as severe glycogen depletion and fatty vacuolation), relative to control, in both virgin and marine-aged polyethylene treatments. Single cell necrosis and a single incidence of a tumour (a hepatocellular adenoma) was observed in the marine-aged LDPE treatment. These effects were considered to be related to endocrine disruption but Duis and Coors (2016) note that they could also be related to energy depletion. Second is the study of Rummel et al. (2016), who investigated the effects of polyethylene microspheres on the bioaccumulation of PCBs in rainbow trout in a nine week experiment. Condition factors and growth rates in both treatment and control groups were similar; as was the depuration kinetics, indicating that ingestion of 'clean' microplastics in food does not enhance the depuration of PCBs in rainbow trout.

Overall, the effects of microplastics are hypothesised to be the same in both marine and freshwater systems, although (as discussed in subsequent sections of this report) the concentrations observed to affect organisms via water in laboratory studies are generally much higher than concentrations measured in the environment. Similarly, studies that use high concentrations of microplastics typically result in feeding appendages becoming overwhelmed or the effects observed are thought to be compounded by a lack of food (as it is replaced by microplastics).

Compared to aquatic species, the effects of microplastics on terrestrial biota are not well studied[31]. Studies to date have reported that terrestrial arthropods (worms, collembolans and Oribatid mites) interact with and transport soil deposited microplastic particles Huerta Lwanga et al. (2016). Huerta Lwanga et al. (2016) observed mortality, reduced burrow construction and growth in earthworms exposed to polyethylene particles (PE), with effects observed a high exposure concentrations compared to expected microplastic concentrations in the environment. Rodriguez-Seijo et al. (2017) reported that earthworms (*Eisenia andrei*) exposed to polyethylene microplastics (250 and 1000 µm) in the laboratory showed serious histological damage of the gut, including inflammation, accompanied with immune system responses.

Cao et al. (2017) report the effects of polystyrene microplastics (58 µm) on the fitness of the worm *Eisenia foetida* in agricultural soils after a 30 day exposure. Exposure to concentrations ≤ 0.5 % (w/w) were reported to have no effect, whilst concentrations of 1 and 2 % (w/w) significantly inhibited the growth and increased mortality.

Zhu et al. (2018a) investigated the effects of exposure of PVC microplastics (80 to 250 µm diameter) in soil collembolans, *Folsomia candida*, and reported inhibition of growth (16.8%) and reproduction (28.8%), as well as changes to microbial gut composition and elemental incorporation (N and C) at an exposure concentration of 1g microplastics per kg of soil (0.1 % w/w). Although not a classical dose-response study (van Gestel and Selonen, 2018, Zhu et al., 2018b) it is noteworthy that this concentration of

[31] In addition to the review by Horton et al. (2017), discussed above and in Annex C, additional reviews of the effects of microplastics in the terrestrial compartment have recently been published by Chae and An (2018) and Machado et al. (2018).

microplastics tested by Zhu et al. (2018a) is similar to the microplastic concentration that has been reported in some sewage sludge (Danish Environmental Protection Agency, 2017).

Not all studies report effects on terrestrial organisms exposure to microplastics. Jemec Kokalj et al. (2018) report the results of a 14 day study with terrestrial isopods, *Porcellio scaber*, observing no effects on food ingestion, food assimilation, growth, mortality or energy reserves (proteins, carbohydrates and triglycerides) in digestive glands after exposure to microplastics derived from a facial cleaner (137 ± 51 µm).

Huerta Lwanga et al. (2017) report the transfer of micro- and macroplastic debris from soil to chickens.

To date, negative population-level effects in aquatic species have not been demonstrated (Lusher et al., 2017). However, exposure to microplastics (2.5 or 25 µg L^{-1}) has been reported to alter the function and structure (in terms of infaunal invertebrate assemblages) of bivalve-dominated mesocosms containing European flat oysters (*Ostrea edulis*) (Green, 2016, Green et al., 2017). In a further study of community-level responses to microplastic exposure, Green et al. (2016) also reported that exposure to microplastics (three types: polylactic acid, polyethylene and PVC at 2% w/w wet weight) in outdoor mesocosms reduced cast formation in lugworms, *Arenicola marina*, while simultaneously reducing microalgal biomass (primary productivity).

Table 14 Summary of published effects concentrations for microplastics and nanoplastics in aquatic species. Reproduced from Besseling et al. (2018)

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

Notes: Effect concentrations converted to mg/L; plastic ingestion is not considered as an endpoint of effect

1.4.4.9 Derivation of 'no effect' thresholds and quantitative risk characterisation

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

Everaert et al. (2018) reported the derivation of a 'safe concentration' ($PNEC_{pelagic}$) of microplastics in the marine environment of 6 650 buoyant particles/m^3 using the HC5 from a species sensitivity distribution together with an assessment factor of 5. The SSD was constructed from 14 species from four taxonomic groups (algae, molluscs, crustaceans and echinoderms) using NOEC data for a range of apical (survival, growth and reproduction) and non-apical (e.g. metabolic rate, DNA damage, energy balance and gametogenesis) endpoints.

Based on a model of microplastic exposure in the environment over time, Everaert et al. (2018) conclude that limited direct effects of microplastics in the marine environment can be expected until the year 2100, although they note that the 'safe concentration' is already exceeded at sites heavily polluted with buoyant microplastics (Figure 7). A complimentary analysis of the marine benthic compartment is limited by limited ecotoxicity data, but tentatively predicts that exposures above safe concentrations (540 particles/kg sediment based on an assessment factor of 1 000) will occur in the second half of the 21st century.

Everaert et al. (2018) clearly state that the PNEC values derived should be interpreted with caution. Nevertheless, with reference to applicable ECHA Guidance on the use of SSDs for hazard assessment, the Dossier Submitter notes that the datasets used in this study would not be considered appropriate for PNEC derivation for chemical safety assessment under REACH. Primarily as the minimum standards of taxonomic diversity required for SSD derivation for the marine compartment are not achieved (fish are a notable omission for the available dataset), but also as non-apical endpoints are included in the curve, including the most sensitive taxon (NOEC of 0.16 particles/mL for effects on energy balance and gametogenesis in *Pinctada margaritifera*, after Gardon et al. (2018))

Burns and Boxall (2018) construct an SSD for microplastics between 10 and 5000 µm from apical NOEC and LOEC data from nine freshwater and marine species (comprising data for fish, isopods, copepods, echinoderms and crustaceans) and report an HC5 value of 6.4 x 10^4 particles/L. Based on the data on environmental exposures collated in the study the authors report that the confidence intervals of the 95% measured environmental concentrations and the HC5 do not overlap, suggesting that risks are limited. However, the authors acknowledge that the limitations of the data underpinning the SSD, which is presented as a starting point for further update in the future as more reliable and relevant data become available.

Besseling et al. (2018), in the most sophisticated risk assessment reported to date, constructed separate provisional SSDs for microplastics and nanoplastics for exposure via water using the available literature data for apical endpoints (survival, reproduction and growth). As effects thresholds were expressed in terms of either LC_{50}, EC_{50}, or LOEC values, and exposures varied from 'minutes to months', all effects data were converted to chronic LOEC values using extrapolation factors (acute to chronic ratios), after Diepens et al. (2017). Effects thresholds for marine, estuarine and freshwater species were combined in the same SSD (Figure 8).

Using these assumptions, Besseling et al. (2018) report HC5 (hazardous concentration for 5% of species) for microplastic of 2.0 ng/L (95% confidence interval of 1.8×10^{-3} to 2.2×10^{3} ng/L). The statistical goodness-of-fit of the curve, typically estimated for SSDs, was not reported, although the R^2 value was estimated to be 0.78. The curve was comprised of data for 10 species from six taxonomic groups (one rotifer, one mollusc, five crustaceans, one diatom, one higher aquatic plant and one echinoderm). The confidence interval for the HC5 value spans six orders of magnitude, emphasising the uncertainty in the estimates[32].

The corresponding HC5 value for nanoplastic was 5.4 µg/L (95% confidence interval from 0.93 to 31 µg/L, R^2 value of 0.93). The curve was comprised of data from 10 species from five taxonomic groups (one rotifer, four crustaceans, three algae, one echinoderm and one amphibian).

Based on these HC_5 values Besseling et al. (2017a) derived PNEC values, termed preliminary safe standards (PSS), using an assessment factor of five or 0.4 ng/L and 1.1 µg/L for microplastics and nanoplastics, respectively.

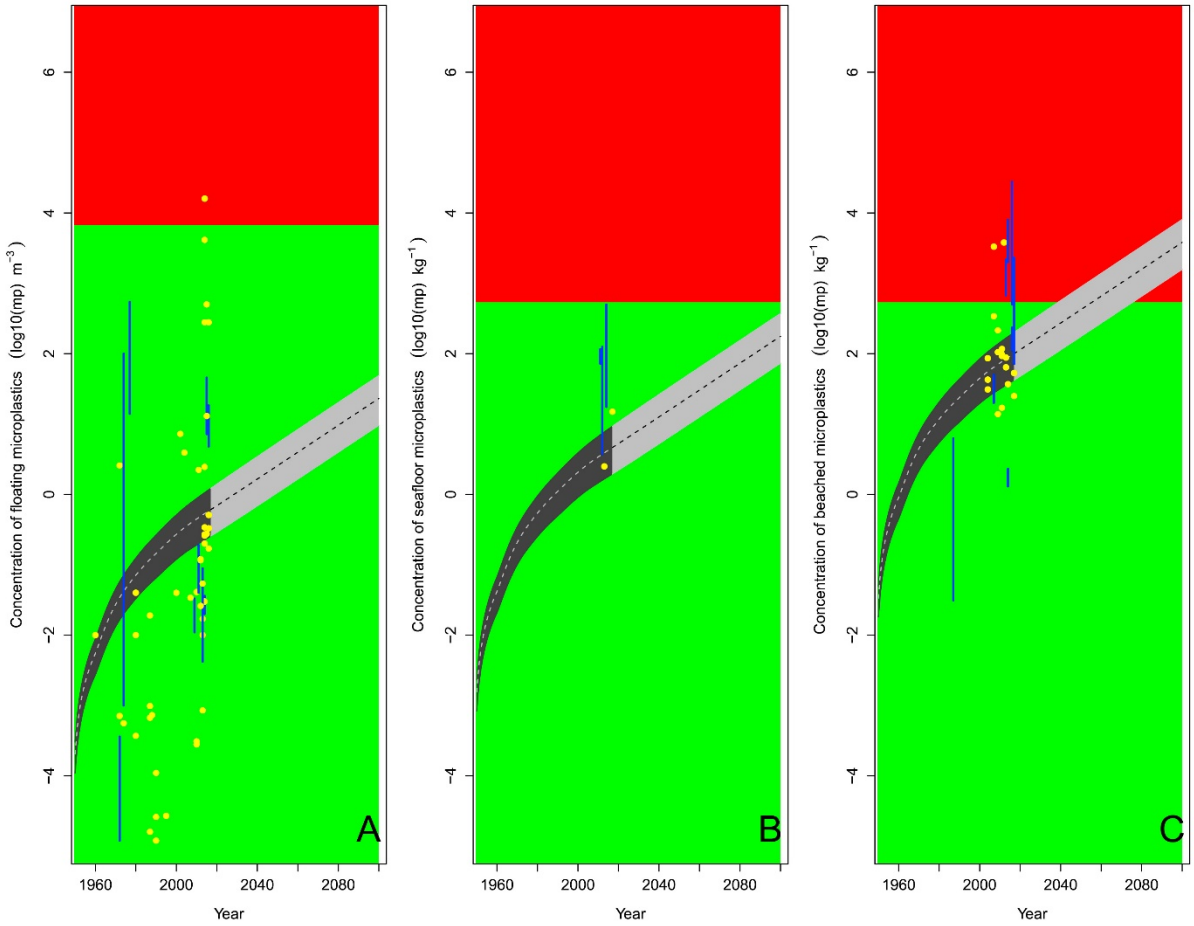
Using the derived HC5 values (not the PSS values) and microplastic concentrations in the marine environment reported up to 2016 for risk characterisation, Besseling et al. (2018) conclude that microplastic concentrations at 'hot-spot' locations in near-shore surface waters could present a risk to 10-20% of species. Should the PSS value of 0.4 ng/L have been used for the risk characterisation then 'safe' exposure concentrations would have been exceeded by a greater margin at 'hot spot' sites. Environmental concentrations in freshwater and open ocean surface waters were several orders of magnitude below HC5 values.

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

The conventional approach to threshold derivation in the absence of the extensive ecotoxicity datasets necessary for robust application of SSDs would be to apply assessment factors to the most sensitive reliable and relevant NOEC/EC10 value from

[32] After the publication of the Annex XV report the authors of the Besseling et al. (2018) study advised the Dossier Submitter that a correction to the microplastic SSD reported in the study is pending with the publisher of the journal. The HC5 value for microplastics will be corrected in due course to 1.67 µg/L, with a 95% confidence interval of 0.086 to 32.6 µg/L and an R^2 value of 0.85. The corresponding PSS (PNEC) will be corrected from 0.4 ng/L to 0.33 µg/L. The risk characterisation reported for near shore surface waters indicates that microplastics could present a risk to the most sensitive species at hotspot locations, rather than the 10-20% of species initially reported.

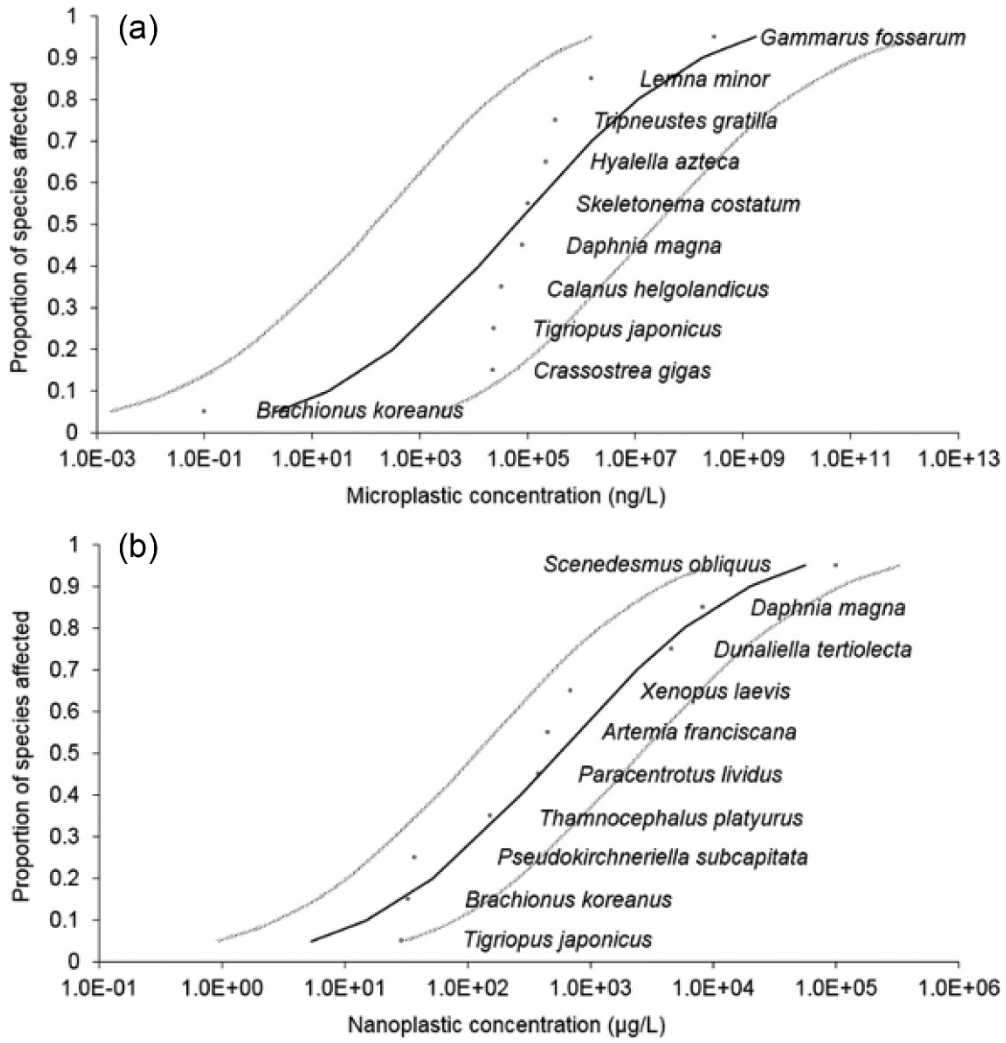
the ecotoxicity dataset, with the size of the factor dependent on the scale of the residual uncertainty (typically ranging from 10 to 1000 for long-term exposure data). Such an approach could be applied to microplastics, although because of the uncertainties surrounding the potential for trophic-transfer and effects from nanoplastics (microplastic transformation/degradation products), this is not considered by the Dossier Submitter to allow the derivation of a reliable PNEC that could be used for quantitative risk characterisation.



Source: Everaert et al. (2018), reproduced under licence

Notes: Past, present and future projections of the concentration of global marine free-floating microplastics (panel A), the concentrations of microplastics that end up on the seabed (panel B), and the concentration of microplastics that wash ashore (panel C) in the marine environment. Historic retrospective microplastic abundances (pre-2016) are represented by the black polygon, while future predicted abundances (2017–2100) are depicted in grey. The dotted line represents the average predicted concentrations and is surrounded the best (lower) and worst (upper) case scenario. Yellow dots are actual in situ observations as reported in scientific literature (see List S1 for all references used). If a concentration range was reported in a certain study, a blue line was drawn between the minimum and maximum reported concentration. Measured and predicted environmental concentrations at which no adverse ecological effects of microplastics are to be expected are plotted against a green background. A red background indicates that the safe concentration as calculated in the present study was exceeded, hence adverse ecological effects are likely to occur at these sites.

Figure 7 Past, present and future projections of microplastics in the marine environment, after Everaert et al. (2018)



Source: Besseling et al. (2017a), reproduced under licence

Figure 8 SSD for microplastics (a) and nanoplastics (b), reproduced from Besseling et al. (2018)

Effects in terrestrial and freshwater organisms have not been studied in enough detail to allow similar comparisons between observed and effect concentrations.

In terms of human health risks, a worst case scenario for human intake estimates ingestion of seven micrograms of microplastic from a 225g portion of mussels, which the Lusher et al. (2017) conclude would have a negligible effect on chemical exposure to contaminants and plasticisers in humans. In addition to this evidence, EFSA (2016) suggest that up to 90% of ingested microplastics and nanoplastics will be excreted following consumption.

1.4.4.10 Microplastic as vectors to facilitate the bioaccumulation of environmental pollutants, including POPs

The hazard posed by microplastics has also been attributed to the potential for the leaching after ingestion of hydrophobic organic contaminants or metals that have adsorbed or adsorbed onto microplastics from the surrounding environment.

In terms of hydrophobic organic contaminants, exposure to contaminants such as PDBEs, BPA, NP and PCBs from direct ingestion or transfer through the food chain (Teuten et al., 2009) have been linked to negative biological effects such as impaired immune function, stress and mortality in fish and worms in the laboratory (Besseling et al., 2013, Browne et al., 2013, Rochman et al., 2013, Oliveira et al., 2013). However, the exposure concentrations in some of these laboratory studies were unlikely to be representative of those occurring in the environment (Koelmans et al., 2016). Only Besseling et al. (2013) used environmentally relevant concentrations and accounted for all exposure pathways when reporting a 29% increase in total PCB accumulation in lugworms after exposure to microplastics, which was considered by the authors to have been facilitated by the physical effects of microplastic ingestion and not contaminant transfer. On this basis the available information contaminant transfer is difficult to interpret (Eerkes-Medrano et al., 2015).

However, Duis and Coors (2016) indicate that microplastics are not likely to contribute significantly to bioaccumulation of pollutants compared to other sources, such as food, for example (Koelmans et al., 2017a). This is in agreement with Lusher et al. (2017) and Koelmans et al. (2016), who report that contaminated microplastics are not likely to increase PBT exposure in marine organisms.

Limited information exists on the transfer of hydrophobic organic chemicals leached from microplastics to higher trophic levels, such as birds and mammals. However, it has been argued that such a 'carrier effect' of microplastic is likely to be of limited importance for the overall exposure and risks of organic contaminants (GESAMP, 2015, Koelmans et al., 2013). Specifically, Koelmans (2013) presents a summary of the available data and suggest that the effects of microplastic ingestion on bioaccumulation are within a factor of two, which is within typical ranges of biological variability among individuals. Therefore bioaccumulation of contaminants from microplastic is probably overwhelmed by uptake via natural pathways, a conclusion that also has been reached recently by GESAMP (2015).

In conclusion, there is no reason to deny that bioaccumulation of some HOCs from microplastics could occur (Rochman, 2014). However, the relative importance of microplastic ingestion from other routes of HOC bioaccumulation is hard to disentangle, but is considered to be limited (Koelmans et al., 2016).

Despite the relatively clear consensus in the literature on the issue of bioaccumulation and transport of environmentally derived HOCs via microplastics, limited research has been conducted on long-term chronic exposure to additives (e.g. plasticisers) typically present in microplastics through their manufacture (Oehlmann et al., 2009).

In addition, there is currently no information on the bioaccumulation behaviour of nanoplastics, although they are likely to be more biologically active than larger microplastics, and the role that these materials could play in the bioaccumulation and transport of HOCs or plastic additives.

1.4.4.11 Uncertainties, data gaps and discussion

A number of independent assessments have concluded that, whist there a growing understating of the hazard and risks posed by microplastics, there is currently insufficient evidence to fully assess these risks (EFSA, 2016, Koelmans et al., 2017a, Everaert et al., 2018, Rist and Hartmann, 2018). Therefore, it is not currently possible to conclude with reasonable certainty that adverse effects are not currently occurring in the environment, or will not occur in the future based on forecasts of increasing exposure concentrations.

To date, a significant proportion of the studies conducted document the occurrence and concentration of microplastics in different environmental compartments with fewer focussing on hazard assessment and even fewer still reporting the dose-response relationships for apical endpoints (e.g. survival, growth or reproduction) that typically underpin regulatory risk assessment.

As such, although knowledge is increasing rapidly, there remain significant uncertainties in relation to the types of (eco)toxicological effects (endpoints) that could be elicited in response to exposure to microplastics, and by which mechanisms these arise; particularly after long-term exposures to environmentally-relevant exposure concentrations. These uncertainties are present across different taxonomic groups and environmental compartments and are greatest in the terrestrial and freshwater compartment, where exposure to intentionally added microplastics is most likely to occur.

Whilst the role of microplastics in facilitating the bioaccumulation of HOCs (particularly POPs) would appear to be less significant than initially considered (Koelmans et al., 2016), understanding the role of plastic additives (such as fillers, UV stabilisers and plasticisers) to observed (eco)toxicity of microplastic remains an important data gap. Conventional risk assessment of these substances is unlikely to have considered exposure to organisms via a microplastic vector.

In relation to this, there is therefore a corresponding paucity of knowledge on robust 'safe' concentrations of microplastics in the environment. Although several authors have proposed threshold values based on the currently available ecotoxicity datasets for marine taxa, these should be considered as tentative as they have not been derived strictly in accordance with the appropriate standards required for a conventional chemical safety assessment (such according to REACH Guidance). Nevertheless, application of these 'tentative' threshold values suggests that concentrations of microplastics in certain locations in the marine environment may currently be sufficiently high to be causing adverse effects (Everaert et al., 2018, Besseling et al., 2018). Given the persistent nature of microplastics (without potential for remediation) it is clear that the scale of these risks, should they be occurring, are likely to increase in the future.

Comparable ecotoxicity datasets for freshwater and terrestrial taxa are not currently available. In addition, although the trophic transfer of microplastics is a fact in aquatic and terrestrial food chains, the data and knowledge required to undertake an assessment of the risks arsing through secondary poisoning is not currently available.

The available information on environmental fate and exposure is also limited. Conventional approaches for modelling exposure, which would normally be applied in chemical risk assessment in the absence of information on measured concentrations, are not applicable. Novel methods for modelling exposures have been reported in the

literature, but are mainly focussed on the marine compartment.

There are also gaps in knowledge in relation to the combined effects of microplastics and additional stressors in the environment. From the literature reviewed, Besseling et al. (2014b) was the only demonstration of mixed stressors (of nanoparticles of polystyrene and fish kairomones) that produced an additive stress effect on body size and reproduction. Furthermore, Burns and Boxall (2018) highlight that environmental microplastics exist as a mixture, and this could perhaps be reflected in ecotoxicity studies; for example, it could be that testing fibres, fragments, and beads simultaneously in the appropriate proportions would provide useful information.

Very little published literature has examined the effect of microplastic in humans (direct or via food; EFSA (2016)). Given the extreme persistence of many polymers in the environment, additional research is required to adequately assess the risks that accumulation of micro- and nanoplastics in the body may pose (Galloway, 2015). Indeed, there is some evidence that exposure to certain chemicals could cause infertility, genetic disruption, poisoning, reduced feeding and increased mortality in marine organisms and in humans if ingested in very large quantities (Hollman et al., 2013, Galloway, 2015, Auta et al., 2018).

There are several key questions that remain unanswered, which are highlighted by many of the review articles, as follows:

- What analytical methods should be used to locate, identify and quantifying micro- and nanoplastics in complex matrices including biological tissues? Further development of suitable methods for extracting microplastics from biological materials would appear to be necessary.
- How does ageing of microplastics affect their physicochemical properties and potential (eco)toxicity?
- Following ingestion, does uptake of micro- and nanoplastics occur? Does this vary for different types of microplastics and what cell types are most affected?
- Does significant bioaccumulation and trophic transfer for microplastics occur in the environment? If so, what species and food chains are most affected?

1.4.4.12 Conclusions

Overall, the available literature describes an emerging understanding of the potential effects of microplastics, including intentionally-added microplastics, but only limited evidence that risks are occurring in the environment; despite ingestion and the presence of microplastics in organisms across different trophic levels being clearly observed.

Inconsistencies in methods and the lack of a standardised definition of microplastics has limited the comparability of (eco)toxicity studies, even from the perspective of consistent reporting of concentration units (e.g. mass vs particle number). The absence of standardisation, as well as issues surrounding the statistical power, reliability and repeatability of some of the laboratory studies conducted to date, means that it remains challenging to apply the observations reported in the literature for microplastics to a traditional risk assessment paradigm (Connors et al., 2017).

Bioaccumulation and biomagnification of HOCs (including POPs) are a possible indirect mechanisms of microplastic (eco)toxicity but the contribution occurring via microplastics in relation to other sources is currently thought to be negligible (Koelmans et al., 2016). Transport of contaminants from microplastics along soil pathways remains to be

explored.

The scientific literature does not suggest that microplastics are currently causing significant adverse impacts in the environment or that they are increasing the bioaccumulation of hydrophobic organic compounds into organisms. However, there are significant gaps in knowledge that prevent a comprehensive and robust assessment of risks and these conclusions should be interpreted as evidence that risk may not be occurring now, or would not occur in the future. As discussed, there is already some evidence that the tentative threshold concentrations proposed may already be exceeded in the environment, and that the scale of these impacts will increase in the future.

The largest body of evidence exists for the marine environment, with only limited data available for freshwater environments, and even less for terrestrial systems; despite evidence that exposures in these environments could be greater than those in the marine environment (Burns and Boxall, 2018).

For nanoplastics, there is insufficient information to undertake any meaningful assessment of either hazard or risk, which is a particularly significant data gap.

The Dossier Submitter notes that some previous studies have questioned the perception that microplastics pose an unacceptable risk to the environment (Koelmans et al., 2017a, Burton, 2017). However, based on all the evidence, the Dossier Submitter concludes that it is impossible to conclude with certainty that microplastics, and by analogy intentionally added microplastics, do not cause harm to the environment from the perspective of a conventional (eco)toxicity risk assessment based on the derivation of a 'no effect' threshold.

Conventional risk assessment approaches, including the use of assessment factors, may not be appropriate to assess the risks of micro and nanoplastics.

1.4.5 PBT/vPvB assessment

Some authors have specifically highlighted the similarities between the concerns posed by microplastics and PBT/vPvB substances (Worm et al., 2017, Lohmann, 2017), specifically the similarity observed in the potential for microplastics to accumulate within environmental compartments and biota, transfer between trophic levels, and the fact that they are practically impossible to remove from the environment once released.

PBT/vPvB substances give rise to specific concerns due to their potential to lead to unpredictable and irreversible adverse effects on the environment or human health over time. In this respect, the hazard of microplastics appears similar to that posed by PBT/vPvB substances.

Specifically, exposure to PBT/vPvB may lead to an impact in a manner which is difficult to predict and prove by testing, regardless of whether there are specific effects already known or not. In the case of vPvB substances, there is concern that even if no toxicity is demonstrated in laboratory testing, long-term effects might be possible since being very persistent, high levels with unpredictable effects may be reached in humans or the environment over extended time periods.

Recognising these concerns, the REACH regulation established that 'safe' concentrations of PBT/vPvB substances in the environment cannot be established with sufficient reliability for undertaking quantitative risk assessment. Therefore, registrants of PBT/vPvB substances are obliged to implement, and recommend to downstream users, risk management measures (RMMs) which minimise releases to environmental

compartments throughout the life-cycle of the substance. Risk management, such as Authorisation or Restriction, may be required to ensure that the minimisation of releases is achieved.

However, the Dossier Submitter does not describe a PBT/vPvB assessment for microplastics as, based on the currently available information, the criteria in Annex XIII may not be applicable to microplastics. Specifically, the classical concept of bioaccumulation and biomagnification, established on a molecular level, may not be satisfied by polymer particles; despite the evidence that microplastics are present in top predators and can be subject to trophic transfer (Lohmann, 2017).

Nevertheless, non-biodegradable microplastics will readily meet the criteria for very persistent substances outlined in Annex XIII of REACH having half-lives of several hundred years or more (see Section 1.4.6). Because of this 'extreme' persistence the approaches established for the risk assessment of PBT/vPvB substances are likely to be applicable to microplastics.

1.4.6 'Case-by-case' risk assessment (extreme persistence in the environment)

Analytical approaches are available to detect, characterise and quantify microplastics in environmental samples. There is, however, a lack of standardised methods and agreed approaches to obtain data in spatial and temporal scales to assess persistence and fate of these materials (Rocha-Santos and Duarte, 2015, Klein et al., 2018). Even if there is monitoring data available on the presence of microplastics in the environment, information on degradation rates is scarce.

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

The main biotic and abiotic degradation processes in the environment are:

- Physical degradation (abrasive forces, heating/cooling, freezing/thawing, wetting/drying)
- Photodegradation (UV light)
- Chemical degradation (oxidation and hydrolysis)
- Thermic degradation
- Biodegradation by microorganisms

Degradation of microplastic may be the combination of all of the above degradation processes. The predominant degradation process and rate is dependent on several factors. The same properties that make plastics so versatile, durable and resistant to degradation, make them difficult or impossible for nature to assimilate. The additives such as inorganic fillers, thermal stabilisers, plasticisers and UV-stabilisers used to improve the performance of (micro)plastics, also influence the degradation behaviour. During the degradation process, the additives may remain in the polymer matrix, be

either fully or partially degraded, or released to the surrounding environment.

Commonly used plastics are not biodegradable in the relevant environmental conditions. Extreme persistency of conventional plastics leads to accumulation in the environment (fresh water, marine, sediment and soil). Degradation of synthetic polymers in the environment is often initiated by photooxidation or hydrolysis. Temperature in the environment is usually not high enough to induce chemical changes and thus impacting reduced rate of degradation compared to the laboratory results (Klein et al., 2018). Mechanical degradation or fragmentation leads to decreased particle size and increased surface area but cannot be counted as biodegradation. As a result of mechanical degradation plastic particles still remain and may accumulate in the environment.

It has been reported that most of the synthetic polymers/conventional plastics have extremely low degradation rates and long resistance time in the environment and thus can stay in the aquatic environment for decades or for hundreds of years (Duis and Coors, 2016, Klein et al., 2018). For example, low density polyethylene (LDPE), high density polyethylene (HDPE) and polypropylene (PP) have shown to loose only 1.5–2.5 % (LDPE), 0.5–0.8 % (HDPE) and 0.5–0.6 % (PP) of their initial weight after 6 months in sea water (Sudhakar et al., 2007b).

Plastic ingredients are typically not mineralised at measurable rates in the environment, either by biodegradation or by photo- and or thermal degradation processes. While some biodegradation and even hydrolysis may take place in the environment, the reactions proceed too slowly to result any significant level of degradation in the environment leading to estimates of half-lives of hundreds of years (Andrady, 2017). Even if there is evidence of some biodegradation of for example PE by isolated microorganisms in laboratory-accelerated conditions (1% to 1.7% decrease in mass over a 30-day duration) (Harshvardhan and Jha, 2013) and 12 % in compost at 58 °C after being exposed for one year to natural weathering (Sivan, 2011), these type of conditions are not comparable to degradation in relevant environmental conditions. Conventional plastics are however weakened and fragmented in the environment for example due to UV-radiation, abrasion, and weathering (Andrady, 2011, Geyer et al., 2017a). The durability and slow rate of degradation allow these fragments, constituted by synthetic polymers, to remain in the environment for years to decades or longer (Sudhakar et al., 2007b, Sudhakar et al., 2007a).

Biodegradation of solid materials, such as microplastics, takes place on the surface, as the inner part of the plastic particle is not readily available for degraders. Therefore, the increased surface area for example due to fragmentation is expected to result in faster degradation if the polymer is susceptible for biodegradation. The influence of surface area on the biodegradation rate has been demonstrated for example by (Yang et al., 2005) and (Modelli et al., 1999) for biodegradable plastics films compared to powder form of PCL, PBSA, PLLA, PBS and PHB. Chinaglia et al. (2018) demonstrated the correlation between the surface area (33-1650 cm^2) and maximum biodegradation rate of polybutylene sebacate determined using ASTM D 5988-12 (aerobic biodegradation in soil). Therefore, if the biodegradation of microplastic is estimated relative to a reference material, it is important that both the test material and reference materials are of the same surface area. In addition, biodegradation results from the larger plastic fragments could therefore be considered as a "worst" case scenario for the biodegradation rate.

However, there are biodegradable plastics available which even meet the criteria for ready biodegradability. For example, McDonough et al. (2017) demonstrated fast

degradation of down to drain biodegradable plastics, milled and pre-wetted PHBV polymer (< 32 µm) and milled PHBV foam (125 µm, 250 µm and 500 µm), using modified OECD TG 301B. In this study, after 28 days the mineralisation of milled PHBV polymer and PHBV foam was 88 % and > 66%, respectively.

To illustrate the high variability of the (bio)degradation potential of different type of plastics in variable environments, some examples of the (bio)degradation of conventional and biodegradable plastics are presented in Annex C.

1.4.7 Conclusions on hazard

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

Hazards have also been associated with environmental pollutants, such as Persistent Organic Pollutants (POPs) or metals that adsorb/absorb to microplastic particles in the environment and which may subsequently be released if microplastics are ingested, leading to enhanced bioaccumulation and/or adverse effects from the 'transferred' substances[33]. However, the current scientific consensus on this issue would suggest that ingestion of microplastics does not significantly enhance bioaccumulation of POPs relevant to other types of particulates present in the environment.

The Dossier Submitter has considered the risk assessment of microplastics using threshold, non-threshold and 'case-by-case' approaches outlined in Annex I of REACH.

Tentative 'effect' thresholds for microplastics have been recently proposed by various authors for the marine environment using species sensitivity distributions. However, the Dossier Submitter has concluded there is currently insufficient information to derive a robust predicted no effect concentrations (PNECs) for microplastics, that could be used to underpin a conclusion that risk are adequately controlled, either now or on the future; including in the marine compartment where the hazards of microplastics have been most extensively studied.

The lack of information for threshold-based risk assessment is particularly apparent for the terrestrial compartment, which is a key receptor for intentionally added microplastics either via direct application or the spreading of biosolids. Equally, the bioaccumulation properties and hazard of nanoplastics, that are likely to be formed during the (bio)degradation of microplastics, are only currently poorly understood, which currently prevents an assessment of the risks posed by relevant breakdown/transformation products of microplastics in the environment. Theoretical considerations on cellular uptake mechanisms would suggest that nanoplastics would be more readily taken up into cells than microplastics.

Coupled with the uncertainty associated with measured and/or modelled exposure

[33] The microplastic in this sense can be considered as a vector facilitating exposure to another substance, rather than associated with adverse effects itself.

concentrations of microplastics the Dossier Submitter has concluded that conventional threshold-based risk assessment cannot currently be carried out for microplastics with sufficient reliability, even with PNEC values derived using large assessment factors e.g. 1000 to 10 000.

A important property of microplastics to also bear in mind when considering appropriate risk assessment is their 'extreme', arguably permanent, persistence in the environment. This property will lead to any releases that occur contributing to the environmental stock over time, which would eventually exceed a PNEC in the future, assuming that sufficient information becomes available to derive one.

Based on these two considerations, the Dossier Submitter considers that microplastics should be treated as a non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment assumed to result in a risk. Therefore, the Dossier Submitter has concluded that the risks arising from intentional uses of microplastics that result in releases to the environment are not adequately controlled.

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

Despite these conclusions, the Dosser Submitter notes that provisional quantitative risk assessment for the marine environment reported in the scientific literature has indicated that the concentrations of microplastics occurring at some 'hot spot' locations in coastal regions could currently already exceed tentative effect thresholds. The concentrations of microplastics are forecast to increase in the environment over time. Therefore, the number of locations exceeding these tentative thresholds is likely to increase. The Dossier Submitter's conclusions do not contradict these.

1.4.8 Risk characterisation

On the basis of the conclusions of the hazard assessment it is proposed that microplastics are considered as non-threshold substances and that releases to the environment are considered as a proxy for risk.

This is consistent with recent restrictions on substances where it is not possible to derive a threshold, such as decaBDE, PFOA and lead (in PVC and in gunshot), etc. The quantities of microplastics released to the environment from each of the uses assessed are reported in Table 15 and in Section 1.6.1.

1.5 Justification for an EU wide restriction measure

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

EU.

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

1.6 Baseline

1.6.1 Annual uses and emissions

On the basis of information provided in the ECHA Call for evidence as well as literature review, the Dossier Submitter estimated that in 2017, more than 51 000 (11 000 - 63 000) tonnes of microplastics were used in the EEA. About 70% of these microplastics were subsequently emitted to the EEA environment. The methodology for estimating the tonnage of microplastics used in the EEA are explained in greater detail in Annex D. Section 1.4.2 details the methodology for estimating emissions to the environment for those sectors where available information allowed quantification of the use and therefore, releases. Table 15 summarises the baseline situation.

Table 15 Summary table of releases to the environment from sector-specific product groups containing intentionally added microplastics

Sector / Product group	Use/disposal/loss [a] (tonnes/year)	Release to the environment [b] (tonnes/year)
Cosmetic products	9 300 (4 100 - 14 400)	3 800 (1 700 - 5 900)
- Rinse-off containing microbeads (exfoliators/cleansers) [c] - Other rinse-off - Leave-on	107 6 500 (2 900 - 10 000) 2 700 (1 100 - 4 300)	55 3 100 (1 400 - 4 900) 650 (300 - 1 000)
Detergents and maintenance	9 700 (2 000 - 17 400)	4 400 (1 000 - 8 000)
- Detergents containing microbeads [c] - Detergents containing fragrance encapsulation - Other detergents - Waxes and polishes	200 150 (0 – 300) 7 100 (1 100 - 13 100) 2 400 (900 - 4 000)	100 80 (0 - 150) 3 600 (600 - 6 700) 700 (300 - 1 200)
Agriculture and horticulture	23 500 (5 400 - 39 700)	23 500 (5 400 - 39 700)
- Controlled release fertilisers - Fertiliser additives - Treated seeds - Capsule suspension PPPs	10 000 (1 000 - 17 000) 12 500 (4 000 - 21 000) 500 (250 - 1 000) 500 (100 - 700)	10 000 (1 000 - 17 000)[g] 12 500 (4 000 - 21 000) 500 (250 - 1 000) 500 (100 - 700)
Oil and gas	1 200 (300 - 2 000)	270 (~0 - 550)
Paints and coatings [d]	5 200 (0 - 10 200)	2 700 (0 - 5 200)
- Consumer uses - Professional uses	5 200 (4 900)	2 700 (2 500)
Construction products	n/d[e]	n/d
Medicinal products	2 300 (800 - 3 700)	1 100 (400 - 1 800)
- Ion exchange resins - Matrix or polymer film for controlled release	700 (300 - 1 000) 1 600 (500 - 2 700)	300 (100 - 500) 800 (300 - 1 300)

Sector / Product group	Use/disposal/loss [a] (tonnes/year)	Release to the environment [b] (tonnes/year)
Medical devices and *in vitro* diagnostic medical devices	50 (0.5 – 100)	0.27 (0.25-0.29)
Total[h]	**51 500 (11 000 - 63 000)**	**36 000 (8 500 - 61 300)**

Notes:
[a] Releases via down-the-drain (wastewater), municipal solid waste (trash/bin) and/or direct application/deposition to soil pathways (as outlined in 1.4.2.1);
[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] no information on tonnages of microplastics used;
[f] during use, microplastics are essentially contained in equipment or cartridge and treated as hazardous waste/incinerated at their end of life, hence the limited release to the environment;
[g] about 50% are assumed to be reduced as a result of the entry into force of the FPR (ca. 2025);
[h] All figures are rounded so may not add up precisely to the totals presented.

A recent project for the European Commission estimated the scale of annual releases of microplastics emitted by (but not intentionally added to) products to EU surface waters (Eunomia, 2018). This study reports releases of 176 300 tonnes per year, with a lower and upper range of 71 800 to 280 600 tonnes per year. The greatest contributors to surface water were identified to be road tyre wear (94 000 tonnes per year) and losses of pre-production plastic pellets (41 000 tonnes per year), followed by road marking (15 000 tonnes per year) and the washing of clothes (13 000 tonnes per year). Therefore, although not of comparable size to total annual releases of microplastics from unintentional sources to surface waters, the quantities of intentionally added microplastics estimated to be released to the environment per year are comparable to some unintentional sources and, therefore, should not be considered to be insignificant, particularly when the 'stock' effects of microplastics are considered.

One further way to contextualise these releases is by means of a comparison to plastics currently produced, consumed, recycled, incinerated, landfilled and otherwise disposed of in the EU. Below, the Dossier Submitter provides such comparison based on the best available information. The comparison should be interpreted with caution, however, since it relies on several assumptions that are beyond robust assessment.

The Dossier Submitter considers the latest estimate by Plastics Europe (2017) as the most reasonable starting point. This estimate indicates that 60 million tonnes of plastics were produced in the EU28 plus Norway and Switzerland (referred to as 'EU28+' hereafter) in 2016.[34] In the same year, roughly 27 million tonnes of plastic waste were collected through official schemes in the EU28+ for recycling, incineration or landfill (Plastics Europe, 2017:30). Taking the assumption from a recent study on global plastics production (Geyer et al., 2017a) that for each 4 million tonnes of plastics entering the use phase, 3 million tonnes of plastics exit the use phase, one can estimate that the total amount of plastic waste that corresponds to the 2016 production is 45 million tonnes (of which 27 million tonnes were collected). This then suggests that in 2016

[34] Plastic production increased by 3.5% from 2015 (Plastics Europe, 2017:16).

about 18 million tonnes of plastics (of different size, shape and composition) were disposed of in the EU28+ environment without proper control.

A first comparison to relate the extent of emissions from intentionally added microplastics can be made against this volume. By weight, the 2016 emissions of microplastics in scope of the restriction corresponded to approximately 0.2% of the total plastic waste that is disposed without proper control in the EU28+ in 2016 (see Figure 9).

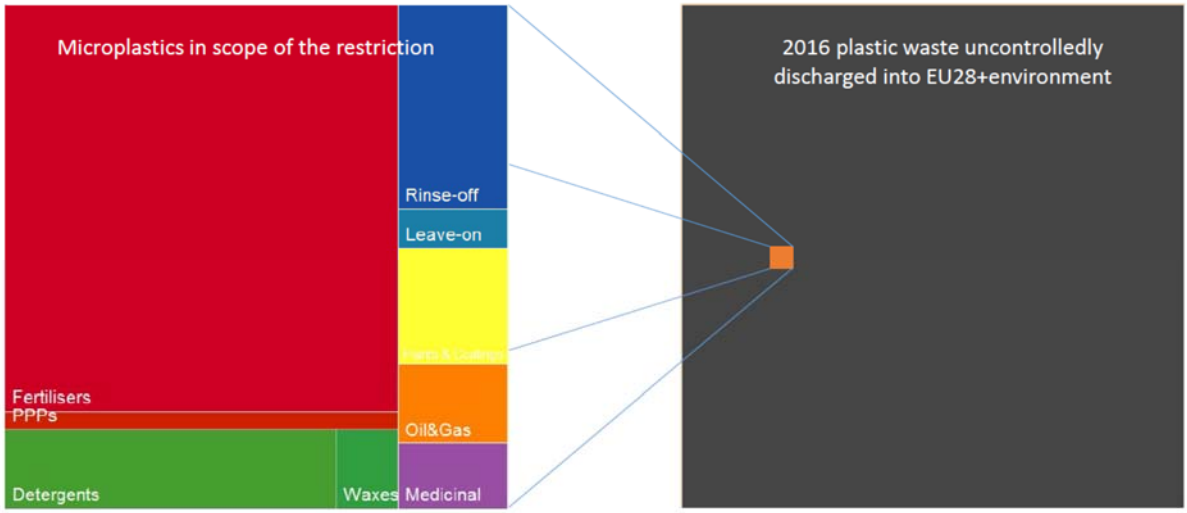


Figure 9 Weight-based comparison of microplastics to overall plastic waste

However, an additional, and perhaps more relevant, illustration can also be made by expressing the 36 000 tonnes of microplastics released annually in terms of the quantity of plastic waste in the environment required to release an equivalent quantity of microplastics. Such an estimate can be made based on a recent study of the composition of the Great Pacific Garbage Patch (GPGP) by Lebreton et al. (2018)[35]. Based on the relative proportion of plastics across different size classes reported in the GPGP, the

[35] Lebreton et al. (2018) predicted that the GPGP contains a total of 1.8 (1.1-3.6) trillion plastic pieces weighing 79 (45-129) kilotonnes, comprised of debris categorised in 4 size classes:

- microplastics (0.05-0.5 cm): 1.7 (1.1–3.5) trillion pieces and 6.4 (4.1-12) kilotonnes;
- mesoplastics (0.5-5 cm): 56 (39-104) billion pieces and 10 (6.9-19) kilotonnes;
- macroplastics (5-50 cm): 821 (754–908) million pieces and 20 (18-22) kilotonnes;
- megaplastics (>50 cm): 3.2 (2.7-3.6) million pieces and 42 (16-75) kilotonnes.

As the GPGP is composed of partially degraded plastic particles, the estimates of weight and numbers of particles reported by Lebreton et al. (2018) can be used to derive a realistic number of microplastic particles based on a given weight. Therefore, the 36 000 tonnes of microplastics in the scope of this restriction correspond to 9.76 trillion microplastic particles. Given the composition of the GPGP, this suggests a garbage patch 5.64 times larger than the GPGP. Crucially, this comparison assumes that the plastic litter is of the same composition as that of the GPGP, which is the result of more than 70 years of degradation and fragmentation.

microplastics in scope of this restriction (estimated based on the data reported in Lebreton et al. (2018) to be comprised of 9.76 trillion particles) can be estimated to correspond with a weight of plastics 5.64 times the total weight of the GPGP (79 kilotonnes), i.e. 445 kilotonnes.

Alternatively, if virgin plastic was assumed as the basis for the comparison, rather than partially degraded plastic in the environment, then the total weight of source material corresponding to the estimated 9.76 trillion microparticles in the scope of the restriction would be larger. For instance, assuming a typical single use 1L plastic bottle contains between 0.05 and 0.1 kg of plastic and that 1 000 microparticles are produced from each bottle per year, equivalence would suggest that 9.76 billion bottles or between 488 and 976 kilotonnes of plastics would be needed to be disposed in the environment per year to generate the 36 000 tonnes of microplastics within the scope of the proposed restriction[36]. In practice, however, the majority of bottles are disposed of appropriately in municipal solid waste and will not be released into the environment.

1.6.2 Use and emission forecast

The future use and emissions of microplastics will depend on a number of diverse elements, such as demand and supply conditions as well as planned regulatory changes, which are often unique to each of sectors within the scope of the proposed restriction. The baseline scenario presented in Figure 10 takes into account existing trends (e.g., as a result of a voluntary phase out of microbead use in some rinse-off cosmetics and detergents) as well as planned regulatory changes (under the EU Fertilising Products Regulation). It further takes into account the work of two opposing influences:

- Increased intentional use of microplastics as a result of increased demand for the end-products containing microplastics: There is indication that microplastic use has increased in recent years[37] and an increase commensurate with GDP growth (for agricultural or industrial uses) or consumer spending and population growth (primarily for consumer uses) is likely to influence end-product demand.

- Downward trend of use due to growing awareness and concern with microplastic emissions to the environment.

As it is challenging to estimate the impact of awareness on future use of microplastics in cosmetics, it is assumed that this downward trend is equal but diametrically opposite to the upward trend due to increased demand. The result of this assumption is no net change from 2020 levels to 2041: the end of the temporal scope of the analysis, i.e., the intentional use of microplastics is expected to exceed 51 500 tonnes annually (ranging from 11 000 tonnes to 63 000 tonnes per year under the Low and High tonnage scenarios). The share of the different sectors using microplastics is shown in Figure 10. Annex D elaborates on the assumptions for the Low, Central and High scenarios and discusses the uncertainties and their impact on the conclusions on the effectiveness of the proposed restriction.

[36] Convert 9.76 x 10^{12} particles into bottles: if 1 000 microplastic particles were to be produced per bottle, one would require 9.76 billion bottles; if each bottle weighs of 0.1 kg, then 9.76 billion bottles corresponds to a total weight of 976 kilotonnes.

[37] Plastic production increased by 3.5% from 2015 (Plastics Europe, 2017:16)

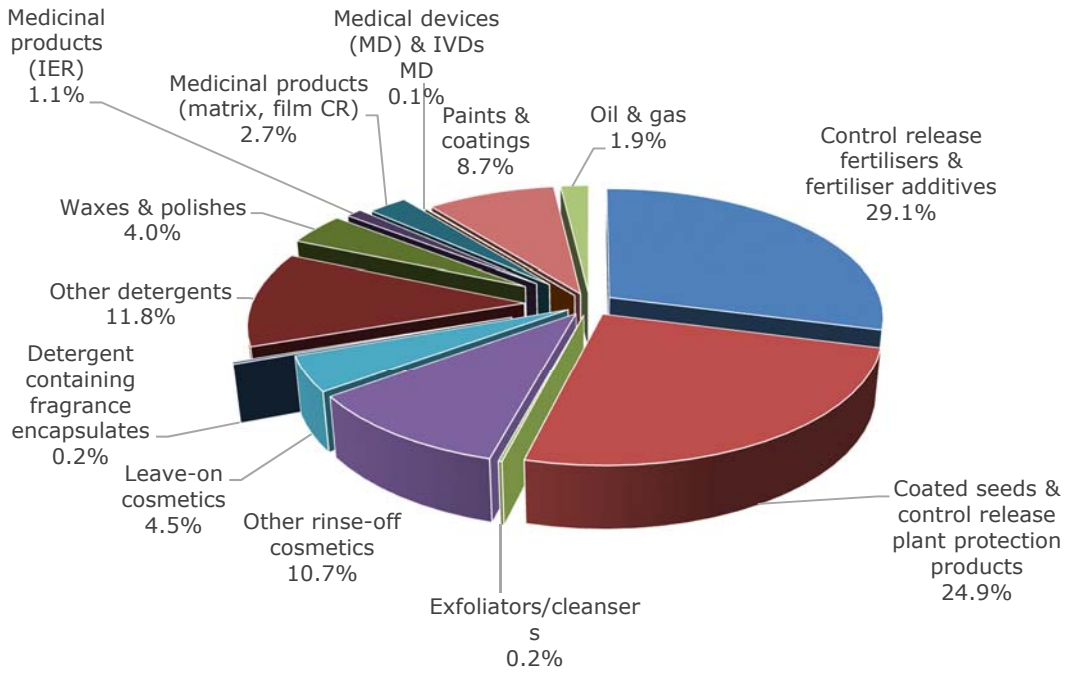


Figure 10 Microplastic use: Baseline, share of total use (51 500 tonnes/annum)

Future emissions of intentionally added microplastics will depend on future trends of their use as well as any technological improvements related to the collection and removal of microplastics, for example via waste water or sludge treatment, which is relevant for a number of products in the scope of the proposed restriction. (See Section for 1.4.2 for detailed assumptions.)

Based on the aggregate annual emissions reported in Table 15, the emissions from products containing intentionally added microplastics are forecast over a 20-year period after the restriction enters into force. Similar to the use forecast, it is assumed in the central case that in the absence of the proposed restriction, under baseline conditions, microplastic emissions will remain at 2020 levels for the remainder of the study period (year 2041), i.e., approximately 36 000 tonnes per annum as estimated for the uses where quantitative information is available. Such a forecast is associated with uncertainties, although these are likely to be captured in the Low and High tonnage scenarios which forecast that releases to the environment would range from 8 300 to 61 100 tonnes per annum. (See Annex D for detailed assumptions and their impact on the conclusions on the effectiveness of the proposed restriction.)

The resulting cumulative emission forecast is shown in Figure 11. By the end of the study period, cumulative emissions under the baseline are forecast to exceed 640 000 tonnes. This relies on the central annual emission estimates reported in Table 15. Whilst the central estimate presents the Dossier Submitter's best prediction, when taking into account the uncertainty about sector-specific emissions, the aggregate emission estimate is forecast to range from 160 000 tonnes to 1.1 million tonnes over the study period. The corresponding uncertainty interval is also represented in the cumulative emission forecast depicted in Figure 11.

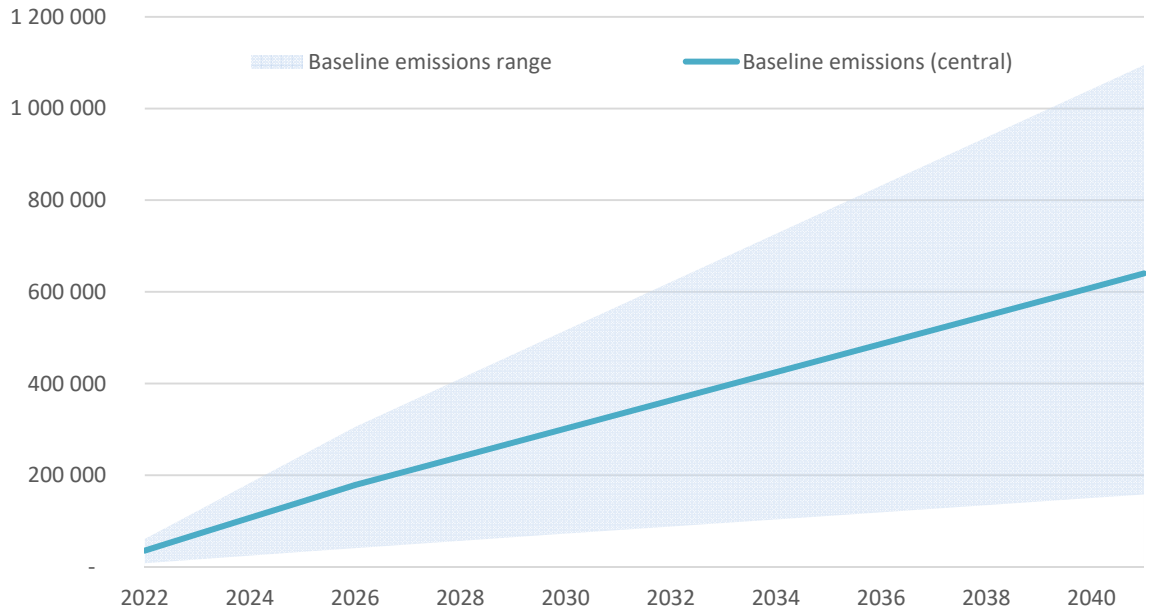


Figure 11 Microplastic emissions under the baseline scenario (cumulative, 20-year analytical period)

2 Impact assessment

2.1 Analysis of risk management options (RMOs)

The Annex XV restriction dossier on the use of intentionally added microplastic particles in consumer or professional products was prepared at the request of the European Commission. As identified in Section 1.4.2, uses of certain consumer and professional products containing microplastics will inevitably result in microplastics being released to the environment. On the basis of the conclusions of the risk assessment reported in Section 1.4.8, these releases are considered to pose a risk to the environment that is not adequately controlled.

In response to the identification of this risk, the Dossier Submitter has conducted an analysis of diverse risk management options (RMOs) to identify the most appropriate risk management measure to address these risks.

As a first step, the possibility to address the risks posed by the use of microplastics under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors, such as the recast of the fertilising products regulation (FPR), these were assessed as inappropriate to address *all* of the sectors and products contributing to risk.

Therefore, the option to use a restriction under REACH to address the identified risks was investigated further. The following restriction options, alone and in combination, were considered in addition to the proposed option:

1. **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);*
2. **Labelling** – *labelling of all mixtures or articles for consumer and professional use containing intentionally added microplastics (≥ 0.01 % w/w) with the phrase 'contains microplastics > 0.01%', with a requirement for user instructions to minimise releases to wastewater e.g. dispose to municipal waste);*
3. **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*);
4. **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);*
5. **Smaller size characteristics** - *Restriction on the use of microplastics in consumer and professional products (≥ 0.01 % w/w) with a size range of 1 µm ≤ x ≤ 1 mm;*
6. **Thermoform and thermoset plastics** – *restriction on thermoform and thermoset organic polymer 'plastics' only (> 0.01% w/w)*;

Each of the options was assessed against the main criteria for restriction identified in

Annex XV of REACH: effectiveness, practicality and monitorability.

As a result of this assessment, the restriction option presented in Table 17 is proposed, whilst those summarised in Table 16 were discarded. The detailed rationale for not proposing the discarded restriction options is presented in Annex D. In summary, the proposed restriction (Table 17), was found to fulfil the criteria for effectiveness, practicality and monitorability better than the other evaluated restriction options.

Table 16: Summary of rejected restriction options (compared to the proposed restriction option)

	Restriction option	**Effectiveness** (risk reduction/ proportionality)	**Practicality** (implementability, enforceability, manageability)	**Monitorability**	**Other**
1	All uses	+ risk reduction - proportionality	-	-	-
2	Labelling	- risk reduction - proportionality	-	-	-
3	Specific uses	= Risk reduction = proportionality	=[1]	=	Option unable to prevent new uses in the future.
4	Microbeads	- Risk reduction - proportionality	+	+	
5	Smaller size characteristics	- Risk reduction ? proportionality	+?	-	
6	Thermoform and thermoset plastics	- Risk reduction ? proportionality	=	=	

Notes: (+) increase related to the proposed restriction option; (-) decrease related to the proposed restriction option; (=) equal to the proposed restriction option.

[1] Assuming that industry have highlighted all significant uses during the Dossier preparation process.

2.2 Restriction scenario

Brief title: Restriction on the use of microplastics in consumer and professional products.

Table 17 Proposed restriction on the use of microplastics

Polymers within the meaning of Article 3(5) of Regulation (EC) No 1907/2006)	1. Shall not, from [entry into force (EiF)], be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than [0.01]% w/w. 2. For the purposes of this entry: a. 'microplastic' means a material consisting of solid polymer-containing particles, to which additives or other substances may have been added, and where ≥ 1% w/w of particles have (i) all dimensions 1nm ≤ *x* ≤ 5mm, or (ii), for fibres, a length of 3nm ≤ *x* ≤ 15mm and length to diameter ratio of >3. 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. d. 'polymer-containing particle' means either (i) a particle of any composition with a continuous polymer surface coating of any thickness or (ii) a particle of any composition with a polymer content of ≥ 1% w/w. e. 'solid' means a substance or a mixture which does not meet the definitions of liquid or gas. f. 'gas' means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa. g. 'liquid' means a substance or mixture which (i) at 50 °C has a vapour pressure of not more than 300 kPa (3 bar); (ii) is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa; and (iii) which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. 3. Paragraph 2a and 2b shall not apply to: a. Polymers that occur in nature that have not been chemically modified (other than by hydrolysis). b. Polymers that are (bio)degradable, as set out in the criteria in Appendix X. 4. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastics for use at industrial sites. b. Medicinal products for human or veterinary use. c. Substances or mixtures that are regulated in the EU under Regulation (EC) No xxx/xxxx on Fertilising Products[38] 5. Paragraph 1 shall not apply to the placing on the market of: a. Substances or mixtures containing microplastic where the microplastic is both (i) contained by technical means throughout their whole lifecycle to prevent releases to the environment and (ii) any microplastic containing wastes arising are incinerated or disposed of as hazardous waste. b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a).

[38] Regulation under development.

	c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix when used. 6. Paragraph 1 shall apply from: a. EiF for cosmetic products (as defined in Article 2(1)(a) of regulation (EC) No 1223/2009) and other mixtures containing microbeads. b. EiF + 2 years for medical devices as defined in regulation (EC) 2017/745 and *in vitro* diagnostic medical devices as defined in regulation (EC) 2017/746. c. EiF + 4 years for 'rinse-off' cosmetic products (as defined in regulation (EC) No 1223/2009) not already included in paragraph 6(a). d. EiF + 5 years for detergents (as defined in regulation (EC) No 648/2004) and maintenance products. e. EiF + 5 years for fertilising products not regulated in the EU as fertilising products under Regulation (EC) No xxx/xxxx on Fertilising Products that do not meet the requirements for biodegradability contained in that Regulation. f. EiF + 5 years for other agricultural and horticultural uses including seed treatments, plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012. g. EiF + 6 years for 'leave-on' cosmetic products (as defined in regulation (EC) No 1223/2009). 7. From [EIF + 18 months] any manufacturer, importer or downstream user responsible for the placing on the market of a substance or mixture containing a microplastic derogated from paragraph 1 on the basis of paragraphs 4(a), 4(b) or 5 shall ensure that the label and/or SDS, where applicable, '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. The instructions shall be clearly visible, legible and indelible. The label shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information labelling shall be included on the instructions for use. 8. From [EiF +12 months], any downstream user using a microplastic derogated from paragraph 1 on the basis of paragraph 4(a) or any importer or downstream user placing a microplastic derogated from paragraph 1 on the market on the basis of paragraphs 4(b), 5(b) or

	5(c) shall send to ECHA in the format required by Article 111 of REACH, by 31 January of each calendar year: e) the identity of the polymer(s) used in the previous year, f) a description of the use of the microplastic, g) the quantity of microplastics used in the previous year, and h) the quantity of microplastics released to the environment, either estimated or measured in the previous year. ECHA shall publish a report summarising the information received by 31 March every year.

Note: Appendix X can be found in Table 21 in Section 2.2.1.6

2.2.1 Justification for the scope of the proposed restriction

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

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

The Dossier Submitter has undertaken an extensive investigation into possible uses of microplastics using a deliberately inclusive working definition at the start of its investigation. The Dossier Submitter also hosted an online information session (with 217 participants) to explain the scope of the investigation and the importance of providing information to avoid the potential for uses to be included in the scope where they had not been assessed. On 9/04/2018, 13 242 letters were sent to registrants, and classification and labelling notifiers of substances potentially used in intentionally added microplastics (see Annex G for further information). It was clearly explained that the working definition was applicable to all polymers and not just thermosets and thermoplastics.

The Dossier Submitter undertook a call for evidence and a workshop to explore the impact on various sectors. Further investigations and sector specific discussions have been undertaken along with additional publicity, such as the publication of additional considerations on the microplastic identification and the scope of a potential restriction in June 2018[39] and in conjunction with the Micro2018 international conference on microplastics in November 2018[40].

Annex G contains further information on the consultations undertaken and the information is referenced in the report. The Dossier Submitter is therefore confident that industry has either sent in information on the impact to its sector or that the impact on

[39] https://echa.europa.eu/documents/10162/13641/note_on_substance_identification_potential_scope_en.pdf

[40] https://echa.europa.eu/-/intentionally-added-microplastics-likely-to-accumulate-in-terrestrial-and-freshwater-environments

other uses is limited as no information to the contrary was submitted.

Therefore, on the basis of the uses assessed, the Dossier Submitter considers that the scope of the restriction is justified, despite its inclusive scope. However, if the proposal were to capture uses in addition to those that were assessed, then the Dossier Submitter estimates that the impact would be limited. This wide scope is also important to prevent the new uses of intentionally added microplastics.

Nevertheless, if evidence is presented in the Public Consultation that additional uses that would be restricted from the initial entry into force and result in a significant socio-economic impact (although this is not considered to be the case as industry did not indicate this during the Dossier Submitter's investigation) then the proposal could be further developed to either (i) introduce further sector-specific transitional arrangements where this can be justified, or (ii) 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 6 years). The second option would allow the Commission to decide if further derogations should be investigated by ECHA during the implementation phase of the restriction.

The Dossier Submitter has identified that the granular infill material (i.e. the granules produced from end-of-life tyres (ELT) or other synthetic elastomeric materials) used in synthetic turf, is consistent with the definition of an intentionally-added microplastic[41].

ECHA has recently evaluated the possible health risks of recycled rubber granules used as infill in synthetic sports fields. In addition, a restriction proposed by the Netherlands on polycyclic aromatic hydrocarbons (PAH) in sports field infill material is currently under discussion in ECHA's Scientific Committees. ECHA are also investigating the need to restrict other substances in these materials on the basis that they could also lead to a concern to human health and the environment.

Although information on the costs to society of the 'non-use' of ELT granules is contained in the Annex XV dossier submitted by the Netherlands, the Dossier Submitter notes that further information on the impacts of a restriction on synthetic turf infill (as microplastics) would be beneficial to obtain from stakeholders during the public consultation on the Annex XV restriction proposal on intentionally-added microplastics. Notably as synthetic alternatives to ELT granules would also be restricted under the proposed restriction on intentionally-added microplastics.

The restriction applies to microplastics that are substances on their own or in mixtures. We assume that microplastics are not substances in articles, based on version 4.0 of the Substances in Articles Guidance, specifically section 2.2 that discusses manufactured solid materials[42]. However, if this understanding changes then relevant wording should be included in the proposed restriction to ensure that relevant articles are also included within the scope.

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

[41] Synthetic infill material, irrespective of its source, is typically comprised of solid polymer-containing particles that are between 0.7 and 3 mm in size https://echa.europa.eu/documents/10162/13563/annex-xv_report_rubber_granules_en.pdf.

[42] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

intentional addition of microplastics and an exemption for industrial uses (that take place at industrial sites). The most appropriate concentration of microplastics that has been identified to achieve a function is for certain detergents, waxes and polishes as well as anticaking agents in fertilisers where they are added in concentrations of around 0.01% w/w. Table 18 gives an understanding if the concentration limit is changed what types of intentionally added microplastics will be allowed by the restriction.

Table 18: Percentage of microplastics added per sector to achieve a function (intentional addition)

Sector	% microplastics added for function
Controlled release fertilisers and fertiliser additives	Anticaking agents 0.01 – 0.5%
Capsule suspension PPPs (CSPs) and treated seeds	Unknown
Rinse-off cosmetic products containing microbeads (exfoliating & cleansing)	Unknown[43]
Other rinse-off cosmetic products	Unknown[43]
Leave-on cosmetic products	Unknown[43]
Detergents containing microbeads	Unknown
Detergents containing encapsulated fragrance	Unknown but likely to be <0.1% for a share of the products
Other detergents[A]	Mean: 3.1%, median 1.00%. Reported values range from 0.01% to 43.25%.
Waxes and polishes[A]	Mean: 3.1%, median 1.00%. Reported values range from <0.01% to 40%.
Construction products (fibre-reinforcement of concrete and other adhesives)	Unknown
in vitro diagnostic medical devices (IVD MD): reagents and assays	Reported values[A] range from 0.02-4.6%
in vitro diagnostic medical devices (IVD MD): calibration	Reported values[A] range from 0.001-10%
Medicinal products (Diffusion controlled systems)	Estimated[B] value range from 5 to 50% w/w in matrix-diffusion system Estimated[B] value 1-20% w/w in membrane-diffusion system (e.g. film coated tablets)
Medicinal products (Ion-exchange based controlled release)	Estimated[B] value range from 2 to 70%
Medicinal products (Osmotic systems)	Estimated[B] value 3-5% w/w
Food supplements and medical food	Similar to the medicinal products (Diffusion controlled systems), i.e.: Estimated[B] value range from 5 to 50% w/w in matrix-diffusion system Estimated[B] value 1-3% w/w in membrane-diffusion system (film coated tablets)
Paints and coatings	20%
3D printing	Unknown
Printing inks	Unknown

Notes:
[A]: According to CfE definition of microplastics

[43] The concentration of microplastics in cosmetics products can be as low as 0.00003% w/w; however, the percentage of cosmetic products with lower concentration than 0.01% or between 0.01% and 0.1% is not known.

[B]: Estimated values based on literature research

2.2.1.1 Regulatory definition of a microplastic

Paragraph 2 of the restriction proposal sets out the definitions relevant for the proposal. The relevant justification for these definitions are provided in Annex B.

Further explanation is given below with regard to point 2.d on 'polymer-containing particle' as outlined in Table 17. A polymer containing particle is a particle in which the polymer does not comprise the whole material (for example inorganic particles stabilised with polymer) or a particle with a polymeric outer shell (i.e. a polymeric encapsulation).

In the former case, when assessing the minimum content of polymer in a particle for it to be considered as a microplastic the proposed threshold is set at 1 % (w/w). This means that if the polymer content in the particles is greater than 1 % w/w, and if other criteria given in the definition for 'microplastics' are met, the particles are considered to be within the scope of the proposed restriction.

In the case of polymer encapsulation, it is proposed not to set a minimum threshold for the (w/w) % of polymer coating relative to the mass of the coated material. This means that where the polymer-coated particle is within the size range specified in the definition, the particle itself is considered as a microplastic.

The reason for this is that the amount of polymer used for coating could differ considerably based on the application and the amount of polymer used for the coating application is less of an importance compared to the final particles that are created by the coating application.

2.2.1.2 Derogations

A number of derogations have been included in the restriction where the polymer is not expected to be emitted to the environment in the form of a particles or to avoid double regulation.

Table 19 Derogations from the scope of the proposed restriction

Paragraph	Derogation	Explanation
3.a	Polymers that occur in nature that have not been chemically modified (other than by hydrolysis).	To clarify that polymers that occur in nature, as long as their chemical structure has not been modified, are exempt from the restriction on the basis that they are inherently biodegradable in nature. Hydrolysis of the polymer, as would shortening of the polymer chain length, is permitted as this is not expected to prevent biodegradation. This is consistent with Annex V of REACH and the Guidance on monomers and polymers (April 2012 Version 2.0) section 3.2.1.3.
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.
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

Paragraph	Derogation	Explanation
		action if needed.
4.b	Medicinal products for human or veterinary use.	Derogation from the scope of the restriction on use to avoid potential double regulation. The Commission is developing a strategy on pollution from medicines' uses. 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.
4.c	Substances or mixtures that are regulated in the EU under Regulation (EC) No xxx/xxxx 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.
5.a	Substances or mixtures containing microplastic where the microplastic is both (i) contained by technical means throughout their whole lifecycle to prevent releases to the environment and (ii) any microplastic containing wastes arising are incinerated or disposed of as hazardous waste.	Generic derogation from the restriction for uses where OC and RMM are implemented that are appropriate to adequately control the risk from the use of microplastics. Includes a requirement that appropriate OCs and RMMs are identified on product labelling and instructions for use (IFU). This derogation is generic, but is primarily intended to cover uses of microplastics in non-industrial laboratory settings, including *in vitro* medical diagnostic uses at clinical laboratories (e.g. at healthcare centres or hospitals). 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).
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 given in paragraph 2(a).	Generic derogation from the restriction for uses of microplastics as a substance or in a mixture where the microplastics are 'consumed' or otherwise cease to exist at the point of use; this principally corresponds to the loss of the particulate nature of the microplastic through various physico-chemical processes or chemical reactions. This would derogate film-forming functions of microplastics in all sectors, including those in cosmetic products, household care and maintenance products and in paints/coatings; as well as any products where the microplastic particles cease to exist at the point of use, such as in instances where they 'dissolve' (e.g. polyelectrolytes or certain detergents) or 'swell' in contact with water to such an extent that they can no longer be considered to be solid particles (e.g. super absorbent polymers; SAPs.). However, as there could be some releases of 'unconsumed' microplastics under reasonably foreseeable conditions of use, these releases should be minimised. Therefore, uses benefiting from this derogation shall be required to 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).
5.c	Substances or mixtures containing microplastics where the microplastic are permanently incorporated into a solid matrix when used.	Generic derogation from the restriction for uses of microplastics as substances or mixtures where the microplastics are permanently 'contained' at the point of use. 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

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

It should be noted for the exemptions from paragraph 1 described in paragraph 5 b and 5 c we have assumed that all upstream uses related to the end use of the substances are industrial uses and do not need to be further exempted. However, if it becomes clear during the opinion making this is not the case (that the upstream uses are not industrial uses) then consideration of a derogation can be made (if the need is properly justified).

2.2.1.3 Transitional periods

Paragraph 6 introduces a number of transitional periods for different sectors or product types. Table 20 gives an overview of the various entry into force dates for the sectors or product types and an overview of the reason for the specific transition period. Further information can be found in Annex D.

Table 20 Transition arrangements for different sectors included in the proposed restriction

Subject of transitional period	Entry into force	Examples	Reason for transition period
Rinse-off cosmetic products containing microbeads	EiF	Rinse-off cosmetic products containing microbeads i.e., intended specifically to remove dirt, unclog pores, or remove dead skin cells (e.g., facial exfoliating products, face wash, soaps, make-up remover, toothpaste, tooth whiteners)	No transitional period necessary as alternatives are widely available and European industry has voluntarily agreed to phase out the use of microbeads by 2020. Several national bans on this use in the EEA.
Detergents or maintenance products containing microbeads	EiF	Hard surface cleaners, bathroom acid cleaners and stainless steel cleaners	No transitional period necessary as alternatives are available and substitution is ongoing with the use decreasing rapidly.
Medical devices as defined in regulation (EC) 2017/745 and *in vitro* diagnostic medical devices as defined in regulation (EC) 2017/746.	EiF + 2 years	IVD reagents for calibration of IVD instrument, solid phase capture reagent in immune- and other IVD-assays (e.g. blood screening, cancer, cardiac, metabolic tests)	To allow sufficient time to implement technical means where microplastics would be contained throughout their use and incinerated at the end of their life-cycle. It also matches the EiF of the new EU IVDR[44] (May 2022)
Other rinse-off cosmetic products	EiF + 4	All remaining rinse-off products (other than those described in the column 1): e.g., hair colouring products, bleach for body hair products, hair (nourishing) masks, etc. but also shampoos, soaps, etc., which contain microplastics with	To allow sufficient time to reformulate and transition to alternatives

[44] EU Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices. Adopted in 2017 and entry into force on 26 May 2022.

Subject of transitional period	Entry into force	Examples	Reason for transition period
		functions other than exfoliating or cleansing	
Detergents containing polymeric fragrance encapsulation	EiF + 5	Laundry detergents and fabric softeners	To allow sufficient time to reformulate and transition to alternatives
Other detergents	EiF + 5	Laundry detergents, manual dishwashing liquid and automatic dishwashing detergents	To allow sufficient time to reformulate and transition to alternatives
Waxes and polishes (maintenance products)	EiF + 5	Floor polishes	To allow sufficient time to reformulate and transition to alternatives
Fertilising products not regulated in the EU as fertilising products under Regulation (EC) No xxx/xxxx on Fertilising Products that do not meet the requirements for biodegradability contained in that Regulation.	EIF + 5		Time is required for development of biodegradable polymers suitable for this function; alignment with the Fertilising products regulation.
Other agricultural and horticultural uses including seed treatment, plant protection products as defined in Regulation (EC) No 1107/2009 and biocides as defined in Regulation (EU) 528/2012.	EiF + 5		Time is required for development of biodegradable polymers suitable for this function.
'Leave-on' cosmetic products	EiF + 6	skin care products (e.g., moisturisers, body lotions), make-up (e.g., foundation, powder, concealer, mascara, eye shadow/pencil/liner), lip products (e.g., lipstick or sealer, lip balm), products for correction of body odour or perspirations (e.g., deodorants), sun and self-tanning products, hair care and styling products (e.g., leave-on conditioner, dry shampoo, hair spray/foam/gel), nail care (e.g., polish, hardeners, glue), etc.	To allow sufficient time to reformulate and transition to alternatives

2.2.1.4 Labelling

The purpose of the labelling requirement specified in paragraph 7 of the proposed restriction is to inform users of substances or mixtures about conditions of use to minimise releases to the environment. The labelling requirement is proposed for specific mixtures where it is expected that the behaviour of the users can be successfully influenced by providing relevant instructions for use, for example in relation to the correct disposal of wastes arising from the use (e.g. brush/roller residues of paints/coatings). The requirement is intended to cover end uses as well as preceding

life-cycle steps, including at industrial sites.

A wider labelling requirement informing users that the mixtures and articles in question contain microplastics or hazardous substances was also considered. The purpose of such a labelling requirement would be to provide information to allow users to make informed decisions regarding the purchase and use of the mixtures and articles. It is likely that such information can influence negatively demand for microplastic-containing products. Since the magnitude of the costs associated with reduced sales are unknown but potentially large, this option was discarded.

2.2.1.5 Reporting requirement

The proposal for a reporting requirement will contribute to the monitorability of the effectiveness of the restriction and indicate if there is a need for further action related to those uses that are derogated, including for industrial uses. Several uses of microplastics have been exempted from the prohibition of placing on the market under the proposed restriction. However, to monitor the effectiveness of the restriction and to ensure that significant emissions are not occurring from these uses that are exempted, the proposal requires that certain information is reported to ECHA.

The proposal will require any downstream user using a microplastic at an industrial site (paragraph 4a) or any importer or downstream user placing a substance or mixture containing a microplastic on the market for an end use allowed on the basis of paragraphs 5(b) or 5(c), to report certain information to ECHA using a prescribed electronic format[45]. This information can then be compiled and published annually. The information gathered will allow the tracking of the identity and quantities of the microplastics used and released to the environment in certain derogated uses and allow in the future for adaptations to the restriction to be made using this information, where these are considered necessary.

2.2.1.6 (Bio)degradability criteria

As outlined in the risk assessment presented in Section 1.4, the persistence of a synthetic polymer-containing particle in the environment is a key, but not the only, criterion underpinning the 'microplastic concern' and the associated risk to the environment that is not considered to be adequately controlled. Following this rationale, a synthetic polymer-containing particle that does not persist in the environment should not be included within the scope of the restriction. This reasoning already underpins the derogation outlined in Paragraph 5b that exempts uses of microplastics from the scope of the restriction where they are consumed or otherwise cease to exist (e.g. as particles) at the *point of end use* by a consumer or professional. The derogation for (bio)degradable substances that is proposed in Paragraph 3b applies the identical rationale but considers the behaviour of the substance, specifically its (bio)degradation[46],

[45] The electronic format will need to be designed and tested before use (justifying the 12 month transition time proposed in addition to the time needed by downstream users to collate the necessary information to report). However, it is foreseen that a similar electronic reporting system to that currently implemented for downstream users to notify ECHA that they are using an Annex XIV substance for an Authorised use (so called Article 66 notifications) could be readily adapted for this purpose: https://echa.europa.eu/support/dossier-submission-tools/reach-it/downstream-user-authorised-use.

[46] The term (bio)degradation in this Annex XV report is intended to include both abiotic and biotic mechanisms of degradation. Both are relevant and applicable to the rationale underpinning the derogation.

in the period after the release resulting from the end use in relation to risk that is not adequately controlled.

Testing methods, and associated pass/fail criteria, for assessing the (bio)degradability of substances are well established within regulatory regimes, including REACH (e.g. Annex XIII and associated ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11 - PBT/vPvB assessment, (Version 3.0, June 2017), and are routinely used to assess the potential for a substance to be persistent or 'very persistent' in the environment.

Relevant testing methods have been subject to standardisation at international level for many years (e.g. there are numerous relevant OECD and ISO testing guidelines). Test methods are typically applied in a tiered approach, with relatively rapid screening tests (with stringent pass/fail criteria) applied at early tiers, with increasingly more sophisticated and lengthy (costly) simulation studies becoming necessary at latter tiers. The conventional rationale for using simulation studies at early tiers is that where rapid and extensive (bio)degradability is apparent within these types of studies (bio)degradation can be assumed to occur in all relevant environmental compartments.

It is recognised that the (bio)degradation assessment of polymer-based materials, including the microplastics identified in the restriction proposal, which are typically poorly water soluble, can be more complicated than for water soluble substances. This is already recognised in existing ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11 - PBT/vPvB assessment (Version 3.0, June 2017) in relation to the specific considerations for poorly soluble substances that have already been developed. Variations to existing standardised (bio)degradation testing methods, or potentially entirely new standardised testing methods, are likely to be necessary to appropriately assess the (bio)degradability potential of some microplastics in the environment. However, application of existing standardised methods can provide valuable information on the (bio)degradability of microplastics such that, based on the existing rationale for the risk assessment of chemicals, certain microplastics could be derogated from the scope of the restriction where their (bio)degradation is shown to meet certain thresholds in either screening or simulation studies. Failure to apply such a derogation would be contrary to the existing risk assessment paradigm within REACH.

Therefore a framework of test methods and pass/fail acceptability criteria have been developed for the purposes of this restriction. As there is likely to be significant scientific progress on this issue in the future, the acceptable test methods and pass/fail criteria are detailed in an appendix to the restriction entry, such that they can be more easily adapted by the Commission in response to scientific progress in the future, if and when necessary. As such, the criteria may need to be reviewed within the short to medium term (a review five years after the entry into force of the restriction would not appear unreasonable), particularly recognising that the (bio)degradability criteria adopted by the Commission in relation to the recast of the Fertilising Products Regulation should be adopted within a similar timeframe and there is clearly an advantage to harmonising the relevant test methods and pass/fail criteria, where appropriate.

The proposal for the appendix (Appendix X) is set out in Table 21.

Table 21 Criteria for demonstrating the (bio)degradation of microplastics according to Paragraph 3b (APPENDIX X).

The derogation from the proposed restriction on the basis of the (bio)degradability of a

microplastic should be assessed against the following criteria, in a tiered approach.

A test material can be considered to be (bio)degradable, and therefore derogated from the restriction, if it meets one or more of the 'screening-tier' criteria described under elements 1-4, below. If the test material does not meet any of the criteria described under elements 1-4, further 'higher-tier' assessment (5) can be conducted to demonstrate (bio)degradability under relevant environmental conditions.

The overall (bio)degradation of a microplastic observed in a test system may be the result of a combination of several processes, for example mechanical degradation (fragmentation), abiotic degradation (e.g. hydrolysis) and biodegradation by micro-organisms. However, characterisation of these processes, without adequate accompanying information on biodegradation, is not considered to be sufficient to describe the persistency of a microplastic in the environment.

The polymer/microplastic shall not contain additives that exceed a concentration limit of 0.1 % (w/w), which meet the criteria for PBT/vPvB set in REACH Regulation No 1907/2006 Annex XIII.

The (bio)degradation potential of the microplastic shall be demonstrated by the following:

Demonstrating (bio)degradability using screening criteria.

1. Ready biodegradation
    - 60 % mineralisation measured as evolved CO_2 or consumed O_2 in 28 days (10-day window does not apply).
    - *Permitted test methods: OECD TG 301 B,C,D,F and OECD TG 310.*

Or

2. Enhanced/modified ready biodegradation
    - Test duration may be extended to up to 60 days and larger test vessels used
    - 60 % mineralisation measured as evolved CO_2 or consumed O_2 in 60 days (10-day window does not apply)
    - *Permitted test methods: OECD TG 301 B,C,D,F, OECD TG 310, and modified OECD TG 306 (mineralisation measured as evolved CO_2)*

Or

3. Inherent biodegradation
    - ≥ 70 % mineralisation (measured as O_2 uptake or evolved CO_2) fulfilling the TG specific criteria as indicated below.
    - *Permitted test methods[47]:*
        i. *OECD 302B (Zahn-Wellens), ≥70 % mineralisation within 7 d, log phase no longer than 3d, removal before degradation occurs below 15%, pre-adapted inoculum is not allowed*

[47] Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11- PBT/vPvB assessment (Version 3.0, June 2017)

ii. *OECD 302C (MITI II test), ≥ 70% mineralisation within 14 days, and the log phase should be no longer than 3 days, pre-adaptation of the inoculum is not allowed.*

Or

4. Bio(degradation) relative to a reference material;

- Ultimate degradation of ≥ 90 % relative to the degradation of the reference material within 6 months in aquatic test, and 24 months in soil and water/sediment interface tests.
- Result shall be reported as the maximum level of biodegradation determined from the plateau phase of the biodegradation curve (or the highest value if the plateau has not been reached).
- Potential reference materials; micro-crystalline cellulose powder, ashless cellulose filters or poly-β-hydroxybutyrate as positive controls and polyethylene (PE) or polystyrene (PS) as negative controls. The form, size and surface area of the reference material should be comparable to that of the test material.

Permitted test methods:

i. *Determination of the ultimate aerobic biodegradability of plastic materials in an aqueous medium (EN ISO 14852:2018 or EN ISO 14851:2004), pre-adaption of the inoculum is not allowed.*

ii. *Plastics – Determination of aerobic biodegradation of non-floating plastic materials in seawater/sediment interface (EN ISO 19679:2016 or EN ISO 18830:2006), pre-adaption of the inoculum is not allowed.*

iii. *Ultimate aerobic biodegradability of plastic materials in soil (EN ISO 17556:2012), pre-adaption of the inoculum is not allowed.*

Demonstrating (bio)degradability using higher tier assessment

Where higher tier tests are necessary they shall be conducted under relevant environmental conditions. Relevant environmental compartments depend on the fate of the microplastic after use and could include fresh/estuarine water, fresh/estuarine water sediment, marine water, marine sediment, and soil as specified in corresponding testing guidelines. (Bio)degradability shall be demonstrated in the most relevant environmental compartment. Relevant test temperatures correspond to average temperatures in the EU and are 12 °C for fresh/estuarine water and fresh/estuarine water sediment and soil and 9 °C for marine water and marine sediment.

5. Half-life in the environment (under relevant environmental conditions)

a. The degradation half-life in marine, fresh or estuarine water is less than 60 days

b. The degradation half-life in marine, fresh or estuarine sediment is less than 180 days

c. The degradation half-life in soil is less than 180 days.

Permitted test methods: OECD TG 307, OECD TG 308 and OECD TG 309

Results should be interpreted with caution and the half-life should be estimated with

care when the particle size (surface area) is a degradation rate-limiting factor and the degradation is not following the first order kinetics.

Demonstrating (bio)degradability if microplastics are deliberately applied to soil or foliage

The screening criteria above (1-3 and 5) may also be used to assess the (bio)degradability of microplastics that are directly applied to soils, e.g. controlled-release fertilising products.

The application period in soil may be taken into account when demonstrating the biodegradability of microplastics with direct soil application. The allowed time for reaching the screening criteria as specified in (4) for soil, ultimate degradation of 90 % relative to the degradation of the reference material within 24 months, may be extended by the application period in soil, but not to exceed 48 months in total.

Test material in (bio)degradation tests

The test material should be comparable to the microplastic on the market in terms of the composition, form, size, and surface area as these parameters have an influence on the (bio)degradation behaviour of the microplastics

When the degradation is assessed in relation to a reference material, the form, size and surface area of the reference material should be comparable to that of the test material.

In case, test material is used as capsulation agent of organic materials, when performing the (bio)degradation test, the organic core should be replaced with an inert material such as glass. Test material should be with comparable thickness to the produced microplastic coating.

Tests shall be conducted by laboratories accredited to ISO 17025.

2.3 Approach to impact assessment

Microplastics have various applications in consumer, professional, agricultural or industrial products. These products have various modes of use, which lead to emissions of microplastics to the environment via various pathways. Furthermore, the availability of suitable alternatives (and their market share) for different uses varies, as do the anticipated resources required to substitute current uses of microplastics. Because of the variations in these key factors, different impacts are expected for separate uses of microplastics. Recognising these variations, the socio-economic impacts and the proportionality of the proposed restriction are assessed on a per-sector basis, i.e., separately for agriculture and horticulture, construction, cosmetics, detergents and maintenance products, oil and gas, paints and coatings, medicinal products for human and veterinary use, medical devices (including *in vitro* diagnostic devices for human and veterinary use), food supplements and medical food, 3D printing, and printing inks.

Where the available information permits, and where the socio-economic impacts within a sector are likely to vary substantially, the analysis is performed at 'product group' level rather than a sector level. For example, within the cosmetics sector, the availability of alternatives for rinse-off and leave-on products vary, as do the resources required to transition to alternatives. This warranted a separate analysis for rinse-off cosmetics

containing microbeads (i.e. those with exfoliating and cleansing functions), other rinse-off cosmetics and leave-on cosmetics. Furthermore, as the release pathways for some products within the leave-on cosmetics group also showed variance on the basis of information of consumer habits (i.e., discharge directly into the drain vs partial removal and disposal as household waste), an analysis of the product subgroups ("down-the-drain" vs "trash disposal") was also prepared for sensitivity purposes.

Overall, the Dossier Submitter has strived for a level of granularity of the analysis that balances the need to conclude on the likely socio-economic impacts and justify the proposed restriction with the resources required for detailed analysis. Therefore, a more detailed (quantitative) assessment is presented where a use restriction is proposed, i.e., for sectors included in paragraph 6 of the proposed restriction wording. For other sectors, where labelling and reporting requirements are proposed, a (semi-)quantitative analysis is presented.

The geographical scope of the impact assessment is the European Economic Area (EEA or EU28 plus Norway and Liechtenstein) 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.[48] 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) or annualised costs over the study period.[49]

Microplastics, as defined in this restriction proposal, are extremely persistent and therefore accumulative in the environment. Quantification of benefits is typically not possible for PBT/vPvB substances or substances of similar concern (such as microplastics), which makes it difficult to demonstrate quantitatively whether the benefits of a proposed restriction outweigh its costs. Instead, the Dossier Submitter has adopted a cost-effectiveness approach similar to that recommended by SEAC for evaluating restriction proposals for PBT/vPvB (-like) substances[50].

The approach rests on the assumption that emission reduction is a reasonable proxy of the benefits of the restriction. In that case, cost-effectiveness is informative about the abatement efficiency and can be used as a measure to underpin the proportionality of the proposed restriction. Hence, where the available information permits, cost-effectiveness ratios are calculated separately for the sectors/product groups assessed. In Section 2.7.2, these are compared to the cost-effectiveness of previously adopted restrictions on PBT/vPvB or similar substances. The reduction in releases to the environment (as a proxy for the benefits) is presented in Section 2.4, alongside some qualitative considerations. Further considerations underpinning the need for action are

[48] As a result of triggering Article 50 of the Treaty on European Union, the United Kingdom is poised to lead the EU on 29 March 2019. However, at the time of writing, the future relationship with the EU is not determined and it is uncertain to what extent future amendments of Annex XVII of REACH would be applicable on the territory of the UK. Therefore, under baseline it is assumed that the current status of the UK in the EU/EEA is maintained for the temporal scope of the analysis.

[49] The calculations presented in this report would change if a different discount rate or analytical period was applied. A sensitivity analysis can be undertaken to show what impact this would have on the values reported in this report.

[50] https://echa.europa.eu/documents/10162/13580/approach_for_evaluation_pbt_vpvb_substances_seac_en.pdf

provided in Section 2.7.3.

2.4 Environmental and human health impacts

As discussed in the risk assessment reported in Section 1.4, the environmental and human health risks posed by microplastics are difficult to quantify. However, the extent of the scientific understanding of the hazards and risks posed by microplastics are summarised in Section 1.4.4 and in Annex C.

For the purposes of this restriction proposal, microplastics are considered as non-threshold substances with releases considered as a proxy for risk. Therefore, the impact of the restriction can be appreciated simply by the reduction in predicted releases that were forecast to occur.

The proposed restriction is estimated to result in a cumulative emission reduction of about 400 thousand tonnes of microplastics over the 20 year period (central scenario) following its entry into force. This is a reduction of 85-95%[51] of the quantified emissions of intentionally added microplastics that would otherwise have occurred in the absence of the restriction entering in effect (Figure 12).

In qualitative terms, the reduction in releases will contribute to minimising releases of microplastics to the environment, where they persist over long time periods and are associated with various adverse effects on organisms and accumulation in food (see Section 1.1.1 (microplastic concern) and Section 1.4 (risk assessment). The proposed restriction will reduce the quantity of persistent microplastics in wastewater effluents and sludge, reducing the likelihood that organisms in the environment will encounter and interact (possibly ingest) these materials either directly, or via their food.

[51] Range dependent on assumed effectiveness of labelling requirements and scenario assumptions. Annual emission reduction after all transitional periods have expired is calculated to be >90%.

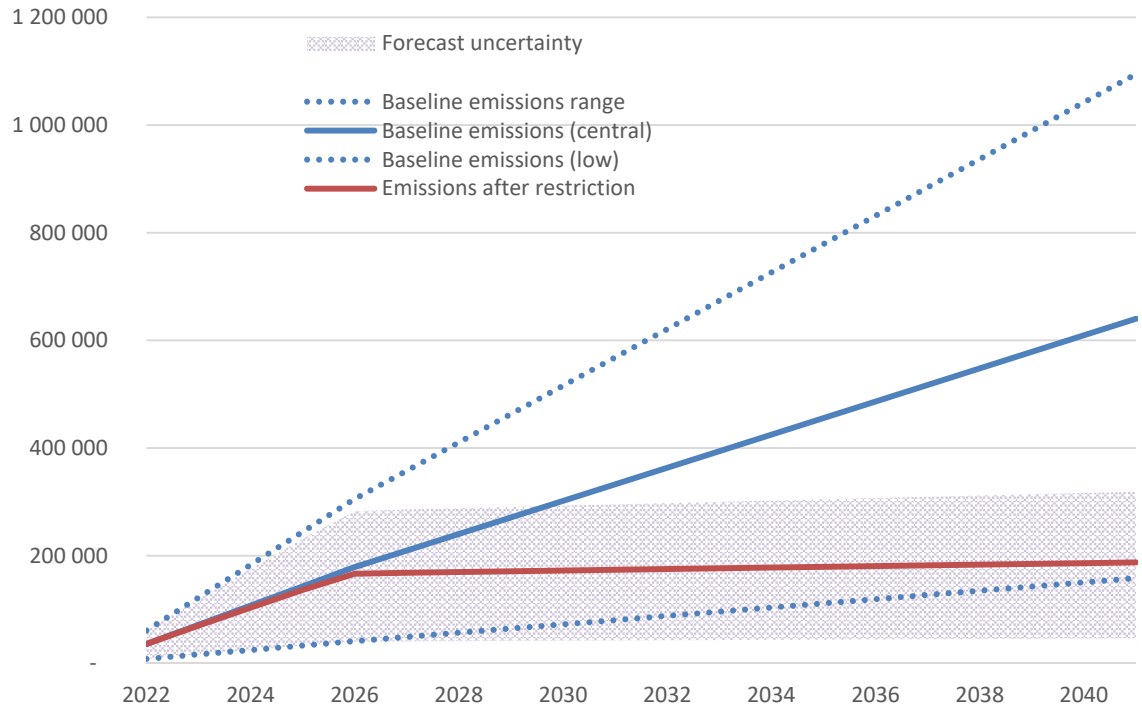


Figure 12 Effect of restriction over the period of analysis

2.5 Economic and other impacts

The proposed restriction would lead to impacts primarily to end-users of microplastic-containing products and their supply chains that place these products on the EEA market. The economic costs and other impacts are anticipated to be associated primarily with compliance with the restriction on the placing on the market of selected microplastic-containing products. Costs to comply with labelling and reporting requirements are negligible in comparison.

The following section briefly highlights the main categories of costs to society, focusing on those which have the largest influence on the conclusions of the proportionality to risk of the proposed restriction. A summary of the underlying assumptions, description of the anticipated impacts, estimated costs and main conclusions are presented in Table 23 to Table 33. Detailed analysis and conclusions for individual product groups are presented in the relevant sections of Annex D of this report.

The Dossier Submitter considers the following main categories of economic and other impacts arising from the proposed restriction on intentional uses of microplastics:

2.5.1 Reformulation costs

While for some microplastic uses there are already alternatives on the market (e.g., for microbeads with exfoliating and cleansing functions in rinse-off cosmetics or used in some detergents and maintenance products), for the majority, the existing critical mass of microplastic-free products is not sufficient to meet demand for products with similar functions, and reformulations would be needed in the event that the proposed restriction enters into force.

On the basis of detailed estimates for the necessary resources to complete these

reformulations for agriculture, horticulture, cosmetics, detergents and maintenance products, total quantified reformulation costs are estimated at €9.2 billion (€1.7 billion – €18 billion) in NPV. These reformulation costs are expected to be incurred from the date of entry into force to the date of entry into effect, i.e., 2026-2028 as specified for each relevant sector in Table 17 and Table 20.

Reformulation costs have the highest impact on the proportionality of the restriction. They account for more than 95% of all quantified costs of the proposed restriction. The reformulation costs estimated to be associated with the transition to microplastic-free cosmetic products are estimated to represent the largest share of these costs – more than 90%, although the costs are much smaller for rinse-off cosmetics when expressed in terms of estimated costs per kilogram of emissions reduced.

Although the Dossier Submitter has based the reformulation cost estimates on best available information, these are associated with considerable uncertainty, primarily related to:

- the amount of time required for successful reformulations, where the alternatives do not represent a substantial share of the products currently on the market,
- the number of incremental reformulations associated with the proposed restriction, and
- the amount of microplastic-containing products on the market that meet the proposed definition.

To address these and other uncertainties, sensitivity analysis is performed and the results are presented in Table 22.

2.5.2 Raw material costs

As a result of the proposed restriction, it is estimated that industry can incur additional material costs as some alternatives to microplastics are assumed to be of higher costs, e.g., for cosmetics, detergents and maintenance products. These costs are anticipated to incur annually from the entry into effect of the proposed restriction.

The NPV of the estimated raw material costs for the proposed restriction are approximately €145 million (€20 – €575 million).

2.5.3 Enforcement costs, including costs associated with labelling and reporting requirements

Enforcement costs are incremental costs to society to comply with requirements of a restriction that has come into effect. These costs are likely to be borne by two main groups of stakeholders: enforcement authorities and industry placing on the market microplastic-containing products. Enforcement costs can be broken down in two main cost groups: administrative and analytical or testing costs. The former costs consist of incremental administrative costs for staff salaries, materials, equipment and overhead to be incurred to ensure compliance. Analytical testing costs include costs to develop testing methods and to test products whether they meet the requirements of the restriction.

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). The Dossier Submitter

recognises the limitations of this approach, however, in the absence of other estimates, assumes that each of the sectors for which a restriction on the placing on the market is proposed would result in administrative enforcement costs of €55 000 per year. To put these costs in perspective, the following observations need to be made:

- To reflect that the proposed restriction has broad scope which impacts diverse uses in several different sectors which may require diverse enforcement expertise, the Dossier Submitter has taken the conservative stance by assuming that each product category with a proposed restriction on the placing on the market would incur incremental administrative enforcement costs of €55 0000 annually. However, this could be a source of overestimation as the administrative costs estimated in ECHA 2017 are per restriction entry and they have not been differentiated on the basis of narrow vs broad scope or low vs high complexity of the Annex XVII restrictions. Another source of overestimation is that some of the sectors can demonstrate compliance based on already existing legislation (e.g., fertilisers and PPPs are already heavily regulated and the enforcement of existing regulatory requirements would occur even without the current restriction proposal, the CPR requires all cosmetic ingredients be included on the label). Therefore, this approach may lead to an overall overestimation of incremental costs to society associated with the proposed restriction.

- The enforcement costs are assumed to be incurred annually from the entry into effect to the end of the study period. This again is seen as a source of an overestimation of administrative enforcement costs as non-compliance, and therefore, enforcement efforts to ensure compliance, decline with time, as supply chains become familiar with the restriction requirements. Therefore, enforcement costs tend to be higher in the years immediately following the entry into effect of a restriction and approach zero by the end of the study period as compliance increases.

- Compliance of several restrictions or other existing EU-wide legislation can be pursued at the same time leading to synergies and cost savings.

Incremental analytical costs for the proposed restriction are also anticipated to be comparatively minor. Testing methods to assess the presence of microplastics in cosmetics are being developed (see Section 2.6.1). Compliance can be ensured on the basis solely on labelling, for many products, already required under existing legislation (e.g., under the CPR, detergents regulation, medicinal products regulation, medical devices regulations, CLP). 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), therefore, enabling information to be passed down the supply chain, including the enforcement authorities. 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.

The restriction also proposes labelling and/or reporting requirements for a number of other sectors (other than those sectors listed in paragraph 6 of the proposed restriction entry, see Table 3). Incremental labelling costs to the proposed restriction are expected to be minor, as requirements for product labelling (or updates of SDS) exist for almost all sectors under existing legislation (e.g., CLP, CPR, medicinal products regulation, etc.). They are updated on a regular basis, both due to regulatory requirements and due to

periodic changes to products, as a result of market-driven updates (reformulations). It is also likely that in the course of the transitional period (18 months from entry into force), labels would have to be redesigned and reprinted (e.g., due to the reasons outlined above); therefore, costs for new labels would not be solely attributable to the proposed restriction. Furthermore, the proposed transitional period is expected to allow sufficient time to deplete existing label stocks and printing of new labels. Therefore, given the length of the transitional period any such labelling costs would be low and unlikely to be solely associated with the proposed restriction.

The proposed restriction also includes reporting requirements (identity, quantity used and emitted) for a number of sectors (paragraph 8 of the proposed restriction entry in Table 3). The main purpose of this requirement is to provide information for decision-makers to facilitate further action but the requirement will also facilitate enforcement.

The costs associated with this proposed requirement would consist of a one-time cost to develop the reporting format and software to submit and process the information for regulators and ongoing costs for industry to gather the required information and submit it annually. The latter costs are difficult to estimate as it would depend on the complexity of company structure and the number of products/materials with reporting requirements. These however would likely be minor, also taking into account the proposed labelling (or SDS or instructions on use) requirements which will facilitate information exchange throughout the supply chain. The one-time costs to ECHA are also unlikely to exceed €50 000, especially when considering the possibility to develop the functionality under existing tools such as REACH-IT or Article 66 notifications. The latter would also minimise costs for annual compiling and disseminating of the information.

In summary, the enforcement costs of the proposed restriction are estimated at about €3 million for the duration of the study period. Despite their considerable uncertainty, these costs are expected to remain negligible in comparison to other restriction costs and the estimated costs (despite the deficiency of the methodology) provide information on the order of magnitude of the costs to society of enforcing the proposed restriction.

2.5.4 Other economic costs

The proposed restriction may lead to other incremental economic costs. These are described and their likelihood is discussed in the context of the anticipated impacts for different product groups. E.g., costs to implement technical/procedural means where microplastics would be contained throughout their use and incinerated or disposed as hazardous waste at the end of their life-cycle (medical devices and IVDs), potential performance loss of tangible or perceived product benefits to consumers (associated with worst case assumptions in the event of unsuccessful reformulations), profit losses in the event successful reformulations are delayed and there is no sufficient critical mass of alternatives on the market to take over their market share. The latter costs have been quantified by the Dossier Submitter for two product groups (in the cosmetics and detergents sectors), in the High scenario, under the worst-case assumptions. These costs are estimated to less than €2.3 billion (NPV).

2.5.5 Social costs and impacts on SMEs

Based on analysis in Annex D and summarised in Table 23 to Table 33, the Dossier Submitter concludes that substantial net social costs arising from possible closures, mergers or acquisitions instigated by the restriction for the majority of sectors are unlikely. Overall, the proposed restriction may negatively affect employment in

companies engaged in supply chains of microplastic-containing products but positively, those engaged in alternative products.

The expected restriction-induced reformulations may have a short-term impact on the deployment of staff to reformulation activities, leading also to positive employment effects. On the other hand, any unsuccessful reformulations or discontinuation of products could have some temporary negative implications for employment. On balance, and given the transitional period aiming to allow sufficient time for reformulations, no major net impacts on employment are expected, as any negative employment impacts are likely to be compensated by gains to companies producing microplastic-free 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. These are estimated not to exceed €25 million for the study period.

The proposed restriction impacts a number of sectors. By nature of the EEA economy, the majority of companies are SMEs which tend to have more limited resources. However, the requirements of the proposed restriction that would impact a broad range of sectors entail activities such as labelling or reporting requirements which do not require substantial resources. (See also Section 2.5.3.) 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 3). 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. For the sectors with the highest estimated restriction costs such as the cosmetics industry, there is information that larger companies tend to use more microplastics than SMEs which tend to specialise in natural and organic cosmetics. These SMEs could directly benefit from a restriction on microplastic-containing products as they already have on the market microplastic-free formulations. Furthermore, some suppliers maintain both microplastic-containing and –free products. Therefore, it is unclear whether on balance the impacts on EEA SMEs would be negative as a result of the proposed restriction.

2.5.6 Impacts on trade and competition

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 provided 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.

2.5.7 Other impacts

Other impacts are discussed qualitatively for individual sectors and product groups in Annex D of the report and summarised in Table 23 to Table 33 below.

Table 22 Summary of quantified economic and other impacts of the proposed restriction

Impacts\ Scenarios	Low	Central	High
Economic			
- Material	20	145	575
- Reformulation	1 740	9 200	18 200
- Enforcement	3	3	3
- Other economic	-	-	2 300
Other impacts			25
Total Restriction Costs	1 800	9 400	21 100

Notes: NPV, 2017 values, million

Table 23 to Table 33 summarise the anticipated socio-economic impacts of the proposed restriction on the sectors in its scope. Detailed assessment of these impacts are presented in Annex D of this report.

Table 23 Summary of the socio-economic impacts of the proposed restriction on agriculture and horticulture

Impacts/Sectors	Controlled release fertilisers (CRF) & fertiliser additives	Capsule suspension PPPs (CSPs) & coated seeds
Sector characteristics		
Use description	Polymers in fertilising products are primarily used to ensure the following functions: controlled release of nutrients over a period of up to 18 months through micro-encapsulation anti-caking, prilling and other preservative functions as fertiliser additives reduced dust formation during application of fertilisers reduced run-off of fertilisers	Polymers in CSPs and treated seeds are primarily used to ensure the following functions: controlled release of PPPs over a period of up to 18 months through micro-encapsulation reduced dust formation during application of PPPs reduced run-off of PPPs adhesion of PPPs (and nutrients) to seeds physical protection of seeds during sawing
Justification for inclusion	Direct and unfiltered emissions of microplastics; largest contributor to releases of intentionally added microplastics; cost-effective means to abate emissions.	Direct and unfiltered emissions of microplastics; equal treatment of A&H products; cost-effective means to abate emissions.
Proposed action		
Objective	Harmonisation with the biodegradability requirement for polymers established in the new EU regulation on CE marked fertilising products for all fertilising products placed on the internal market.	Emulation of the biodegradability requirement for polymers established in the new EU regulation on CE marked fertilising products for all PPPs and treated seeds placed on the internal market.
Specific remarks	Should no biodegradable polymers become available during the transition time set, then that would require a review of proportionality of the proposed action.	Should no biodegradable polymers become available during the transition time set, then that would require a review of proportionality of the proposed action.
Proportionality		
Emissions reduced	262 500 (67 500-442 500)	15 000 (5 250-25 500)
Cost-effectiveness [a] Central-cost scenario High-cost scenario	 €1.2/kg (€0.2-9.6/kg) €2.4/kg (€0.3-18.7/kg)	 €3.9/kg (€1.1-25.4/kg) €9.4/kg (€2.8-60.3/kg)
Affordability	Since the total weight of polymers is negligible compared to any output produced, unit price increments caused by R&D for finding biodegradable polymers might be passed through and absorbed by consumers without any affordability issues for producers expected.	
Economic impacts		
Reformulation costs [b] Central-cost scenario High-cost scenario	 €325m (€70m-€650m) €631m (€133m-€1 263m)	 €58m (€29m-€133m) €142m (€71m-€317m)
Key assumptions	Assumptions made on CRFs: 100-1 000 major reformulations Cost per major reformulation: €850 000 (€150 000) for large companies (SMEs) 100-1 000 minor reformulations Cost per minor reformulation: €150 000 Half of cost attributable to restriction (rest to FPR) Effort factor of 2 assumed for high-cost scenario	Assumptions made on CSPs: 50-200 reformulations Cost per reformulation: €250 000 Central-cost scenario represents case where CSPs would benefit from R&D on biodegradable polymers in other products Effort factor of 3 assumed for high-cost scenario High-cost scenario reflects case where no R&D read-across feasible Assumptions made on seed

	Assumptions on fertilising agents: Overall reformulation cost to members of Fertilizers Europe: €20 million As Fertilizers Europe presents 2/3 of producers, range estimate of €20-100 million Only half of cost attributable to restriction (rest to FPR) Effort factor of 1.25 assumed for high-cost scenario	coating: 10-50 primary reformulations Cost per primary reformulation: €1 million 100-500 adaptations Two thirds of cost attributable to restriction (rest to FPR) Cost per adaptation: €150 000 Effort factor of 2 assumed for high-cost scenario
Enforcement costs	Default cost of €55 000 p.a., enforced via existing fertiliser legislation	Default cost of €55 000 p.a., enforced via existing PPP legislation
Product quality	Quality of fertiliser additives unlikely to be negatively affected as polymer function less crucial Quality of CRFs may suffer since function is linked to non-degradability of polymers	Quality of coated seeds unlikely to be negatively affected as polymer function needed for limited period Quality of capsule suspension PPPs may suffer since function is linked to non-degradability of polymers
Profit losses	Limited, for the same reason as listed under 'Affordability' any extra costs to firms are likely to be passed on to the supply chain and eventually to consumers.	
Other impacts		
Social	None expected	
Distributional & wider economic	None expected	
Practicality	Implementable & manageable: provides timeline for transitioning to alternatives aligned with the FPR, which minimises costs to industry whilst ensuring a push to the development of biodegradable polymers for microencapsulation of A&H products. Other EU-wide legislation could also address the risks of microplastics in A&H uses, but REACH restriction is proposed as a means for closing regulatory loopholes and harmonisation of requirements across Member States. Enforceable: clearly defined scope & analytical methods in development	
Monitorability	Once biodegradability criteria are developed, compliance can be monitored via existing authorisation processes for PPPs (Regulation (EC) No 1107/2009) and fertilising products (FPR). An extra mechanism for coated seeds may need to be developed.	
Uncertainties [c]	Uncertainties related to CRFs: Number of products to be reformulated (minor) Cost per reformulation (minor) Time needed for reformulation (medium) Compatibility of biodegradable polymers with controlled release function (major) Uncertainties related to fertiliser additives: Number of products to be reformulated (minor) Cost per reformulation (minor) Time needed for reformulation (minor)	Uncertainties related to CSPs: Number of products to be reformulated (minor) Cost per reformulation (medium) Time needed for reformulation (medium) Compatibility of biodegradable polymers with controlled release function (major) Uncertainties related to seed coatings: Number of products to be reformulated (minor) Cost per reformulation (minor) Time needed for reformulation (minor)

Source: Annex D – Impact assessment for agriculture and horticulture
Notes: a) assumes first full year of EiF in 2022 and a 5-year transition period, ignores costs and emissions attributable to the new FPR; b) based on 2018 costs attributable to REACH restriction (ignores costs attributable to the new FPR); c) those relevant to proportionality.

Table 24 Summary of the socio-economic impacts of the proposed restriction on construction products (fibre-reinforcement of concrete and other adhesives)

Impacts/Sectors	Cement
Use description	Microplastics are increasingly used in reinforced concrete (polymeric fibre-reinforced concrete or polymer-modified concrete) as a (partial) substitute to conventional steel 'rebar' (reinforcing bars, rods or mesh embedded within concrete to increase its tensile strength). Fibre is cheaper, lighter and safer to handle than steel and is also corrosion resistant. Polymeric fibres may also increase the fire-resistance of concrete by preventing 'spalling'. Plastic may also be used in as a filler in concrete/cement as either a means of disposing/recycling of waste plastic and/or as partial substitution for conventional aggregates. The size of this plastic has not been clarified. However, at least to some extent, microplastics are likely to be present i.e. particles from shredded and/or ground end of life tyres or plastic pallets. Typical applications for microplastics in concrete are: • Suspended floors and roof elements • Large-scale industrial floors • Lightweight applications • Architecturally sensitive buildings • Complex, geometric elements • Mining • Oil field[52] Fibre-reinforcement is also used in certain 'polymer modified' wall and floor tile adhesives to improve bond, flexibility and grab (https://www.instarmac.co.uk/wp-content/uploads/2016/01/Ultra_Tile_FibreGripFX_Nov17.pdf). Polymers are also used in cement/concrete 'admixtures' as plasticisers, defoamers etc, but may not be present as microplastics. The shape, dimension and length of the fibres is important. According to ATL Lantbrukets Affarstidning (2011) the fibres can be up to 0.8 mm in diameter and between 25-60 mm long. Polypropylene fibres were mostly found in an internet survey, but other types of polymers are probably also used. The concentration of microplastic fibres in cement is estimated to be around 1% or up to 2% (Gowri and Rajkumar, 2011).
Justification for action	Potential releases of microplastics are expected mostly from accidental spills during production or at the construction site. Instructions for use for polymer-modified wall and floor tile adhesive typically advise that '*tools should be thoroughly cleaned in water to remove excess material immediately after use',* which could be reasonably expected to lead to releases to municipal wastewater systems in many cases. Disposal of surplus (unused) cement/adhesive into wastewater systems has also been reported, but to what extent this occurs in practice has not been assessed.
Proposed action	Labelling and reporting requirement
Justification for action	Limited releases of microplastics are expected under specific circumstances. A labelling requirement is intended to inform users about how to minimise the releases, where possible.
Sector characteristics	
Tonnes used p.a.	No information available. However, microplastics-containing cement is commonly available on the market.
Alternatives	The traditional alternative to fibre in reinforced concrete is steel 'rebar', but fibres can also be made from materials other than microplastics. Fibres of steel, graphite, glass and natural fibres (cellulose-based) are used. Compared to steel, plastic reduces the carbon footprint, especially when recycled plastic is used.
Effectiveness & Proportionality	
Targeted at risk/ capable to reduce risk	The measure is aimed at uses in cement applications that lead to releases to the environment.
Costs	Product labels are often updated on a regular basis, both due to regulatory requirements and due to changes in trends and demands. It is envisaged that the labelling requirement could at least to some extent be coordinated with the regular updates to labels. The costs of meeting the reporting

[52] See Table 33.

Impacts/Sectors	Cement
	requirements will likely be minimal, and therefore affordable.
Cost-effectiveness & affordability	Labels on products that the users are less familiar with are according to research more likely to be effective. While it is not known how much a labelling requirement may affect emissions, the labelling costs are expected to be relatively low.
Other SE impacts	-
Practicality	Given the uncertainty related to the uses and availability of alternatives for critical applications, the proposed measure is a practical approach to gather information for possible further action.
Monitorability	The proposed measure has a monitoring element, which will enable the EC to monitor whether emissions are declining under existing measures or further action under REACH is required.
Impact of scope modifications	
• All dimensions < 1mm	There are indications that the plastic fibres may be above 1mm, which implies that a modification of scope would mean that a smaller share of plastic fibres would be affected by the regulatory action.
• Film forming in scope	N/A
Main Uncertainties (impact on Proportionality conclusions)	Tonnages Emissions to the environment

Table 25 Summary of the socio-economic impacts of the proposed restriction on cosmetic products

Impacts/ Sectors	Rinse-off w/ microbeads	Other rinse-off cosmetics	Leave-on Cosmetics
Proposed action/TP	Restriction on placing on the market (no TP)	Restriction on placing on the market with TP of EiF + 4 yrs	Restriction on placing on the market with TP of EiF + 6 yrs
Sector characteristics			
Use description	Use w/ exfoliating or cleansing functions in rinse-off cosmetics to remove dirt, unclog pores, or dead skin cells (e.g. exfoliants, face wash, toothpaste)	Used in products intended to be removed after application, e.g., conditioners (exc. leave-in), hair colouring, nourishing masks, etc. but also shampoos, soaps, etc., (excluding those with exfoliating/ cleansing functions)	Used in products intended to have a prolonged contact with the skin, the hair or the mucous membranes, e.g., skin care, make-up, lipstick & care, deodorants, sun & self-tanning, hair care & styling products, etc.
Justification for inclusion	Microplastics at point of use and release (primarily to waste water) with dimensions of < 5mm		
Function	Exfoliating or cleansing	Primarily opacifying	Various functions (see Annex D)
Tonnes used/yr	107 tonnes	6 500 tonnes (2 900 – 10 000)	2 700 tonnes (1 100 – 4 300)
Proportionality			
Emissions reduced/yr	Likely fully phased out by industry by 2020	3 100 tonnes (1 400 – 4 900)	650 tonnes (300 – 1 000)
Cost-effectiveness	n/a	€22/kg (€2-€27/kg)	€820/kg (€380 – €1 040/kg)
Affordability	No costs as industry likely to fully phase out use prior to EiF	Affordable (total restriction cost are less than 20% of profit margin)	Affordable (total restriction cost are less than 20% of profit margin)
Total restriction costs (NVP)_	Negligible	€1.1 bill (€0.05 – €2.1 bill)	€7.4 bill (€1.6 – €14.4 bill)
Material (NPV)	n/a	€34.4 mill (€15.4 – €53.4 mill)	€12 mill (€5 – €19 mill)
Reformulation (NPV)	n/a	€1 bill (€36.3 mill - €2 bill)	€7.4 bill (€1.6 – €13.3 bill)

Enforcement	Negligible, enforced via existing CPR labelling req	€55 000/yr, enforced primarily via existing CPR labelling requirements	€55 000/yr, enforced primarily via existing CPR labelling requirements
Product quality	n/a	Negligible as share of alternatives is high (70-90% for total product group)	Unlikely as the TP provides sufficient time to transition to alternatives but also consumers place importance on env & HH friendly products
Profit losses	n/a	Unlikely	Unlikely and of temporary nature as TP allows sufficient time to transition to alternatives and as only associated with product categories with low share of alternatives and high number of different microplastic ingredients (often associated with film forming functions or liquid polymers, which are out of scope)
Social	n/a	Negligible as share of alternatives is high	Unlikely and of temporary nature (see Profit losses)
Distributional & wider economic	n/a	Likely negligible	Likely negligible
Assumptions	Industry is on track to fully phase out the use via voluntary measure by 2020 – prior to the proposed EiF. Several MS with national bans in effect prior to 2022.	- Price premium for alternatives: €650/tonne - 8 800 (300 – 17 400) reformulations - Cost per major reformulation: €365 000 (€42 000) for large companies (SMEs) - Cost per minor reformulation: €36 500 (€4 200) for large companies (SMEs) - Coordination with baseline reformulations - Reformulations dependent on share of alternatives in product subcategory (80-90% for total product group)	- Price premium for alternatives: €650/tonne - 51 000 (11 000 – 92 000) reformulations - Cost per major reformulation: €547 500 (€63 000) for large companies (SMEs) - Cost per minor reformulation: €55 000 (€6 300) for large companies (SMEs) - Coordination with baseline reformulations - Reformulations dependent on share of alternatives in product subcategory (20-80% for total product group)
Practicality	Implementable & manageable: Allows sufficient time to transition to alternatives, minimising costs to society, while ensuring the proposed restriction enters without undue delay. No other EU-wide measure can address the risks of microplastics in cosmetics. Enforceable: clearly defined scope & analytical methods in development		
Monitorability	Compliance can be monitored via existing CPR labelling requirements and compliance testing.		
Impact of scope modifications			
All dimensions < 1mm	n/a	Difficult to estimate but 99% of microplastics < 1mm	Difficult to estimate but 99% of microplastics < 1mm
Excluding primarily "trash disposal" products	n/a	N/A	If labelling requirements only for "trash disposal" products, cost-effectiveness improves to

			€430/kg
Film forming in scope	n/a	N/A	Profit & employment losses may be more likely within the proposed TP
Shorter/Longer TP	n/a	Shorter TP would increase the costs but also the benefits of the restriction. Longer TP would decrease the costs but also the benefits. It is likely unnecessary as 4 yrs is sufficient time to reformulate and scale up production to respond to growing demand.	Similar to other rinse-off. A shorter TP would increase the likelihood of profit & employment losses as the TP may be insufficient to reformulate & scale up production to respond to demand.
Concentration limit (CL) of 0.1% w/w		Microplastics can be present in very small concentrations, although exact estimates of the percent of products containing microplastics in concentrations between 0.01% and 0.1% is uncertain. Therefore, a CL=0.1% would likely lead to lower benefits but also costs to society. Given the small concentrations (therefore, low emissions to the environment and therefore, low benefits) and the high costs per reformulation, it is likely that a restriction with a CL or 0.1% will be more cost-effective than the proposed.	
Main Uncertainties (impact on Proportionality conclusions)	N/A	Latency of benefits (↓) Related to analytical challenges: - based on historical data: exfoliating & cleansing functions have not been excluded (↓) - learning curve & economies of scale (↓) - some polymer uses are likely out of scope because they may not meet the microplastic definition at point of use/release or could meet the biodegradability requirements, e.g., liquid or water soluble polymers (↓) - other polymers may also fall in scope, e.g., some chemically modified natural polymers (↑)	

Source: Annex D – Impact assessment for cosmetic products

Notes: 2017 values, 2022 – assumed entry into force, 20 year temporal scope, 4% discount rate, TP – transitional period, annual data, CPR – EU Cosmetic Products Regulation. Primarily "trash disposal products" include those which are more likely to be removed via cotton pad which is then more likely disposed via household trash according to consumer responses (ECHA AI 2018, #6), e.g., nail polish/remover, make-up and lip products.

Table 26 Summary of the socio-economic impacts of the proposed restriction on detergents and maintenance products

Impacts/Sectors	Detergents and maintenance products containing microbeads	Detergents containing encapsulated fragrance[1]	Other detergents	Waxes and polishes
Proposed action/TP	Restriction on placing on the market (no TP)	Restriction on placing on the market with TP of EiF + 5 yrs	Restriction on placing on the market with TP of EiF + 5 yrs	Restriction on placing on the market with TP of EiF + 5 yrs
Sector characteristics				
Use description	Hard surface cleaners, toilet cleaners, bathroom acid cleaners and stainless steel cleaners	Laundry detergents and fabric softeners	Laundry detergents, manual dishwashing liquid and automatic dishwashing detergents	Waxes and polishes, e.g. for floors, cars and leather
Justification for inclusion	Microplastics at point of use and release with dimensions of < 5mm	Microplastics at point of use and release with dimensions of < 5mm	Microplastics at point of use and release with dimensions of < 5mm	Microplastics at point of use and release with dimensions of < 5mm
Function	Abrasive and cleaning	To increase deposition on fabrics and allow for gradual release of perfume	A range of functions, including opacifier, rheology modifier, anti-foaming agent, emulsifier	As processing aids, base material or additive to provide product properties, such as surface protection and slip agent
Tonnes used p.a.	200 (decreasing)	150 (0 – 300)	7 120 (1 140 – 13 100)	2 430 (860 – 4 000)
Proportionality				
Emissions reduced over 20-year analytical period	Likely fully phased out by industry by 2020	1 140 (0 – 2 280)	54 270 (8 685 – 99 855)	11 025 (3 900 – 18 150)
Additional sector specific benefits	n/a	Decreased use of perfume required (economic and environmental benefits)	-	-
Cost-effectiveness	n/a	€101/kg (€0 - 249/kg)	€5/kg (€1 - 19/kg)	€8/kg (€2 - 32/kg)
Affordability		As the proposed restriction is expected to lead to small costs per kilogram of microplastics used, significant price increases are not expected. Therefore, the proposed regulatory actions are expected to be affordable to the impacted supply chains.		
Total restriction costs over 20-year analytical period	No costs as industry likely to fully phase out use prior to EiF	€114.7 mill (€0 – €566.8 mill)	€265.7 mill (€10.2 – €1 869.4 mill)	€92.1 mill (€7.8 mill – €574.8 mill)
Material	n/a	€57.9 mill (€0 – €362.4 mill)	€29.4 mill (€0 – €108.2 mill)	€10 mill (€0 – €33 mill)
Reformulation/R&D	n/a	€56.4 mill (€0 - €177.9 mill)	€235.9 mill (€9.8 mill – €890.9 mill)	€81.7 mill (€7.4 mill – €273.9 mill)
Enforcement	Negligible, enforced via existing labelling requirements	€413 100, enforced primarily via existing CLP labelling requirements	€413 100, enforced primarily via existing CLP labelling requirements	€413 100, enforced primarily via existing CLP labelling requirements
Product quality	n/a	Possible	Possible	Possible
Profit losses	n/a	Unlikely but tested for upper bound in sensitivity analysis (up to €26.1 mill)	Unlikely but tested for upper bound in sensitivity analysis (up to €869.8 mill)	Unlikely but tested for upper bound in sensitivity analysis (up to

				€267.4 mill)
Social	n/a	Likely negligible	Likely negligible	Likely negligible
Distributional & wider economic	n/a	Likely negligible	Likely negligible	Likely negligible
Alternatives	n/a	No suitable alternatives in major applications	No known alternatives for most applications	No known alternatives for most applications
Assumptions	Industry is on track to fully phase out the use by 2020 – prior to the proposed EiF	- Increased use of perfume oil: 75% (50%-100%) - Increased cost of alternatives: 50% (0-100%) - 750 (0 – 1 500) reformulations - Cost per reformulation/R&D: €40 000 (€30 000 – €50 000) - R&D premium of 5% - Coordination with baseline reformulations over transitional period	- Increased cost of alternatives: 50% (0-100%) - 21 038 (2 075 – 40 000) reformulations - Cost per reformulation: €15 000 (€10 000 – €20 000) - R&D premium of 12.5% - Coordination with baseline reformulations over transitional period	- Increased cost of alternatives: 50% (0-100%) - 7 283 (1 565 – 12 388) reformulations - Cost per reformulation: €15 000 (€10 000 - €20 000) - R&D premium of 20% - Coordination with baseline reformulations over transitional period
Practicality	Implementable & manageable: Allows sufficient time to transition to alternatives, minimising costs to society, while ensuring the proposed restriction enters without undue delay. Enforceable: clearly defined scope & analytical methods in development			
Monitorability	Compliance can be monitored via existing labelling requirements and compliance testing.			
Impact of scope modifications				
• All dimensions < 1mm	n/a	Likely similar impacts because the majority of microplastics used are less than 1 mm	Likely similar impacts because the majority of microplastics used are less than 1 mm	Likely similar impacts because the majority of microplastics used are less than 1 mm
• Film forming in scope	n/a	N/A	N/A	A larger share of microplastics would be in scope
• Concentration limit of 0.1% w/w	n/a	Microplastics can be present in very small concentrations, most likely in many cases below 0.1%. Therefore, if a concentration limit of 0.1% was proposed, fewer of the products would be affected by the restriction, meaning that the emissions reduced and the costs to industry would be smaller.	Similar impacts	The emissions reduced and costs to industry may be smaller since some of the polymers are currently present below 0.1%
Main Uncertainties (impact on Proportionality conclusions)	n/a	Large variations in scope depending on definition of microplastic particles. The scope of affected formulations and tonnages are expected to be in between the two definitions commented on by industry. A range of lower and upper values are therefore tested in Annex D.		

Notes: [1)] The low tonnage scenario for detergents and maintenance products is based on the definition of microplastics proposed by A.I.S.E. in the call for evidence. Since polymeric fragrance encapsulates are not in the scope of this definition, the lower range for this category is 0. When considering only the scenarios where fragrance encapsulates are in scope, the lower value of the range is €24.6 million for total costs and €21 for cost-effectiveness.

Source: Annex D – Impact assessment for detergents and maintenance products

Table 27 Summary of the socio-economic impacts of the proposed restriction on medical devices (MD) and *in vitro* diagnostic medical devices (IVD MD)

Impacts	Description
Use description	Industrial and professional (e.g. in hospital) uses only. MD and IVD MD containing microplastic particles are used by healthcare professionals in hospitals, and laboratories in order to treat patients or improve their health conditions. They also provide reliable diagnostic test results. In MD: e.g. adsorbers for blood treatment, IER (ions exchange resins) used for water treatment, ultrasound transducers In IVD MD: e.g. IVD reagents and assays (including calibration), analytical and purification chemistry for IVD
Microplastics description	Microplastics at point of use: solid polymers with dimensions of < 5mm During use, the microplastics are contained in a closed equipment without direct release to the aquatic environment. Release to the environment can happen at the end of life if the microplastics are not disposed of correctly (e.g. discharged down the drain for IVDs MD).
Proposed action/TP	1) For the uses with releases of microplastics to the environment: restriction with transition period to allow sufficient time for the actors in the supply chain, to implement technical/procedural means where microplastics would be contained throughout their use and incinerated or disposed as hazardous [clinical] waste at the end of their life-cycle. 2) For the uses where technical means are implemented to prevent releases to the environment (during use and at end of life): labelling requirement – i.e. obligation for the actors in the supply chain responsible for the placing on the market of the MD and IVDs MD, to update the labels, SDS, Instructions for Use (IFU) of the MD and IVDs MD, and provide sufficient instructions to prevent releases to the environment (including at the end of their life-cycle).
Justification for action	Releases to the environment are limited, and the uses have high societal value. Therefore, an appropriate restriction would entail continued use subject to specific risk management measures and accompanying instructions to ensure that microplastics are appropriately contained during their life-cycle and, specifically, that waste containing microplastics is not discarded to municipal wastewater. Such an approach would minimise further the releases, whilst ensuring continued socio-economic benefits of the use.
Sector characteristics	
Tonnes used	Estimated: ca 100 tonnes (essentially in contained equipment or cartridge)
Alternatives	None readily available
Proportionality	
Risk reduction capacity	Estimated: ca 0.27 tonnes (0.25–0.29)
Costs	1) Cost to implement technical/procedural means to ensure that the microplastics are collected and incinerated/disposed of as hazardous waste at the end of their life-cycle. It could be simple solution such as gathering the waste and send them to a relevant waste treatment facility (e.g. incineration). 2) Cost for the incineration/hazardous substance disposal of the microplastics at the end of their life cycle. 3) Cost to update label, SDS and IFU (which are revised regularly)
Cost-effectiveness	Not calculated but estimated to be high – qualitative assessment only
Affordability	Incremental costs of the proposed restriction are considered affordable and likely able to be passed on end-users.
Other SE impacts	With the proposed risk management option, MD and IVD MD remain fully available to treat patients and provide reliable diagnostic test results.
Practicality	Implementable & manageable: the proposed restriction reinforces the sector-specific EU regulations on MD and IVD MD that will come into force in 2020 and 2022. The proposed restriction is also allowing sufficient time to update the labelling and IFU, minimising the costs to society, while ensuring that the users take the necessary actions to minimise the releases to the environment. As the update of labelling and IFU is done on a regular basis, the proposal is also considered implementable and manageable for the companies placing MD and IVDs MD on the market. With regard to the technical/procedural means to contain the uses of the microplastics and incinerate them/treat them as hazardous substance at the end of their life, the feasibility and practicalities would have to be confirmed by the end-user during the public consultation. Enforceable: The possibility to perform audit and inspections at MD and IVD MD producers/importers level is foreseen by the sector-specific EU regulations, but would

Impacts	Description
	have to be confirmed for end-user site inspections (e.g. in hospitals) during the public consultation.
Monitorability	The compliance can be monitored at member state levels for example by reviewing the PSUR (Periodic Safety Update Report) of MD and IVDs MD (administrative monitoring).
Impact of scope modifications	
• All dimensions < 1mm	Similar impacts (microplastics < 1mm)
• Film forming in scope	N/A
• Microplastic concentration in mixture > 0.1%	Some uses might not be considered as microplastics anymore as the concentration of solid polymers in some reagents and assays (including calibration) might be below 0.1%. No sufficient information provided to evaluate the exact impact, but expected to be negligible at the scale of the entire restriction due to the limited contribution of this sector to the overall releases of microplastics.
Main Uncertainties (impact on Proportionality conclusions)	Tonnages Feasibility and practicalities to contain microplastics throughout their use in order to not discard them with municipal waste water at the end of their life-cycle Enforceability at end-user sites

Source: Annex D – Impact assessment for medical devices and in vitro diagnostic medical devices (qualitative approach)

Table 28 Summary of the socio-economic impacts of the proposed restriction on medicinal products

Impacts/Sectors	Diffusion controlled systems (matrix and film diffusion)	Ion exchange based controlled release	Osmotic systems
Use description	In medicines for HH and veterinary uses, microplastics are essentially used for their Controlled Release (CR) and taste masking functions essentially in solid dosage form (tablets and capsules), but also in parenteral and inhalation drug formulation (microencapsulation). In addition, microplastics can be used as binder, disintegrant, diluent, lubricant (in solid dosage form formulation only). Microplastics are classified either as excipient or API (Active Product Ingredient) in the EU pharmacopeia. Controlled-release formulations are often used to extend the patent protection, and market life of drugs (+5 years).		
Microplastic description	If the solid polymer has a film coating function: • Microplastic at formulation stage • Microplastic at point of use by consumer and release (100% excreted) only if the core/granule/tablet dimensions are ≤ 5 mm (aka 'mini-tablets' or pellets)[53] If the solid polymer has any other function (e.g. taste masking, binder, disintegrant, diluent, lubricant function): • Microplastic at point of use and release by consumer (100% excreted)	Ion exchange resins (IER) are solid polymers, ca. 200 µ, water insoluble, non-degradable, 100% excreted down the drain.	Solid shell made of water insoluble, non-degradable polymer (100% excreted): • Microplastic at point of use and release if the medicine/osmotic system is ≤ 5 mm in all dimensions[54]
Proposed action/TP	1) Reporting requirement of the uses of polymers and their subsequent releases in the environment. 2) Labelling requirement to provide sufficient instructions in the Package Leaflet (PL) on how to dispose unused medicines containing microplastics.		
Justification for action	Medicinal products are already heavily regulated under other sector specific EU regulation (for the HH aspects), and the Commission is working on a strategy re. pollution from medicines (focussing essentially on API effect on the environment). They also have a high societal value. Use and releases of microplastics appears to be important in this sector, but very little information was provided during the call for evidence to the Dossier Submitter. It is therefore proposed to first gather more systematic information on the use of microplastics, in order to decide if and which EU action would be the most efficient (e.g. REACH, Medicinal product regulation, other) to address this issue, and avoid potentially double regulation. Meanwhile, to address the issue of microplastics that can be released to the environment because of improper disposal of unused medicines, it is proposed to reinforce the existing provisions under the medicinal product regulations (and in particular the SmPC), hence a labelling requirement is also proposed.		
Sector characteristics			
Tonnes used	Estimated: ca 1 600 tonnes (500–2 700)	Estimated: ca 700 tonnes (300 – 1 000)	Limited as the osmotic system is a niche market, and the osmotic system < 5mm represent a small proportion of this use.
Alternatives	For the CR function: Alternative substances: none readily available which offer the same type of CR.	Alternative substance: none readily available	Alternative substance: none readily available. But alternative medicines seems to exist for

[53] If the core/granule/tablet dimensions are > 5 mm: does not fulfil the definition of 'Polymer-containing microplastic' at point of use by the consumer, but secondary microplastic can be excreted from the body. Coated medicine/tablet dimensions > 5 mm can be described using the paragraph 5.b. of the restriction proposal (i.e. 'physical properties of microplastics are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of microplastic').

[54] If the osmotic system is > 5 mm: does not fulfil the definition of 'Polymer-containing microplastic' at point of use by the consumer, but secondary microplastic can be excreted from the body.

Impacts/Sectors	Diffusion controlled systems (matrix and film diffusion)	Ion exchange based controlled release	Osmotic systems
	Nevertheless, other medicines (without CR function), sometimes old formulation of the same medicine, exist for the same therapeutic areas. These medicines are nevertheless expected to trigger more side-effects for the patients. For the other functions: limited alternatives exist (go back to what used before the use of polymers) that are not suitable for all formulations and patients (e.g. lactose intolerant patients)	Nevertheless alternative medicines seems to exist for most of the therapeutic area using IER.	most of the therapeutic area using osmotic systems
Proportionality			
Risk reduction capacity	Limited for the moment as only a labelling requirement is proposed. If an EU action is taken later, the risk reduction capacity is estimated to: ca 800 tonnes (300–1 300)	Limited for the moment as only a labelling requirement is proposed. If an EU action is taken later, the risk reduction capacity is estimated to: ca 300 tonnes (100-500)	Limited for the moment, and extremely limited if an EU action is taken later.
Costs	1) Reporting cost: estimated to be negligible - the pharmaceutical sector is already well-organised to report regularly information to the relevant authorities. This is part of the route post-marketing activities in the pharmaceutical sector. 2) Cost to build the reporting format and receiving tool: the information to be reported are simple, and existing regulatory IT system could be used for that purpose (e.g. REACH-IT, PSUR electronic submission) 3) SmPC and PL update cost: estimated to be negligible as they are revised regularly already		
Cost-effectiveness	N/A		
Other SE impacts	N/A		
Practicality	The reporting requirement is considered implementable and manageable for the pharmaceutical sector. A central receiving/consolidating system needs to be put in place on the authority side.		
Monitorability	Monitorability of the labelling implementation (change of PL) could be done via a monitorability of the SmPC update.		
Impact of scope modifications			
• All dimensions < 1mm	Same impact. Reporting requirement would apply to all microplastics used in the formulation.	Same impacts (microplastics < 1mm)	Would be out of scope
• Film forming in scope	Same impact	N/A	N/A
• Microplastic concentration in mixture > 0.1%	Same impact	Same impact	Same impact
Main Uncertainties (impact on Proportionality conclusions)	Polymers that would fall under the microplastic definition / (bio)degradability of polymers. Tonnages, including the tonnages split between the different functions. Availability of alternatives	Tonnages Availability of alternatives	Tonnages Availability of alternatives

Source: Annex D – Impact assessment for medicinal products (qualitative approach)

Table 29 Summary of the socio-economic impacts of the proposed restriction on food supplements and medical food

Impacts	Description
Use description	Food supplement include vitamins, minerals, herbals and botanicals, amino acids, enzymes, and many other products. In this sector, microplastics seem to be essentially used for their Controlled Release (CR) and taste masking functions, with a film forming function. Some microplastics are authorised as food additives under the EU Regulation (1333/2008) for use in solid food supplements.
Microplastics description	The solid polymer has a film coating function: • Microplastic at formulation stage • Microplastic at point of use by consumer and release (100% excreted) only if the food supplement or medical food has all its dimensions ≤ 5 mm (aka 'mini-tablets' or pellets)[55]
Proposed action/TP	Restriction
Justification for action	No information to justify any other action than a restriction. Availability of alternatives: instant release food supplement microplastics-free are available on the market.
Sector characteristics	
Main Uncertainties (impact on Proportionality conclusions)	Uses, presence of microplastic at the point of use by the consumers, tonnages, alternatives, SEA impact

Source: Annex D – Impact assessment for food supplements and medical food

[55] If the medicine/tablet dimensions are > 5 mm: does not fulfil the definition of 'Polymer-containing microplastic' at point of use by the consumer, but secondary microplastic can be excreted from the body. Coated medicine/tablet dimensions > 5 mm can be described using the paragraph 5.b. (physical properties of microplastics are permanently modified when the substance or mixture is used such that the polymers no longer fulfil the meaning of microplastic).

Table 30 Summary of the socio-economic impacts of the proposed restriction on paints and coatings

Impacts	Description
Use description	Use of microplastics in paints and coatings.
Microplastics description	Microplastic particles in water-based paints and coatings can have both film-forming properties or be used as additives for a multitude of functions. Microbeads are used for weight reduction, to facilitate application of the paint, to increase elasticity of the film and for scratch resistance. Microfibres are used for wear resistance, concealing cracks and increased thixotropy of the wet paint. Releases of microplastics to the environment mainly come from the cleaning of painting equipment and through the improper disposal of waste.
Proposed action/TP	Labelling and reporting requirements
Justification for action	Releases of microplastics to the environment mainly come from the cleaning of painting equipment and through the improper disposal of waste. A labelling requirement is intended to inform users about how to minimise these releases.
Sector characteristics	
Tonnes used p.a.	5 260 tonnes of polymers are expected to be released down the drain from paints and coatings (could be up to 10 200 if professionals are assumed to dispose of left-over paints and coatings the same way as consumers). In total, decorative paints contain 840 000 tonnes of polymers.
Alternatives	Inorganic binding agents, pure silicate paints, glass beads, cellulose-based beads, natural materials (such as cotton fibres, onyx jojoba beads, olive stone, kahl wax or pistachio shells)
Effectiveness & Proportionality	
Targeted at risk/ capable to reduce risk	There is currently no obligation for paint and coating producers to include information on how to properly dispose of waste and how to clean painting equipment. Therefore, a labelling requirement is expected to reduce these emissions to the environment. It is not known how effective the labelling requirement will be. However, the reporting requirement will help to assess changes to emissions.
Costs	Product labels are often updated on a regular basis, both due to regulatory requirements and due to changes in trends and demands. It is envisaged that the labelling requirement could at least to some extent be coordinated with the regular updates to labels. The costs of meeting the reporting requirements will likely be minimal, and therefore affordable.
Cost-effectiveness & affordability	Labels on products that the users are less familiar with and that are perceived as hazardous are according to research more likely to be effective. Since paints and coatings are not everyday consumer items and there is likely to be some perceived risk related to them, it is assumed that consumers would be likely to read and comply with the labels, thereby reducing emissions from the disposal of waste and cleaning of equipment. Considering that the costs are expected to be relatively low, the labelling requirement is considered cost-effective for consumer products.
Other SE impacts	-
Practicality	Paints and coatings are already subject to labelling requirements under the CLP Regulation. Considering the similarity with existing CLP requirements, the proposed labelling requirement should be practical and monitorable. Given the uncertainty related to the uses and availability of alternatives for critical applications, the proposed reporting requirement is a practical approach to gather information for possible further action.
Monitorability	The proposed measure has a monitoring element, which will enable the EC to monitor whether emissions are declining under existing measures or further action under REACH is required.
Impact of scope modifications	
• All dimensions < 1mm	Similar impacts as the polymer particles in paints and coatings are typically <1 mm
• Products included	Not evaluated.
• Film forming in scope	N/A
Main Uncertainties (impact on Proportionality conclusions)	How much emissions would be reduced as a result of the labelling requirement.

Table 31 Summary of the socio-economic impacts of the proposed restriction on 3D printing

Impacts/Sectors	3D printers
Product description	3D-printing, also called Additive Manufacturing (AM) makes three-dimensional objects from layers of material, including metals, ceramics, fibre composites and polymers. Objects of any shape can be designed with computer programs and 3D printed. 3D printing can be used for new complex designs and to reduce the number of operations in the manufacturing process. This may shorten lead times, reduce costs and improve product properties.
Microplastics description	Several techniques are used for 3D printing, most of them for industrial use and only one is used regularly by consumers. Industrial techniques that use polymeric materials include Lithography-based Ceramic Manufacturing (LCM), Stereolithography (SLA), Fused Filament Fabrication (FFF) and Continuous Filament Fabrication (CFF), Industrial Robot Based Additive Manufacturing (IRBAM) and Selective Laser Sintering (SLS). The main technique for consumers that use polymeric materials is Fused Deposition Modelling (FDM) printers. These printers are smaller than industrial ones and can be bought by private consumers to print smaller objects. The most commonly used filament is made of PLA (polylactic acid). Alternative filament materials include ABS (Acrylonitrile-Butadiene-Styrene) which is less common because it emits "smoke" when used. PET (polyethylene terephthalate or polyester) is also an option. No releases of microplastics to waste water is expected, although some ultrafine particles in the nanosize range may be released during use. All material that is not sintered or glued during printing, is reused (CfE #667).
Proposed action/TP	Labelling and reporting requirement
Justification for action	Limited releases of microplastics are expected. A labelling requirement is intended to minimise the releases, where possible.
Sector characteristics	
Tonnes used p.a.	No information available
Alternatives	No information available
Effectiveness & Proportionality	
Targeted at risk/ capable to reduce risk	No information available
Costs	Product labels are often updated on a regular basis, both due to regulatory requirements and due to changes in trends and demands. It is envisaged that the labelling requirement could at least to some extent be coordinated with the regular updates to labels. The costs of meeting the reporting requirements will likely be minimal, and therefore affordable.
Cost-effectiveness & affordability	Labels on products that the users are less familiar with are according to research more likely to be effective. While it is not known how much a labelling requirement may affect emissions, the labelling costs are expected to be relatively low.
Other SE impacts	3D printing opens up a range of opportunities. For example, it can create customised objects, aid in eliminating issues associated with inventories and stock build-up, reduce supply chain restrictions in production systems and reduce the use of transport.
Practicality	Given the uncertainty related to the uses and availability of alternatives for critical applications, the proposed measure is a practical approach to gather information for possible further action.
Monitorability	The proposed measure has a monitoring element, which will enable the EC to monitor whether emissions are declining under existing measures or further action under REACH is required.
Impact of scope modifications	
• All dimensions < 1mm	Similar impacts.
• Products included	Not evaluated.
• Film forming in scope	N/A
Main Uncertainties (impact on Proportionality conclusions)	Tonnages Availability of alternatives Emissions to the environment

Table 32 Summary of the socio-economic impacts of the proposed restriction on printing inks

Impacts/Sectors	Printing inks
Product description	Laser printing is an electrostatic digital printing process using powdered ink (toner) for transfer of an image to paper. The toner is then heated to permanently fuse the text to the paper. Generally, the toner is provided in a toner cartridge.
Microplastics description	The toner is mostly made of granulated plastic from e.g. polypropylene (PP), fumed silica and various minerals to make the powder electrostatic. The specific polymer used could also be based on styrene-acrylate copolymers, polyester resins, styrene-butadiene copolymers or a few other special polymers. The formulation, granule size and the resulting melting point vary. The particle size is typically around 10 µm (CfE #747), although in the report by Amec (2017) styrene acrylate copolymer particles of about 2-10 µm are mentioned. The toners are developing towards smaller granule sizes through the application of new technologies, such as Emulsion Aggregation. In general, only minor intentional (or unintentional) release of microplastics to waste water is expected as recycling of post-consumer toner cartridges is done by most manufacturers. Emission of microplastics can be expected primarily in the maintenance of printing machines. It is estimated that on average 3% of the toner in each cartridge can be released.
Proposed action/TP	Labelling and reporting requirement
Justification for action	Limited releases of microplastics are expected under specific circumstances. A labelling requirement is intended to inform users about how to minimise the releases, where possible.
Sector characteristics	
Tonnes used p.a.	No information available
Alternatives	No information available
Effectiveness & Proportionality	
Targeted at risk/ capable to reduce risk	No information available
Costs	Product labels are often updated on a regular basis, both due to regulatory requirements and due to changes in trends and demands. It is envisaged that the labelling requirement could at least to some extent be coordinated with the regular updates to labels. The costs of meeting the reporting requirements will likely be minimal, and therefore affordable.
Cost-effectiveness & affordability	While it is not known how much a labelling requirement may affect emissions, the labelling costs are expected to be relatively low.
Other SE impacts	-
Practicality	Given the uncertainty related to the uses and availability of alternatives for critical applications, the proposed measure is a practical approach to gather information for possible further action.
Monitorability	The proposed measure has a monitoring element, which will enable the EC to monitor whether emissions are declining under existing measures or further action under REACH is required.
Impact of scope modifications	
• All dimensions < 1mm	Similar impacts.
• Products included	Not evaluated.
• Film forming in scope	N/A
Main Uncertainties (impact on Proportionality conclusions)	Tonnages Availability of alternatives Emissions to the environment

Table 33 Summary of the socio-economic impacts of the proposed restriction on oil & gas

Impacts	Description
Proposed action	Reporting & labelling/ SDS requirements.
Justification for action	Microplastics are used and emitted. However, there's considerable uncertainty related to the microplastic use within scope and the available substitutes for critical uses. The proposed measure will reduce this uncertainty
Sector characteristics	
Use description	Microplastics are used in cement/cement additives, viscosifiers, lost circulation materials, drilling lubricants, defoamers, fluid loss control chemicals, asphaltene inhibitors, friction reducing agents and other drilling, production or pipeline applications
Tonnes used	1 150 (300 – 2 000) tonnes
Alternatives	Microplastic-free products are available for all applications; however, alternatives may not be available for critical uses, e.g., in high temperature/ high pressure environments
Effectiveness & Proportionality	
Targeted at risk/ capable to reduce risk (or Risk reduction capacity)	Based on current information, emissions are estimated at 270 tonnes (from min to 550). Further action under REACH can be initiated in the event emissions are not reduced under existing measures (e.g., OSPAR & other regional sea conventions).
Cost-effectiveness & affordability	Resources required for meeting the reporting requirements will likely be minimal, and therefore affordable, as already actions are taken to identify microplastic-containing chemical mixtures (e.g., under OSRAP)
Practicality	Given the uncertainty related to the uses and availability of alternatives for critical applications, the proposed measure is a practical approach to gather information for possible further action.
Monitorability	The proposed measure has a monitoring element, which will enable the EC to monitor whether emissions are declining under existing measures or further action under REACH is required.
Impact of scope modifications	
All dimensions < 1mm	Some microplastics reported are larger and can exceed the 1 mm upper bound. Microplastic characteristics, including their dimensions, are proprietary information. They are selected to deliver specific performance required by e.g., the well/formation characteristics.
Concentration limit of 0.1%	It is unlikely that the increase in the concentration limit will have an impact on the conclusions.
Main Uncertainties (impact on conclusions)	The following uncertainties are an impediment for a use restriction under REACH but are anticipated to be addressed via the proposed action: Polymer uses in scope which impacts tonnes used & emitted Availability of alternatives for critical applications The impacts associated with next best alternatives.

Source: Annex D – Impact assessment for oil and gas

Notes: 2017 values, 2022 – assumed entry into force (EiF), annual data.

2.6 Practicality and monitorability

To be implementable and monitorable within a reasonable time frame the restriction should be designed so that a supervision mechanism exists and the proposed restriction is practically implementable for companies and enforcement authorities.

2.6.1 Enforceability

To be implementable and enforceable the scope of this restriction has been designed so that it allows a tiered approach when assessing if a given product contains microplastic particles which are covered by the definition and the scope of the restriction proposal.

2.6.1.1 Tier 1

The restriction is for intentional use of microplastics, therefore it is reasonable to assume that formulators of mixtures will know whether or not they are using microplastics in their products. In addition, given the producers responsibility to understand what is in their products, they should make reasonable enquiries or include requirements in their contracts to understand if polymers are in their mixtures. It was considered if a labelling requirement of 'contains >0.01% microplastics' could assist with the understanding of producers but it was rejected (see Section 2.2.1). Sector specific labelling requirements, such as INCI labelling for cosmetics, may help formulators and other downstream users to identify if there are polymers included in the mixture or raw material (a mixture formulated with other mixtures to produce the final product).

For the products which contain polymer(s), it should be considered if the polymers are present in a particle form and what is the state of the polymer (e.g. solid or not solid). If this is not evident from the information provided by the supplier, the presence of solid particles can be determined by applying well-known analytical methods such as sieving. As noted earlier, the simplicity of implementation was a factor when proposing that the threshold of [0.01]% should be set by weight and this should allow relatively straightforward quantification of the particles present in a product. However, it should be noted that different sample preparation techniques such as extraction, dissolution etc. will need to be applied depending on the type of product.

2.6.1.2 Tier 2

If it is determined that there are particles present in the product which do contain polymer, the size of these particles can be determined for example by using sieving, laser diffraction and image analysis methods as noted in Annex B.

Analytical methods based on spectroscopy such as Fourier transform infrared spectroscopy (FT-IR) or Raman spectroscopy could be one choice when it comes to chemical characterisation (Prata et al., 2019). These techniques are based on comparison with reference spectra. In FT-IR spectroscopy the infrared radiation excites molecular vibrations whereas in Raman spectroscopy the samples are irradiated with a monochromatic laser source (Loder and Gerdts, 2015, Prata, 2018a). In cases where the identification of plastic polymer (microplastic) by visual inspection is ambiguous confirmation of the identity of the polymer particles can be performed by spectroscopic techniques (European Commission Joint Research Centre (JRC), 2013). Depending on the setup of the application small particles can also be measured down to the range of 20 µm or if needed even lower to the range of 1 µm using micro-FTIR or micro-Raman (Primpke et al., 2017). On the other hand, larger particles can be analysed by "attenuated total reflectance" (ATR) FTIR spectroscopy with high speed and accuracy (Loder and Gerdts, 2015). Sometimes FT-IR technique is combined with the extension of focal plane array (FPA) which does not need any preselection of particles and allows detailed analysis of total microplastics.

Every spectroscopic method has its limitation which needs to be taken into account when selecting the best suitable measurement technique depending on the sample to be analysed.

In addition to gain information about the chemical composition of the microplastic, several different analytical methods are available based on Gas chromatographic coupled with mass spectrometry (GC-MS) principles. For instance, in pyrolysis GC-MS (pyro GC-

MS) the microplastic is decomposed by pyrolysis and then the gas is chromatographically separated and analysed by mass spectrometry. It gives information about the chemical composition of the microplastic but not about the size, shape or number of microplastics in the sample. Thermo-extraction and desorption (TED) GC-MS is a two-step method that starts with the pyrolysis of the sample and the decomposition products are trapped on a solid-phase adsorbent. As next this products are thermally desorbed, chromatographically separated and in the last step identified with mass spectrometry. The advantage of the TED GC-MS over the pyro GC-MS that it allows the characterisation of complex polymers with heterogeneous matrices.

Similarly liquid chromatogram such as High Performance Liquid Chromatography (HPLC) or Size Exclusion Chromatography/Gel Permeation Chromatography (SEC/GPC) coupled with suitable detector can also deliver information about the chemical composition of the microplastic especially about the molecular distribution of the constituents which is based on the size of the analytes.

Evaluation of the different elements (especially from deriving from additives or adsorbed metals) of the microplastic can be characterised by X-Ray Fluorescence (XRF), and Scanning Electron Microscope (SEM) could reveal information on morphology and composition of microplastics.

As noted above, the type of the product will ultimately determine the most suitable techniques to be used in order to obtain meaningful results from identifying and quantifying the microplastics content of the product. The manufacturer or importer are ultimately best placed to decide which set of analyses would be most applicable for their individual cases. Independently on the kind of performed analysis it is the responsibility of the manufacturer/importer to have the proper documentation available to ensure that substance or mixture does or does not fall under the scope of the proposed restriction and to be able to show the documentation to the Enforcement Authority, upon request in case of control.

2.6.1.3 Tier 3

In addition to determining the presence of particles which meet the definition of microplastic, it is important to consider whether or not there are conditions which would permit the microplastic particles present in the product to be derogated from the proposed restriction. For example, based on the restriction proposal naturally occurring polymers would be derogated as they would be expected to be biodegradable. Similarly, if during the use of the product, the microplastic does not retain the particle form (for example due to coalescence in film forming), the product may be derogated. It is expected that the manufacturer/importer of the product would provide a justification on the use of specific derogation.

Methods for the enforcement of bans on microbeads in cosmetics is already available (Canada: Microbeads in toiletries Method 445)[56].

2.6.1.4 Conclusions

Based on the steps noted above, it should be possible to determine if the product include particles which contain polymer and which have no dimension greater than 5mm. For the

[56] https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/publications/microbeads-toiletries-method-445-0.html

cases where the particle is mainly non-polymer, there is also a need to determine the amount of polymer present in the particle. As noted before, the applied method for determining the amount of polymer will need to be decided on a case-by-case basis.

2.6.2 Periodic review of the restriction

A number of the derogations in the proposed restriction are based on the certain assumptions such as that biodegradable polymers will be developed to take up the functions of many of the current polymers that meet the definition of microplastics. This is also assumed by other current EU legislation, such as the new EU Fertiliser Regulation. If it is not the case that such biodegradable polymers are developed, then the costs will be increased as will potentially the proportionality be decreased. Therefore, the Dossier Submitter recommends that the restriction is reviewed after [5] years. The Commission can review a restriction at any time so a formal review period is not required.

In addition, the review can also be informed by the information submitted through the reporting requirement which will give information on industrial uses, and the other derogated uses. This will allow further uses to be included in the restriction if justified.

2.7 Proportionality considerations

Unlike other uses of plastics that can be collected and properly disposed of after use to limit environmental pollution (via incineration, recycling, or landfilling if other methods are not available), the uses of microplastics in the scope of the restriction proposal lead to direct or indirect releases to the environment. Due to their small, typically microscopic size, they cannot be systematically collected and recycled or disposed of via incineration or landfilling. Microplastics once released in the environment are practically impossible to remove with current technology and remediation costs can therefore be considered to be prohibitive. Therefore, released microplastics accumulate in the environment. Given their persistent nature, stocks in the environment increase on an annual basis, by an estimated 36 000 tonnes (approximately 10 000 – 60 000) annually for the twelve product groups where the available information allowed quantification of emissions to the environment.[57] The proposed restriction is expected to avoid 85% - 95%[58] of these emissions from its entry into effect, reducing the risk of irreversible damage to ecosystems now, or in the future. The Dossier Submitter is proposing a restriction to avoid uses which inevitably lead to releases to the environment where:

- there are currently no viable means to collect, properly dispose of or remediate once in the environment and
- alternatives currently exist or there is information that suggests that alternatives can be developed within the medium term.

To demonstrate the proportionality to risk, the Dossier Submitter pursues an indicative abatement cost approach as suggested by SEAC for the evaluation of restriction

[57] Sufficient information was available to quantify the following 12 product groups: control release fertilisers and fertiliser additives, coated seeds and capsule suspension plant protection products, other rinse-off cosmetics, leave-on cosmetics, detergents containing fragrance encapsulates, other detergents, waxes and polishes, medicinal products (IER), medicinal products (matrix, film control release), medical devices and IVDs, paints & coatings (consumer), oil & gas.

[58] Depending on the effectiveness of labelling requirements and other scenario assumptions, the proposed restriction would reduce cumulative emissions by 85-95% from its entry into effect.

proposals and applications for authorisation for PBT and vPvB substances, as it is for the time being methodologically challenging to quantify any potential welfare loss related to the impairment of both use and non-use values of ecosystems (ECHA 2016a). This is an overall analytical challenge for substances with environmental impacts and is not limited to microplastics. The key premise of the abatement cost approach is the use of emissions as a proxy for the associated risks and, as a corollary of this assumption, abatement efforts can be equated to reductions in risk (ECHA 2016a). To further demonstrate the proportionality to risk, the Dossier Submitter discusses qualitatively the benefits from microplastic emission reduction (see Section 2.4) and other cost-benefits considerations. The affordability of the proposed restriction is also demonstrated below.

2.7.1 Affordability considerations

As shown in Section 2.5, reformulations are expected to constitute the largest impact of the proposed restriction (other than the impact on environment), requiring considerable time and other resource investments. Therefore, aligning the transitional period of the proposed restriction with the reformulation time required by industry would minimise the economic, but also social and distributional, impacts of the restriction.[59] As demonstrated in Annex D and summarised in Table 34, the proposed restriction is expected to lead to a relatively small cost per kilogram of microplastics used. Table 34 shows that the costs per kg used are the highest for the proposed action on leave-on cosmetics. A closer look at the estimated costs show that they represent less than 20% of the estimated average profits per reformulation (see Annex D), suggesting that also the proposed action on leave-on cosmetics can be seen as affordable. Therefore, overall, the proposed restriction is an affordable regulatory action to curb microplastic emissions to the environment.

Table 34 Restriction costs per kilogram microplastics used

Sectors\ Scenarios	Low	Central	High
Control release fertilisers & fertiliser additives	0.2	1	19
Coated seeds & control release plant protection products	1	4	60
Other rinse-off cosmetics	1	8	11
Leave-on cosmetics	71	138	169
Detergents containing fragrance encapsulates	-	38	95
Other detergents	0.4	2	7
Waxes & polishes	0.5	2	7

Source: Annex D.

[59] This consideration for the determination of the transitional periods has been balanced against the need to minimise emissions to the environment, as each additional transitional year of the restriction would lead to further releases of microplastics, increasing the environmental pressure from their rising stock in the environment. Therefore, unnecessary delays of the effective application of the proposed restriction are minimised.

2.7.2 Abatement cost (cost-effectiveness) considerations

Table 35 shows that the overall cost-effectiveness of the restriction is about €23/kg (€16/kg - €31/kg), taking into account information on the uses, emissions and costs where those could be quantitatively estimated.[60]

Table 35 Summary of cost-effectiveness of proposed restriction on placing on the market

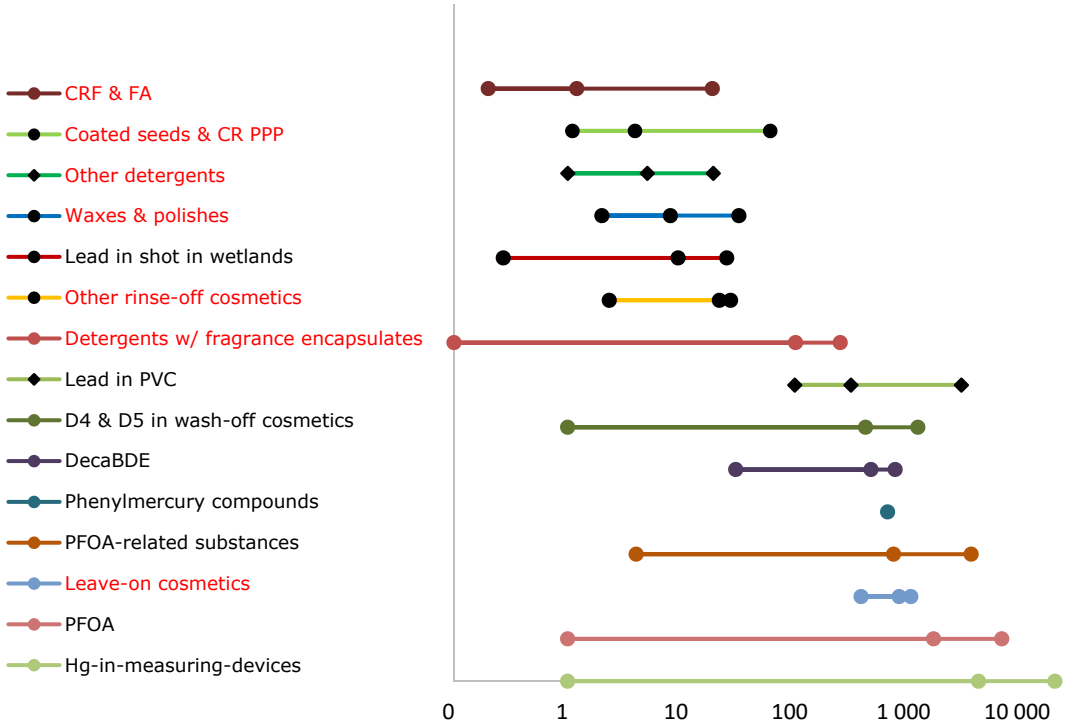
Sectors \ Scenarios	Low	Central	High
Control release fertilisers & fertiliser additives	0.2	1.2	18.7
Coated seeds & control release plant protection products	1.1	4	60
Other rinse-off cosmetics	2	22	27
Leave-on cosmetics	380	820	1 040
Detergents containing fragrance encapsulates	0	101	249
Other detergents	1	5	19
Waxes & polishes	2	8	32
Overall cost-effectiveness (€/kg)	**16**	**23**	**31**

Source: Annex D

In order to allow decision-makers to select the optimal risk reduction strategy, separate cost-effectiveness values are presented for the main uses of microplastics. Table 35 shows that these range from €1/kg to €820/kg.

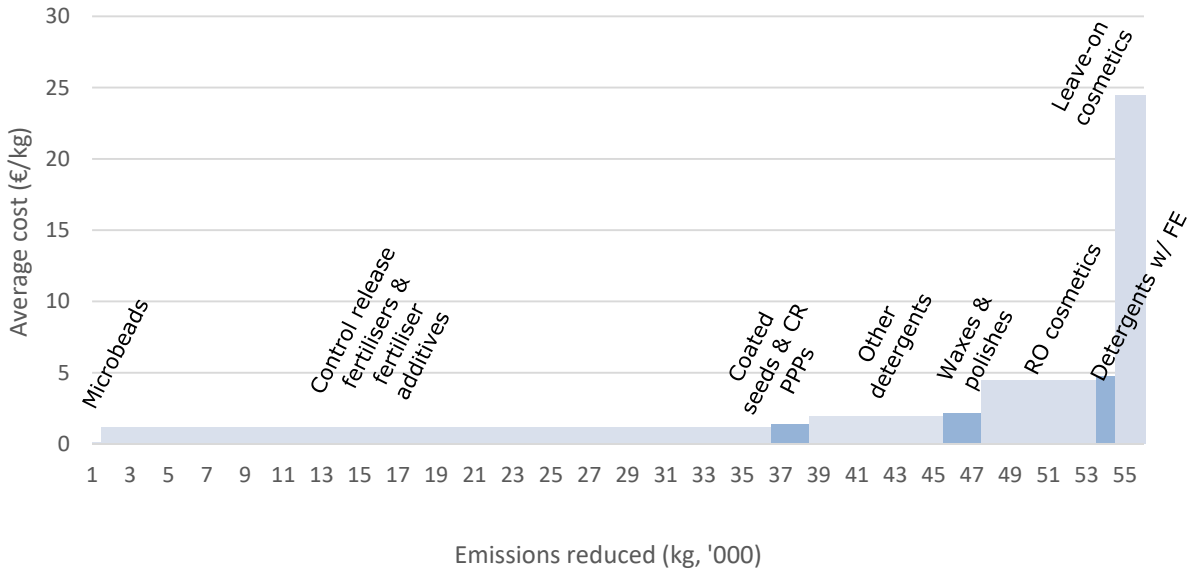
Figure 13 shows that the proposed actions on microplastics are as cost-effective as other adopted restriction measures on environmental pollutants. On the basis of the suggested approach by ECHA 2016a, it can be concluded that the costs associated with the proposed restriction can be viewed as acceptable for society to reduce microplastic emissions to the environment. 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, roughly speaking, the available evidence suggested that measures costing less than €1 000 per kilogram PBT use or 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).

[60] Depending on the effectiveness of the proposed labelling requirements, the overall cost-effectiveness is calculated as €21/kg (€16/kg - €27/kg). Latency of benefits not addressed.



Notes: Low, central and high estimates as reported by Dossier Submitters. CRF & FA – Controlled release fertilisers and fertiliser additives. CR PP – controlled release plant protection products. Sectors in red font are in the scope of the proposed restriction. Others include adopted restrictions (see ECHA Restrictions - Adopted opinions, https://echa.europa.eu/previous-consultations-on-restriction-proposals).

Figure 13 Comparison of the cost-effectiveness of the proposed restriction measures on microplastic uses with previous regulatory actions of PBT/vPvB or similar substances



Abbreviations: CR PP – controlled release plant protection products; RO cosmetics – other rinse-off cosmetics; Detergents w/ FE – detergents with fragrance encapsulates.

Figure 14 Average restriction cost per kilogramme emissions reduced

As shown in Figure 14, the average costs of restricting the uses in agriculture & horticulture, microbeads, other detergents, waxes & polishes are low. It slightly increases with further extending the restriction scope to include other rinse-off cosmetics and detergents with fragrance encapsulates. The addition of leave-on cosmetics in the restriction scope significantly increase the average restriction costs per kilogramme emissions reduced.

As shown above, the cost-effectiveness of restricting this use is the lowest: €820/kg, although still comparable with previously adopted restrictions addressing similar environmental concern. (See Figure 13.) The cost-effectiveness of leave-on cosmetics is higher than the other sectors in scope as the proposed measure would lead to the highest share of the total restriction costs, while it is estimated to account for about 2% of the emissions anticipated to be reduced as a result of the proposed restriction.

Figure 15 and Figure 16 show the share of the estimated total restriction costs and emissions by product group. [61]

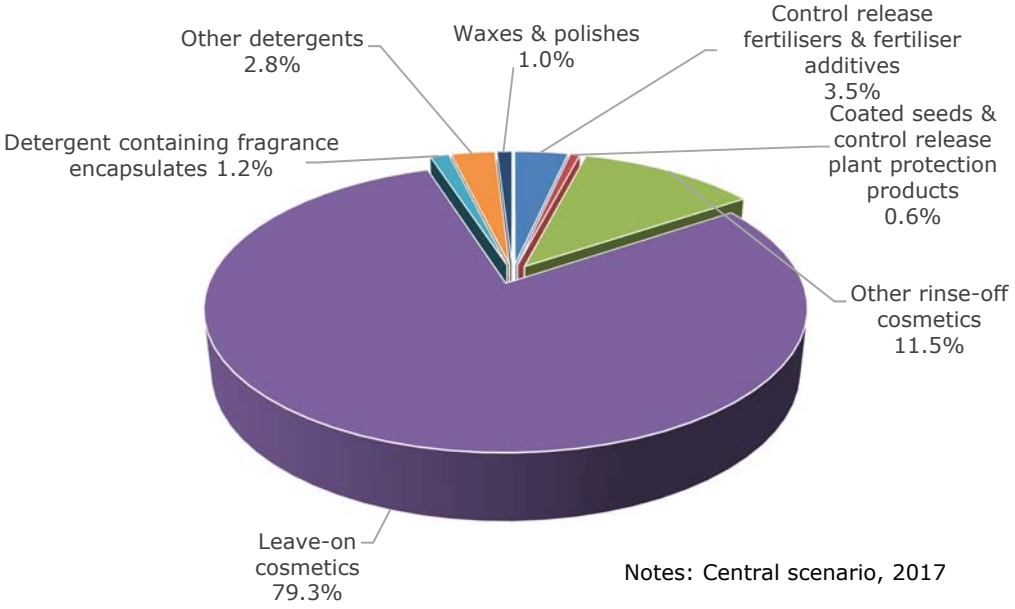


Figure 15 Share of total restriction costs

[61] When considering a restriction on the placing on the market only on leave-products which are primarily released down-the-drain (e.g., body lotions, sun care), and proposing labelling requirements for those that are primarily disposed of in municipal solid waste, the cost-effectiveness of this product group is comparable to the cost-effectiveness of the adopted restriction on D4/5 in rinse-off cosmetics (ECHA 2016).

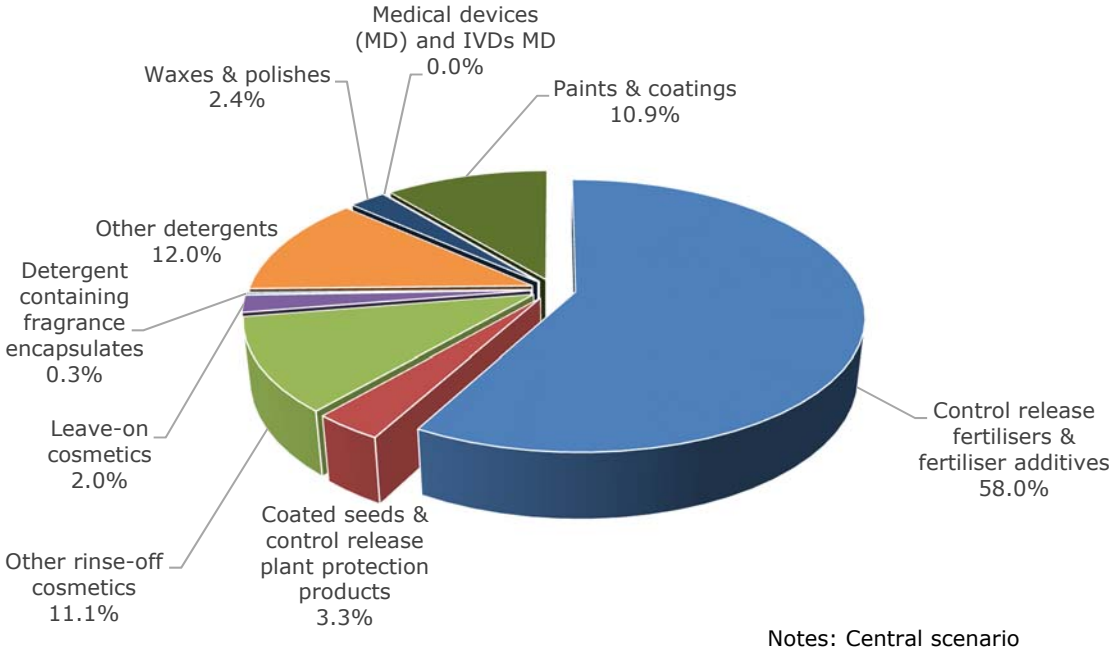


Figure 16 Share of total emissions

2.7.3 Cost-benefit considerations

In addition to the considerations above, a link can be made to the option value theory of resource economics.[62] As further elaborated in Annex D, the option value may provide an economic underpinning for why regulatory action in the face of an uncertain harm may be justified if learning is expected to occur over time. There are close parallels to research on the emission of greenhouse gases (GHG), as these have several aspects in common with microplastic pollution:

- just as GHG, microplastics are released to the environment by numerous individual point sources;
- it is prohibitively expensive and impractical to clean up environment polluted with microplastic particles;
- their (bio)degradation is expected to take many hundreds, possibly thousands of years, microplastic releases into the environment are in a practical sense irreversible and a pollution stock has been building up.

There are also a number of distinctive features of the microplastics problem:

- microplastics are often the product of unintended releases, e.g. through decay and/or abrasion of larger plastics;
- in some applications they are not the undesired by-product of a beneficial use, but have an intrinsic function that makes their use beneficial in the first place;
- microplastics are not volatile (compared to GHG), and although their fate in the terrestrial environment is not well understood they are likely to accumulate in this

[62] In this context, the concept of *option value* is best understood as the value that is given to preserving nature in such a condition that it is unrestrictedly available for future use.

compartment if this is where they are ultimately disposed (although it is likely that over long periods of time they will eventually be transported to the ocean via river catchments);

- terrestrial accumulation means that unilateral cessation of releases (from EU sources) will prevent the further growth of the pollution stock in the EU (whilst GHG emission schemes are prone to by-standing and free-riding);
- the potential harm of microplastics to humans and the environment is not yet well understood, but ongoing research initiatives are likely to substantially improve our understanding within the next decade;
- because of the lack of understanding, no economic metric such the social cost of carbon exists to quantify the damages associated with emissions of (micro-) plastics to the environment.

In a nutshell, the emissions of (micro-) plastics into the environment causes irreversible effects. Irreversibility poses a challenge to conventional policy analysis—especially if the consequences are poorly understood and cannot be priced with some degree of certainty (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).

Further cost-benefit considerations are included in Annex D of the dossier.

2.7.4 Conclusion on proportionality to risk

The proposed restriction is a cost-effective and affordable measure to abate environmental pollution from microplastics which are persistent and would otherwise accumulate in the environment in excess of 400 thousand tonnes of microplastics over the study period. Therefore, the proposed restriction can be seen as a proportional to the risk measure to avoid emissions from uses which lead to releases to the environment where:

- there are currently no viable means to collect, properly dispose of or remediate once in the environment
- alternatives currently exist or there is information that they can be developed within the medium term.

Specifically, the proposed restriction on microplastics will:

- Abate environmental pollution by 85%-95% of annual microplastic emissions to the environment. This is in excess of 26 000 tonnes annually which given the persistent nature of microplastics would otherwise accumulate in the environment.
- This measure will reduce existing local risk to ecosystems and the potential for widespread risk if current trends of microplastic releases continue in the future, although the exact impacts of the proposed restriction are uncertain in isolation from other measures on plastics which the EU is undertaking.
- Each use of microplastics in specific product categories is demonstrated to be affordable and as cost-effective as previously adopted restrictions on environmental pollutants.

3 Assumptions, uncertainties and sensitivities

The risk assessment of microplastics is complicated by the current uncertainties apparent in relation to hazards, fate, exposure and risks. These uncertainties are described in the respective sections of this report. 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. 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 the agriculture and horticulture sector, the conclusion on proportionality is conditional on biodegradable coatings 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 agriculture and horticulture are substantial.

When one considers 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.

4 Conclusions

A regulatory definition of microplastics can be derived based on terminology already defined in the EU under REACH, CLP or as part of the definition of nanomaterials.

Information on the hazard and risk of microplastics are available, although in general they would not appear to lend themselves to 'conventional' risk characterisation or PBT/vPvB assessment. Therefore, a case-by-case assessment of risks was used to demonstrate that intentional uses of microplastics that inevitable result in releases to the environment present a risk that is not adequately controlled.

This conclusion recognises the extreme persistence of these materials in the environment leading to a pollutant stock in combination with evidence that:

- Exposure to microplastics results in adverse ecotoxicological effects,
- It would be difficult to reverse adverse effects in the future.

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

The proposed restriction is estimated to result in a cumulative emission reduction of approximately 400 thousand tonnes of microplastics over the 20 year period following its entry into force (a reduction of 85-95%[63] of the quantified emissions of intentionally added microplastics that would otherwise have occurred in the absence of the restriction taking effect) at a cost of approximately €9.4 billion (NPV). The average cost effectiveness of avoided emissions, for sectors where those have been quantified, is estimated to be €23/kg per year ranging from €1/kg to €820/kg per year. The costs of the labelling requirements could not be quantified, but are considered to be negligible.

The proposed restriction is considered to be proportionate to the risk. Its cost-effectiveness is similar to REACH restrictions that have been decided previously. Furthermore, the proposed restriction is considered affordable for the impacted supply chains. The Dossier Submitter considers that the proposed restriction is also justified for the following reasons:

- Microplastics are extremely persistent in the environment, are difficult to remove once they are there (irreversibility) and are continuing to be added to the environment (stock effects);
- Transition periods and derogations for certain sectors have been proposed with aim to minimise costs to society, without unnecessary delay in emissions reduction. In this manner industry will have enough time to develop and transition to suitable alternatives, including biodegradable polymers where this is appropriate;

[63] Range dependent on assumed effectiveness of labelling requirements and scenario assumptions. Annual emission reduction after all transitional periods have expired is calculated to be >90%.

- Labelling requirements have been proposed for uses where risks can be minimised by appropriate conditions of use and disposal. This provision will also enable information exchange along the supply chain; or
- Reporting requirements have been proposed to improve the evidence base on the remaining uses of microplastics. This is considered a cost-effective way to enable the Commission and Member States to consider if and to what extent additional action could be needed in 5-10 years;
- While the risks posed by microplastics in the environment (and humans) are currently considered as uncertain the Dossier Submitter expects that understanding of risks will increase significantly over the next 10 years as microplastics, nanoplastics, and their impacts continue to be further studied. As microplastics are extremely persistent and are practically impossible to remove from the environment once there, based on the option value theory of resource economics, it is appropriate to take cost-effective action now, despite these uncertainties;

For the sectors where specific transitional arrangement are proposed, the measure is justified in the following manner:

- Cosmetic products: The measure is justified for 'microbeads' contained in rinse-off products (i.e. microplastic with an exfoliating or cleansing function) with no transitional arrangements as industry is expected to have voluntarily phased out their use by 2020. The measure is also justified for other rinse-off and leave-on cosmetic products, with respectively four- and six year transitional periods, based on the similarity to the cost-effectiveness of previous restrictions for substances with similar concerns.
- Controlled-release fertilisers: a relatively long (5-10 year) transitional period is justified to allow manufacturers to reformulate their products so that they achieved appropriate (bio)degradability in the environment (and that the benefits of the encapsulation technology can be retained in the interim period). Products typically require a minimum level of persistence in the environment to achieve their intended function (12-18 months). Fertiliser additives (e.g. anti-caking agents) could be restricted with a shorter transitional period. These transitional arrangements is intended to be synchronised with those for (bio)degradable polymers foreseen in the recent recast of the EU Fertilising Products Regulation.
- Detergents and maintenance products using 'microbeads': the measure is justified with no transitional arrangements as industry is expected to be able to phase out the use of microbeads as an abrasive by 2020.
- Detergents, waxes and polishes containing microplastics other than microbeads: a transitional arrangement of five years is considered appropriate to give industry sufficient time to substitute microplastics (and that the benefits of the encapsulation technology can be retained in the interim period).
- Capsule suspension plant protection products and biocides: The measure is justified with reference to the cost-effectiveness of previous restrictions for substances with similar concerns. A transitional arrangement of five years is considered appropriate to give industry sufficient time to substitute microplastics (and that the benefits of the encapsulation technology can be retained in the interim period).

- Medical devices and *in vitro* diagnostic medical devices[64]: The measure is justified with reference to the cost effectiveness of previous restrictions for substances with similar concerns. Continued use of existing medical devices and *in vitro* diagnostic medical devices is foreseen with improvements to risk management measures implemented to prevent release of microplastics throughout the product life-cycle.

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 to progress beyond the criteria proposed here.

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

The restriction is designed so that enforcement authorities can set up efficient supervision mechanisms to monitor compliance with the proposed restriction and is practically implementable for companies. The Dossier Submitter considers that it is possible to determine if a product includes polymer-containing particles with all dimensions less than 5mm, or 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.

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.

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.

The Dossier Submitter believes that the derivation of test methods and criteria for establishing (bio)degradable microplastics will be important to ensure that the proposed restriction does not prevent innovation e.g. the further development of polymer encapsulation technologies. The Dossier Submitter considers that it is important to ensure that the benefits of polymer encapsulation, and similar innovative technologies

[64] as defined in regulations (EC) 2017/745 and (EC) 2017/746

can remain on the market, as long as their environmental sustainability is assured.

Regulating microplastics is based on current knowledge on science and the uses of microplastics. Science will evolve and the impact or the proposed restriction may be different from what is estimated in this restriction proposal. Therefore the Dossier Submitter has proposed a way to collect additional information on the uses so that if additional measures are needed in the future, they would be based on the best possible information.

For the above reasons the Dossier Submitter recommends that the restriction is reviewed [5] years after entry into force to see how the market has adapted to the restriction, how well biodegradable polymers perform for the relevant uses and what additional information is available of the impacts of microplastics to the environment and human health.

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